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SAGES peritoneal dialysis access guideline update 2023

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Abstract

Background Minimally invasive surgery has been used for both de novo insertion and salvage of peritoneal dialysis (PD) catheters. Advanced laparoscopic, basic laparoscopic, open, and image-guided techniques have evolved as the most popular techniques. The aim of this guideline was to develop evidence-based guidelines that support surgeons, patients, and other physicians in decisions on minimally invasive peritoneal dialysis access and the salvage of malfunctioning catheters in both adults and children.

Methods A guidelines committee panel of the Society of American Gastrointestinal and Endoscopic Surgeons reviewed the literature since the prior guideline was published in 2014 and developed seven key questions in adults and four in children. After a systematic review of the literature, by the panel, evidence-based recommendations were formulated using the Grading of Recommendations Assessment, Development and Evaluation approach. Recommendations for future research were also proposed.

Results After systematic review, data extraction, and evidence to decision meetings, the panel agreed on twelve recommendations for the peri-operative performance of laparoscopic peritoneal dialysis access surgery and management of catheter dysfunction.

Conclusions In the adult population, conditional recommendations were made in favor of: staged hernia repair followed by PD catheter insertion over simultaneous and traditional start over urgent start of PD when medically possible. Furthermore, the panel suggested advanced laparoscopic insertion techniques rather than basic laparoscopic techniques or open insertion. Conditional recommendations were made for either advanced laparoscopic or image-guided percutaneous insertion and for either nonoperative or operative salvage. A recommendation could not be made regarding concomitant clean-contaminated surgery in adults. In the pediatric population, conditional recommendations were made for either traditional or urgent start of PD, concomitant clean or clean-contaminated surgery and PD catheter placement rather than staged, and advanced laparoscopic placement rather than basic or open insertion.

Keywords Chronic renal failure · Guidelines · Laparoscopic peritoneal dialysis catheter insertion · Pediatrics · Peritoneal dialysis access

Abbreviations

AL	Advanced laparoscopic technique
BL	Basic laparoscopic technique
CAPD	Continuous ambulatory peritoneal dialysis
CI	Confidence interval
CKD	Chronic kidney disease
ESRD	End stage renal disease
EtD	Evidence to decision
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
HD	Hemodialysis
HPD	Concomitant hernia repair and peritoneal dialysis access
IR	Interventional radiology
ISPD	International Society for Peritoneal Dialysis
KQ	Key question
OR	Odds ratio
PD	Peritoneal dialysis
PICO	Population, intervention, comparator, outcome
RCT	Randomized controlled trial
RRT	Renal replacement therapy

Extended author information available on the last page of the article

RIGHT	Essential Reporting Items for Practice Guidelines in Healthcare
SAGES	The Society of American Gastrointestinal and Endoscopic Surgeons
US	United States of America

Executive summary

Background

Continuous ambulatory peritoneal dialysis (CAPD) has become a widespread mode of renal replacement therapy (RRT) for patients with chronic renal failure. The surgeon's role in caring for these patients is to provide access to the peritoneal cavity via a peritoneal dialysis (PD) catheter and to diagnose and manage catheter complications. Since the early 1990s many surgeons have utilized laparoscopy for insertion of PD catheters as well as salvage of malfunctioning catheters. In 2014, the Society for American Gastrointestinal and Endoscopic Surgeons (SAGES) published clinical practice guidelines for laparoscopic peritoneal dialysis access surgery [1]. Topics included: Indications and contraindications, insertion options, advanced laparoscopic techniques to avoid catheter dysfunction, peri-operative considerations, surgical techniques, postoperative protocols, outcomes in adults, postoperative complications, and PD catheter malfunction. Since that publication, the guidelines committee has adopted a more formal methodology using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [2].

Methods

This document is an evidence-based guideline based on a systematic review of current literature and expert opinion. It provides specific recommendations to assist physicians who care for PD patients.

Interpretation of strong and conditional recommendations

The strength of these evidence-based recommendations is either "strong" or "conditional" as per the GRADE approach [2, 3]. The phrase "the guideline panel recommends," is used for strong recommendations and "the guideline panel suggests," for conditional recommendations [2, 4]. Strong recommendations can be adopted as a policy in most situations. Conditional recommendations require shared decision-making between the surgeon and their patients. When insufficient evidence existed to inform recommendations, expert opinion consensus was sought.

How to use these guidelines

These guidelines are primarily intended to help surgeons make decisions about the peri-operative management of their patients undergoing minimally invasive surgery. Other purposes are to educate, inform policy and advocacy, and to define future research needs. Guidelines are applicable to all physicians facing patient management uncertainties addressed herein without regard to specialty, training, or interests. Due to the complexity of the healthcare environment, these guidelines are intended to indicate the preferred, but not necessarily the only, acceptable approach to management. Guidelines are intended to be flexible depending on individual circumstances. Given the wide range of variation in any health care problem, the surgeon must always tailor the approach to the individual patient. These guidelines can also be used by patients as a basis of discussion with their treating surgeon.

Recommendations

KQ1: In adult patients needing both renal replacement therapy and hernia repair, should hernia repair be performed concurrently with peritoneal dialysis catheter placement or be staged?

The panel suggests staged hernia repair and peritoneal dialysis catheter placement rather than simultaneous operations for adults needing both renal replacement therapy and hernia repair (conditional recommendation, very low certainty evidence).

KQ2: Should urgent start (less than 2 weeks) or traditional start be used for adult and pediatric patients who are initiating peritoneal dialysis?

For adult patients initiating peritoneal dialysis, the panel suggests that traditional start is favored over urgent start. (conditional recommendation, very low certainty evidence).

However, if urgent initiation of renal replacement therapy is deemed medically necessary, the panel suggests that the benefits of urgent start peritoneal dialysis may outweigh the risks of interval hemodialysis prior to traditional start of peritoneal dialysis (conditional recommendation, expert opinion due to insufficient evidence).

For pediatric patients, the panel suggests either traditional or urgent start when initiating peritoneal dialysis (expert opinion due to insufficient evidence).

KQ3: Should clean-contaminated surgery be performed concomitantly with peritoneal dialysis catheter placement or as separate procedures in adult and pediatric patients who are initiating peritoneal dialysis?

For adult patients, the panel suggests concomitant laparoscopic cholecystectomy and peritoneal dialysis catheter

placement when patients are initiating peritoneal dialysis and also require cholecystectomy (expert opinion due to insufficient evidence).

The panel did not find sufficient evidence to make recommendations for other clean-contaminated operations in adults.

For pediatric patients, the panel suggests concomitant clean or clean-contaminated operations when patients are initiating peritoneal dialysis and also require another operation (expert opinion due to insufficient evidence).

KQ4: Should advanced laparoscopic insertion techniques or basic laparoscopic insertion techniques be used for adult and pediatric patients needing renal replacement therapy?

For adult patients, the panel suggests advanced laparoscopic insertion as opposed to basic laparoscopic insertion (conditional recommendation, very low certainty of evidence).

For pediatric patients, the panel suggests advanced laparoscopic insertion as opposed to basic laparoscopic insertion (expert opinion due to insufficient evidence).

KQ5: Should advanced laparoscopic insertion techniques or open insertion be used for adult and pediatric patients needing renal replacement therapy?

For adult patients, the panel suggests advanced laparoscopic insertion as opposed to open insertion (conditional recommendation, very low certainty evidence).

For pediatric patients, the panel suggests advanced laparoscopic insertion as opposed to open insertion (conditional recommendation, very low certainty evidence).

KQ6: Should advanced laparoscopic insertion techniques or ultrasound-guided percutaneous techniques be used for adult patients needing renal replacement therapy?

The panel suggests either advanced laparoscopic or image-guided percutaneous insertion for adults needing renal replacement therapy (conditional recommendation, very low certainty evidence).

KQ7: In adult patients with peritoneal dialysis catheter malfunction, should operative or nonoperative salvage be attempted?

The panel suggests either operative or nonoperative salvage for adult patients with peritoneal dialysis catheter malfunction (conditional recommendation, very low certainty evidence).

Aim of these guidelines and specific objectives

The aim of these evidence-based guidelines by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) is to provide recommendations regarding the perioperative performance of laparoscopic peritoneal dialysis (PD) access surgery and salvage of malfunctioning catheters. The key target audiences include surgeons, nephrologists, interventional radiologists (IR), and patients. Policy makers and insurance providers involved in delivering health care services related to PD access surgery or evaluating direct and indirect benefits, harms, and costs related to the various procedures used to insert or salvage malfunctioning PD catheters may also consider these recommendations in their deliberations.

