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*Elisa Mäkäräinen*

# PREVENTION AND SURGICAL TREATMENT OF PARASTOMAL HERNIAS

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*UNIVERSITY OF OULU,*
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*OULU UNIVERSITY HOSPITAL*

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# PREVENTION AND SURGICAL TREATMENT OF PARASTOMAL HERNIAS

Academic Dissertation to be presented with the assent of the Doctoral Training Committee of Health and Biosciences of the University of Oulu for public defence in Auditorium 1 of Oulu University Hospital (Kajaanintie 50), on 20 August 2021, at 12 noon

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## *Abstract*

Parastomal hernia (PSH) is not merely a complication but rather an inevitable consequence of a stoma, occurring in up to 50% of ostomies. However, the surgical treatment for PSH has high complication and recurrence rates. Prophylactic mesh placement at the index surgery has been used to reduce the incidence of PSH, but despite its promising early results, the significance of PSH prevention has been questioned. The aim of this thesis was to discover the long-term results of PSH prevention and the nationwide results of surgical treatment for PSH. Additionally, the thesis explored whether emergency surgery for diverticulitis is a significant risk factor for PSH.

Study I investigated the long-term efficiency and safety of the intra-abdominal keyhole technique for preventing PSH after laparoscopic abdominoperineal resection (APR) for rectal adenocarcinoma. Although the mesh lowered the PSH repair rate and the risk of stomal prolapse, the technique failed to decrease PSH incidence during long-term follow-up.

Studies II and III reported nationwide retrospective registry data for end ostomy (Study II) and ileal conduit (Study III) PSH repairs performed in nine Finnish hospitals. The results were poor, with high recurrence, complication, and reoperation rates, and the keyhole technique was associated with a significant risk of recurrence. Therefore, this technique should not be used for PSH repair.

Study IV was a systematic review of parastomal and incisional hernia incidences after emergency surgery for Hinchey III–IV diverticulitis. The review revealed that hernia incidences have been widely ignored in the literature.

To conclude, the results of both the prevention and surgical treatment of PSH were unsatisfactory. Therefore, future studies should find better solutions and new techniques to prevent and treat PSH. Further studies on emergency surgery for diverticulitis should pay attention to hernia incidence and its prevention.

*Keywords:* abdominoperineal resection, diverticulitis, incisional hernia, parastomal hernia, rectal cancer

**Mäkäräinen, Elisa, Avannetyrän ehkäisy ja hoito.**
Oulun yliopiston tutkijakoulu; Oulun yliopisto, Lääketieteellinen tiedekunta; Medical Research Center Oulu; Oulun yliopistollinen sairaala
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### *Tiivistelmä*

Avannetyrä on lähes väistämätön paksusuolen pääteavanteen seuraus. Koska avanne¬tyrän leikkaushoitoon liittyy paljon sekä tyrän uusiutumisia että komplikaatioita, avannetyrä on pyritty välttämään ennalta ehkäisevillä verkoilla. Vaikka ensimmäi¬set tulokset ennalta ehkäisevistä verkoista ovat olleet lupaavia, niiden hyöty on sit-temmin kyseenalaistettu. Väitöskirjan tarkoituksina oli selvittää avannetyrän ennalta ehkäisyn ja korjauksen tuloksia Suomessa. Lisäksi selvitimme, onko paksusuolen umpipussitaudin päivystysleikkaus erityinen riskitekijä avannetyrän muodostumiselle.

Osatyössä I julkaisimme avannetyriä ennalta ehkäise¬vän verkon pitkäaikaistulokset. Tutkimuspotilaat leikattiin tähystystekniikalla peräsuolisyövän vuoksi 2010–2013. Vaikka verkon todettiin ehkäisevän sekä avanteen pullis¬tumista että myöhempää leikkaushoidon tarvetta avannetyrän vuoksi, verkko ei ehkäissyt avannetyrien ilmaantumista pitkän aikavälin seurannassa.

Osatöissä II ja III julkaisimme yhdeksästä sairaalasta kootun rekisteriaineiston tulokset pääteavanteiden (osatyö II) ja ohutsuolen virtsa-avanteiden (osatyö III) avannetyrien leikkaushoidosta. Tulokset ovat huonoja, ja avannetyrän leikkaus johtaa usein avannetyrän uusiutumiseen, leikkauskomplikaatioihin ja uusintaleikkauksiin. Usein käytetyn niin kutsutun keyhole-tekniikan tulokset olivat erityisen huonoja, eikä sitä tulisi käyttää enää avannetyrän leikkaushoidossa.

Osatyössä IV selvitettiin paksusuolen umpipussitaudin vuoksi päivystys¬leikkaukseen joutuvien avanne- ja arpityräriskiä systemaattisessa kirjallisuuskatsauksessa. Tutkimus paljasti, että avannetyrien toteamista ei ole aikaisemmissa tutkimuksissa huomioitu riittävästi.

Koska sekä avannetyrän ennalta ehkäisyn ja hoidon tuloksissa on parantamisen varaa, lisätutkimusta tarvitaan erityisesti parempien tekniikoiden kehittämiseksi. Paksusuolen umpipussitautitutkimuksen tulee jatkossa huomioida myös avannetyräriski ja avannetyrän ennalta ehkäisy.

*Asiasanat:* abdominoperineaalinen resektio, arpityrä, avannetyrä, peräsuolisyöpä

***To my family***

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*Oulu, May 2021* *Elisa Mäkäräinen*

# Abbreviations

| | |
|---|---|
| ACPGBI | The Association of Coloproctology of Great Britain and Ireland |
| ANOVA | Analysis of variance |
| APR | Abdominoperineal resection |
| ASA | American Society of Anaesthesiologists |
| BMI | Body mass index |
| CI | Confidence interval |
| cIH | Concomitant incisional hernia |
| CT | Computed tomography |
| EHS | European Hernia Society |
| HP | Hartmann procedure |
| ICD | International Classification of Disease |
| IH | Incisional hernia |
| IPOM | Intraperitoneal onlay mesh |
| LL | Laparoscopic lavage |
| NR | Not reported |
| PP | Polypropylene |
| PR | Primary resection |
| PRA | Primary anastomosis |
| PSH | Parastomal hernia |
| RCT | Randomized controlled trial |
| QoL | Quality of life |
| SD | Standard deviation |
| SR | Secondary resection |
| SSI | Surgical site infection |
| TAR | Transversalis abdominis release |
| 3D | 3-dimensional |

# Original Publications

This thesis was based on the following publications:

I Mäkäräinen-Uhlbäck, E. J., Klintrup, K., Vierimaa, M. T., Carpelan-Holmström, M. A., Kössi, J., Kairaluoma, M. V., … Rautio, T. T. (2020). Prospective, randomized study on the use of prosthetic mesh to prevent a parastomal hernia in a permanent colostomy: Results of a long-term follow-up. *Diseases of the Colon and Rectum, 63*(5), 678–684. https://doi.org/10.1097/DCR.0000000000001599

II Mäkäräinen-Uhlbäck, E., Vironen, J., Falenius, V., Nordström, P., Välikoski, A., Kössi, … & Rautio, T. (2021). Parastomal hernia: A retrospective nationwide cohort study comparing different techniques with long-term follow-up. *World Journal of Surgery*, 10.1007/s00268-021-05990-z. Advance online publication. https://doi.org/10.1007/s00268-021-05990-z

III Mäkäräinen-Uhlbäck, E., Vironen, J., Vaarala, M., Nordström, P., Välikoski, A., Kössi, J., Rautio, T. (2021). Keyhole versus Sugarbaker techniques in parastomal hernia repair following ileal conduit urinary diversion: A retrospective nationwide cohort study. *BMC Surgery, 21*(1), 231. https://doi-org.pc124152.oulu.fi:9443/10.1186/s12893-021-01228-w

IV Mäkäräinen, E., Rautio, T., Rintala, J., Muysoms, F., & Kauppila, J. (2021). Parastomal and incisional hernias following emergency surgery for Hinchey III–IV diverticulitis: A systematic review. *Submitted.*

# Contents

# 1 Review of the Literature

## 1.1 Parastomal hernia history

The first parastomal hernia (PSH) repairs were accomplished by suturing (Mayo, 1901; Shouldice, 1953; Thomas & Rogers, 2004) and change of stoma location (Cheung, Chia, & Chiu, 2001; Rubin, Schoetz, & Matthews, 1994). However, these techniques are no longer used as they come with almost inevitable recurrence (Antoniou et al., 2018; DeAsis et al., 2015; Hansson et al., 2012).

