ASSESMENT OF EARLY SURGICAL COMPLICATIONS OF PERITONEAL DIALYSIS CATHETERS FOR ACUTE KIDNEY INJURY IN CHILDREN AT KENYATTA NATIONAL HOSPITAL.

DR.ODIRA EDWIN OMONDI

H58/68488/2011

A dissertation submitted in part fulfillment for the award of Master of Medicine in General Surgery, University of Nairobi.

DECLARATION

I declare that this research dissertation is my own original work and has not been presented for a degree in any other University.

Sign…….. Date……

Dr. ODIRA EDWIN OMONDI

H58/68488/2011

SUPERVISORS' APPROVAL

This dissertation has been submitted for examination with my approval as university supervisor.

Dr Ndungu JM

MBChB, M.Med general surgery, Fellow paediatric surgery

Senior lecturer and consultant paediatric surgeon

Department of surgery, UON.

Sign…….. Date……

Dr Githaiga JW

MBChB, M.Med FCS(ESCA)

Senior lecturer and consultant general and laparoscopic surgery

Department of surgery, UON.

Sign…….. Date……

Dr Francis Osawa

MBChB (U.O.N), M.Med Surgery (U.O.N), F.C.S (ECSA)

Lecturer

Department of Surgery, University of Nairobi

Sign…….. Date……

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Sign…….. Date……

Chairman, Department of Surgery,

School of Medicine,

University of Nairobi.

DEDICATION

This book is dedicated to my family. With their love, support and intercessions have the completion of this book been possible.

ACKNOWLEDGEMENT

I extend my heartfelt appreciation to my family for their great patience and support.

I am indebted to my supervisors Dr. Ndung'u JM, Dr Githaiga JW and Dr Francis Osawa for their invaluable input in this work.

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ABBREVIATIONS

ESRD - End Stage Renal Disease

ERRC - Ethics Research Review Committee

CRRT - Continuous Renal Replacement Therapy

GFR - Glomerular Filtration Rate

HD - Hemodialysis

ISPD - International Society for Peritoneal Dialysis

KNH - Kenyatta National Hospital

PD - peritoneal Dialysis

RRT - Renal Replacement Therapy

SIRS - Systemic inflammatory response syndrome

SLP - Sanduku la Posta

SSI - Surgical Site Infection

SPSS - Statistical Package for Social Sciences

UoN - University of Nairobi

WBC - White Blood Cells

ABSTRACT`

Background

Peritoneal dialysis is a commonly deployed renal replacement therapy (RRT) option in children who have acute kidney injury (AKI) in many centers worldwide including Kenyatta National Hospital (KNH). Special catheters which are placed using various surgical techniques are used in peritoneal dialysis. The catheters may sometimes be associated with increased rates of infection and flow disturbances, probably related to the technique and type of catheter used hence the need to establish the rate of these complications and any impact of these different catheter types or techniques on the outcomes as seen at KNH.

Objective

This study aims to assess the rate of early surgical complications during peritoneal dialysis in children who have acute kidney injury.

Materials and methods

This was a prospective descriptive study carried out in KNH pediatrics wards and the paediatric specialized unit over a period of six months. All pediatric patients with AKI requiring PD were entered into the study .Data on type of PD catheter used, technique of insertion of the PD catheter, and complications were entered into a questionnaire and analyzed by Analysis was done using Software for statistical analysis STATA version 11.0.

Summary data were produced to report characteristics of participants using simple frequencies. Continuous variables were represented using degrees of central tendency such as means and medians with interquartile ranges (IQR).The data is presented in forms of tables, pie charts and bar charts.

Results

The average age of the study population was twelve days with interquartile range of nine days to three years with a slight male preponderance (51.69%). All the patients received prophylactic antibiotics before PD catheter insertion. These catheters were fixed by general surgery or paediatric surgery residents using the open method only. The procedures were done in theatre where different kinds of anaesthesia were employed. There were neither visceral injuries nor excessive bleeding during the insertion process. The majority of the

catheters were single cuffed (70.97%) and tunneling of these catheters was done in 93.55%. Omentectomy was rarely done (16.13%).Mechanical PD failure (outflow obstruction and pericatheter leakage) was seen in 35.48% while infectious complications (exit site infection and peritonitis) were seen in 45.16 %. During the two week follow up period 87.10% had resolution of AKI, 6.45% progressed to CKD while another 6.45% succumbed to their illness.

Conclusion

Peritoneal dialysis is commonly employed in children for management of AKI. The open method is used for insertion and little complication is encountered during the process. However mechanical and infectious complications are fairly common. Most of the patients do well following peritoneal dialysis.

1.0 INTRODUCTION

Dialysis is used in RRT for AKI. Different dialysis methods available are peritoneal dialysis (PD), intermittent hemodialysis (IHD) and continuous renal replacement therapy (CRRT). Peritoneal dialysis as a mode of renal replacement therapy is increasingly being utilized in many centers around the world. While the outcomes continue to improve and are comparable to hemodialysis , the fraction of end-stage renal disease (ESRD) patients being treated with this modality in developed countries has declined [1,2]. Little data is available from the developing countries.

Peritoneal dialysis takes advantage of the peritoneal space which is lined by single layer of mesothelium. It is semi permeable and selectively filters solutes to varying degrees. The capillaries within the membranes provide blood pathway. Water and solutes move across this barrier made up of mesothelium, capillary wall and the interstitium. Solute movement is mainly by diffusion but aided by solvent drug during osmosis. In general, dialysis can be considered as a process during which the composition of one solution (the blood plasma) changes because of its interaction with another solution (the dialysate) via a semi permeable membrane. This interaction consists essentially of transport of water and solutes from one side to the other.

There are three main phases in peritoneal dialysis .In the fill phase dialysate flows from a bag into the peritoneum usually for about 10 minutes. This is followed by a dwell phase lasting 4-5 minutes in which solute transport occurs between the dialysate and capillary blood with urea, creatinine, electrolytes moving into the dialysate and glucose moving into the blood. In the final phase or the drain phase, dialysate flows from the peritoneum into the draining bag for 10-25 minutes.

A resting period may reduce leaks before starting dialysis[3] .global guidelines have advised that catheters should be inserted two weeks prior to use[3,4]. A delay of PD for about six weeks after catheter insertion may accelerate wound healing[5] . In the developing world, many patients are dialyzed urgently due to late presentation or rapid decline of renal function[6,7] . The optimal time of the break-in period remains unresolved. Anecdotically nearly all patients treated for AKI at the KNH present late when their renal function have markedly deteriorated and therefore undergo dialysis immediately after the placement of the catheter. This may impact negatively on the outcomes of peritoneal dialysis.

Some of the common surgical complications of PD are exit site infection, peritonitis, , dialysate leakage, blocked catheter from omentum or fibrin and abdominal wall hernia; rarely organ perforation in case of stiffer catheter use[8].

Although acute kidney injury is rare in infants and young children, when it occurs it can be related with telling sickness and fatality.. Through multidisciplinary team a favorable outcome can be achieved. Peritoneal dialysis is the preferred renal replacement modality and serves as an essential therapy to prevent death.

1.1 LITERATURE REVIEW

In 1948 Bloxsom and Powell published the initial reports describing PD use in treating children suffering from AKI in the initial issue of the journal, *pediatrics*. Gordon in 1949 had a more successful experience[6]. Gordon used continuous peritoneal dialysis. Development of nylon catheters and commercially prepared dialysate in the 1950's made PD a practical treatment for AKI. Dialysis catheters were first used successfully in management of ESRD in 1959 by Richard Ruben using the open technique[9]. In the early 1960's Segar et al, Ettledorf et al described the use of this technique in children, especially demonstrating its use in treatment of boric and salicylate acid poisoning in small children. Other following reports established PD as the commonest form of RRT in children as it is simple, safe, easy and readily adapted for different children as compared to HD. This was also perpetuated by the notion that peritoneum of a child was more efficient than that of an adult. During this time HD required large ECBC that were poorly tolerated at best by children.

AKI occurrence has been documented in 2–3% of children admitted to pediatric tertiary care centers and up to 8% of infants in the neonatal intensive care unit[10] .Acute kidney injury (AKI) affects 3.9/1000 at-risk children in the United States. However ,critically ill and injured children can access improved care ,diagnosis is being made more accurately. This number may be an underestimate[11].the exact figures on the burden of acute kidney injury (AKI) in poor countries are bare because of a lack of renal services and an failure to recognize and diagnose AKI appropriately[12].

In a 4-year retrospective review conducted at the University of Lagos by Ladapo et al[13] , Kidney diseases made up for 8.9% of pediatric admissions. It had a prevalence of 22.3 admissions per 1000 child-admissions per year. Acute renal injury, nephroblastoma and Nephrotic syndrome contributed for 70% of admissions. There was an overall mortality of 14.4% ; acute kidney injury accounting for 36% of this[13].

In Congo Brazzaville, 15% of admissions for kidney disease had a AKI with a mortality of 37%[14] recorded in children.

Only 10% of AKI are due to primary renal causes in the west. Most of them are secondary to sepsis, systemic illnesses, nephro- toxic medications and cardiac surgery for congenital heart disease. Hemolytic uremic syndrome is implicated as the main cause of kidney failure in pediatrics in developing countries[15].

In Africa, The major causes of AKI are infectious:-either sepsis or dehydration from diarrhea. Traditional medicines also suspected to be an important albeit poorly documented cause[16,17]. .