Description of the health problems

In 2022 over 786,000 patients in America suffered from stage V chronic kidney disease and relied on renal replacement therapy (RRT) according to the National Institute of Diabetes and Digestive and Kidney Diseases [5]. Of these, 71% were on dialysis and 29% had a functioning transplant. PD has been a proven mode of renal replacement therapy since 1980 and while its use has risen globally, it has waxed and waned in the United States of America (USA). There has been slow growth since 2008 in the USA with current statistics showing that in 2020 16,528 patients initiated PD, representing 12.7% of individuals with incident end stage renal disease (ESRD). Hemodialysis (HD), the alternative to PD, requires central venous cannulation or creation of a fistula and has been found to be inferior to PD with regards to patient autonomy, quality of life, preservation of residual renal function, survival for the first 2 years, and cost [6–13]. Absolute contraindications to PD include documented ultrafiltration failure of the peritoneal membrane, severe protein calorie malnutrition and/or proteinuria > 10 g/day, active intraabdominal infection, loss of domain / unrepairable abdominal wall hernia, and loss of peritoneal volume due to dense abdominal adhesions not amenable to laparoscopic lysis. There are also perceived barriers to PD such as advanced age, obesity, and polycystic kidney disease [14].

Once a patient is deemed an appropriate candidate for PD, the preoperative evaluation includes consultation with a surgeon, history and physical examination, medical evaluation, risk stratification for anesthesia, and patient education. If an abdominal wall hernia is found, there are three options: hernia repair followed by PD catheter insertion, concomitant hernia repair and catheter insertion, or watchful waiting with interval hernia repair if patients develop symptoms. Unfortunately there is no consensus in the literature regarding the optimal strategy, leading to the first key question on this topic.

Postoperative protocols for initiation of PD as per International Society for Peritoneal Dialysis (ISPD) guidelines include a 2 week healing or "break-in" period between PD catheter insertion and PD initiation [15]. The "urgent start" of PD less than 2 weeks after PD catheter insertion has also been described with the goal of avoiding HD in patients who

need RRT urgently [16]. Therefore the use of urgent start PD was also considered a relevant guideline question.

Surgeons who place PD catheters must have knowledge of various insertion options and be able to follow best practices for PD catheter insertion to optimize outcomes. Popular options currently include laparoscopic, open, and percutaneous fluoroscopic-guided insertion. In addition, advanced laparoscopic (AL) techniques have been described such as rectus sheath tunneling, suture fixation, and omentectomy or omentopexy to help improve catheter survival. However, there is still debate regarding when each technique should be utilized [15]. Three key questions were formulated to address the differences in these approaches.

Finally, patients who experience PD catheter dysfunction need urgent attention to avoid a lapse in dialysis. The surgeon often plays a role in assessing and managing these patients, though non-surgical interventions are also available. Multimodal evaluation of the cause of dysfunction usually includes plain X-ray, interventional radiology fluoroscopic catheter evaluation, attempted nonoperative management, and exploratory laparoscopy with surgical management [1]. The aim of the final key question was to assess how nonoperative management of catheter dysfunction compares with operative management.

Properly addressing these clinical questions in the pediatric population requires consideration of additional factors. For example, vascular access for HD in these patients can be incredibly challenging to manage [17]. Omentopexy, frequently employed during AL PD catheter placement in the adult population, may not be feasible in very young patients with fragile omentums. Where the panel members felt the recommendations may differ between adult and pediatric populations, the data in the pediatric population was collected, analyzed, and reviewed separately by the panel to generate recommendations specific to the pediatric population.

Methods

The creation of this guideline followed SAGES standard operating procedure and was initiated in consultation with members of the SAGES guidelines committee, Executive Committee, and Board of Governors [2, 18]. A group of content experts and SAGES Guidelines Committee members conducted a systematic review of the literature to inform guideline recommendations. Upon review completion, the lead invited subject matter experts from outside the group to join the expert panel. This group reviewed the results of the systematic review and used it according to the GRADE Evidence to Decisions (EtD) approach as the basis for its recommendations [19, 20]. These guidelines were drafted according to the Essential Reporting Items for Practice Guidelines in Healthcare (RIGHT) checklist [21]. The general methods and reporting standards for SAGES Guidelines have been previously published [2].

Guideline panel organization

The guideline panel was composed of volunteer members from the SAGES Guidelines committee and peritoneal dialysis access experts including both adult and pediatric surgeons. A systematic review methodologist (A.M.A), a guideline development methodologist (M.T.A), and two committee research fellows (A.C., S.K.) were part of the panel as non-voting members. A full list of contributing members is included in Online Appendix A.

Guideline funding & declaration and management of competing interests

SAGES provided funding for the methodologists, the librarian, and partial salary support for the research fellows. A portion of this funding came from a SAGES Education & Research Foundation grant. All participated in the process as non-voting members. All voting members of the guideline panel participated on a volunteer basis without funding. Industry did not provide any financial support or input on the development of these guidelines. All guideline panel members filled out conflict-of-interest forms. The guideline lead and committee chair evaluated these declarations for any pertinent conflicts. All disclosed potential conflicts of interest are listed in Online Appendix D.

Selection of questions and outcomes of interest

Under the guidance of the current committee chair and guideline methodologist, the systematic review group generated KQs relating to PD access surgery using the population, intervention, comparator, outcome (PICO) format. Guided by clinical experience, the guideline panel members reached consensus regarding the relative importance and patient-centeredness of each outcome. Outcomes deemed "critical," or "important," to decision-making for each KQ were defined and reviewed. The importance of these outcomes was revisited by panel members during the formulation of recommendations after they had reviewed the systematic review evidence. Outcomes included: Bleeding, early catheter dysfunction (< 30 days), late catheter dysfunction (> 30 days), exit-site infection, dialysate leak, peritonitis, and mortality.

Key questions (KQ) addressed by these guidelines

KQ1: In adult patients needing both renal replacement therapy and hernia repair, should hernia repair be performed

concurrently with peritoneal dialysis catheter placement or be staged?

KQ2: Should urgent start or traditional start be used for adult and pediatric patients who are initiating peritoneal dialysis?

KQ3: Should clean-contaminated surgery be performed concomitantly with peritoneal dialysis catheter placement or as separate procedures in adult and pediatric patients who are initiating peritoneal dialysis?

KQ4: Should advanced laparoscopic insertion techniques or basic laparoscopic insertion techniques be used for adult and pediatric patients needing renal replacement therapy?

KQ5: Should advanced laparoscopic insertion techniques or open insertion be used for adult and pediatric patients needing renal replacement therapy?

KQ6: Should advanced laparoscopic insertion techniques or ultrasound-guided percutaneous techniques be used for adult patients needing renal replacement therapy?

KQ7: In adult patients with PD catheter malfunction, should nonoperative or operative salvage be attempted?

Evidence synthesis and grading the certainty of evidence

A standard systematic review approach using two independent reviewers (± third party arbitration) was adopted to synthesize the best available evidence for each KQ. A librarian searched PubMed, the Cochrane Library, ClinicalTrials.gov and Embase from 2012 to April 2020. The search criteria for the pediatric population were expanded to 2005 due to a paucity of literature. Systematic reviews and the bibliography of select included studies were hand-searched for additional studies missed in the literature search. Given the paucity of data, both randomized controlled trials (RCTs) and observational studies addressing the KQs of interest were eligible for inclusion. Retrieved records were reviewed, duplicates removed, and results screened for eligibility at two levels (title & abstract, and full-text review) against the eligibility criteria. Only peer-reviewed English language studies were included during study selection, which comprised the bulk of the existing literature. An updated literature search was performed in September 2021. The search strategy and results can be found in Online Appendices B and C.

Study data extraction included general study characteristics and PICO elements which was performed in *Covidence* digital software [22]. The Cochrane *Risk of Bias Tool* for RCTs and the *Newcastle Ottawa Scale* for non-RCTs were used to assess study risk of bias [23, 24]. Meta-analysis was conducted in *Revman* using the Mantel–Haenszel random-effects model [25]. Heterogeneity between studies was quantified by the I^2 statistic and tested for statistical significance with the Chi^2 test. Study risk of bias and clinical covariates were used to explore important observed heterogeneity. Publication bias could not be assessed because of insufficient evidence. When direct comparative evidence was lacking, evidence from non-comparative studies was used to make indirect comparisons when no important concerns were noted regarding comparability of patient population and healthcare setting (albeit with lower certainty).

For each outcome, the certainty of evidence was graded as per the GRADE approach based on the overall risk of bias, inconsistency, indirectness, and imprecision, and summarized in Evidence Tables in the online *GradePro* tool [26, 27]. RCT evidence was preferred over non-RCT evidence with the intent of generating higher certainty.

Development of clinical recommendations

The panel took an individual patient perspective, using patient-based values to formulate recommendations for a target audience composed of practicing physicians as well as patients. The GRADE EtD framework in the *GRADEPro* tool [19, 20] was utilized, which requires panel members to make deliberate judgments about the magnitude of desirable and undesirable effects across the important and critical outcomes. The value (and potential variability in value) patients place on those outcomes are taken into consideration. The balance of desirable and undesirable effects, the overall certainty of evidence across the critical outcomes, and acceptability and feasibility of the favored management option determine the recommendation and its strength. In the absence of literature that investigated the relative values and preferences patients assign to the various outcomes of interest, the panelists used their clinical experience as a proxy for patient values. Dissenting judgments and views were captured in a preliminary voting to foster further discussions and consensus development. Re-voting was used after the discussions. Final recommendation required ≥ 80% panel agreement**.** Evidence for the pediatric population was considered separately and was evaluated by pediatric surgeons in the same manner.