The idea of using a prosthetic material to repair a hernia arose in the late nineteenth century (Baylón et al., 2017; Read, 2004). Thereafter, synthetic meshes revolutionised hernia surgery. After much trial and error, a heavyweight, small-pore polypropylene (PP) mesh was invented (Usher, Hill, & Ochsner, 1959). Such meshes continued to be developed with a light weight and large pores to reduce tissue inflammation and therefore yield a better outcome (Klinge & Klosterhalfen, 2018; Weyhe et al., 2007). The first reported mesh repair occurred in 1977, when a case of PSH was repaired using an onlay PP mesh (Rosin & Bonardi, 1977), and the first intra-abdominal PSH mesh repair was described by Sugarbaker in 1985. A slight modification of this technique is still widely used (Antoniou et al., 2018; DeAsis et al., 2015; Hansson et al., 2012).

PSH was recognised as a complication of end colostomy in the 1990s (Cheung, 1995; Londono-Schimmer, Leong, & Phillips, 1994). Research focused on surgical techniques and the significance of the stoma location to decrease the otherwise high PSH incidence (Ortiz et al., 1994; Sjödahl, Anderberg, & Bolin, 1988). The first randomised controlled trial (RCT) on PSH prevention used the keyhole technique in the retrorectus space (Jänes, Cengiz, & Israelsson, 2004), and this technique has been widely utilised for PSH prevention since then, despite its pitfalls (Odensten et al., 2019). The highlights of the history of PSH surgery are presented in Figure 1.

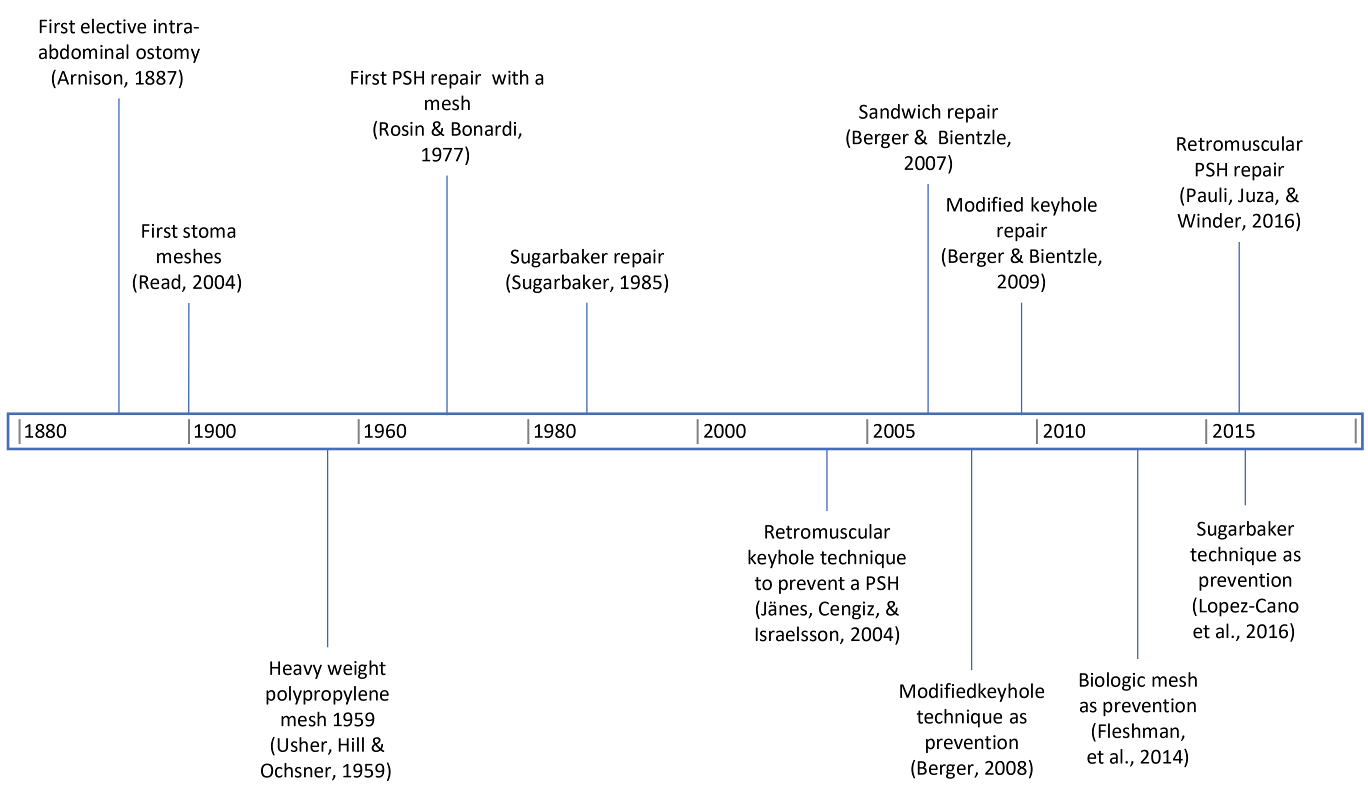


**Fig. 1. History of parastomal hernia (PSH) surgery.**

The era of laparoscopic hernia surgery started with the use of the intraperitoneal onlay mesh (IPOM) and the conduct of totally extraperitoneal and transabdominal preperitoneal repairs in the early 1990s (Corbitt, 1993; Filipi, Fitzgibbons, Salerno, & Hart, 1992; Lucas & Arregui, 1999; MacFadyen et al., 1993; Spaw, Ennis, & Spaw, 1991). However, minimally invasive techniques for PSH repair are seldom used worldwide (Gavigan, Stewart, Matthews, & Reinke, 2018; Halabi et al., 2013). While robotic surgery has gained popularity in hernia surgery since its invention, its advantages over laparoscopic surgery have yet to be proven (Henriksen, Jensen, & Muysoms, 2019; Lanfranco, Castellanos, Desai, & Meyers, 2004).

## 1.2 Parastomal hernia

### *1.2.1 Definition*

The exact definition of PSH has remained elusive, resulting in different interpretations of parastomal bulging (Israelsson, 2005). The European Hernia Society (EHS) defines PSH as an "abnormal protrusion of the contents of the abdominal cavity through the abdominal wall defect created during placement of a colostomy, ileostomy or ileal conduit stoma" (Śmietański et al., 2014).

### *1.2.2 Parastomal hernia classification*

PSH classification allows for a comparison of the results of previous studies on PSH repair. None of the five published classification systems (Table 1) have undergone a validation process. The oldest classification systems, which are by Devlin and Rubin et al., rely on intra-operative findings (Devlin, 1998; Rubin et al., 1994) and have no clinical significance (Śmietański et al., 2014). The classification system by Gil and Szczepkowski is based on clinical evaluation (Gil & Szczepkowski, 2011) and divides PSH into four categories based on the hernia size and the coexisting incisional hernia (IH). The Moreno-Matias classification system relies on the content of the PSH sac as determined via computed tomography (CT) scan. This classification system has clinical relevance, as the risk of developing symptoms and the clinical detectability increase along with the classification (Moreno-Matias et al., 2009). Additionally, the results of the Moreno-

Matias system have been confirmed in a retrospective cohort study (Seo, Kim, Oh, Lee, & Suh, 2011).