RRT is required when there is no improvement despite optimum supportive therapy. Early institution of RRT results in optimum results[18,19].

PD is an enviable RRT option for the treatment of selected patients with AKI especially those who are hemodynamically unstable or have severe coagulation abnormalities or when other modalities are not readily available.

The popularity of PD over HD is based on these characteristics: easy peritoneal access and better tolerability by sick and unstable children.

However PD is not without limitations. PD is ill suited in severe metabolic disturbances and acute toxin ingestions [20]. In cases of extreme fluid overload, the rate of fluid exchange of PD is slow with ensuing injury and morbidity. Manual PD is labor intensive especially if the cycle frequency is high. PD is contraindicated in children who have congenital abdominal malformations such as omphalocele, gastroschisis, and bladder exstrophy, or in patients with significant abdominal adhesions.

The improvement in PD outcomes and the similarity in long-term outcomes of patients treated with PD and HD has been reported from countries with a wide range of PD uptake, from as low as 6-7% in the United States to almost 50% in Colombia[21]

PD has been shown to improve outcomes and overall mortality in children with AKI. However it is dependent on the underlying condition of the child. Multi-organ failure, fluid overload at initiation of therapy, younger age , hemodynamic instability are factors that will alter the outcomes of kidney injury regardless of CRRT therapy[22,23].

Before 2001, a lot of published data on pediatric CRRT was limited to single-institution studies with small groups of patients[24].

In 2001, Goldstein et al[25] developed the Prospective Pediatric CRRT (ppCRRT) Registry group as a multicenter United States collaboration which enrolled patients undergoing CRRT. Their overall survival was 58%, with 31% survival in patients with liver failure, 45% in pulmonary failure patients, and 45% in stem cell transplant patients. Patients who were less than 10kg had lower survival (43%) vs. those above 10 kg (64%). However, survival of children under 5 kg was no different from those between 5 and 10 kg. CRRT was feasible

even amongst the smallest of children, and extended duration greater than 28 days had 35% survival rates. Finally, the use of CRRT in children with inborn errors of metabolism, drug intoxication, or tumor lysis syndrome also had good survival at 62%, 95%, and 82%[26,27].

Callegari et al noted that developing viable treatment programs for kidney failure in sub-Saharan Africa is an imposing challenge. They also noted that peritoneal dialysis (PD) is an effective and simpler modality compared to hemodialysis (HD). Amongst the 28 patients included in a pediatric program at the Komfo Anokye Teaching Hospital in Kumasi, Ghana, treated with PD for AKI, half were discharged having fully recovered kidney function. Seven patients (25%) had end-stage renal disease and a further 7 (25%) died during hospitalization[28].

A Study in southwest Nigeria on PD in children with AKI recorded a survival of 70%.It concluded that, in low-resource settings, PD can be successfully performed for the treatment of childhood AKI. This study included 27 children with 55.6% being female with mean age of 3.1 ± 2.6 years. The causes of AKI were intravascular hemolysis (40.7%), septicemia (29.6%), acute glomerulonephritis (11.1%), gastroenteritis (11.1%), and hemolytic uremic syndrome (7.4%). Peritoneal dialysis was performed using percutaneous or adapted catheters. The duration of PD extended from 6 hours to 12 days with mean of 5.0 ± 3.3 days. The recorded complications were mainly peritonitis (37.0%), pericatheter leakage (33%), and catheter outflow obstruction (18.5%)[29]

A similar study by Kilonzo et al[30] at the Kilimanjaro Christian medical center in Moshi, Tanzania also demonstrated that optimal results from PD are possible. In this study they recorded an 80% survival rate .

1.1.1 PD Catheter Type and Design

Many catheter types and designs are available for PD. In common use is the double cuff catheter which has straight intra-abdominal section known as the Tenckhoff catheter .Others in use include the Missouri and the Toronto western catheters[31]. Silicone is used in most catheters. Others are made from polyurethane e.g. the Cruz catheters. However none resists biofilm formation. Some guidelines prefer double over single cuff catheters as they seem to have fewer complications. They also have longer time to first peritonitis with longer survival[32].A study in 2000 showed the Tenckhoff catheter to be superior to the stiffer Cook

catheter in terms of complication free survival. More recently there is an equal outcome with the cook multipurpose catheter that is easily placed at the bedside. The 2005 ISPD guidelines however suggest that no catheter type has been shown to be superior to the standard Tenckhoff catheter for peritonitis prevention[33] .

Several studies have looked at different PD catheter designs to determine whether any one catheter design is more protective against infection. Data on use of single- versus double-cuff catheters are conflicting[34,35]. In theory, the presence of a second, more superficial cuff could act as an additional microbial barrier. A randomized control trial that tested whether single-cuff catheters are inferior to double-cuff catheters for peritonitis prevention was conducted by Eklund et al[34]In this study, 60 patients were randomized to insertion of a single- or double-cuff catheter and followed for 2 years. There was no difference in the peritonitis rate between these groups. Peritonitis is a relatively rare event. The use of a double-cuff catheter would only be expected to reduce the rate of peritonitis episodes caused by periluminal entry of organisms, a large number of patient-years of follow-up evaluation might be required to detect such a difference, if one does exist. More recently, using the multicenter Canadian peritonitis organism exit sites tunnel infections (POET) database, use of a double-cuff catheter relative to a single-cuff catheter was found to be independently associated with a reduced risk of peritonitis, although this effect was most pronounced before the year 2000[36].There was a 54% reduction in peritonitis caused by *S aureus*. Because this is the organism most likely to enter the peritoneal cavity via migration along the catheter tunnel, it supports the hypothesis that double-cuff catheters provide an added barrier to periluminal movement of organisms into the peritoneal cavity.

1.1.2 Placement Technique

Traditionally PD catheters have been inserted via the open surgical method.

Newer techniques via laparoscopic and subcutaneous roots have since been developed. From observation the main method used at KNH is the open method.

The experience of the surgeon is the most important consideration for the successful placement and function of a PD catheter in the young infant [37].Various other factors also require consideration when inserting a PD catheter:- use of prophylactic antibiotics ,location of exit site, , implantation technique, pre- and post operative care of the catheter and temporal needs for dialysis.

1.1.2.1 Exit site location:

The exit site should also be placed outside of the diaper area. potential gastrostomy site should be avoided. The superficial cuff should be located approximately 2 cm from the skin surface[38].Due to the small size of the infant patient, these can be difficult to meet. A paramedian location rather than the midline allows for positioning of the deep cuff in or below the rectus muscle for better tissue ingrowths around the cuff due to superior vascularization. This also enables better structural support for and around the catheter thus minimizing leaks as it forms a strong seal around the catheter[39]. Pre-sternal location may be preferable in obese, the very young, ureterocutaneostomies and patients with recurrent exit site infections with abdominal PD catheters. The smallest possible hole for exiting the catheter is preferred as large holes are associated with infections and catheter removal[40]. Suture material should never be placed at this site as it acts as a nidus for infection. In any case the fibroblast in growth around the Dacron cuff forms a sufficient anchor.

1.1.2.2 Antibiotics at the Time of Catheter Insertion

The skin is colonized by many organisms, and typically this skin flora consists predominantly of gram-positive organisms. Although the PD catheter is inserted under sterile conditions after appropriate cleansing of the skin, this procedure nevertheless may serve as an entry point for organisms into the peritoneal cavity, leading to peritonitis within the first few weeks after catheter insertion.

The effectiveness of prophylactic antibiotics was first reported in a study comparing perioperative gentamicin with no prophylaxis[41].The favorable effect of prophylaxis in this study was subsequently confirmed in a large American observational study, in which use of antibiotics before catheter insertion was associated with a 29% reduction in peritonitis

risk[42].Although a favorable effect of antibiotics was also seen in another study, not all observational studies have shown this association[43,44].

There have been randomized controlled trials (RCT) of antibiotic prophylaxis pre-PD catheter insertion. In one of the RCT involving 38 patients randomized to placebo or cefuroxime, the proportion of patients in the placebo group who developed peritonitis was unusually high in this study[45]. Despite the limited data and relatively small study size, it appears that use of prophylactic antibiotics before catheter insertion is beneficial.

The optimal regimen is less clear because there is significant variability in antibiotic susceptibility across hospitals, cities, and countries. Antibiotic choice therefore should be guided by local susceptibility patterns. With regard to the optimal timing of antibiotic administration, there are few specific PD catheter insertion data, but extrapolation from the general literature on surgical wound infections would suggest that optimal timing of administration is in the 2 hours before the procedure[46]. Vancomycin may be an exception to this recommendation, owing to its longer half-life in the setting of impaired renal clearance.

1.1.2.3 Open surgical technique

Traditional open surgical insertion usually involves a general anesthetic because this provides better pain control than local anesthetic and the abdominal muscle tone is reduced, facilitating catheter insertion. A 3 to 5 cm infraumbilical vertical paramedian or midline incision is made and after blunt dissection through the rectus muscle to the peritoneum. The catheter is then placed deep in the pelvis. The deep cuff is placed in the rectus, the muscle layer is closed, and a tunnel and exit site subsequently is created. The catheter then is tested for function with in-and-out instillation of small-volume dialysate[47]. The decision whether to routinely perform an omentectomy is somewhat controversial. A survey of pediatric surgeons indicated that an omentectomy is performed routinely in 53% of pediatric centers at the time of catheter placement[48].

The basis for its performance in children is because catheter obstruction (usually caused by omentum wrapping) is second commonest of major catheter complications in the age group[49].