All EtD tables are summarized in Online Appendix E, including the evidence important to decision-making, the additional considerations, and judgements on each component of the guideline. These components are summarized in the recommendations that follow.

Guideline document review

After composition of the guideline, this manuscript was reviewed and appropriately revised as previously described [2] including panelists, the Guidelines Committee members, SAGES Executive Committee, and SAGES Board before submission for publication. Prior to final publication, the document was available online for a period of public comment.

Recommendations

KQ1: In adult patients needing both renal replacement therapy and hernia repair, should hernia repair be performed concurrently with peritoneal dialysis catheter placement or be staged?

The panel suggests staged hernia repair and peritoneal dialysis catheter placement rather than simultaneous operations for adults needing both renal replacement therapy and hernia repair (conditional recommendation, very low certainty evidence).

Introduction

Abdominal wall hernias are diagnosed in approximately 10% of patients initiating peritoneal dialysis [28]. These hernias are a concern because the increased intraabdominal pressure associated with PD can make hernias enlarge faster than the normal rate and increase the rate of complications such as PD fluid leak, incarceration, obstruction, and strangulation [28–30]. Therefore, it is important for surgeons placing PD catheters to thoroughly evaluate patients preoperatively for hernias and determine the appropriate management strategy. The options include hernia repair after or prior to PD catheter placement (staged repair), simultaneous repair and PD catheter insertion, or watchful waiting. When timing allows, repair prior to initiation of PD can avoid potential disruption of dialysis once it starts. Concomitant repair has been advocated by many groups to avoid a second operation, allow earlier initiation of PD, and prevent hernia complications, but the evidence is lacking regarding the best option. The previous SAGES guideline for laparoscopic peritoneal dialysis access surgery recommended: "Patients with abdominal wall hernias should be diagnosed and repaired before or at the same time as PD catheter insertion. A repair should be chosen that minimizes peritoneal dissection and does not place mesh intraperitoneally (++Evidence, Weak recommendation)" [1]. The panel agreed with this strategy even though Thomas et al. in 2021 advocated watchful waiting [31]. They followed 41 patients who had ventral hernias and started PD without repair. Six (15%) patients underwent repair an average of 12 months later and two (5%) developed an incarceration. Therefore, more prospective studies need to be performed to evaluate watchful waiting for patients who start PD and have a hernia. This analysis compares patients who underwent concomitant hernia repair and placement of PD catheter (HPD) versus staged hernia repair and PD catheter placement.

Summary of the evidence

Only three comparative studies were found that met criteria [28, 32, 33]. Unfortunately, there were no events to report in any of these so they were noninformative in decision-making. Single-arm data was used to make indirect comparisons between the intervention and comparison [28, 31–41]. These studies included patients with umbilical, epigastric, inguinal, and incisional hernias. Mesh was frequently utilized but not in all cases. The most notable benefits associated with staged repair were lower rates of dialysate leakage and peritonitis. The most notable harm associated with staged repair was a higher rate of exit-site infection. The outcomes deemed critical were early hernia recurrence and mortality. This question did not address the optimal time to start PD after hernia repair; the time between hernia repair and initiating PD was mixed both across and within studies.

Benefits

Based on the evidence the desirable effects of staged repair are lower incidence of bleeding, dialysate leak, and peritonitis. The favorable effects of staged repair were judged to be moderate in magnitude.

Bleeding: Staged repair event rate of 1.6% in 2 studies [33, 34] vs simultaneous repair event rate of 2.8% in 1 study [33].

Dialysate leak: Staged repair event rate of 3.8% (range 1.5–10.0%) in 2 studies [28, 32] vs simultaneous repair event rate of 10.4% (range 2.8–17.4%) in 5 studies [28, 32, 35, 37, 39].

Peritonitis: Staged repair event rate of 6.4% in 1 study [34] vs simultaneous repair event rate of 35.7% (range 14.3–52.2%) in 2 studies [35, 36].

Harms and burdens

With regards to undesirable effects, early catheter dysfunction, early hernia recurrence, late hernia recurrence, and mortality were similar. However the difference in rates of exit-site infection were quite different. This was deemed a small effect favoring simultaneous repair.

Early catheter dysfunction: Staged repair event rate of 4.8% in 1 study [38] vs simultaneous repair event rate of 2.3% in 1 study [40].

Early hernia recurrence: Staged repair event rate of 4.0% (range 1.6–10.0%) in 4 studies [28, 31, 33, 38] vs simultaneous repair event rate of 3.0% (range 2.1–6.3%) in 5 studies [28, 33, 36, 37, 40].

Late hernia recurrence: Staged repair event rate of 9.8% (range 2.3–11.1%) in 4 studies [28, 31, 34, 38] vs simultaneous repair event rate of 7.1% (range 2.1–21.8%) in 5 studies [28, 35–37, 40].

Exit site infection: Staged repair event rate of 10.0% in 1 study[28] vs simultaneous repair event rate of 4.1% (range 3.1–4.8%) in 2 studies [28, 40].

Mortality: Staged repair event rate of 5.3% (range 1.6–10.0%) in 4 studies [28, 33, 34, 38] vs simultaneous repair event rate of 2.2% (range 1.2–16.7%) in 7 studies [28, 33, 35, 36, 39–41].

Since only single-arm studies were used, the certainty of the evidence was very low. The panel also noted there was possibly important uncertainty regarding how an individual patient may value each of these outcomes.

Decision criteria and additional considerations

The panel used the evidence as well as their expert opinion to conditionally recommend for staged repair. However, ideally the staged repair would consist of hernia repair and recovery followed by PD catheter placement and traditional transition to start PD. This may not be possible in a patient who needs to start renal replacement therapy urgently or at least within 2 weeks. In these cases, simultaneous repair and insertion may be a better option than interval HD requiring venous catheter insertion. This decision will ultimately depend on the relative value the patient places on avoiding two operations and starting PD sooner; this underlines the importance of shared decision-making when considering staged versus simultaneous operations.

Conclusions

In patients who need renal replacement therapy and are diagnosed with a hernia, the panel suggests staged hernia repair and PD catheter placement when possible due to potentially lower incidence of bleeding, dialysate leakage, and peritonitis (conditional recommendation, very low certainty evidence).

Research needs

Multicenter controlled trials comparing simultaneous versus staged repair are needed. The panel also recognized the need for a protocol for PD initiation after hernia repair addressing volume of fills, time to initiation, and frequency. It also identified the need for larger comparative studies addressing the use and positioning of mesh and laparoscopic versus open approaches to hernia repair.

What others are saying

A study by Tom et al. compared PD catheter alone vs PD catheter and hernia repair (HPD) using a NSQIP database and found there was no significant difference in mortality, morbidity, superficial surgical site infection, deep SSI, organ/space SSI, readmission, or reoperation rates [41]. HPD was associated with shorter length of stay (1.1 vs 1.7 days, $p = 0.010$) and longer mean operative time (66.1 vs 43.7 min, $p < 0.001$). On multivariate analyses, HPD was not an independent predictor of morbidity or mortality. They concluded that simultaneous PD catheter insertion and hernia repair can be safely performed to prevent future complications and additional operations. Unfortunately they did not report any events for the outcome measures that the working group considered critical or important.

KQ2: Should urgent start or traditional start be used for adult and pediatric patients who are initiating peritoneal dialysis?

Adult

For adult patients, the panel suggests traditional start as opposed to urgent start when initiating peritoneal dialysis. (conditional recommendation, very low certainty evidence).

Introduction

In patients who need urgent RRT due to rapid deterioration of function or poor preoperative follow-up, "urgent start" PD has been proposed to avoid temporary HD. This is defined as initiation of PD prior to the standard 2 week break-in period after implantation surgery, suggested by the International Society of Peritoneal Dialysis guidelines [15]. The benefits of avoiding bridging HD include preservation of vascular access, better outcome after renal transplantation, and lower risk of hepatitis B and C infection [42].

Summary of the evidence

A total of nine observational studies that compared urgent start to traditional start PD and reported at least one of the outcomes the working group were deemed important [42–50]. The outcome of mortality was deemed critical to decision-making.

Benefits

Based on the outcomes reviewed, the panel considered the desirable effects of urgent start to be small. However, the true desirable effect is beginning renal replacement therapy urgently to improve patients' clinical status and avoid fluid overload, hyperkalemia, uremia, and even death, while avoiding temporary hemodialysis. In this group, there was a lower incidence of late catheter dysfunction and fewer exit-site infections.

Late Catheter dysfunction: estimated 60 fewer events per 1000 patients (95% CI 119 fewer to 21 more) based on 4 studies with 828 patients [40, 43, 46, 49].

Exit site infection: estimated 11 fewer events per 1000 patients (95% CI 41 fewer to 46 more) based on 6 studies with 914 patients [42–44, 47, 49, 50].