**Table 1. Parastomal hernia classification systems.**

| Classification system | Basis | Subclasses |
| --- | --- | --- |
| Devlin | Intraoperative | Type I: interstitial hernia |
| (Devlin,1998) | findings | Type II: subcutaneous hernia |
| | | Type III: intrastomal hernia |
| | | Type IV: peristomal hernia (stoma prolapse) |
| Rubin | Intraoperative | Type Ia: interstitial PSH[1] |
| (Rubin et al., 1994) | findings | Type Ib: subcutaneous PSH |
| | | Type II: intrastomal hernia |
| | | Type III: subcutaneous prolapse |
| | | Type IV: pseudohernia |
| Gil and Szcepkowski | Clinical | Type I: isolated small PSH |
| (Gil & Szczepkowski, 2011) | evaluation | Type II: small PSH with coexisting midline IH[2] |
| | | Type III: isolated large PSH with significant front abdominal wall deformity |
| | | Type IV: large PSH with coexisting midline IH with significant front abdominal wall deformity |
| Moreno-Mattias | CT[4] | Type 0: the peritoneum follows the wall of the bowel forming the stoma, with no formation of a sac |
| (Moreno-Matias et al., 2009) | | Type Ia: bowel forming the colostomy with a < 5 cm sac |
| | | Type Ib: bowel forming the colostomy with a > 5 cm sac |
| | | Type II: sac containing omentum |
| | | Type III: intestinal loop other than the bowel forming the stoma |
| EHS[3] | CT | Type I: PSH size ≤ 5 cm, no concomitant IH |
| (Śmietański et al., 2014) | | Type II: PSH size ≤ 5 cm, with concomitant IH |
| | | Type III: PSH size > 5 cm, no concomitant IH |
| | | Type IV: PSH size > 5 cm, with concomitant IH |
| | | Abbreviations: P = primary; R = recurrent |

[1] parastomal hernia, [2] incisional hernia, [3] European Hernia Society, [4] computed tomography

The EHS created its own PSH classification system in 2012 (Śmietański et al., 2014). This system categorises PSH according to hernia sac size as determined via computed tomography (CT) scan. The cut-off limit of the hernia sac is 5 cm, and the hernia is divided into subgroups with or without coexisting IH. However, the clinical significance of this classification system remains unclear (Lin et al., 2019; Su et al., 2020; Vierimaa et al., 2015), and further research on PSH classification systems is needed to determine whether they can be utilised in treatment planning or prediction of PSH complications (Śmietański et al., 2014).

### 1.2.3 Risk factors for parastomal hernia

Several patient- and surgery-related factors increase the risk of developing PSH. Female gender and advancing age are both significant patient-related risk factors (Hong, Oh, Lee, Kim, & Suh, 2013; Mylonakis, Scarpa, Barollo, Yarnoz, & Keighley, 2001; Pilgrim, McIntyre, & Bailey, 2010; Sohn, Moon, Shin, & Jee, 2012). Obesity and a larger waist circumference also increase the risk of developing PSH (De Raet, Delvaux, Haentjens, & Van Nieuwenhove, 2008; Funahashi et al., 2014; Sohn et al., 2012), as does prior ventral hernia at the time of stoma creation (Ripoche, Basurko, Fabbro-Perray, & Prudhomme, 2011). Surgery-related risk factors, such as aperture size (Yeon Hong et al., 2013; Pilgrim et al., 2010), can also increase the risk of developing PSH. Surprisingly, the laparoscopic surgical technique seems to predispose patients to PSH (Funahashi et al., 2014; Ihnát et al., 2019). Furthermore, PSH predisposes patients to IH by altering the biomechanical conditions in the abdominal wall (Timmermans, Deerenberg, Lamme, Jeekel, & Lange, 2014; Timmermans et al., 2014).

### 1.2.4 Incidence

PSH incidence is likely higher following end colostomy formation than following ileostomy or ileal conduit urinary diversion (Ripoche et al., 2011). PSH incidence may rise by over 50% in long-term follow-up for end colostomy, (Antoniou et al., 2018; Jänes, Cengiz, & Israelsson, 2009), while it ranges from 7–36% for ileostomies (Carne, Robertson, & Frizelle, 2003; Etherington, Williams, Hayward, & Hughes, 1990; Ripoche et al., 2011) and 10–32% following ileal conduit urinary diversion (Donahue et al., 2014; Ho & Fawcett, 2004; Hussein et al., 2018; Narang et al., 2017; Nomura et al., 2003; Rodriguez Faba et al., 2011).

### 1.2.5 Diagnosis

The primary method for diagnosing and evaluating treatment options for PSH is clinical assessment. However, clinical diagnosis is inaccurate, with a 63–96% negative predictive value (Moreno-Matias et al., 2009; Serra-Aracil et al., 2009; Vierimaa et al., 2015). Additionally, the specificity of clinical evaluation is low, with considerable inter-observer variation (Gurmu et al., 2011). Therefore, imaging via CT scan is a crucial additional diagnostic modality for PSH evaluation (de Smet, 2020), as CT scan detects PSH more often than clinical evaluation (Cingi, Cakir, Sever, & Aktan, 2006; de Smet et al., 2020; Vierimaa et al., 2015). However, the significance of PSH detection via CT scan in the absence of clinical findings remains unclear.

The specificity and sensitivity of three-dimensional (3D) ultrasound are equal to those of CT scan (de Smet et al., 2020; Näsvall, Wikner, Gunnarsson, Rutegård, & Strigård, 2014), but 3D ultrasound has significant inter-observer variation (Strigård, Gurmu, Näsvall, Påhlman, & Gunnarsson, 2013). The role of 3D ultrasound in PSH diagnosis and decision-making has been unspecified (Antoniou et al., 2018).

### *1.2.6 Hernia-related morbidity and quality of life*

Most PSHs may be symptomatic (Ripoche et al., 2011). The most common symptoms of PSH are pain and a bearing-down sensation, as well as leakage, skin problems, and difficulty with the stomal appliance (Ho & Fawcett, 2004; Huang, Pan, Chen, Cai, & Fang, 2018; Krogsgaard et al., 2017; Ripoche et al., 2011). While stoma reduces the level of physical activity (Krogsgaard et al., 2017; Russell, 2017) and decreases the quality of life (QoL) of the patient (Mäkelä & Niskasaari, 2006; Näsvall et al., 2017), the presence of PSH lowers QoL even further (Kald, Juul, Hjortsvang, & Sjödahl, 2008; Näsvall et al., 2017; van Dijk et al., 2015). Thus, successful surgical treatment of PSH will improve the patient's QoL (Gavigan et al., 2018). Overall, the symptom burden is likely to decrease after PSH repair, but with only minor or no relief of skin problems and leakage (Krogsgaard et al., 2017).

### *1.2.7 Parastomal and incisional hernias after emergency surgery for diverticulitis*

The rate of IH also depends on both patient- and surgery-related risk factors (Bosanquet et al., 2015). The surgical treatment of peritonitis results in over 50% IH incidence (Moussavian et al., 2010), and elective surgery for diverticulitis poses an 11–15% IH risk—higher than the IH risk posed by surgery for cancer (Perez et al., 2020; Pogacnik et al., 2014; Shao et al., 2020). However, the rates of both PSH and IH after emergency surgery for diverticulitis are still unknown.

## 1.3 Parastomal hernia repair

### *1.3.1 Indications*

Due to a lack of research on the issue, the existing guidelines on PSH repair do not elaborate on the indications for surgery (Antoniou et al., 2018). As PSH repair is associated with high risks of mortality and morbidity, patients with significant comorbidities should be treated conservatively (Kroese et al., 2018). Furthermore, asymptomatic PSH is unlikely to cause indication for emergency surgery (Kroese et al., 2018; Krogsgaard et al., 2020), which poses an increased risk of morbidity and even death (Gregg, Dao, Schechter, & Shah, 2014; Helgstrand et al., 2013).

### *1.3.2 Meshes*

PP is still the most widely used mesh material, alongside polyester and polytetrafluoroethylene. These mesh materials lead to comparable results in terms of hernia recurrence and post-operative infection rate (Eriksen, Gögenur, & Rosenberg, 2007; Totten, Becker, Lourd, & Roth, 2019). In addition to their lighter weight compared to the first PP materials, meshes have been developed with a coating to reduce adhesion formation in the intra-abdominal space and a 3D shape to help them better adapt to the abdominal wall curvature (Amato et al., 2014; Champault & Barrat, 2005; Champault et al., 2011; Koch, Bringman, Myrelid, Smeds, & Kald, 2008; Köckerling & Schug-Pass, 2014).