After standard surgical PD catheter placement, there is a need for nursing resources for dressing changes and flushing and heparinization of the catheter. There is no evidence that routine postoperative flushing of PD catheters is needed, although this has not been studied

properly, and most centers perform regular flushing and heparinization of the catheter until PD training starts[50].

Use of the catheter immediately after insertion is possible if urgent initiation of dialysis is required for uremic symptoms or fluid overload. In these cases, small-volume, automated PD in the supine position is the best approach to minimize the risk of leakage.

1.1.3 Complications of peritoneal dialysis

PD catheter insertion is relatively considered a minimal invasive procedure but it is associated with some complications. These are divided into mechanical (bleeding, visceral perforation, dialysate leaks, catheter dysfunction, hernia formation, cuff extrusion) and infectious (early peritonitis, surgical wound, tunnel and exit site infections).

After insertion of the peritoneal catheter, bleeding into the peritoneal cavity(Haemoperitoneum) occurs in less than 5 percent of cases[51]. This is recognized by bloody peritoneal dialysate. Such bleeding is usually mild and resolves with the performance of several exchanges. Intra- peritoneal bleeding can induce peritoneal inflammation resulting in the formation of intra-abdominal adhesions and entrapment of the catheter tip. Bleeding also can result in clot obstruction of the catheter. If significant intra- peritoneal bleeding is suspected, then imaging of the abdomen should be done. Early Laparoscopy or laparotomy may be needed.

Reported outcomes with open surgical insertion are highly variable[50,52,53]

The major mechanical outcomes of interest are early leaks and early outflow obstruction because these are the common technical causes of early catheter failure.

Pericatheter leakage is recognized by the presence of fluid in the area surrounding the catheter. However, the initial manifestations of pericatheter leakage may be subtle. Subcutaneous swelling, which may be overlooked, and diminished outflow volumes, may precede frank leakage. Genital and abdominal wall edema may also indicate the presence of a subcutaneous leak. If the source of the fluid is unclear, dextrostick testing will yield an extremely high glucose concentration if the fluid is dialysate. By comparison, serosanguineous fluid leaking from subcutaneous tissue will not be strongly positive for glucose.

Leaks are in part dependent on surgical technique (e.g. proper placement of the deep cuff of the catheter in the rectus muscle), but also depend on how long the catheter is allowed to heal. For example, Tzamaloukas et al[54] reported that 90% of early leaks occurred in patients whose catheters were inserted less than 10 days before use. The International Society of Peritoneal Dialysis (ISPD) recommends waiting 2 weeks after insertion before using the catheter, and optimal catheter healing times are the subject of an ongoing randomized controlled trial[3,55].

Rates of early catheter obstruction/outflow failure are highly variable with rates between 6% to 29% in recent prospective studies[53,56]. Outflow failure, is defined as incomplete recovery of instilled dialysate.

Data on early catheter mechanical failure, such as primary catheter failure, or requirement for a procedure to establish patency, are not widely reported. Outflow obstruction refractory to conservative measures is unfortunately common and usually caused by anatomic problems. In reports of refractory obstruction, omental wrapping is the most common cause and is reported in 35% to 80% of cases[57]. In many cases, migration of the catheter out of the pelvis is the result of omental wrapping and subsequent displacement, although some series have reported migration without other anatomic findings, suggesting that surgical technique and excessive torque on the catheter may be responsible in some cases [57]. Obstruction as a result of adhesions is reported in 8% to 40% of cases, and catheter wrapping by fimbriae of the fallopian tubes also has been reported[58]. Intraluminal obstruction as a result of fibrin plugs, blood clots, or kinking is reported, but its true prevalence is likely underestimated in the surgical literature because it seldom is refractory to the point of requiring surgery[57].

Despite substantial advances in peritoneal dialysis (PD) as a renal replacement modality, PD-related infection remains an important cause of morbidity, technique failure, and mortality. The most frequent type of PD-related infection is peritonitis. In older children, abdominal pain is a common symptom. PD-related peritonitis, the catheter exit site may show purulent drainage and the tunnel sinus may be tender or swollen. A PD patient presenting with cloudy effluent or abdominal pain should be presumed to have peritonitis. This is confirmed with a cell count, 100 or more WBC per microlitre, 50% or more polymorphonuclear white cells. Patients with a bowel perforation causing secondary or enteric peritonitis may have stool in the dialysate.

Less commonly, PD patients can develop catheter infections, including exit site infection and/or tunnel infection. In a study looking at the outcome of acute kidney injury in Sudanese children, Abdelraheem et al[59] found that 15.4% of the patients developed peritoneal dialysis related peritonitis while Ademola and his group[29] in Nigeria recorded peritonitis in 37% of their patients . Although the microbiology of peritonitis and catheter infection has varied to some extent over time and across different PD centers and countries, several findings are relatively consistent. For peritonitis, gram-positive organisms are at least twice as common as gram-negative infections, accounting for about 50% to 70% of episodes[60,61]. The most common gram-positive organism is coagulase-negative *Staphylococcus* (CNS), followed by *S aureus* and *Streptococcus* species. Gram-negative organisms currently account for approximately 20% to 25% of peritonitis episodes[62] . The most common gram-negative organism is *Esch- erichia coli*, seen in approximately 6% of patients, followed by *Klebsiella*, *Pseudomonas*, and, more rarely, other enteric gram-negative bacteria [60].Fungal peritonitis accounts for about 3% of infections, and mycobacterium infections are even less common.

Catheter infections most often are caused also by gram-positive organisms, accounting for two thirds to three quarters of episodes[60]. Although *S aureus* has been the most common exit site organism, use of prophylactic measures has led to a significant reduction in the frequency of this organism as a culprit in catheter infections [63]. Exit site infection is identified by erythema, skin color change, drainage, swelling, crusting or tenderness around the catheter exit. Tunnel infection presents with erythema, edema or tenderness along the subcutaneous pathway but often occult. It occurs almost always in conjunction with exit site infection. S *aureus* and P *aeruginosa* often causes tunnel infection. Tunnel sonography can be used to diagnose and monitor progress of tunnel infection.

The most frequent cause of catheter infection among gram-negative organisms by far is *Pseudomonas*, accounting for 13% to 18% of exit site infections in North America[60] . Exit site/tunnel infections should be treated with oral antibiotics. The catheter however should be removed if there's no improvement in three weeks, P *aeruginosa* is cultured or peritonitis develops.

1.2 STUDY JUSTIFICATION

Peritoneal dialysis is a common method of RRT in our hospital. Different techniques and catheter types are available for use and this procedure is not without complications. The surgical outcomes of this intervention, the impact of the different techniques and catheter types have not been assessed in a local study.

1.3 MAIN OBJECTIVE

To assess the rate of early surgical complications during peritoneal dialysis in children with acute kidney injury.

1.3.1 Specific objectives

- To determine the catheter types used in peritoneal dialysis.
- To determine the surgical techniques used to insert peritoneal dialysis catheters.
- To estimate the rate of early surgical complications during peritoneal dialysis.

2.0 METHODOLOGY

2.1 Study design

This was a descriptive cross sectional study.

The study was carried out at KNH in the pediatrics ward and the paediatric specialized unit over a period of five months. All the children twelve years and below who met the inclusion criteria were consecutively recruited for the study. A data sheet was used for data entry .The data to be entered was abstracted from the patients records during the period of admission in the hospital and included records of biodata ,history, physical findings ,laboratory reports, theatre procedures and patient disposition among others.

2.2 Inclusion criteria

Admitted Paediatric Patients with AKI and consenting guardians with indication(s) for and who underwent PD catheterization.

2.3 Exclusion criteria

- Patients with non consenting guardians.
- Patients with chronic renal failure.
- Patients with AKI and previous abdominal surgeries or abdominal wall defects.
- Children with AKI who will have died before placement of PD catheter.
- Patients who have catheters already on admission.

2.4 Sample size calculation

For a descriptive study:

Assumptions made include:-

Estimated incidence of AKI is 2%[21]

Confidence level set at 95%

Using the formula:

$$n=\frac{Z^2 p(1-p)}{e^2}$$

Where n = sample size,

Z = Z statistic for a level of confidence,

P = expected prevalence or proportion

And

e = precision

(In proportion of one; if 5%, e = 0.05).

For the level of confidence of 95%, which is conventional, Z value is 1.96

n= $(1.96^2*0.02*0.98)/0.0025=31$

2.5 Data collection

Two experienced nurses, residents in paediatric surgery rotation were requested to be research assistants. They were briefed on the study objectives and methodology. The data collection form was explained to them. The pediatrics wards, intensive care units and the paediatric specialized unit were the sites of recruiting patients into this study. The researcher and research assistants collected data from consenting patients' parents/guardians on a pretested data sheet.

Details on antibiotic prophylaxis, type of anaesthesia used, surgical technique, catheter type and visceral injury were obtained. From the paediatric specialized unit and paediatric wards the patients were observed for pericatheter leaks. In case of doubt glucose dipstick was used to differentiate leaks from inflammatory fluids. Amounts of dialysate in versus amount out were recorded to detect any outflow failure. The colour of dialysate output was observed every day. Cloudy dialysate, new onset abdominal pain in older children along with rigidity/guarding with SIRS were evaluated for peritonitis. Signs of exit sign infections was sought and noted in the data sheet. The patients were followed up daily for up to two weeks or when the PD catheter was removed.