Harms and burdens

The undesirable effects were considered moderate and included a higher risk of bleeding (OR 8.72), although only one study was used for this calculation, there was no difference in the insertion technique used (open surgical insertion), and no patients needed surgical intervention or temporary hemodialysis. In addition, early catheter dysfunction was more common in the urgent start group (OR 2.87). Dialysate leakage is one of the most important outcomes in this review and, not surprisingly, urgent start is associated with a higher risk of dialysate leakage (OR 3.42) based on 8 studies included in the analysis. There was also higher all-cause mortality which may not be pertinent, given that the mortality is not likely related to the timing of initiation of peritoneal dialysis. Finally peritonitis was slightly more likely in the urgent start group (OR 1.41).

Bleeding: estimated 75 more events per 1000 patients (95% CI 1 fewer to 472 more) based on 1 study with 129 patients [49].

Early catheter dysfunction: estimated 71 more events per 1000 patients (95% CI 2 fewer to 238 more) based on 6 studies with 468 patients [42, 44, 45, 47–49].

Leakage: estimated 78 more events per 1000 patients (95% CI 24 more to 171 more) based on 8 studies with 1018 patients [42–45, 47–50].

Mortality: estimated 125 more events per 1000 patients (95% CI 30 more to 254 more) based on 4 studies with 636 patients [46, 48–50].

Peritonitis: estimated 49 more events per 1000 patients (95% CI 6 fewer to 120 more) based on 9 studies with 1167 patients [42–50].

The certainty of this evidence was very low.

Decision criteria and additional considerations

Peritoneal Dialysis offers clinical and quality of life advantages over HD and there are cost benefits to home dialysis. In 2021, CMS passed the End-Stage Renal Disease (ESRD) Treatment Choices Model, to improve or maintain the quality of care and reduce Medicare expenditures for patients with CKD, which promotes PD and kidney transplantation for its recipients [51]. This has prompted a movement among nephrologists in the US to increase the penetration of PD and urgent start is one way to do this. In the past, patients needing urgent dialysis were given a venous catheter for inpatient HD and then discharged on scheduled outpatient HD. Once the patient developed this routine, they rarely switched to PD. Therefore, there are several benefits to avoiding urgent HD and instituting an urgent start PD program. In fact, these may outweigh the increased risks involved. The data presented in this guideline may help guide nephrologists and surgeons with education of patients when they are making this decision. The ultimate decision must weigh the advantages to the patient with the slight increased risk of the above complications which are deemed moderate.

There are potential barriers to implementation of urgent start PD. Urgent start usually requires a surgeon trained in PD catheter insertion and operating room availability on an urgent basis, sometimes while the patient is hospitalized with a new diagnosis of stage V CKD. In addition, the PD team of nurse practitioners and nephrologists will need to be available for urgent institution of PD and expedited training.

Conclusions

The panel suggests a traditional start as opposed to urgent start when initiating PD (conditional recommendation, very low certainty evidence). The urgent start of PD prior to the traditional 2 week break-in period is probably associated with higher risk of dialysate leakage, early catheter dysfunction, and bleeding. This question specifically addresses urgent versus traditional start when the patient has the ability to delay initiation of PD. The panel does recognize that for certain patients, the benefits of avoiding HD-access procedures and interval HD may outweigh the risks associated with an urgent start of PD. This decision should be made between the patient and physicians taking into the aforementioned factors.

Research needs

A well-constructed multicenter RCT that can adequately compare the outcomes of starting HD and converting to PD versus initial urgent start PD is needed.

What others are saying

A Cochrane database review in 2019 identified 16 studies (2953 participants) examining the outcomes of urgent versus conventional start PD [52]. When they compared results from patients who initiated dialysis 2 weeks after catheter insertion to those who initiated dialysis urgently, the latter were more likely to have leakage of dialysis fluid outside the abdominal cavity into the skin near the exit-site of peritoneal dialysis catheter. The study was unable to make conclusions about differences in rates of peritonitis, exit-site infection, mechanical complications of peritoneal dialysis (including catheter blockage, catheter malposition and catheter readjustment), patients remaining on peritoneal dialysis (technique survival), and death.

The ISPD 2019 guideline update also addressed this question and concluded, "There are no RCTs comparing urgent start on PD with urgent start on hemodialysis. In the urgent setting, the choice of modality has to be balanced between the potential for increased risk of mechanical complications

related to urgent start on PD and the increased risk of bloodstream infections and central venous stenosis and thrombosis known to be associated with urgent start on hemodialysis using a central venous catheter" [15].

Pediatric

For pediatric patients, the panel suggests either traditional or urgent start when initiating peritoneal dialysis (expert opinion due to insufficient evidence).

Summary of the evidence

Three studies pertaining to this question in the pediatric population were found in the literature search [53–55]. This was judged to be insufficient for an evidence-based recommendation and instead expert opinion was used to formulate this recommendation.

Decision criteria and additional considerations

In the pediatric population, the goal of urgent start PD is to initiate dialysis as soon as possible while avoiding the need for urgent initiation of HD. The use of HD catheters in small children can result in permanent loss of that vascular access due to the large catheter size relative to the vein's diameter [17]. In addition, the probability of pediatric renal insufficiency being temporary may be greater than in the adult population [56]. Finally, inadequate HD may occur in the pediatric population due to insufficient flow.

Ultimately, the existing data do not favor either urgent or traditional start. The significant variability in the size of pediatric patients, and therefore in the flow dynamics, limit the ability to make an evidence-based recommendation. The panel judged that long-term outcomes such as hernia occurrence are not as critical in patients who need to initiate dialysis urgently. Patients and families will likely weigh short-term outcomes, particularly the rate of catheter dysfunction in the first 3 months, more heavily in decision-making. Although a higher leakage rate is seen with urgent start PD, there were lower rates of peritonitis and exit-site infection. This may be due to exit-site care protocols and other measures taken to maintain sterility, leading to the possibility of dialysate leakage without peritonitis or infection [57]. Other interventions such as application of fibrin glue, utilization of purse string sutures, or creation of longer tunnels may help mitigate dialysate leakage.

In regards to implementation of urgent start in the pediatric population as opposed to the adult population, any institution with the ability to perform pediatric PD will most likely have the ability to perform it on an urgent or traditional start basis, though some of the interventions to mitigate dialysate leakage are unlikely to be universally available.

Conclusions

In select pediatric patients, an urgent start of PD may permit the patient to avoid the morbidity associated with vascular access and HD and therefore be worth the increased risk of catheter dysfunction and dialysate leakage.

Research needs

Large, multicenter studies in the pediatric population should be prioritized. A large-scale database would provide the opportunity to track outcomes for monitoring purposes. This would also allow for the assessment of efficacy of the aforementioned methods of mitigating catheter leakage.

KQ3: Should clean-contaminated surgery be performed concomitantly with peritoneal dialysis catheter placement or as separate procedures in adult and pediatric patients who are initiating peritoneal dialysis?

Adult

For adult patients, the panel suggests concomitant laparoscopic cholecystectomy and peritoneal dialysis catheter placement when patients are initiating peritoneal dialysis and also require cholecystectomy (expert opinion due to insufficient evidence).

The panel did not find sufficient evidence to make recommendations for other clean-contaminated operations in adults.

Introduction

Patients with stage IV CKD who have chosen PD as their mode of dialysis may have other surgical diseases which require treatment such as chronic cholecystitis, morbid obesity, colon cancer, or failure to thrive. There is uncertainty regarding the safety of performing clean-contaminated surgery at the same time as PD catheter insertion. The goal of this KQ was to determine the optimal timing for clean-contaminated cases in renal failure patients requiring PD dialysis. Unfortunately, there were very few studies on this topic and none were comparative. In addition, some studies included clean cases such as hernia repair with clean-contaminated cases such as laparoscopic cholecystectomy in their results. The working group decided this question needs further study and should be investigated separately, based on which clean-contaminated operation was performed. In the literature, one of the most common scenarios is the adult patient with both chronic calculous cholecystitis and CKD

and thus, the panel elected to summarize the data on this subject.

Summary of the evidence for adults

Regarding simultaneous laparoscopic cholecystectomy and PD catheter placement, Janez published a retrospective review in 2021 [58]. They analyzed 15 patients who underwent simultaneous operations and found no complications related to the gallbladder removal. Of the 428 patients reviewed by Crabtree and Burchette in 2009, 9 patients underwent concomitant cholecystectomy and suffered no complications [59]. Finally, the 2019 update to the ISPD guidelines addressed cholecystectomy and simultaneous PD catheter insertion and concluded that: "Patients with symptomatic biliary tract disease without signs of active infection can safely undergo cholecystectomy at the time of catheter placement. Following sound surgical principles, the clean procedure (catheter placement) should precede the clean-contaminated portion (cholecystectomy) with closure and protection of PD catheter-related wounds and exit site" [15].