Biological meshes derived from human, porcine, or bovine tissue were developed in the hope that they would better resist infections compared to synthetic meshes. However, this has been doubted since their development (Atema, de Vries, & Boermeester, 2016; Cross, Kumar, & Chandru Kowdley, 2014; Huerta, Varshney, Patel, Mayo, & Livingston, 2016; Köckerling et al., 2018; Lee et al., 2014). Synthetic meshes are safe in a contaminated surgical site (Morris et al., 2021; Warren et al., 2020), and both PSH repair and prevention have been studied mainly using synthetic meshes (Antoniou et al., 2018).

The safety and side effects of hernia repair with a mesh are of special concern (Wise, 2018), but the data obtained from research do not support the avoidance of using a mesh for hernia repair (Bittner et al., 2019; Henriksen et al., 2020; López-Cano, Martin-Dominguez, Pereira, Armengol-Carrasco, & García-Alamino, 2018; Nguyen et al., 2014; Öberg, Andresen, Klausen, & Rosenberg, 2018). The significance of the newest mesh invention—the absorbable synthetic mesh—remains to be seen (Miserez et al., 2019; Morris et al., 2021; Rosen et al., 2017).

### *1.3.3 Historical techniques*

Suture repair, onlay repair, local retrorectus keyhole repair and stoma relocation without a preventive mesh have been nearly abandoned due to their high risk of recurrence (DeAsis et al., 2015; Hansson et al., 2012).

### *1.3.4 Parastomal hernia repair techniques*

#### *Keyhole technique*

Keyhole repair with different meshes can be utilised on all abdominal wall layers, including the anterectus, retrorectus, preperitoneal and intraperitoneal planes. The flat mesh is incised in the middle, and the bowel is brought through the central hole. Systematic reviews and meta-analyses have found that the results of keyhole repair are inferior to those of Sugarbaker repair (Table 2), so the EHS has recommended avoiding the use of the keyhole technique in laparoscopic PSH repair (Antoniou et al., 2018).

#### *Sugarbaker technique*

Sugarbaker described a new intra-abdominal PSH repair technique in 1985. The bowel ending with the stoma is lateralised with an intra-abdominal mesh and fixed onto the abdominal wall. Since the technique was introduced, it has been used (with modifications) in PSH repair (DeAsis et al., 2015; Hansson et al., 2012) and prevention (López-Cano et al., 2016).

#### *Sandwich technique*

The sandwich repair technique was first described by Berger and Bientzle in 2007. Using two meshes, this operation combines the keyhole and Sugarbaker techniques. As in the keyhole technique, a mesh with a central hole is first fixed onto the intra-abdominal layer. Thereafter, a mesh from the modified Sugarbaker technique is used to cover the stomal orifice and lateralise the bowel (Berger &

Bientzle, 2007). Since its introduction, this technique has been rarely reported on, possibly due to its technical demand.

*Modified keyhole technique*

The use of a 3D-shaped mesh as a modification of the keyhole technique may lower the risk of recurrence compared to the traditional keyhole technique. The mesh (Dynamesh-IPST™, FEG Textiltechnik, Aachen, Germany) has a central chimney-like funnel and can be used as an IPOM in both PSH repair (Berger & Bientzle, 2009; Fischer, Wundsam, Mitteregger, & Köhler, 2017; Köhler, 2014) and prevention (Berger, 2008; Köhler et al., 2016; López-Borao, Madrazo-González, Kreisler, & Biondo, 2019).

*New inventive approaches*

A modification of the retrorectus keyhole technique has been described by Raigani et al. (2014). Their technique includes repositioning the stoma to the contralateral side with a preventive keyhole mesh and repairing the consequent hernia defect as an IH through posterior compartment separation and transversalis abdominis release (TAR; Raigani et al., 2014). Likewise, Majumber et al. reported the early results of stabled transabdominal ostomy reinforcement with a retrorectus mesh in a small patient series, replacing the stoma and repairing the hernia defect with TAR (Majumder, Orenstein, Miller, & Novitsky, 2018). However, the results of this technique have been disappointing, with a recurrence rate of up to 22% (Beffa et al., 2017).

As a different approach, the Sugarbaker technique was modified by the American surgeon Eric Pauli. He created a technique in which the traditional Sugarbaker repair is combined with TAR, wherein the mesh and lateralised colon are placed in the retromuscular plane (Pauli, Juza, & Winder, 2016). The combination of the two procedures enables the concomitant repair of abdominal wall defects and large PSH. However, Pauli's technique is technically demanding and has been reported to have high complication rates (Tastaldi et al., 2017).

### *1.3.5 Results of parastomal hernia repair*

The results of PSH repair have been reported in several large cohort and registry studies (Table 3). However, these studies did not enable a comparison of different

PSH repair techniques. According to the registry data, the PSH recurrence rate may exceed 50%, and the reoperation rate may reach one-third of patients (Table 2). The rate of complications in patients after emergency repair was equal to that in patients following elective procedure (Gavigan et al., 2018; Helgstrand et al., 2013; Odensten, Strigård, Dahlberg, Gunnarsson, & Näsvall, 2020). However, both mortality and morbidity were significantly increased after emergency repair (Gavigan et al., 2018; Helgstrand et al., 2013).

PSH repair techniques are compared in Table 2 based on the published systematic reviews and meta-analyses. The Sugarbaker technique, which uses an open or laparoscopic approach, yields better results than the keyhole technique in terms of recurrence rate (Table 3). However, a low recurrence rate following sandwich repair has been reported in a case series after the meta-analyses were published (Bertoglio et al., 2020; Hufford et al., 2018; Köhler et al., 2015). Additionally, a low recurrence rate has been reported after the use of a specific funnel-shaped mesh (Dynamesh-IPST™, FEG Textiltechnik, Aachen, Germany; Fischer et al., 2017; Köhler, Fischer, & Wundsam, 2018; Köhler et al., 2014).

### *1.3.6 Parastomal hernia repair following ileal conduit urinary diversion*

The incidence of cystectomy is 2.7/100,000 results for 150 ileal conduits in Finland each year (Salminen et al., 2018). The research on ileal conduit PSH repair has been limited to a case series (Narang et al., 2017), but the recurrence rate has been found to be as high as 27–50% (Donahue et al., 2014; Kouba, Sands, Lentz, Wallen, & Pruthi, 2007; Liu et al., 2014). The modified keyhole technique using Dynamesh-IPST™ (FEG Textiltechnik, Aachen, Germany) has been reported to have a low recurrence rate of 7.4% (Tully, Roghmann, Pastor, Noldus, & von Bodman, 2019).

**Table 2. Parastomal hernia repair, results of systematic reviews and meta-analyses.**

| Author | Year | Study | Stoma type | Recurrence |
|---|---|---|---|---|
| Slater | 2011 | Systematic review | NR | Biological implant repair with various techniques 15.7% |
| Hansson et al. | 2012 | Systematic review and meta-analysis | All (colostomies, ileostomies, ileal conduits) | Suture repair 69.4% |
| | | | | Onlay mesh 17.2% |
| | | | | Retrorectus mesh 6.9% |
| | | | | Open keyhole repair 7.2% |
| | | | | Open Sugarbaker repair 15.0% |
| | | | | Laparoscopic keyhole repair 34.6% |
| | | | | Laparoscopic Sugarbaker repair 11.6% |
| | | | | Laparoscopic sandwich repair 2.1% |
| Al Shakarchi & Williams | 2014 | Systematic review and meta-analysis | NR | Suture repair 57.6% |
| | | | | Onlay mesh 14.8% |
| | | | | Retrorectus mesh 7.9% |
| | | | | Non-specified intra-abdominal mesh repair 9.2% |
| DeAsis et al. | 2015 | Systematic review and meta-analysis | NR | Laparoscopic keyhole repair 27.9% |
| | | | | Laparoscopic Sugarbaker repair 10.2% |