2.6 Data analysis

Data from questionnaires were entered into Epi-data software version 1.4.4.6. Analysis was done using Software for statistical analysis STATA version 11.0. Continuous variables were represented using degrees of central tendency such as means and medians with interquartile ranges (IQR).Data editing and reconciliation including coding and cross tabulation was undertaken before analysis was done.

2.7 Study limitation

1. Short duration of study compared to the number of cases
2. Small sample size which statistically may not prove much.

2.8 Results dissemination

Results of this study will be disseminated to the head of department of paediatric surgery at KNH and to the overall head of surgery KNH. Copies will also be availed to the UoN department of surgery and the College of Health Sciences library.

3.0 ETHICAL CONSIDERATION

This study commenced after approval from the Department of Surgery UoN and the UoN-KNH ERRC.

The parent/ guardian received a pre-consent counseling on the study after which an informed consent was obtained from them.

With a signed informed consent the patients were enrolled into the study.

Parents/guardians were not coerced to enroll the patients into the study. Non-participation did not affect such a patient's care in the hospital.

Participation in this study did not attract extra cost to the medical care of the participants.

Patients' hospital file number will be included into the data sheet to facilitate easy tracing and capture missed information during data collection.

The data sheet was kept safely with the researcher and confidentiality maintained throughout. Electronic data file generated was encrypted with a password only availed to the research team. Any hard copy research data was kept in a safe locked cabinet only accessed by the research team. The collected data was destroyed after completion of this study.

4.0 RESULTS

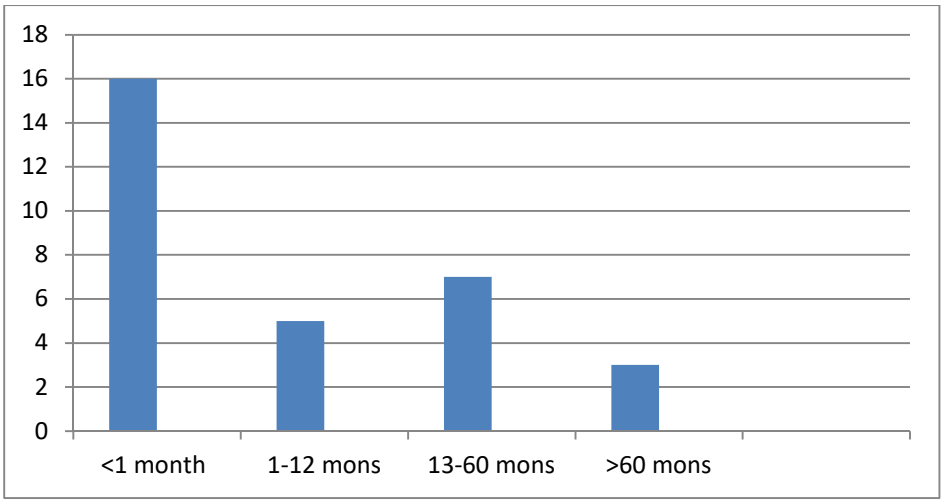
Data collection began on December 2015. Thirty one cases were recruited over a period of five months (December 2015 to April 2016).

4.1 Age/sex distribution

The youngest patient was 4 days old while the oldest was 9 years. Most of the patients were less than a month old (51.6%) followed by those between one year to 5 years (22.6%). The average age was twelve days with interquartile range of nine days to three years.

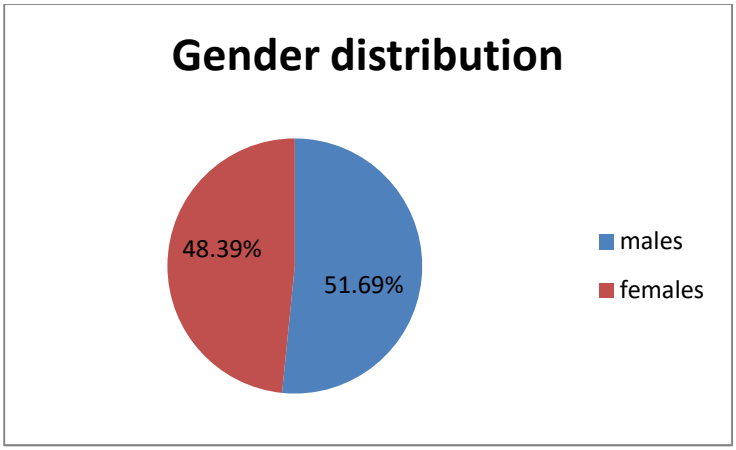
The age distribution is represented in the graph below

Figure 1: Age distribution Graph



The gender frequency had a slight male preponderance with a male to female ratio of 1.07: 1.

Figure 2: Pie chart showing gender distribution



4.2 Prophylactic Antibiotics

All the patients had received antibiotics prior to insertion of PD catheters. Ceftazidime, Ceftriaxone and Meronem were the antibiotics in use with the percentage of 83.87, 9.68 and 6.45 respectively. Most patients were therefore overwhelmingly on Ceftazidime.

Table 1: Frequency distribution table of prophylactic antibiotics given

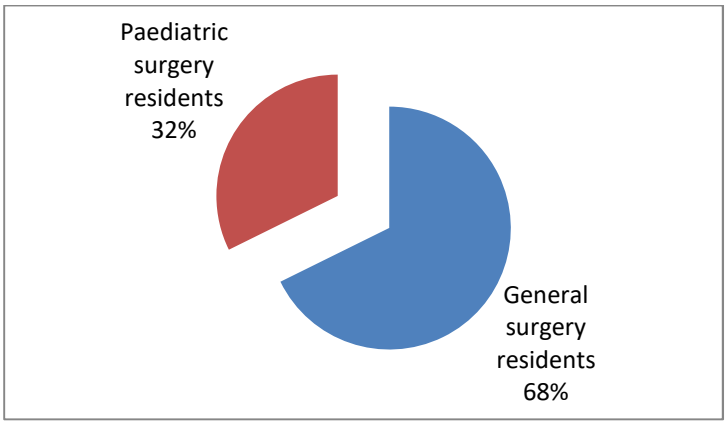
Antibiotic	Frequency	Percentage	cum
Ceftazidime	26	83.87	83.87
Ceftriaxone	3	9.68	93.55
Meronem	2	6.45	100
Total	31	100	

4.3 Cadres inserting the PD catheters

The catheters were either inserted by general surgery residents (67.74%) or paediatric surgery residents (32.26%).

The Pie chart below shows PD catheter insertion by different surgical residents.

Figure 3: PD insertion by Residents



4.4 Type of Anaesthesia used

Almost half (48.38%) the cases were done under general anaesthesia, 25.81% had local anaesthesia while the rest had a combination of general and local anaesthesia.

Table 2: type of anaesthesia used

Type of anaesthesia	Frequency	Percent	Cum
Local	8	25.81	25.81
General	15	48.38	74.18
Local with sedation	8	25.81	100
Total	31	100	

4.5 PD catheter insertion method

All the catheters were inserted by the open method. Catheter exit site was on the left lateral infraumbilical area.

Table 3: PD catheter insertion Method

Insertion method	Frequency	Percent	Cum
Open	31	100	100
Total	31	100	

4.6 PD catheter types

The majority of catheters inserted were single cuff (70.97%). The remaining were double cuff (29.03%) catheters. The double cuff ones were used in the older children (>three years).

Table 4: PD catheter types

Catheter type	Frequency	Percent	Cum
Single cuff	22	70.97	70.97
Double cuff	9	29.03	100
Total	31	100	

4.7 PD catheter tunneling

Regarding tunneling, 93.55% of the PD catheters were tunneled with 6.45% not being tunneled.

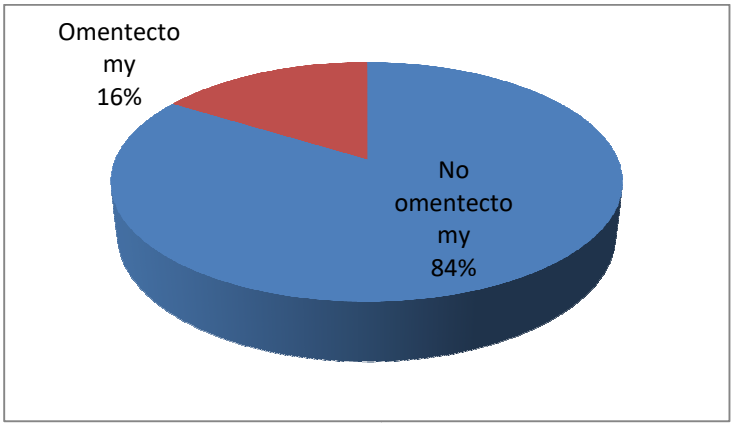
Table 5: tunneling of PD catheter

Catheter Tunneling	Frequency	Percent	Cum
Yes	29	93.55	93.55
No	2	6.45	100
Total	31	100	

4.8 Practice of omentectomy

Omentectomy was done in 16.13%. The majority however did not undergo omentectomy (83.87%). The extent of omentectomy however was not recorded.

Figure 4: practice of omentectomy



Visceral injuries, excessive bleeding during catheter insertion

No visceral injuries or excessive bleeding during catheter insertion were recorded.

4.9 Pericatheter dialysate leak

After initiation of PD catheter dialysis 22.58% were noted to have overt leakage. The mean leak time was 5.857 hours after initiation of catheter use and the largest standard deviation from this was 4.488 hours.