Conclusions and research needs

Further research is needed to assess the true risk of concomitant clean-contaminated cases and PD catheter insertion. The panel suggests looking at three scenarios separately: PD catheter insertion during cholecystectomy, PD catheter insertion during colectomy, and PD catheter insertion during bariatric surgery. Other factors to investigate are whether temporary HD should be used and the optimal time to restart PD after these cases. Further research should also evaluate the safety and efficacy of clean-contaminated surgery performed on patients already using PD for RRT.

Pediatric

For pediatric patients, the panel suggests concomitant clean or clean-contaminated operations when patients are initiating PD and also require another operation (expert opinion due to insufficient evidence).

Summary of the evidence

There was only one study with direct comparative evidence investigating this question in the pediatric population [60]. There were no harms identified in the pediatric literature.

Benefits

A small magnitude of desirable benefits was found, particularly based on mortality and peritonitis.

Exit site infection: estimated 113 fewer events per 1000 patients (95% CI 125 fewer to 19 fewer) based on 1 observational study with 142 patients [60].

Mortality: estimated 36 fewer events per 1000 patients (95% CI 42 fewer to 73 more) based on 1 observational study with 142 patients [60].

Peritonitis: estimated 127 fewer events per 1000 patients (95% CI 149 fewer to 33 fewer) based on 1 observational study with 142 patients [60].

The certainty of evidence was very low.

Decision criteria and additional considerations

Repeated administration of general anesthesia and intraoperative fluid boluses may carry significant morbidity. There is no evidence of harms associated with PD catheter placement and concomitant clean or clean-contaminated operations in the pediatric population. However, the comparative data for this came from one paper which grouped together outcomes for concomitant operations of all wound classes.

Conclusions

In the pediatric population, in the absence of evidence of harms from concomitant operations the panel suggests that concomitant operations may be preferable (expert opinion due to insufficient evidence).

Research needs

Future research in the pediatric population should clearly separate outcomes by wound class and potentially even by operation given the frequency with which concomitant PD catheter and gastrostomy tube placement is required in this population.

KQ4: Should advanced laparoscopic insertion techniques or basic laparoscopic insertion techniques be used for adult and pediatric patients needing renal replacement therapy?

Adult

For adult patients, the panel suggests advanced laparoscopic insertion as opposed to basic laparoscopic insertion (conditional recommendation, very low certainty evidence).

Introduction

Laparoscopy was first used to insert PD catheters in the early 1990s [61] and its efficacy and safety has been documented in many case reports, comparative studies, and RCTs as reported in the 2014 SAGES clinical practice guideline on this subject [1]. Unfortunately there is great variability

worldwide in insertion techniques, making comparisons difficult. In the early 2000s it became evident that the benefits of laparoscopic insertion were related to the addition of adjunct procedures to prevent catheter dysfunction, such as suture fixation, rectus sheath tunnel, omentopexy, and lysis of adhesions. Therefore, Crabtree and Fishman described the combination of rectus sheath tunnel, omentopexy, and lysis of adhesions as "advanced laparoscopic insertion" [62]. Several other authors have used catheter suture fixation to minimize catheter displacement out of the pelvis [63, 64]. Currently, literature advocating the use of AL techniques to avoid catheter dysfunction is growing; this has led to its recommendation in the ISPD Guideline for Creating and Maintaining Optimal Peritoneal Dialysis Access in the Adult Patient: 2019 Update [15]. The goal of this KQ was to compare BL PD catheter insertion to AL insertion based on the following outcomes: Bleeding, early catheter dysfunction, late catheter dysfunction, exit-site infection, peritonitis, dialysate leakage, bowel injury, and mortality. AL was defined as incorporating at least one adjunct technique to prevent dysfunction such as omentopexy, rectus sheath tunnel, or suture fixation. BL was defined as using laparoscopy to place the catheter but without any of the aforementioned adjuncts.

Summary of the evidence

A total of 6 observational studies were included in this analysis [62–67]. In 2005 Crabtree published a retrospective review comparing insertion techniques in his practice over time, including 63 open, 78 BL, and 200 AL insertions [62]. He found that after an average follow-up between 21 and 27 months, the AL group had a significantly lower incidence of catheter dysfunction compared to BL (0.5 vs 12.8%, $p < 0.0001$). Other outcomes were similar. A second paper from the Cleveland Clinic was published in 2010 [65]. They incorporated a similar AL technique using adhesiolysis, rectus sheath tunnel, and selective omentopexy. When comparing 68 patients who underwent BL insertion to 129 who underwent AL insertion, they found a significantly lower incidence of primary catheter dysfunction in the latter (36.7% vs 4.6%, $p < 0.0001$). Omentopexy was performed in 53.5% of the AL cases. Krezalek et al. performed a retrospective review of open ($n = 63$), BL ($n = 80$), and AL ($n = 92$) PD catheter insertions at a single institution in 2016 [66]. Their results corroborated the previous work by Crabtree and Attaluri showing significantly lower catheter obstruction rates in the AL group (4.4% vs 17.5%, $p < 0.01$). Rouse and others in 2020 compared AL using suture fixation of the catheter, but no omentopexy [64]. After a median follow-up of 15.5 months, AL led to lower catheter malposition rates (7.32% vs 19.05%), but no other outcomes were addressed. Finally, in 2021 Musbahi published a retrospective review of 72 BL and 112 AL after the technique was modified to include Proline sling suture fixation of the catheter to prevent migration [67]. The rates of catheter blockage were similar between groups (8.2 vs 8.04%) but the AL group had lower migration rates (2.56% vs 12.5%, $p < 0.008$).

The outcomes deemed critical by the expert panel were bleeding, early catheter dysfunction, late catheter dysfunction, mortality, and peritonitis. No studies reported any peri-operative mortalities so this became a noninformative outcome.

Benefits

The panel judged that there were moderate desirable effects of utilizing AL rather than BL insertion techniques. This was based on the outcomes of bleeding, late catheter dysfunction, hernia occurrence, exit-site infection, and peritonitis.

Bleeding: estimated 3 fewer events per 1000 patients (95% CI 9 fewer to 30 more) based on 5 observational studies with 935 patients [62–66].

Late catheter dysfunction: estimated 181 fewer events per 1000 (95% CI 223 fewer to 91 fewer) based on 4 observational studies with 695 patients [64–67].

Hernia occurrence: estimated 14 fewer events per 1000 patients (95% CI 38 fewer to 142 more) based on 2 observational studies with 1031 patients [62, 63, 66, 67].

Exit site infection: estimated 24 fewer events per 1000 patients (95% CI 38 fewer to 37 more) based on 5 observational studies with 1176 patients [62–64, 66, 67].

Peritonitis: estimated 13 fewer events per 1000 patients (95% CI 95 fewer to 125 more) based on 3 observational studies with 714 patients [63, 64, 66].

Harms and burdens

The panel judged that there were small undesirable effects of utilizing AL rather than BL insertion techniques. This was determined on the basis of bowel injury, early catheter dysfunction, and dialysate leakage.

Bowel injury: estimated 0 fewer events per 1000 patients (95% CI 0 fewer to 0 fewer) based on 1 observational study with 634 patients [66].

Early catheter dysfunction: estimated 54 more events per 1000 patients (95% CI 5 more to 227 more) based on 1 observational study with 397 patients [63].

Dialysate leakage: estimated three more events per 1000 patients (95% CI 2 fewer to 29 more) based on two observational studies with 1031 patients [62, 63, 66, 67].

The certainty of evidence underlying these differences was very low.

Decision criteria and additional considerations

Based on panel review of the analysis and expert opinion, a conditional recommendation was made in favor of AL insertion. Of the outcomes assessed, late catheter dysfunction rate is probably the most significantly related to the technique used and supports this recommendation. This review did find less dialysate leakage in the BL group and the mechanism of this is unclear as the rectus sheath tunnel is theorized to decrease leakage. Larger studies may help clarify this. At the start of the project, the working group chose to define AL insertion as incorporating only one adjunct procedure to decrease catheter dysfunction. However, after the discussion and review of the literature, the panel chose to do a subgroup analysis of only studies defining AL insertion as lysis of adhesions, selective omentopexy, and rectus sheath tunnel. This revealed similar results overall but did show that the effect size favoring AL was slightly stronger for late catheter dysfunction, bleeding, and exit-site infection.

Barriers to implementation are minimal as no additional equipment is needed. The skills required are not greater than those acquired in an accredited general surgery residency. Education and training can occur through instructional video, hands-on courses, and instruction during residency.

Conclusions

The panel suggests that for patients initiating PD, AL insertion of PD catheters may be favored over BL (conditional recommendation, very low certainty evidence). This should be easily implemented by national educational programs for surgeons as standardization of technique is important.

Research needs

Future studies on this subject would ideally be RCTs using a standardized AL technique incorporating omentopexy. In addition, there is discrepancy in the literature regarding the use of rectus sheath tunnel or suture fixation as an adjunct technique to help prevent catheter migration. As of now there are no studies that compare the two, which is why both are included in this guideline. The panel recommends a randomized prospective trial comparing the two to clarify the optimal approach.