**Table 3. Parastomal hernia repair, results of register studies.**

| Author | Year | Study | Stoma type | Technique | PSH recurrence (%) | Reoperation for recurrence (%) |
|---|---|---|---|---|---|---|
| Ripoche et al. | 2011 | Register-based questionnaire | All (colostomies, ileostomies, ileal conduits) | Unspecified mesh repair 50% | 52 | 35 |
| Helgstrand et al. | 2013 | Register | Colostomies, ileostomies | Unspecified mesh repair 85% | NR[1] | 11 |
| Kroese et al. | 2017 | Multicentre retrospective cohort | All (colostomies, ileostomies, ileal conduits) | Unspecified mesh repair 72% | 48 | NR |
| Gavigan et al. | 2018 | Register | NR | Unspecified mesh repair 94% | 1[2] | NR |
| Krogsgaard et al. | 2020 | Register | Colostomies, ileostomies | Unspecified mesh repair 43% | NR | 11 |
| Odensten et al. | 2020 | Register | NR | Unspecified mesh repair 14% | 27 | 21 |

[1] not reported, [2] in 30 days

## 1.4 Parastomal hernia prevention

### *1.4.1 Surgical techniques to prevent parastomal hernia*

Several technical principles for ostomy construction have been suggested to prevent PSH occurrence. For example, the size of the fascial opening may have an impact on the risk of PSH (Hotouras, Murphy, Power, Williams, & Chan, 2013), so disproportionately large openings should be avoided (Antoniou et al., 2018). Neither the transrectus nor the pararectus location of the stoma can be favoured in terms of lower PSH incidence (Hardt et al., 2019; Hardt et al., 2016; Ho, Economou, Smart, & Daniels, 2018). Extraperitoneal stoma creation may decrease the PSH rate, but no RCT has confirmed this hypothesis (Hino et al., 2017; Kroese, de Smet, Jeekel, Kleinrensink, & Lange, 2016). The opening technique (cruciate vs. circular) of the stomal orifice seems to have minor importance concerning the risk of developing PSH (Correa Marinez et al., 2020), but no existing stoma creation technique clearly reduces the PSH rate without a preventive mesh.

### *1.4.2 Parastomal hernia prevention with a mesh*

Most of the published studies on PSH prevention involve only patients with end colostomies. However, the use of a prophylactic mesh is recommended by the EHS when a permanent stoma is to be constructed (Antoniou et al., 2018), and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) agrees with this recommendation (ACPGBI Parastomal Hernia Group, 2018). Despite these recommendations, PSH prevention has not gained wide acceptance among colorectal surgeons (Holland et al., 2019).

The most common preventive technique is to place a keyhole mesh in the rectorectus (Jänes et al., 2009) or intraperitoneal space (Correa Marinez et al., 2020; López-Cano et al., 2012; Odensten et al., 2019; Vierimaa et al., 2015). Two case series reported the results of using a specific funnel-shaped mesh, Dynamesh-IPST™ (FEG Textiltechnik, Aachen, Germany; Köhler et al., 2016; López-Borao et al., 2019), and one RCT reported the results of using the modified Sugarbaker technique (López-Cano et al., 2016). Biological meshes are rarely used for PSH prevention (Fleshman et al., 2014).

Until recently, all reviews and meta-analyses recommended the use of a preventive mesh (Table 4; Chapman et al., 2017; Cornille et al., 2017; Cross et al., 2017; López-Cano et al., 2017; Patel et al., 2017; Pianka et al., 2017; Sajid et al., 2012; Shabbir et al., 2012; Tam et al., 2010; Wang et al., 2016; Wijeyekoon et al., 2010; Zhu et al., 2016, Sahebally et al., 2021). However, recent RCTs using the keyhole technique did not confirm its advantage for PSH prevention (Correa Marinez et al., 2020; Odensten et al., 2019; Prudhomme et al., 2020; Prudhomme et al., 2021). Therefore, the authors of a systematic review concluded that the use of a preventive mesh is not recommended (Prudhomme et al., 2020). However, these results were contradictory to those of another recently published meta-analysis (Sahebally et al., 2021). Although the benefits of using a preventive keyhole mesh have been questioned, these meshes have not been associated with any risk of developing complications (Chapman et al., 2017; Cornille et al., 2017; Cross et al., 2017; López-Cano et al., 2017; Patel et al., 2017; Pianka et al., 2017; Sajid et al., 2012; Shabbir et al., 2012; Tam et al., 2010; Wang et al., 2016; Wijeyekoon et al., 2010; Zhu et al., 2016).

Ileal conduit PSH prevention is a barely researched topic. According to the results of a recent RCT, a retrorectus keyhole mesh significantly reduces the overall risk of developing urinary PHS (Liedberg et al., 2020).

**Table 4. Results of parastomal hernia prevention with a mesh.**

| Author | Year | Study | Stoma type | PSH[1] (M-H, RR[2], 95% CI[3]) | Need for surgical repair of PSH (OR, RR, 95% CI) | Prolapse (RR, 95% CI) |
|---|---|---|---|---|---|---|
| Tam et al. | 2010 | Systematic review and meta-analysis | Colostomy | 0.17 (0.07–0.40) All[4] | NR | NR |
| Wijeyekoon | 2010 | Systematic review and meta-analysis | Colostomy | 0.23 (0.06–0.81) All[2] | 0.13 (0.02–1.02) | NR |
| Shabbir et al. | 2012 | Systematic review and meta-analysis | Colostomy | NR | NR | NR |
| Sajid et al. | 2012 | Systematic review and meta-analysis | Colostomy | 0.11 (0.05–0.27) All[4] | NR | NR |
| Wang et al. | 2016 | Systematic review and meta-analysis | Colostomy | 0.42 (0.22–0.82) All[2] | 0.23 (0.06–0.89) | |
| Zhu et al. | 2016 | Systematic review and meta-analysis | Colostomy | 0.22 (0.13–0.38) All[2] | 0.34 (0.14–0.83) | |
| Chapman et al. | 2017 | Systematic review and meta-analysis | Colostomy, ileostomy | 0.34 (0.18–0.65) All[2] | 0.30 (0.13–0.69) | 0.25 (0.05–1.25) |
| Cornille et al. | 2017 | Systematic review and meta-analysis | Colostomy, ileostomy | 0.40 (0.21–0.75) All[2]<br>0.36 (0.17–0.77) Synthetic mesh[2]<br>0.58 (0.11–2.95) Biological mesh[2] | NR | NR |
| Cross et al. | 2017 | Systematic review and meta-analysis | Colostomy, ileostomy | 0.24 (0.12–0.50) All[4] | NR | NR |
| Lopez-Cano et al. | 2017 | Systematic review and meta-analysis | Colostomy | 0.43 (0.26–0.71) All[2]<br>0.30 (0.15–0.59) Retrorectus mesh[2]<br>0.62 (0.36–1.07) Intra-abdominal[2] | NR | NR |
| Pianka et al. | 2017 | Systematic review and meta-analysis | Colostomy, ileostomy | 0.24 (0.10–0.58) All[4] | NR | NR |

| Author | Year | Study | Stoma type | PSH[1] (M-H, RR[2], 95% CI[3]) | Need for surgical repair of PSH (OR, RR, 95% CI) | Prolapse (RR, 95% CI) |
|---|---|---|---|---|---|---|
| Jones et al. | 2018 | Systematic review and meta-analysis | Colostomy | 0.53 (0.43–0.66) All[2]<br>0.48 (0.36–0.64) Retrorectus mesh[2]<br>0.76 (0.55–1.06) Intra-abdominal mesh[2] | NR | |
| Prudhomme et al. | 2021 | Systematic review and meta-analysis | Colostomy | 0.73 (0.51–1.07) All[2]<br>0.76 (0.43–1.34) Retrorectus mesh[2]<br>0.66 (0.36–1.22) Intra-abdominal mesh[2] | 0.38 (0.15–0.99) | 0.56 (0.23–1.50) |

[1] parastomal hernia, [2] risk ratio, [3] confidence interval, [4] odds ratio

# 2 Aims of the Present Study

Below are the aims of the present study:

1. To assess the long-term efficacy and safety of PSH prevention with an intraperitoneal keyhole mesh (I)
2. To compare the PSH repair techniques in terms of recurrence, complications and reoperations (II, III)
3. To address the risk of developing PSH and IH following surgery for Hinchey III–IV diverticulitis (IV)

# 3 Materials and Methods

## 3.1 Patients

### *3.1.1 Study I*

From February 2010 to April 2013, 83 patients undergoing laparoscopic APR in five Finnish hospitals were randomly assigned to receive either a prophylactic intra-abdominal keyhole mesh (DynaMesh®-IPOM, FEG Textiltechnik mbH, Aachen, Germany) or a conventional colostomy. In each participating hospital, one or two surgeons were responsible for the patients' enrolment and performing the operations. Excluded were patients who did not give their informed consent to participate in this study and/or had a poor general condition (American Society of Anaesthesiologists classes 4–5), incurable cancer or rectal malignancy other than adenocarcinoma and/or any abdominal infection. The study was approved by the local ethics committee of each hospital and registered with Clinical Trials (NCT02368873).