Table 6: Pericatheter dialysate leak

Dialysate leak	Frequency	Percent	Cum
Yes	7	22.58	22.58
No	24	77.42	100
Total	31	100	

4.10 PD outflow failure

Four patients had PD outflow failure representing 12.90%. The rest of the catheters were working well (87.10%). The median time to PD blockage was 60 hours with an interquartile range of 48-84 hours.

Table 7: PD outflow failure

PD outflow failure	Frequency	Percent	Cum
Yes	4	12.90	12.90
No	27	87.10	100
Total	31	100	

Figure 5: Time to outflow failure

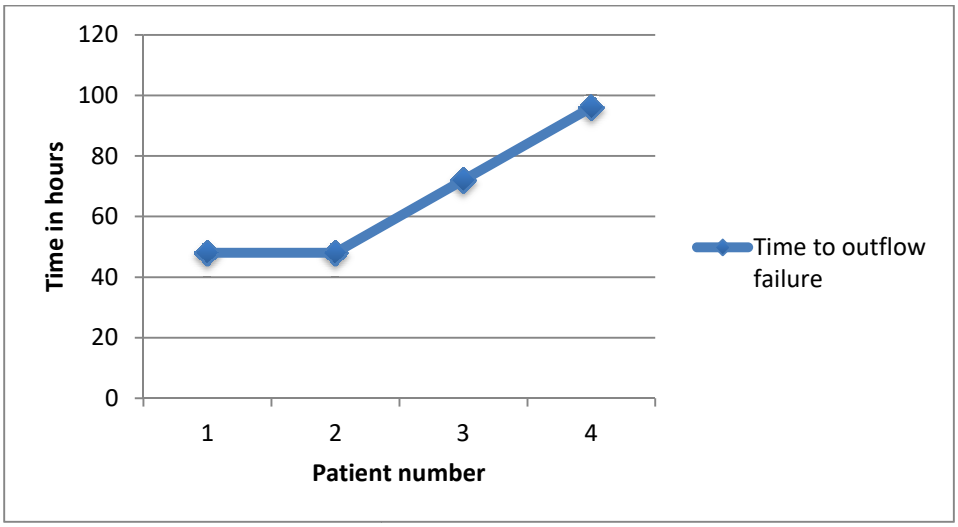


Table 8: outflow failure refractory to conservative management

Refractory failure	Frequency	Percent	Cum
Yes	4	100	100
Total	4	100	

All the patients who had outflow failure needed new PD catheters after conservative measure of flushing the catheter to dislodge possible clots or repositioning had failed.

4.11Peritonitis

One patient was diagnosed with peritonitis based on turbid dialysate and fever. No microbiological studies were done.

Table 9: peritonitis

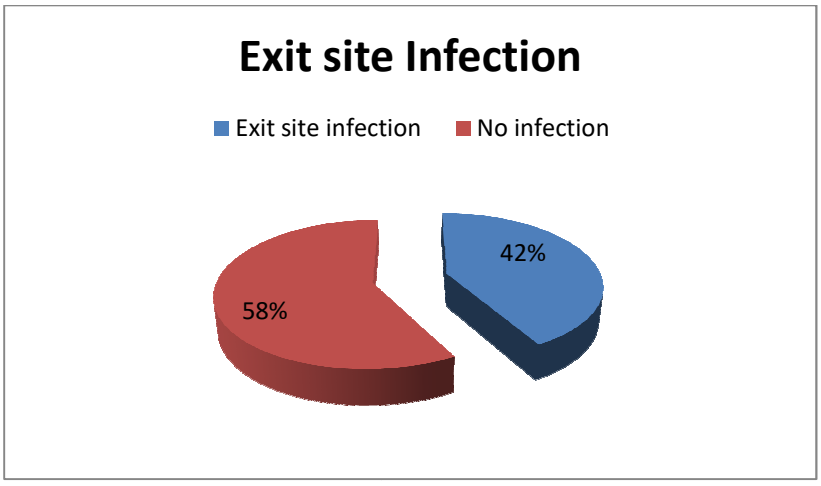
Signs of peritonitis	Frequency	Percent	Cum
Yes	1	3.23	3.23
No	30	96.77	100
Total	31	100	

4.12 Exit site infection

It was noted that 41.94 % of the patients had exit site infection.

None of the patients had microbiology culture done.

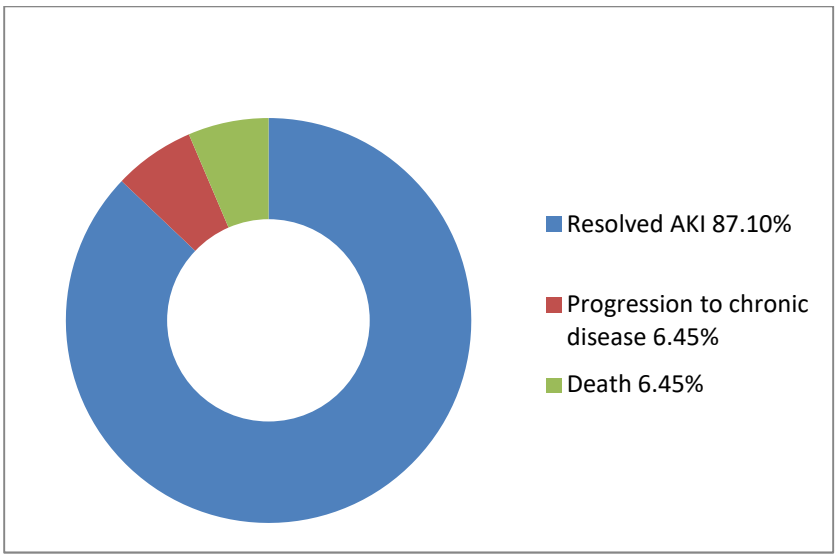
Figure 6: Exit site infection



4.13 Final outcome

A majority of the patients had resolution of AKI (87.10%). However 6.45% progressed to chronic kidney disease while two children passed on representing another 6.45%.

Figure 7: final outcome



4.14 Correlations

4.14.1 Residents and pericatheter leakage
Fischer's exact test was 0.652.

1-sided Fischer's exact test was 0.401. The differences in leak rates between the two groups of residents were therefore not statistically significant.

Table 10: Residents and pericatheter leakage

Resident	Leak presence		Total
	Yes	No	
General surgery	4 57.14%	17 70.83 %	21 67.74%
Paediatric surgery	3 42.86%	7 29.17%	10 32.26
Total	7 100%	24 100%	31 100%

4.14.2 Residents and PD outflow failure

The Fischer's exact was 0.277.

1-sided Fischer's exact was 0.190. . The differences in outflow block rates between the two groups of residents were not statistically significant.

Table 11: residents and PD outflow failure

pd catheter inserted by	PD outflow failure Yes No	Total
General surgery resident	4 17 100.00 62.96	21 67.74
Paediatric surgery resident	0 10 0.00 37.04	10 32.26
Total	4 27 100 100	31 100

4.14.3 Catheter type and dialysate leakage

All the catheters which had leakage were single cuffed. However the 1-sided Fisher's exact test was 0.065 showing no statistical significance.

Table 12: catheter type and dialysate leakage

Catheter type	Leak	Total
	Yes No	
Single cuffed	7 15	22
Double cuffed	0 9	9
Total	7 24	31

4.14.4 Catheter type and PD outflow failure

The 1-sided Fischer's exact test was 0.673. The correlation was not statistically significant.

Table 13: catheter type and outflow failure

Catheter type	PD outflow failure Yes No	Total
Single cuff	3 19	22
Double cuff	1 8	9
Total	4 27	31

4.14.5 Tunneling and dialysate leakage

The two catheters which were not tunnelled did not leak. However the p-value was 0.594 therefore not statistically significant.

Table 14: tunneling and Dialysate leakage

	Leakage		Total
	Yes	No	
Tunnelled catheter	7	22	29
Non-tunnelled catheter	0	2	2
Total	7	24	31

4.14.6 Tunneling and catheter blockage

The four catheters which had outflow failure had all been tunnelled. The P-value though was not statistically significant (0.755).

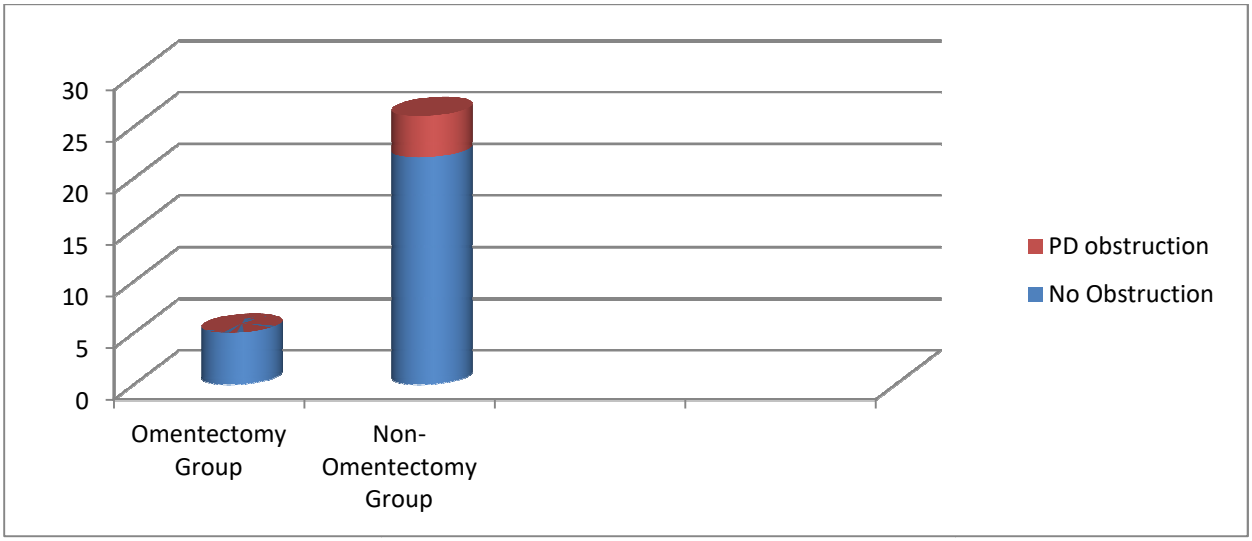
Table 15: tunneling and catheter blockage

	PD outflow failure		Total
	Yes	No	
Tunnelled catheter	4	25	29
Non-tunnelled catheter	0	2	2
Total	7	24	31

4.14.7 Omentectomy and PD outflow obstruction

The four patients who had refractory outflow obstruction had not undergone any degree of omentectomy. In the omentectomy group, no obstruction was recorded. However the 1-sided Fischer's exact test was not statistically significant (0.475).