What others are saying

Shrestha et al. published a systematic review and meta-analysis in 2018 comparing AL to open and BL insertion [68]. They defined AL insertion as using rectus sheath tunnel, omentopexy, and lysis of adhesions. This differs slightly from this guideline's analysis which included suture catheter fixation in the AL group. They found that compared with BL, catheter obstruction and migration were significantly lower in the AL group, whereas catheter survival was similar in both groups. All other outcomes were similar between the AL and BL groups, including the infectious complications such as peritonitis and exit-site infection.

Pediatric

For pediatric patients, the panel suggests advanced laparoscopic insertion as opposed to basic laparoscopic insertion (expert opinion due to insufficient evidence).

Summary of the evidence

There was no direct comparative data for this question in the pediatric population. There were 14 single-arm studies describing outcomes with AL techniques and 2 studies describing outcomes with BL techniques [53, 62, 69–82]. Given the absence of direct, comparative data, the panel judged that the quality of the evidence was too poor to be helpful for decision-making.

Benefits

Early catheter dysfunction: advanced laparoscopic event rate of 24.5% (range 2.0–60.0%) in 8 studies [53, 55, 69, 71–74, 79] vs basic laparoscopic event rate of 88.9% based on 1 study [82].

Harms

Late catheter dysfunction: advanced laparoscopic event rate of 30.8% (range 7.4–74.3%) in 5 studies [69, 70, 76, 77, 80] vs basic laparoscopic event rate of 13.1% in 1 study [81].

Exit site infection: advanced laparoscopic event rate of 9.4% (range 1.6–20.0%) in 7 studies [55, 71–74, 77, 79] vs basic laparoscopic event rate of 2.2% in 1 study [81].

Dialysate leakage: advanced laparoscopic event rate of 10.9% (range 1.6–22.9%) in 8 studies [53, 55, 72–74, 78] vs basic laparoscopic event rate of 1.2% in 1 study [81].

Late mortality (> 30d): advanced laparoscopic event rate of 2.9% in 1 study [53] vs basic laparoscopic event rate of 1.4% in 1 study [81].

Required operative salvage: advanced laparoscopic event rate of 10.7% (range 7.4–13.3%) in 4 studies [70, 73, 74, 79] vs basic laparoscopic event rate of 8.1% (range 5.0–16.7%) in 2 studies [81, 82].

Peritonitis: advanced laparoscopic event rate of 26.0% (range 1.6–98.7%) in 7 studies [73, 75–80] vs basic laparoscopic event rate of 2.9% in 1 study [81].

Decision criteria and additional considerations

Based on this very limited evidence, it seems BL has a significantly higher catheter dysfunction rate and the dysfunction occurs in the early postoperative period rather than the late postoperative period. Peritonitis mostly occurred over 1 year postoperatively which is unlikely to be attributable to the technique used for PD catheter placement. Overall the panel felt that the outcome most directly related to the placement technique would be early catheter dysfunction, which favored AL placement. This is in line with prevailing wisdom that the pediatric omentum can cause obstruction if left in place, as in the BL technique.

Conclusions

In pediatric patients, the panel suggests that the AL technique of PD insertion may be preferable over BL due to lower rates of catheter dysfunction (expert opinion due to insufficient evidence).

Research needs

In the pediatric population, direct comparative evidence is needed. However, it may be unethical to perform a study of PD catheter insertion without omentectomy given the high catheter dysfunction rate when the omentum is left in place. Other types of data capture may be feasible in the future.

KQ5: Should advanced laparoscopic insertion techniques or open insertion be used for adult and pediatric patients needing renal replacement therapy?

Adult

For adult patients, the panel suggests advanced laparoscopic insertion as opposed to open insertion (conditional recommendation, very low certainty of evidence).

Introduction

PD catheter placement was first described in 1968 by Tenckhoff and Schecter [83]. As PD evolved as a viable modality of RRT, open catheter insertion via mini-laparotomy became mainstream [84, 85]. Unfortunately, open insertion uses a blind insertion technique and therefore studies report catheter dysfunction rates up to 38% [86]. As minimally invasive surgery saw exponential growth throughout the 1990s, several authors reported laparoscopic PD catheter insertion techniques were safe and efficacious options for PD catheter placement [87–91]. However, prior studies comparing open and laparoscopic insertion revealed mixed results. A systematic review and meta-analysis in 2012 by Xie using four RCTs and ten observational studies concluded that laparoscopic placement had no superiority over open surgery [92]. However, Hagen in 2013 found lower odds of catheter migration and higher 1 year catheter survival after laparoscopic insertion in their meta-analysis [93]. The greatest limitation of these studies is that AL technique was not defined and studied separately from BL. Therefore the aim of this key question was to compare open to AL insertion. As noted in KQ4, the AL insertion technique was previously described by Crabtree and Fishman [62].

Summary of the evidence

A total of seven observational studies [62, 66, 94–98] were included in this analysis. Of these, all incorporated selective lysis of adhesions, two used selective omentopexy and rectus sheath tunnel [62, 66], one incorporated only rectus sheath tunnel [95], three used suture fixation [94, 96, 98], and one incorporated rectus sheath tunnel and suture fixation [97]. When subgroup analysis was performed including only the papers using omentopexy and rectus sheath tunnel, catheter dysfunction was similar to the full analysis [62, 66].

The outcomes deemed critical were mortality, peritonitis, early catheter dysfunction (< 3 months), and late catheter dysfunction (> 3 months).

Benefits

The panel judged that there was a moderate effect size in favor of AL PD catheter placement over open. This was based on the outcomes of bowel injury, early and late catheter dysfunction, hernia occurrence, exit-site infection, leakage, mortality, and peritonitis. There was a very low certainty of evidence between differences in outcomes between the two approaches.

Bowel injury: estimated 2 fewer events per 1000 patients (95% CI 3 fewer to 27 more) based on 5 observational studies with 707 patients [62, 66, 95, 97, 98].

Early catheter dysfunction: estimated 182 fewer events per 1000 (95% CI 207 fewer to 136 fewer) based on 3 observational studies with 422 patients [94, 96, 98].

Late catheter dysfunction: estimated 174 fewer events per 1000 patients (95% CI 206 fewer to 97 fewer) based on 3 observational studies with 324 patients [66, 95, 97].

Hernia occurrence: estimated 16 fewer events per 1000 patients (95% CI 34 fewer to 20 more) based on 7 observational studies with 1010 patients [62, 66, 94–98].

Exit site infection: estimated 34 fewer events per 1000 patients (95% CI 60 fewer to 19 more) based on 5 observational studies with 692 patients [62, 66, 94, 97, 98].

Leakage: estimated 38 fewer events per 1000 patients (95% CI 54 fewer to 7 more) based on 4 observational studies with 589 patients [62, 66, 95, 97].

Mortality: estimated 36 fewer events per 1000 patients (95% CI 52 fewer to 1 fewer) based on 2 observational studies with 524 patients [94, 96].

Peritonitis: estimated 66 fewer events per 1000 patients (95% CI 121 fewer to 21 more) based on 6 observational studies with 748 patients [66, 94–98].

Harms and burden

The panel judged that the undesirable effects of utilizing AL PD catheter placement over open were trivial. This was based on the outcome of bleeding. Again, the certainty of evidence for this outcome was very low.

Bleeding: estimated 7 more events per 1000 patients (95% CI 10 fewer to 162 more) based on 4 observational studies with 638 patients [62, 66, 97, 98].

The certainty of evidence was very low.

Decision criteria and additional considerations

The panel did note that there could be issues with access to the requisite training and equipment to perform laparoscopic surgery across the world. However, with the widespread adoption of laparoscopy, the equipment required for AL placement should hopefully be easily accessible to most surgeons. With regards to appropriate training, it will be important to both present and publish educational videos of the technique and to train new generations of surgeons in AL placement. Another consideration is that open insertion can be performed under local anesthesia and sedation while AL requires general anesthesia and CO2 insufflation which carries a higher risk of cardiopulmonary complications [99].

Conclusions

The panel suggests advanced laparoscopic insertion as opposed to open insertion due to less catheter dysfunction (conditional recommendation, very low certainty of evidence).

Research needs

There are multiple avenues for future research. RCTs would provide stronger evidence for the advantages and disadvantages of AL placement. The theoretical benefits of AL placement in patients with obesity or prior abdominal surgeries also require further study.

What others are saying

In a 2018 systematic review and meta-analysis, Shresthra found that AL insertion was associated with superior outcomes compared to open insertion [68]. Specifically, a significant reduction was observed in the incidence of catheter obstruction (odds ratio (OR) 0.14, 95% confidence interval (CI)0.03–0.63; $p=0.01$), catheter migration (OR 0.12, 95% CI 0.06–0.26; $p=0.00001$), pericannular leak (OR 0.27, 95% CI 0.11–0.64; $p=0.003$), and pericannular and incisional hernias (OR 0.29, 95% CI 0.09–0.94; $p=0.04$), as well as better 1- and 2-year catheter survival (OR 0.52, 95% CI 0.28–0.97; $p=0.04$ and OR 0.50, 95% CI 0.28–0.92; $p=0.03$, respectively).