The flowchart of the patients in Study I is presented in Figure 2. The results of the 12-month follow-up were published by Vierimaa et al. in 2015.

### *3.1.2 Studies II and III*

Each of the patients in Studies II and III was operated on for elective PSH repair in one of the nine participating hospitals in Finland from January 1, 2007 to December 31, 2017 (Fig. 3). The patients in Study II underwent either end ileostomy or end colostomy PSH repair (Fig. 3, Table 5), while the patients in Study III underwent ileal conduit PSH repair (Fig. 3, Table 6).

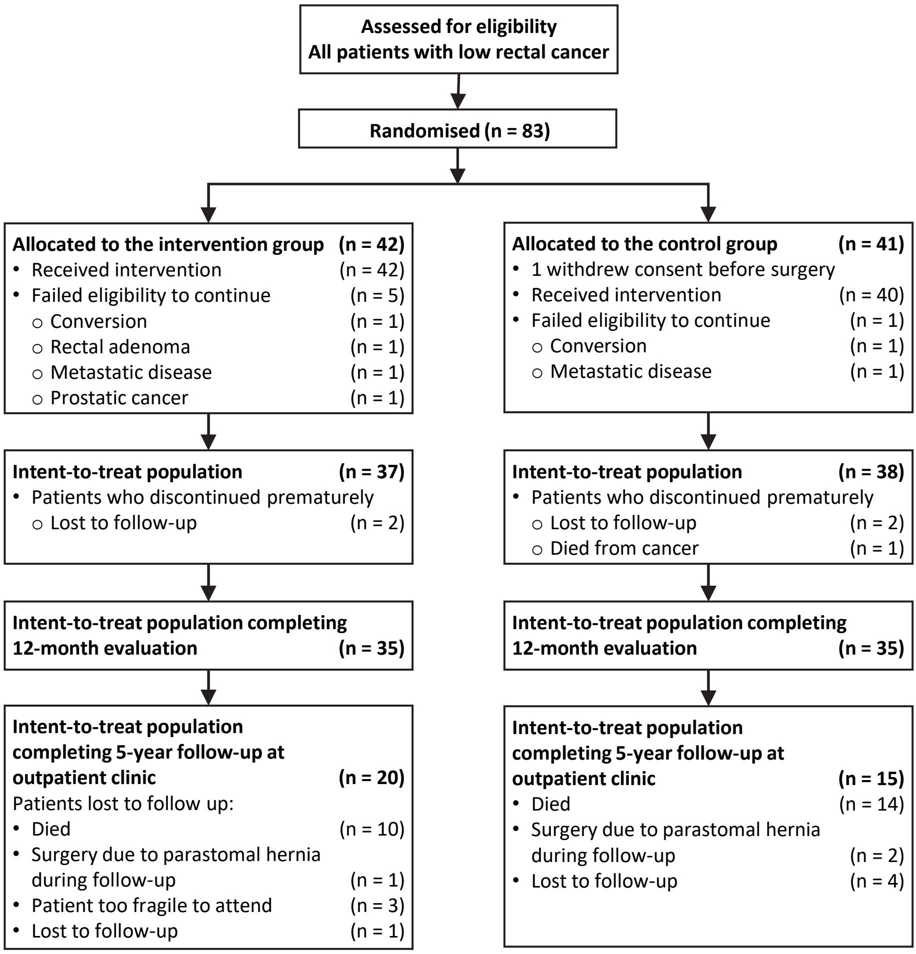


**Fig. 2. The flowchart of the patients in Study I.**

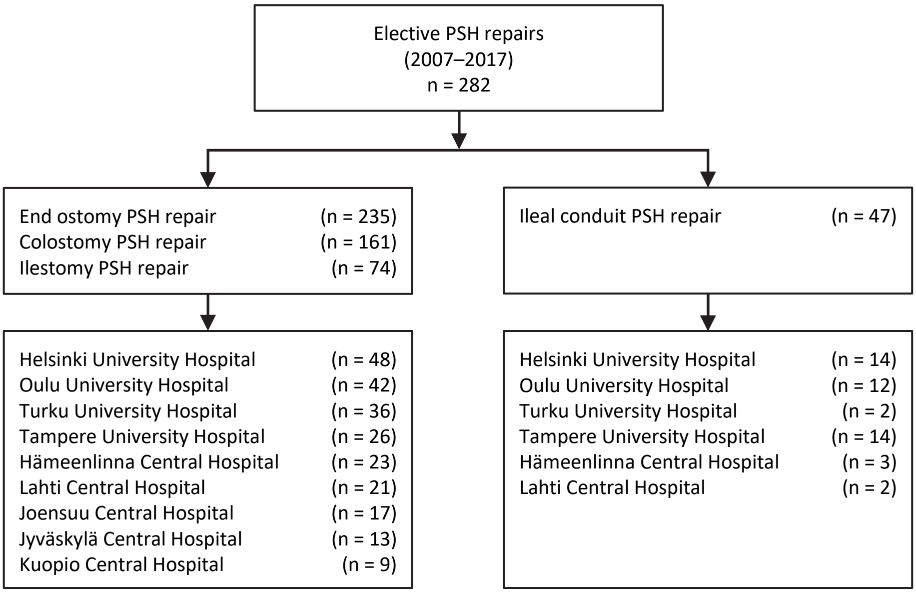


**Fig. 3. Patients in Studies II and III.**

**Table 5. Hospital contributions and techniques used for end ostomy PSH repair.**

| Hospital | All (n = 235) | Keyhole (n = 39) | Sugarbaker (n = 91) | Sandwich (n = 37) | Modified keyhole (n = 20) | Other (n = 48) |
|---|---|---|---|---|---|---|
| Helsinki | 48 (20.4) | 4 (10.3) | 3 (3.3) | 25 (67.6) | 6 (30.0) | 10 (20.8) |
| Oulu | 42 (17.9) | 10 (25.6) | 29 (31.9) | 0 | 1 (5.0) | 2 (4.2) |
| Turku | 36 (15.3) | 12 (30.8) | 17 (18.7) | 0 | 0 | 7 (16.6) |
| Tampere | 26 (11.1) | 3 (7.7) | 2 (2.2) | 2 (5.4) | 8 (40.0) | 11 (22.9) |
| Lahti | 21 (8.9) | 3 (7.7) | 12 (13.2) | 0 | 1 (5.0) | 5 (10.4) |
| Hämeenlinna | 23 (9.8) | 3 (7.7) | 13 (14.3) | 0 | 3 (15.0) | 4 (8.3) |
| Joensuu | 17 (7.2) | 1 (2.6) | 4 (4.4) | 9 (24.3) | 1 (5.0) | 2 (4.2) |
| Jyväskylä | 13 (5.5) | 1 (2.6) | 5 (5.5) | 0 | 0 | 7 (14.6) |
| Kuopio | 9 (3.8) | 2 (5.1) | 6 (6.6) | 1 (2.7) | 0 | 0 |
| All | 235 (100) | 39 (16.6) | 91 (38.7) | 37 (15.4) | 20 (8.5) | 48 (20.4) |

The nominal variables are reported as counts and percentages (in parentheses). The percentage indicates the proportion of patients operated on using each technique.