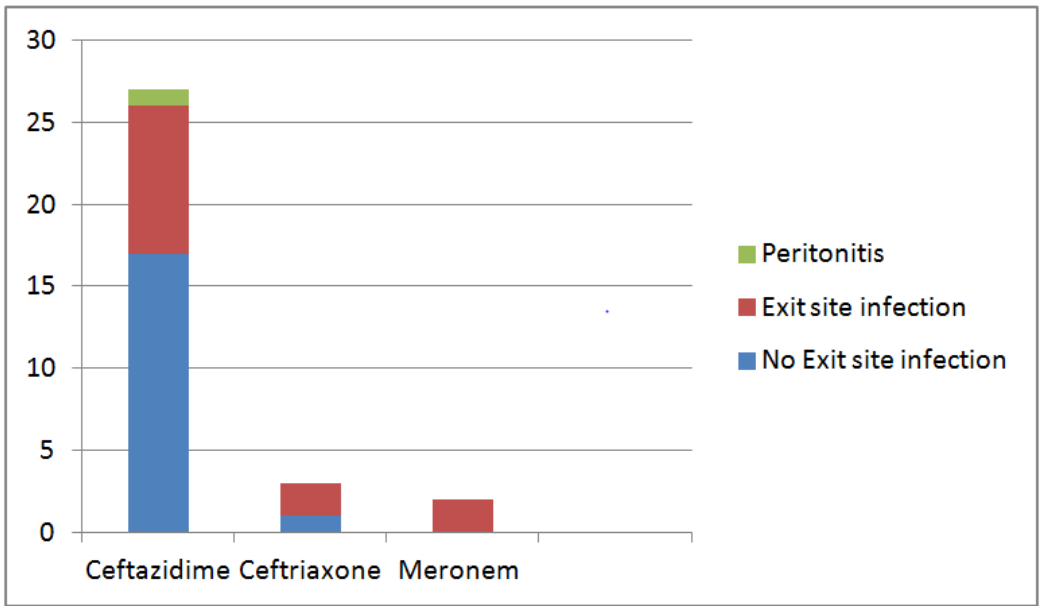
Figure 8: Omentectomy and PD outflow obstruction



4.14.8 Antibiotics and exit site antibiotics and infection/peritonitis

The correlations between the three different antibiotics used and the infectious complications were not statistically significant. For peritonitis Fischer's test was 1.000 while for exit site infection it was 0.147.

Figure 9: Antibiotics and exit site infection/peritonitis



5.0 DISCUSSION

The PD catheter types used were two: - the single cuff or the double cuff catheters. There had been reports of improvised PD catheters from Foley catheters or giving sets but these were not observed during the study. The common catheter in use was the single cuff catheter at 70.97%. Double cuff catheter was used in children older than three years.

All the patients received prophylactic antibiotics before insertion of PD catheters. Despite limited data and relatively small study size, use of prophylactic antibiotics before catheter insertion is beneficial especially in reducing the incidence of peritonitis[45]. In this study all patients received prophylactic antibiotics and the rate of peritonitis was 3.23% which is much lower than other similar studies in Africa. Most of these patients received Ceftazidime (83.87%). This perhaps was not guided by microbiology and sensitivity patterns but it may be empirical use.

General anaesthesia was used in 48.38% of the patients. Local anaesthesia was used in 25.81% while the remaining had a combination of both local anaesthesia and sedation.

The catheters were inserted by the open method (100%). The exit sites for the catheters were placed in the left paramedian, about inch below the umbilicus. This position varied for the patients who needed re-catheterization. There were no presternal exit site locations. A survey of pediatric surgeons indicated that an omentectomy is performed routinely in 53% of pediatric centers at the time of catheter placement[48]. In this study omentectomy was done in only 16.13% of the patients. There were no visceral injuries or severe bleeding during the insertion. The overall incidences of such injuries are low[51] and therefore PD catheter insertion via the open method remains relatively safe. Tunneling of the PD catheters was done in 93.55% of the patients.

The early surgical complications associated with peritoneal dialysis were analysed over a two week period. Right from the point of insertion the study sought whether there were any visceral injuries during insertion or excessive bleeding along the PD truck. None of the two was recorded. Kimmelstiel et al recorded the incidence of intestinal perforation as less than 1%. Other studies have recorded similarly low rates[64 65].

Tzamaloukas et al[54] reported that 90% of early leaks occurred in patients whose catheters were inserted less than 10 days before use. This study had 22.58% of pericatheter leaks. The two week waiting period recommended by ISPD is not practical in the acute setting. The leak

rate reported probably missed out on the smaller volume leakages. Of the leaking catheters, 28.57% required revision surgery to stop the leakage. The rest responded to pressure dressing method. The mean leak time of dialysate was 5.85 hours.

Rates of early catheter obstruction/outflow failure are highly variable. Rates between 6% to 29% have been reported in recent prospective studies[53,56]. We found 12.90% of outflow failure. The median time to PD blockage was 60 hours with an interquartile range of 48-84 hours.

All the blocked catheters did not respond to conservative measures and eventually had to be replaced in theatre. The subsequent catheters did not exhibit outflow failure. Omentectomy wasn't done in the second replacements.

Low peritonitis rate of 3.23% was recorded during the study. . This is in contrast to other studies done in Africa Abdelraheem et al[59] found that 15.4% while Ademola and his group[29] in Nigeria recorded peritonitis in 37% of their patients. This huge discrepancy might be explained by absence of regular dialysate analysis. Gram-positive organisms are isolated at least twice as common as gram-negative infections, accounts for about 50% to 70% of episodes[60,61]. In the study, no microbiology culture was done.

The study revealed exit site infection rate of 41.94%. These were superficial surgical site infection around the catheter characterized by erythema, swelling and sometimes pus discharge. Of these only 15.3%, which were deep SSI required change of catheter to treat the condition. The remaining healed uneventfully from cleaning and antibiotics administration. No biological material was obtained for culture studies.

In the two week period of the study 87.10% of the patients had resolution of AKI following peritoneal dialysis, 6.45% progressed to chronic renal disease while a further 6.45% succumbed to their illness. A study by Om P Mishra et al found a mortality rate of 36% following PD in AKI in children. The follow up period of the patients was not clear.

A number of correlations were done but none was found to be statistically significant.

Between the different residents, the complication rates were not statistically significant.

Between the two catheter types used, the p value of leakage rates was 0.065 while that of outflow obstruction was 0.673.

The p values for correlation between tunneling and dialysate leakage and tunneling and catheter blockage was 0.594 and 0.755 respectively. Amongst the patients who underwent omentectomy no PD outflow failure was recorded. However the p value was 0.475.

There was no significant difference between the antibiotics used and the rate of infectious complications. Regarding the rate of peritonitis amongst the three antibiotics , the Fischer's test was 1.000 , while that for exit site infection was 0.147.

5.1 Conclusion

Peritoneal dialysis is the primary method of treating children who have AKI in KNH.

All the patients receive prophylactic antibiotics and different kinds of anaesthesia are used.

The PD catheters are inserted by general and paediatric surgery residents who only use the open method, employ mostly single cuff catheters and rarely do omentectomy.

Little complication is encountered during insertion of the PD catheters. Leaking /blocked PD catheters is probably rare and may resolve with conservative measures.Peritonitis from PD used is rarely diagnosed /sought after.Catheter site infection is fairly common but the majority resolves without a need for catheter removal. There's no difference in complication rates between the different groups of surgical residents.

The difference in complication rates between the different antibiotics used, catheters ,surgical techniques(tunneling and omentectomy) are not statistically significant.

Most of the patients do well in the two week after initiation of PD treatment.

5.2 Recommendation

I. Interventional study to look at microbiological profile of PD catheter infectious complications.
II. Randomized study to assess the effect of omentectomy on catheter outflow blockage.
III. A study with a longer time frame to assess the chronic surgical complications and eventual outcome of PD treatment.
IV. Assessment of awareness about other PD catheter insertion methods or why they are not being employed and yet they may be more cost effective.

STUDY BUDGET

Budget Item	Amount (K.shs)
Research fee for KNH-ERRC	2000
Statistician consultation fee	20,000
Stationery; (a) Printing (b) Photocopying (c) Binding (d) Pens	 15,000 6000 32000 500
Research assistants fee @15000 each (two assistants)	25000
Contingency fund	20,000
Total	120,000

The researcher funded the budget.