Pediatric

For pediatric patients, the panel suggests advanced laparoscopic insertion as opposed to open insertion (conditional recommendation, very low certainty evidence).

Summary of the evidence

In the pediatric population, a total of 10 observational studies [53, 69–74, 78, 80, 100] were included in this analysis.

Benefits

The panel judged that there was a moderate effect in favor of AL insertion. This was based primarily on the outcome of late catheter dysfunction.

Early catheter dysfunction: estimated 73 fewer events per 1000 patients (95% CI 176 fewer to 43 more) based on 6 observational studies with 562 patients [53, 55, 69, 71–73].

Late catheter dysfunction: estimated 355 fewer events per 1000 patients (95% CI 513 fewer to 94 fewer) based on 4 observational studies with 390 patients [69, 70, 77, 80].

Leakage: estimated 51 fewer events per 1000 patients (95% CI 85 fewer to 36 more) based on 5 observational studies with 370 patients [53, 55, 72, 73, 77].

Mortality: estimated 66 fewer events per 1000 patients (95% CI 90 fewer to 261 more) based on 1 observational study with 49 patients [53].

Required operative salvage: estimated 146 fewer events per 1000 patients (95% CI 274 fewer to 352 more) based on 3 observational studies with 144 patients [70, 73, 80].

Peritonitis: estimated 155 fewer events per 1000 patients (95% CI 241 fewer to 53 more) based on 5 observational studies with 389 patients [53, 73, 77, 80, 100].

Harms

The panel judged that the undesirable effects in the pediatric population were trivial.

Hernia occurrence: estimated 63 more events per 1000 patients (95% CI 44 fewer to 320 more) based on 1 observational study with 157 patients [55].

Exit site infection: estimated 6 more events per 1000 patients (95% CI 40 fewer to 99 more) based on 5 observational studies with 442 patients [55, 71–73. 77].

The certainty of evidence was very low.

Decision criteria and additional considerations

In the pediatric population, the panel noted that omentopexy may be technically challenging to perform in the case of especially small patients.

Conclusions

The panel suggests AL placement may be preferred to open insertion primarily due to lower late catheter dysfunction (conditional recommendation, very low certainty of evidence).

Research needs

Future research should examine technical variations such as the benefits of omentectomy vs omentopexy as well as the effect of patient's size on outcomes. For example, the aforementioned difficulty of omentopexy in particularly small patients likely precludes its use.

KQ6: Should advanced laparoscopic insertion techniques or image-guided percutaneous techniques be used for adults needing renal replacement therapy?

For adult patients, the panel suggests either advanced laparoscopic or image-guided percutaneous insertion (conditional recommendation, very low certainty evidence).

Introduction

The optimal technique for PD catheter insertion remains unclear. As surgeons moved from blind percutaneous to open to laparoscopic to AL procedures, there has been an increasing number of PD catheters inserted by radiologists and nephrologists using an image-guided percutaneous approach usually under ultrasound or fluoroscopic guidance. Since ultrasound allows visualization and avoidance of the inferior epigastric vessels and bowel loops, and fluoroscopy allows injection of contrast to confirm free location in the peritoneal cavity and verification of the guide-wire in the pelvis, this modified Seldinger technique has been shown to be safe and efficacious in several single-arm studies dating back to 2000 [101–105]. Comparative studies have shown this technique has advantages over BL, with lower leakage and peritonitis rates, and less cost while maintaining similar catheter survival. A recent meta-analysis by Esagian reviewed 34 studies and compared percutaneous catheter placement to open and laparoscopic surgical placement [106]. Unfortunately this study included blind as well as ultrasound-guided percutaneous insertion and did not separate open, AL, and BL insertion. Percutaneous placement was associated with significantly lower rates of tunnel/exit-site infection [relative risk (RR) 0.72, 95% confidence interval (CI) 0.56–0.91], catheter migration (RR 0.68,95% CI 0.49, 0.95), and catheter removal (RR 0.73, 95% CI 0.60–0.88). The 2- and 4-week rates of early tunnel/exit-site infection were also lower in the percutaneous group (RR 0.45, 95% CI 0.22–0.93 and RR 0.41, 95% CI 0.27–0.63, respectively). No statistically significant difference was observed regarding other outcomes, including catheter survival and mechanical complications. They found that overall, the quality of published literature on the topic of PD catheter placement is poor, with a small percentage of studies being RCTs. They concluded that percutaneous PD catheter placement is a safe procedure and may result in fewer complications, such as tunnel/exit-site infections and catheter migration, compared to surgical placement. Given the growing evidence that AL insertion offers the best outcomes the panel chose to compare ultrasound-guided percutaneous insertion to AL insertion in this KQ. As noted above, the AL insertion technique was previously described by Crabtree and Fishman [62].

Summary of the evidence

One RCT was included in the analysis. In 2001 Voss published a randomized non-inferiority trial comparing radiologic vs. surgical implantation of PD catheters [107]. There were 51 subjects in each group and patients with severe obesity and prior abdominal surgery were excluded. The surgical group used an AL insertion technique using a long preperitoneal (rectus sheath) tunnel. The radiologic group used fluoroscopic guidance. They found that complication-free catheter survival was significantly higher at 42.5% (95% confidence interval 29.3– 55) in the radiological group compared with 18.1% (95% CI 8.9–29.8) in the laparoscopic group (P-value = 0.03). Excess complications in the laparoscopic group included peritonitis, peritoneal dialysate leaks, and umbilical hernia. One-year overall catheter survival and 1-year subject survival were not different between the groups. Hospital costs were significantly higher in the laparoscopic group by almost a factor of two. Therefore they concluded that radiological insertion of first PD catheters using fluoroscopy is a clinically non-inferior and cost-effective alternative to surgical laparoscopic insertion. There is some selection bias in this paper due to exclusion of severely obese and patients with prior abdominal surgery.

The outcomes initially deemed critical were early catheter dysfunction (< 3 months), late catheter dysfunction (> 3 months), mortality, bowel injury, and peritonitis. However there were no mortalities or bowel injuries in either group so these outcomes were not considered.

Benefits

Of the critical and important outcomes, none were benefits of utilizing the advanced laparoscopic technique as opposed to the fluoroscopically guided percutaneous technique.

Harms

All of these outcomes are based on 1 RCT with 102 patients [107].

Bleeding: OR 9.76 (95% CI 0.51 to 186.1).

Early catheter dysfunction: estimated 20 more events per 1000 (95% CI 30 fewer to 242 more).

Late catheter dysfunction: estimated 20 more events per 1000 (95% CI 41 fewer to 228 more).

Hernia: estimated 78 more events per 1000 (95% CI 29 fewer to 320 more).

Exit site infection: estimated 59 more events per 1000 patients (95% CI 97 fewer to 264 more).

Dialysate leakage: estimated 118 more events per 1000 patients (95% CI 12 fewer to 377 more).

Peritonitis: estimated 156 more events per 1000 patients (95% CI 29 fewer to 352 more).

Papers that addressed prior surgical history and obesity were also analyzed as the panel felt these were important patient characteristics in deciding between advanced laparoscopic and percutaneous catheter placement. There were 2 observation studies that met inclusion criteria. AbdelAal in 2018 compared the outcomes of fluoroscopic and ultrasound-guided versus laparoscopic placement of PD catheters in 240 patients [108]. The laparoscopic group included 190 patients and incorporated rectus sheath tunnel and omentopexy in 10% of patients. The radiologic group used an image-guided percutaneous technique described by Reddy and included 50 patients [103]. Patients who were obese or had a history of prior abdominal surgery were not excluded. They found that 38% had prior abdominal surgery in the radiologic group versus 48.4% in the laparoscopic group ($p = 0.19$). The results show similar complications rates for all outcomes assessed and similar survival at 90 and 365 days. A 2019 study by Glavinovic was also included in the analysis [109]. They reviewed 297 catheters placed at their institution. Ninety-four were inserted by interventional radiology using ultrasound and fluoroscopic guidance. AL insertion was used to implant 203 PD catheters using rectus sheath tunnel, omentopexy, and lysis of adhesions. Exclusion of 95 patients where an embedding technique was used limited analysis to the one hundred eighteen patients where it was not embedded. In this study, prior abdominal surgery was present in 27.7% of IR vs 44.9% AL patients. Dysfunction rates were similar between groups.

Benefits

The panel judged that the desirable effects of AL insertion over percutaneous techniques were small. This was based on the outcomes of bleeding, bowel injury, and peritonitis. The evidence underlying these three outcomes was of very low certainty.

Bleeding: estimated 44 fewer events per 1000 patients (95% CI 57 fewer to 16 more) based on 1 observational study with 240 patients [108].

Bowel injury: estimated 10 fewer events per 1000 (95% CI 13 fewer to 22 more) based on 2 observational studies with 452 patients [108, 109].

Hernia occurrence: estimated 13 fewer events per 1000 patients (95% CI 47 fewer to 100 more) based on 1 observational study with 240 patients [108].