**Table 6. Hospital contributions and techniques used for ileal conduit PSH repair.**

| Hospital | All | Intra-abdominal keyhole | Sugarbaker | Other |
|---|---|---|---|---|
| Helsinki | 14 (29.8) | 12 (26.3) | 1 (10.0) | 1 (5.3) |
| Tampere | 14 (29.8) | 4 (63.2) | 5 (50.0) | 5 (26.3) |
| Oulu | 12 (25.5) | 0 | 2 (20.0) | 10 (52.6) |
| Hämeenlinna | 3 (6.4) | 1 (5.6) | 1 (10.0) | 1 (5.3) |
| Turku | 2 (4.3) | 1 (5.6) | 1 (10.0) | 0 |
| Lahti | 2 (4.3) | 0 | 0 | 2 (10.5) |
| All | 47 (100) | 18 (38.3) | 10 (21.3) | 19 (40.4) |

The nominal variables are reported as counts and percentages (in parentheses). The percentage indicates the proportion of patients operated on using each technique.

### 3.1.3 *Study IV*

Study IV was a systematic review that included RCT and cohort studies comparing the Hartmann procedure to other surgical approaches and reporting either IH or PSH incidence (Fig. 4, Table 7).

## 3.2 Methods

### 3.2.1 *Outcomes*

The outcomes of the studies are presented in Table 8.

**Table 7. Outcomes of the studies.**

| Study | Primary outcome | Secondary outcomes |
|---|---|---|
| Study I | Clinical PSH[1] | PSH by CT scan<br>Complications |
| Study II | PSH recurrence | Complications<br>Reoperations |
| Study III | PSH recurrence | Complications<br>Reoperations |
| Study IV | PSH incidence | IH[2] incidence |

[1] parastomal hernia, [2] incisional hernia

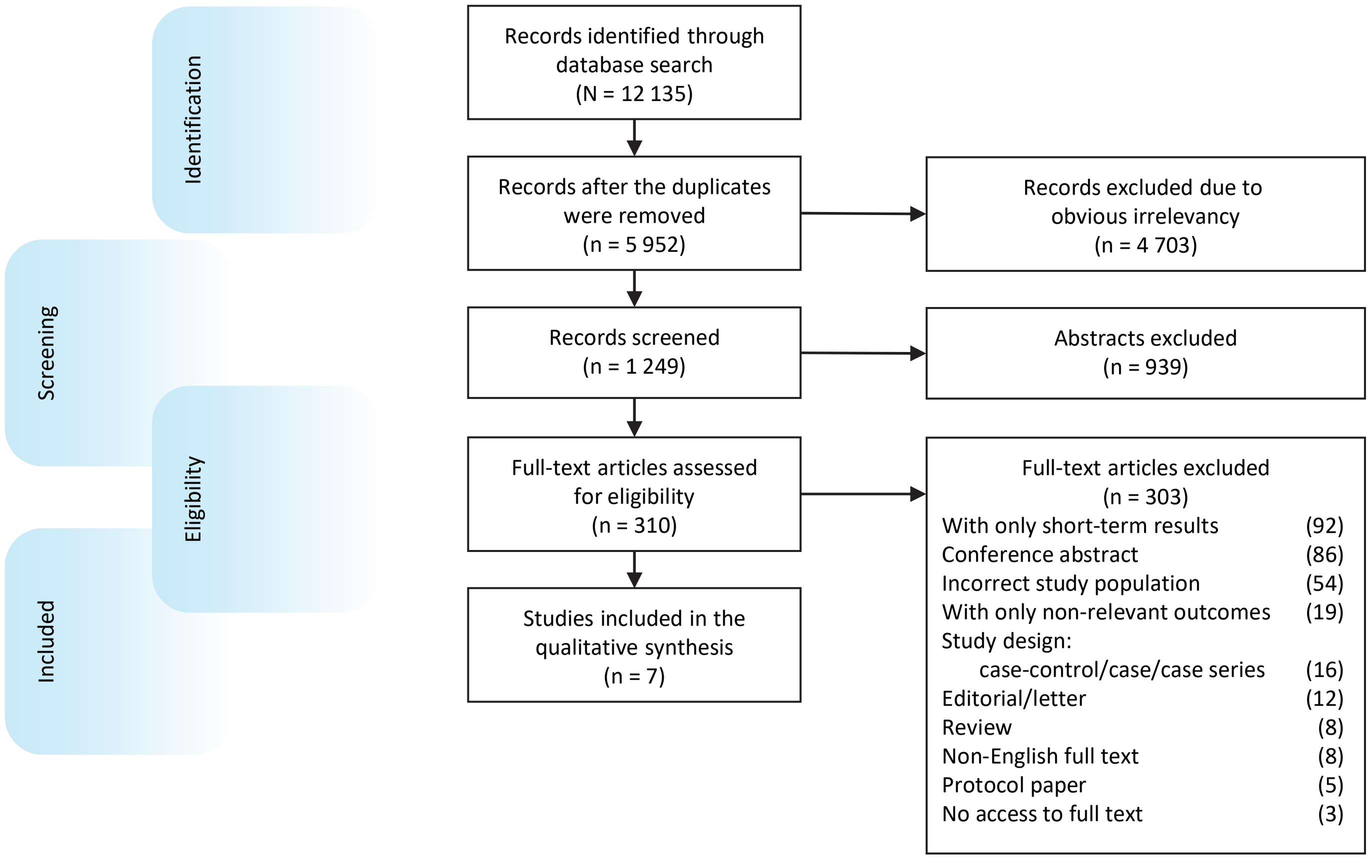


**Fig. 4. Flowchart of the studies included in the systematic review (Study IV).**

**Table 8. Study characteristics (Study IV).**

| Author | Study | Design | Year | Countries | Recruiting centres (n) | Study groups | Patients enrolled (n) | Hinchey I/II/III/IV | Open or laparoscopic | Follow-up method |
|---|---|---|---|---|---|---|---|---|---|---|
| Kronborg | - | RCT[1] | 1978–1992 | Denmark | 1 | PR[2], SR[3] | 62 | 0/0/46/16 | All open | Unclear, 12 months |
| Zeitoun | - | RCT | 1989–1996 | France | 17 | PR (HP[4] or PRA[5] with/without loop ileostomy), SR | 105 | 0/0/77/26 | All open | Unclear, at least 24 months |
| Vennix | LADIES | RCT | 2010–2013 | Belgium, Italy, the Netherlands | 42 | LL[6] - Resection (HP or PRA with/without loop ileostomy) | 90 | 0/0/84/0 | 7/90 laparoscopic | Local protocols/ contact at 12 months |
| Kohl | DILALA | RCT | 2010–2014 | Sweden, Denmark | 9 | LL - HP | 83 | 0/0/83/0 | All open HP | Patient records 12–24 months + 30 days |
| Schultz | Scandiv | RCT | 2010–2014 | Norway, Sweden | 21 | LL - Resection (HP or PRA with/without loop ileostomy) | 199 | 3/12/134/28 | All open HP | Outpatient clinic/phone interview/form sent by mail at 12 months |
| Lambrichts | LADIES | RCT | 2010–2016 | Belgium, Italy, the Netherlands | 42 | HP (PRA with/without loop ileostomy) | 133 | 0/0/93/40 | 37/133 laparoscopic | Local protocols/ contact at 12 months |
| Pizza | - | Retro-spective cohort study | 2008–2018 | Italy | 1 | HP (PRA with loop ileostomy) | 194 | 0/0/74/120 | All open | Patient records at 12 months |

[1] randomised controlled trial, [2] primary resection, [3] secondary resection, [4] Hartmann procedure, [5] primary anastomosis, [6] laparoscopic lavage

### 3.2.2 Surgical technique (Study I)

Laparoscopic APR was performed using the 5-trocar technique. At the end of the abdominal laparoscopic phase, permanent end colostomy was performed in a previously marked ostomy site. After an oval skin excision was made, the anterior rectus sheath was opened with a cross-shaped incision. The rectus abdominis muscle was split in the direction of the fibres, and the posterior fascia and the peritoneum were opened with a longitudinal incision.

In the intervention group, a prophylactic keyhole mesh (DynaMesh™-IPOM) was used. The circumference of the end of the colon was measured, and the 10 x 10 cm Dynamesh™ IPOM was cut crosswise in the middle according to the bowel circumference. The stapled bowel end was then pulled through the mesh, which was fixed circumferentially onto the peritoneum using absorbable tackers (AbsorbaTacks™, Covidien). The stoma was fixed to the skin with resorbable interrupted sutures.