STUDY TIME FRAME

ACTIVITY	Feb 201	Mar 2015	Apr 201	Ma y	Dec 2015	Jan 201	Feb 2016	Mar 2016	Apr 2016	Apr 201	Apr 2016	Ma y
Proposal development												
Ethical Approval												
Data Collection												
Data Analysis												
Dissertation Writing and presentation												

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APPENDICES

Appendix I: Consent form English version

Informed consent;

EARLY SURGICAL COMPLICATIONS OF PERITONEAL DIALYSIS CATHETERS FOR ACUTE KIDNEY INJURY IN CHILDREN AT KENYATTA NATIONAL HOSPITAL

This Informed Consent form is for pediatrics patients less than twelve years with acute kidney injury admitted at the Kenyatta National Hospital who needs peritoneal dialysis. This consent will be administered to the parents/patient's guardians. We are requesting these patients to participate in this research project whose title is "Early surgical complications of peritoneal dialysis catheters for acute kidney injury in children at Kenyatta National Hospital".

Principal investigator: Dr. Edwin Odira.

Institution: School of Medicine, Department of surgery- University of Nairobi

Supervisors: Dr Ndungu JM, Dr Osawa FO and Dr Githaiga JW.

This informed consent has three parts:

I. Information sheet (to share information about the research with you)
II. Certificate of Consent /assent(for signatures if you agree to take part)
III. Statement by the researcher

You will be given a copy of the full Informed Consent Form.

Part I: Information sheet

My name is Dr Edwin Odira; I am a post graduate student at the University Of Nairobi School Of Medicine, department of general surgery. I am carrying out a study to determine the rate of early surgical complications during peritoneal dialysis amongst children who have had sudden onset renal failure in our hospital, KNH. This would be possible through data collection by filling in questionnaire and regular examination of the patient during the course of treatment of the kidney failure. Information obtained from this study will reveal to the doctors the magnitude of surgical complications we have during such treatment in order to be better prepared to handle and indeed avoid them where possible. This study is also a requirement for any doctor who aspires to graduate from our college as a surgeon.

An invitation to participate in this study is hereby extended to you. You will have the opportunity to ask questions before you decide on your Child's/kin's enrollment into the study. You may seek clarification regarding any bit of the study from my assistant(s) or I should any part be unclear.

All the information which you provide regarding your child/kin will be kept confidential; only the researchers will access this information. They will be identified by a number and only the researchers can relate the number to the patient. The information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC).

Your child or kin's involvement in this research will be through an interview and clinical evaluation and they will not expose themselves to any risks if you consent on their behalf, to participate. There will be no extra cost incurred for participating in the study. Participation in this study is voluntary, your child or kin will not be denied medical care in case you refuse to participate in the study .You may stop participating at any time with no consequences whatsoever. There will be no material gain/compensation from participating in the study. All the information that you give us will be used for this research only.

The purpose of this research will be explained to your child too if he/she is between 7 to 12 years old and their willingness/lack thereof to participate in this study will be respected.

This proposal has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm. The contact information is given below if you wish to contact any of them for whatever reason;

Secretary, KNH/UoN-ERC

P.O. Box 20723 KNH, Nairobi 00202

Tel 726300-9

Email: uonknh_erc@uonbi.ac.ke

University of Nairobi research supervisors:-

Dr Ndungu JM

MBChB, M.Med general surgery, Fellow paediatric surgery

Senior lecturer and consultant paediatric surgeon

P.O. Box 19676 KNH, Nairobi 00202

Tel # 0202726300

Dr JW Githaiga

MBChB, M.Med general surgery

Senior lecturer and consultant general and laparoscopic surgery

Department of surgery, UON.

P.O. Box 19676 KNH, Nairobi 00202

Tel # 0202726300

Dr Osawa F

MBChB (U.O.N), M.Med Surgery (U.O.N), F.C.S (ECSA)

Department of pediatrics Surgery, School of Medicine, University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202

Tel # 0202726300

Principle researcher:

Dr. Edwin Odira

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202

Mobile phone 0722992128

Part ii: Consent certificate by patient's guardian.

I……..freely give consent of my child/kin (Name…….) to take part in the study conducted by Dr. Edwin Odira, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care being given to my child or my proxy. The results of the study may directly be of benefit to my child or my kin and other patients.

……

Signature/left thumb print (Guardian/Next of kin)

Date……

Thumb print of participant if

Unable to sign due to illiteracy

Statement by the witness if guardian or proxy is illiterate

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness……

Signature of witness……..

Date……

Part iii: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands the following:

Refusal to participate or withdrawal from the study will not compromise the quality of care and treatment given to the patient.

All information given to us will be treated with confidentiality.

The results of this study may be published to enhance knowledge and to help improve utility/management of peritoneal dialysis surgical complications.

I confirm that the participant was given the chance to ask questions about the study, and all such questions have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher taking consent……

Signature of researcher taking the consent……

Date……

Appendix II: Assent form, English version

Study title: Early surgical complications of peritoneal dialysis catheter in children with acute kidney injury.

Principal investigator: **Dr Odira Edwin**

University of Nairobi, department of general surgery,

P.O. Box 19676 KNH, Nairobi 00202.

Mobile phone: 0722992128

Research supervisors: **Dr Ndungu JM, Dr Githaiga JW, Dr Francis Osawa,**

P.O. Box 19676 KNH, Nairobi 00202.

Phone: 0202726300

Introduction

You are being asked to help us know better about the treatment we are giving you. If you want to know more about helping, you may ask me.

Purpose

Your kidneys are not working properly so we need to clean your blood by putting a catheter in the space between your intestines and put in the cleaning fluid using a catheter. Sometimes this catheter can cause problems such as bleeding, allow germs to get into your body or stop working properly. We want to know how common these problems are so that we deal with them in good time.

You do not have to be in this study if you do not want to. If you decide to stop after we begin, that's okay too. Your participation in this study will not influence your treatment in the hospi Your parents know about the study too.

What will happen to you?

We will write down how your catheter was put in place and whether there was any problem during the procedure, examine your catheter everyday to check that it is working properly; look at your wound and tummy for signs of infection, check the cleaning fluid too for infection. If there is any problem we will address them so that your treatment is without problems.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

_____ _____

(Sign your name here) (Date)

Appendix III: Consent form Kiswahili version

Fomu ya Idhini

ANDIKO: MATATIZO YA KIUPASUAJI YANAYOONEKANA MAPEMA YA MPIRA YA USAFISHAJI WA DAMU KWA NJIA YA TUMBO KWA WATOTO WALIOUMIA MAFIGO

MTAFITI: Dkt Edwin Odira.

KITUO: Shule ya afya, kitengo cha upasuaji. Chuo kikuu cha Nairobi

WALIMU WASIMAMIZI: Dkt Ndungu JM, Dkt Osawa F, na Dkt Githaiga JW.

Fomu hii ya idhini ina sehemu tatu:

1. Habari itayokusaidia kukata kauli
2. Fomu ya makubaliano (utakapo weka sahihi)
3. Ujumbe kutoka kwa mtafiti

Utapewa nakala ya fomu hii.

(1) Sehemu ya kwanza – Maelezo ya kuhusu Daktari mtafiti na utafiti huu.

Mimi ni Dkt Edwin Odira, kutoka Chuo kikuu cha Nairobi (University of Nairobi) kitengo cha afya idara ya upasuaji. Nina tarajia kufanya utafiti wa kuangalia MATATIZO YA KIUPASUAJI YANAYONEKANA MAPEMA YA MPIRA YA USAFISHAJI WA DAMU KWA NJIA YA TUMBO KWA WATOTO WALIOUMIA MAFIGO. Hii itawezekana kwa kusanya ujumbe kwa njia ya dodoso (orodha ya maswali) na uchunguzi wa mgonjwa mara kwa mara. Ujumbe huu utasidia madaktari kujua kadiri ya shida hii ya matatizo wapatanao wagonjwa hawa wetu wanapopewa matibabu haya. Utafiti huu pia ni hitaji kwa madaktari wanoataka kuwa na uzamili wa upasuliaji kutoka chuo kikuu cha Nairobi.

Ninakualika kushiriki katika utafiti huu. Utapewa nafasi ya kuuliza maswali kabla ya kufanya uamuzi wa kushiriki au la, kutoka kwangu mimi au wasaidizi wangu.

Habari yote ambayo utatuarifu ni ya siri kati yako na sisi watafiti. Jina lako ama ya mtoto/jamaa wako halitaandikwa kwenye fomu yoyote wala kwenye vipimo vyovyote.

Ujumbe huu hautapewa kwa watu wengine ila tu walio na Idhini ya kamiti ya utafiti ya KNH/UoN ERC.

Mtoto/jamaa wako hatapata madhara zozote kutokana naye kushiriki katika utafiti huu. Kuhusika kwa mtoto wako au jamaa wako kwenye utafiti huu haina malipo yoyote ila ni kwa hiari yako. Unaweza kujiondoa kushiriki katika utafiti huu wakati wowote bila kuhatarisha matibabu ya mtoto/jamaa wako katika Hospitali Kuu ya Kenyatta.