Harms and burdens

The undesirable effects of AL insertion techniques over percutaneous techniques were small. This was based on the outcomes of late catheter dysfunction, exit-site infection, dialysate leakage, and peritonitis. The outcomes of early catheter dysfunction and mortality were deemed inconclusive by the panel because the data came from only one observational study of 43 patients. In addition, mortality was all cause and not specific to the operation. There was very low certainty evidence underlying all these outcomes.

Late catheter dysfunction: estimated 60 more events per 1000 (95% CI 18 fewer to 181 more) based on 2 observational studies with 452 patients [108, 109].

Exit site infection: estimated 13 more events per 1000 patients (95% CI 28 fewer to 168 more) based on 1 observational study with 240 patients [108].

Dialysate leakage: estimated 45 more events per 1000 patients (95% CI 2 more to 159 more) based on 2 observational studies with 452 patients [108, 109].

Peritonitis: estimated 8 more events per 1000 patients (95% CI 79 fewer to 161 more) based on 1 observational study with 240 patients [108].

The certainty of this evidence was very low.

Decision criteria and additional considerations

The panel made its decision using the evidence above and expert opinion. These studies actually used similar techniques for AL insertion and image-guided percutaneous insertion, affirming these conclusions. Other criteria may come into play in clinical situations. For instance, the percutaneous approach in patients with prior abdominal operations could lead to a high complication rate. In addition, this

evidence may not apply to obese patients. Finally, the elderly or frail may benefit from the "less invasive" radiologic approach but this subgroup analysis has not been performed.

Conclusions

The panel suggests either AL insertion or ultrasound-guided percutaneous insertion should be used for patients needing PD catheter insertion (conditional recommendation, very low certainty evidence). The advantages of the percutaneous technique include not needing general anesthesia and a lower risk of dialysate leakage, hernia, exit-site infection, and late catheter dysfunction. However, there is a higher risk of bleeding and bowel injury and this may be magnified in patients with prior abdominal operations.

Research needs

Future research should investigate the outcomes of the percutaneous approach based on the training background of the physician, e.g. IR, nephrology, surgery. There should also be a prospective randomized trial including patients with severe obesity and prior abdominal operations.

KQ7: In patients with PD catheter malfunction, should nonoperative or operative salvage be attempted?

The panel suggests either operative or nonoperative salvage for adult patients with PD catheter malfunction (conditional recommendation, very low certainty evidence).

Introduction

Successful PD requires a well-functioning catheter which allows flow of dialysate into the abdominal cavity and back out after a dwell. Catheter dysfunction is a relatively common and very disruptive problem. It has been shown to be a prominent reason patients permanently switch to HD [110]. Surgeons caring for these patients should be involved in the diagnosis and management of PD catheter obstruction. An organized, algorithmic approach has been suggested, which starts with distinguishing one- from two-way obstruction [111]. Two-way obstruction is likely a mechanical problem with the tubing or a fibrin plug. One-way obstruction is obstructed outflow only and may be caused by constipation and dilated sigmoid colon, catheter displacement out of the pelvis, entrapment in the omentum or bowel, or compartmentalization by adhesions. The management strategy has changed through the years from open revision or replacement, to laparoscopy, to nonoperative techniques such as TPA instillation and guide-wire manipulation by interventional radiology [112–119]. The prior guideline made the following recommendations: "(1) Malfunctioning peritoneal dialysis catheters should be evaluated by physical examination and plain radiographs to rule out constipation. If negative, further studies such as catheterography or CT peritoneography, followed by diagnostic laparoscopy are indicated. (2) Nonoperative treatments of malfunctioning PD catheters which have been proven effective include flushing, thrombolytics and fluoroscopic wire manipulation. (3) Patients with malfunctioning peritoneal dialysis catheters not amenable to nonoperative measures should undergo laparoscopy with catheter repositioning, adhesiolysis, omentectomy or omentopexy. Patency should be assured by stripping and flushing. Suture fixation of the catheter to the pelvis or polypropylene sling may be utilized to reduce catheter migration. Surgical techniques for catheter salvage require individualization based upon operative findings" [1]. The aim of this question was to compare nonoperative and operative salvage of the malfunctioning PD catheter using the most current evidence.

Summary of the evidence

There were no comparative studies that met inclusion criteria. Instead, single-arm data based on four studies for nonoperative salvage techniques using wire manipulation [120–123] and thirteen studies for operative salvage techniques were reviewed [124–136]. Mortality was designated a critical outcome.

Benefits

The desirable effects of nonoperative intervention include lower risk of bleeding, exit-site infection and peritonitis.

Bleeding: Nonoperative salvage event rate of 1.1% (range 0.9–1.2%) in 2 studies [120, 122] vs operative salvage event rate of 3.3% (range 2.2–5.6%) in 5 studies [127, 130, 133, 135, 136].

Exit site infection: Nonoperative salvage event rate of 0.94% in 1 study [122] vs operative salvage event rate of 6.6% (range 1.5–30.6%) in 5 studies [126, 130, 131, 135, 136].

Peritonitis: Nonoperative salvage event rate of 1.1% (range 0.9–1.2%) in 2 studies [120, 122] vs operative salvage event rate of 7.1% (range 1.5–16.7%) in 8 studies [126–131, 135, 136].

Harms and burdens

The undesirable effects of nonoperative intervention include higher risk of early and late catheter dysfunction.

Early catheter dysfunction: Nonoperative salvage event rate of 36.9% (range 83–50.0%) in 4 studies [120–123] vs operative salvage event rate of 18.5% (range 2.3–98.5%) in 9 studies [124–127, 131, 133–136].

Late catheter dysfunction: Nonoperative salvage event rate of 62.4% (range 31.6–91.7%) in 2 studies [121, 123] vs

operative salvage event rate of 25.6% (range 2.5–56.3%) in 7 studies [124, 127–129, 131, 132, 136].

The certainty of this evidence was very low.

Decision criteria and additional considerations

When managing the patient with catheter dysfunction, a stepwise approach should be used. If outflow obstruction is diagnosed and thought to be due to constipation, it should be aggressively treated as indicated. If inadequate outflow persists, the panel suggests that either nonoperative or operative approaches may be used. If time permits, nonoperative salvage should be attempted first since it is less invasive and has a lower risk of complications. However, it appears to be less effective, with higher rates of early and late recurrent dysfunction. As stated in the previous guideline, exploratory laparoscopy with catheter revision is the most definitive care and therefore should be performed if the patient is urgently in need of dialysis.

Conclusions

The panel suggests that in patients with PD catheter malfunction, either nonoperative or operative salvage may be attempted (conditional recommendation, very low certainty evidence) Nonoperative strategies such as interventional radiology wire manipulation are low risk and should probably be attempted first if time permits. However, operative intervention with exploratory laparoscopy and catheter revision has better long-term results and should be undertaken in a timely manner so temporary HD may be avoided.

Discussion

What's new in this guideline

Most of the recommendations made in the SAGES Guideline for Laparoscopic Peritoneal Dialysis Access Surgery in 2014 are still current and applicable. However, twelve new recommendations were added for adult and pediatric patients, based on clinical trends and updated literature. This guideline reports on hernia repair at the time of PD access creation to better inform clinical decision-making. One of the newest topics in PD surgery is the urgent start of dialysis. This is one of the first evidence-based recommendations on the subject in the literature. We elected to compare outcomes of urgent and traditional start head-to-head and report on this. Further research is needed because when dialysis is needed on an urgent basis, hemodialysis is performed via temporary venous catheter and most patients never switch to PD. In addition, there may be benefits of urgent start PD and avoiding temporary HD that outweigh the risk of urgent start PD. The most significant findings in this review relate to insertion techniques and recommendations for the use of AL insertion over open and BL approaches. In addition, there is increasing use of image-guided percutaneous insertion by both IR and interventional nephrologists and which was found to be comparable to AL insertion in select patient populations. Finally this guideline addresses salvage of a malfunctioning catheter by comparing nonoperative techniques of fluoroscopic wire manipulation with laparoscopic revision.

Implementation

The panel believes that it is feasible to successfully implement these recommendations into local practice and that the recommendations will be accepted by stakeholders. The main considerations regarding implementation of this guideline include costs and availability of the specialized dialysis personnel, interventional radiology capability, and laparoscopic instrumentation. In addition some of the recommended techniques require specialized knowledge and skills which may require continuing postgraduate education with didactic and hands-on courses. Finally, to achieve the full benefit of these recommendations, standardizing surgical technique is required.

Updating these guidelines

After publication of these guidelines, SAGES Living Guidelines Task Force will plan to perform repeat literature searches on a frequent interval to search for any new evidence. When substantive literature is identified, the guideline will undergo formal update.

Limitations of these guidelines

The limitations of these guidelines are inherent to the very low certainty of the evidence identified for all KQs. Specifically, there is selection bias in some instances where severely obese or patients with history of prior abdominal operations were not included. Multiple research priorities were made to try to improve the certainty and quality of the evidence for which recommendations were made.

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