Pendekezo hili la utafiti limeangaliwa na kamiti ya utafiti ya KNH/UoN ERC kuhakikisha kwamba hakuna madhara yoyote kwa mgonjwa kutokana na utafiti yenyewe. Njia ya mawasiliano nao ni:

Katibu wa utafiti , KNH/UoN-ERC

S.L.P 20723 KNH, Nairobi 00202

Simu 020- 726300-9

Barua pepe: uonknh_erc@uonbi.ac.ke

Walimu wakuu wa Chuo kikuu cha Nairobi:

Dkt Ndungu JM

MBChB, M.Med general surgery, Fellow paediatric surgery

Mwalimu mkuu wa upasuaji ya watoto

SLP 19676 KNH, Nairobi 00202

Simu # 0202726300

Dkt JW Githaiga

MBChB, M.Med general surgery

Mwalimu mkuu wa upasuaji

SLP 19676 KNH, Nairobi 00202

Simu # 0202726300

Dkt Osawa F

MBChB (U.O.N), M.Med Surgery (U.O.N), F.C.S (ECSA)

Mwalimu mkuu wa upasuaji ya watoto

SLP 19676 KNH, Nairobi 00202

Simu # 0202726300

Mtafiti mkuu

Dkt. Edwin Odira

Idara ya Upasuaji ya Shule ya Afya – Chuo kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202

Simu ya rununu: 0722992128

(2) Sehemu ya pili – Idhini ya mgonjwa.

Mimi (Jina)…….. natoa ihari kwa niaba ya mgonjwa wangu (Jina la Mgonjwa).....……. kushiriki katika utafiti huu unaofanywa na Daktari Edwin Odira kutokana na hali ambayo nimeelezwa na sio kwa malipo ama shurutisho lolote.

Nimeelewa kwamba ninaweza kujiondoa wakati wowote nitakapotaka na hatua hii haitahatarisha matibabu akayopata mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwa mgonjwa wangu ama kwa wagonjwa wengine kwa ujumla na hata madaktari wenyewe, kwa kuendeleza elimu, na hata kupunguza shida zinazotokea wakati wa matibabu.

……

Kidole Gumba ya mgonjwa ama Ndugu

Kama hu wezi ku andika

Sahihi/ama alama ya kidole cha gumba katika sanduku →

Tarehe…….....

Jina la shahidi……..

Sahihi……

Tarehe……

(3) Sehemu ya tatu – Thibitisho kutoka kwa mtafiti

Hii nikuidhinisha ya kwamba nimemueleza msimamizi wa mshiriki(mgonjwa) kuhusu utafiti huu na pia nimempa nafasi ya kuuliza maswali. Nimemueleza yafuatayo;

- Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo.
- Kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.
- Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu ya mtoto/jamaa wake anayoyapata katika hospital kuu ya Kenyatta.

Habari ambazo atatoa hazitatangazwa hadharani bila ruhusa kutoka kwake (mshiriki) na pia kutoka kwa mdhamini mkuu wa utafiti wa hospital kuu ya Kenyatta na chuo kikuu cha matibabu.

Jina la Mtafiti ama Msaidizi wake …….

Sahihi……

Tarehe……

Appendix IV: Assent form, Kiswahili edition

Kichwa Utafiti: MATATIZO YA KIUPASUAJI YANAYONEKANA MAPEMA YA MPIRA YA USAFISHAJI WA DAMU KWA NJIA YA TUMBO KWA WATOTO WALIOUMIA MAFIGO.

Mtafiti mkuu: Dkt Odira Edwin

Chuo Kikuu cha Nairobi, idara ya upasuaji kwa ujumla,

S.L.P 19676 KNH, Nairobi 00202.

Simu ya mkononi: 0722992128

Watafiti wasimamizi: Dkt Ndungu JM, Dkt Githaiga JW, Dkt Francis Osawa,

S.L.P 19676 KNH, Nairobi 00202.

Simu: 0202726300

Utangulizi

Unaulizwa kutusaidia kujua vizuri kuhusu matibabu unayopewa na shida ambazo hutokea wakati huo .Kama unataka kujua zaidi kuhusu utafiti huu, unaweza kuuliza mimi.

Madhumuni

Figo zako hazifanyi kazi vizuri hivyo basi tunahitaji kusafisha damu yako kwa kuweka mpira katika nafasi kati ya matumbo yako na kutia maji ya kusafisha.Wakati mwingine mpira hii inaweza kusababisha matatizo kama vile kutokwa kwa damu, kuruhusu wadudu kupita ndani ya mwili wako au kuacha kufanya kazi vizuri. Tunataka kujua kiwango cha matatizo haya ili tuweze kukabiliana na changamoto hizo katika wakati mzuri.

Sio lazima ujiunge na utafiti huu. Hata ukikubali na baadaye uamue unataka kutoka ni sawa. Matibabu utapata hata ukiamua kutoshiriki.Wazazi wako wanajua kuhusu utafiti pia.

Ni nini utafanyiwa?

Tutaandika jinsi mpira yako ilivyowekwa na kama kulikuwa na tatizo lolote wakati huo, kuchunguza mpira yako ya kila siku kuangalia kwamba inafanya kazi vizuri;kuangalia jeraha yako ya tumbo kwa dalili za maambukizi, kuangalia maji ya kusafisha pia kwa dalili za maambukizi. Kama kuna tatizo lolote tutashughulikia ili matibabu yako yawe bila shida.

Tukimaliza utafiti huu tutaandika ripoti kuhusu matokeo yetu. Ripoti hii haitakuwa na jina lako wala kusema ulishiriki kwa utafiti.

Kama umeamua unataka kuwa katika utafiti huu, tafadhali andika jina na kisha uweke ishara yako.

Mimi, _____, nimekubali kuwa katika utafiti huu.

_____ _____

(Sahihi) (Tarehe)

Appendix V: Data Collection Sheet

ASSESSMENT OF SURGICAL COMPLICATIONS OF PERITONEAL DIALYSIS CATHETERS IN AKI IN PAEDIATRIC PATIENTS AT KNH.

1. Questionnaire number: _____
2. Admission date (dd/mm/yr) _____

3. SOCIO-DEMOGRAPHIC DATA:

IP NUMBER:	Date of insertion (dd/mm/yr)	AGE(Month/Years)	GENDER Male/ Female

4. Antibiotic Prophylaxis given
    a. Yes (mention antibiotic) _____ b. No _____

5. PD catheter Inserted by:
    a) General surgery resident
    b) Paediatric surgery resident
    c) Consultant pediatric surgeon
    d) Laparoscopic surgeon
    e) Renal physician

6. Type of anesthesia given during PD catheter insertion:
    a. Local Anaesthesia
    b. General Anaesthesia
    c. Local anaesthesia & Sedation

7. PD catheter insertion method utilized:
    a. Open
    b. Percutaneous
    c. Laparoscopic

8. Type of catheter used
    a. Single cuff b. Double cuff

9. Tunneling of the PD catheter:
    a. Done b. Not done

10. Was omentectomy done?
    a. Yes b. No

Complications of PD catheters

11. Was there visceral injury noted during insertion?
    a. Yes (specify) _____ b. No _____

12. Was there excessive bleeding during insertion
    a. Yes_____ b. No_____

13. Was there a dialysate leak
    a. Yes (go to no 14)
    b. No

14. Time of leak in hours/days from initial use of PD catheter -

    _____

15. Was there PD outflow failure
    a. Yes (go to 16)
    b. No

16. Indicate:-

    a. Time in hours/days of catheter blockage from initial use of PD catheter - _____

    b. Was it refractory to conservative management_____

17. Were there symptoms and signs of Peritonitis

    a. Yes (go to 18)

    b. No

18. How was peritonitis diagnosed

    a. Signs and symptoms

	(+)present/(-) absent	Day of recognition
Abdominal pain		
Tachy/bradycardia		
Tachypnoea		
Fever		
Rigidity		
Guarding		
Turbid dialysate		

    b. laboratory work up

Parameter	Done(+)/not done(-)	Count/report
Peritoneal fluid WBC count		
Peritoneal fluid culture		

19. Was there PD catheter exit site infection:

    a. Yes (go to 20) _____ b. No_____

20. If present was microbiology culture done:

    a. Yes (go to 21) _____ b. No_____

21. Culture report

    a. Microbial growth (mention organisms) _____
    b. No microbial growth

22. Final outcome

    a. Resolution of AKI
    b. Progression to Chronic disease
    c. Death

Appendix VI: Data analysis dummy tables

PD catheter Insertion techniques

	Number of patients	%
Antibiotic prophylaxis	Meronem(1), ceftriaxone (1)ceftazidime(13)	
Type of anaesthesia-local	4	
-general	7	
-both	4	
Insertion method-open	all	
- percutaneous	0	
- laparoscopic	0	
Catheter types-single cuff	13	
-double cuff	2	
Tunneling -tunneled	14	
-not tunneled	1	
Omentectomy-done		
-not done	all	

PD catheter inserted by:-

Cadre	Number of patients	%
f) General surgery resident	10	
g) Paediatric surgery resident	5	
h) Consultant pediatric surgeon		

i) Laparoscopic surgeon		
j) Renal physician		

Non-infectious Complications of PD catheters

Complication	Number of patients	%
Excessive Bleeding	0	
Visceral injury	0	
Dialysate leak	3	
Catheter outlow failure	2(reinserted in 3 days)	

Infectious complications

	Number of patients	%	Culture done	Positive culture
Surgical site infections	5			
peritonitis	0			

Common organisms isolated

Organism	Number in SSI	Number in PERITONITIS

Final outcome

	Number	%
Resolution of AKI	12	
Progression to chronic disease	3	
Death		