### 3.2.3 Parastomal hernia definition (Study I)

In study I, clinically significant PSH was defined as PSH associated with (1) stoma appliance dysfunction and leakage that were not responsive to conservative measures, (2) peristomal skin breakdown related to sheer injury or (3) ischemia from pressure on the thinned peristomal skin and recurrent partial bowel obstruction.

### 3.2.4 Clinical evaluation at long-term follow-up (Study I)

The patients in Study I (Fig. 1) were evaluated at an outpatient visit. They were asked about problems with their colostomy and complications of the stoma. Then, they were clinically evaluated for complications of stoma, namely prolapse, stricture, retraction, fistula, skin problem and granulation, among others. The patients were also asked about surgical operations and episodes of small-bowel obstruction during the follow-up period. The clinical evaluation for parastomal bulging was accomplished in both the prone and supine positions, and the abdomen was evaluated for peristomal skin problems. The other incision areas were evaluated for additional IH. The collected data were recorded on a specially designed case report form.

### 3.2.5 Computed tomography evaluation (Study I)

Overall, 95% of the patients in the intervention group and 80% of the patients in the control group underwent a CT scan both for detection of any hernia and as a follow-up intervention for their malignancy. The CT scans were performed using the Valsalva manoeuvre to improve the sensitivity of the scan. A single radiologist who was blinded to the randomisation group analysed all the scans to detect parastomal and other hernias. The PSH were classified according to the EHS classification system (Smietanski et al., 2014).

### 3.2.6 Registry data collection (Study II and III)

The data of all patients who had an elective PSH repair in any of the nine attending hospitals from 2007–2017 were retrieved from the hospital records using the International Classification of Disease-10 (ICD-10) codes K43.9 (ventral hernia without obstruction or gangrene), K45 (other abdominal hernia), K46 (unspecified abdominal hernia) and K94 (colostomy complications), combined with the operation codes JAD11 (laparoscopic repair of IH), JAD30 (repair of IH using a prosthetic material), JAG40 (repair of stomal hernia with sutures), JAG41 (repair of stomal hernia, laparoscopic), JAG43 (repair of stomal hernia with a mesh), JAG46 (repair of recurrent stomal hernia, laparoscopic), JAG47 (repair of recurrent stomal hernia with a mesh), JAG49 (repair of recurrent stomal hernia, other technique), JAG96 (other reconstruction of the abdominal wall) and JAG97 (other laparoscopic reconstruction of the abdominal wall).

The patients who underwent an emergency operation or had a reoperation after recurrence during the study period were excluded. The data retrieved from the patient records included age, body mass index (BMI), indication and date for index ostomy formation, other hernias detected during PSH repair, PSH repair and surgery technique used, complications developed, length of hospital stay, reoperations, recurrence and its date of diagnosis and the type and size of the mesh used.

### 3.2.7 Systematic review (Study IV)

After the study was registered in the PROSPERO database, a systematic search without any language or study design restriction was performed using Cochrane Library, Embase, PubMed (MEDLINE), Web of Science and Scopus. The search strategy, planned with the help of Oulu University Library's informatician, is provided in Appendix I, and the search flowchart is presented in detail in Figure 4. One author searched for and excluded obviously irrelevant titles. Then, two authors independently screened all titles and abstracts for relevance. The reference lists of the included studies and articles citing the included studies were hand-searched for additional studies. The inclusion and exclusion of full texts were agreed upon by two authors.

The data for all the included studies were independently collected by two authors. The extracted data included the study design, study period, number of centres involved in the study, patient demographics, Hinchey classification of the included patients, previous history of abdominal surgery and/or diverticulitis, intervention type, whether the intervention was open or laparoscopic and follow-up duration and method. Data on the IH and PSH were also collected, and the outcome of the modified intention to treat was used for the analyses.

## 3.3 Statistical analysis

### *3.3.1 Study I*

The measurement values that were obtained from study I are presented herein as means with standard deviations (SD) or as medians with twenty-fifth to seventy-fifth percentiles. The between-group comparisons were performed using Fisher's exact test (categorical data) or the Student's t-test (continuous data). The 95% confidence intervals (CIs) for the between-group differences were presented for the primary and secondary outcomes. Kaplan-Meier survival curves were drawn for the PSH operations for both groups, and the statistical difference was assessed using a log-rank test. SPSS for Windows 25.0 (IBM Corp., Armonk, NY, USA) was used for the analyses.

### *3.3.2 Study II*

For study II, the statistical data were presented as means and SD or as medians with twenty-fifth to seventy-fifth percentiles. The between-group comparisons for the continuous variables were performed using analysis of variance (ANOVA) or Welch's test; the latter was used if the assumption of equal variances did not hold. Tukey's test or Tamhane's test (this was used if the assumption of equal variances did not hold) was used as the post-test when comparing separate groups. The categorical data were analysed using the Chi-square test or Fisher's exact test. Kaplan–Meier survival curves were drawn, and the Tarone–Ware test was used for the between-group comparison to determine PSH recurrence. The two-tailed *p*-values were presented. All the analyses were performed using SPSS for Windows 25.0 (IBM Corp., Armonk, NY, USA).

#### 3.3.3 Study III

The statistical data from study III were presented as means with SD or as medians with twenty-fifth to seventy-fifth percentiles. The between-group comparisons for the continuous variables were performed using the Student's t-test or Welch's test; the latter was used if the assumption of equal variances did not hold. The categorical data were analysed using the Chi-square test or Fisher's exact test. The two-tailed *p*-values were presented. All the analyses were performed using SPSS for Windows 25.0 (IBM Corp., Armonk, NY, USA).

#### 3.3.4 Study IV

Both outcomes of the systematic review (i.e., PSH and IH) were considered likely underdiagnosed due to unsuitable follow-up methods for reliable hernia diagnosis and absence of hernia in the predefined outcomes. As such, no meta-analysis was conducted.

### 3.4 Ethical considerations

PSH is a common complication of permanent colostomy; half of the patients who have a permanent colostomy develop PSH (Antoniou et al., 2018; Jänes, Cengiz, & Israelsson, 2009). A significant number of these patients experience symptoms of PSH, which diminishes their QoL (Kald, Juul, Hjortsvang, & Sjödahl, 2008; Näsvall et al., 2017; van Dijk et al., 2015). Therefore, PSH prevention is justified.

No complications related to the use of prophylactic meshes have been reported (Antoniou et al., 2018). Furthermore, CT scan exposes patients to a 6-mSv radiation dose, which is equal to 2 years' background radiation. Hence, the risk of cancer due to radiation is minimal. CT scan is performed to detect not only PSH but also rectal-cancer recurrence or metastasis.

Studies II and III involved patients who had their PSH repaired by the time of the study. The registry data were collected retrospectively to analyse the results of PSH repair, and patients were therefore not exposed to further risk. All the data were analysed without identifying details. The results of the studies did not benefit the patients who were part of it, but the studies could improve the care of PSH patients henceforth.

Study IV was a systematic review of patients enrolled in RCTs or cohort studies. The results were therefore analysed on the basis of previously published data. However, the PSH and IH were likely underdiagnosed due to the unsuitable follow-up methods that were used for reliable hernia diagnosis and absence of hernia in the predefined outcomes.

# 4 Results

## 4.1 Study I

Study I involved 83 patients who had undergone potentially curative laparoscopic APR for rectal adenocarcinoma. The study patients were invited to an outpatient visit for long-term follow-up. Some patients dropped out of the study for various reasons (Fig. 2), and a total of 35 patients attended an outpatient visit. The study groups had similar baseline characteristics (Table 9).

**Table 9. Study I patient characteristics.**

| Study I | Intervention group (n = 20) | Control group (n = 15) | *P*-value ($x^2$) |
|---|---|---|---|
| Age | 70.1 ± 9.8 | 68.7 ± 8.6 | 0.68 |
| Gender | | | > 0.90 |
| Female | 9 (45.0) | 6 (40.0) | |
| Male | 11 (55.0) | 9 (60.0) | |
| BMI[1] | 27.5 ± 4.3 | 25.1 ± 3.2 | 0.071 |
| Follow-up (months) | 69.6 ± 12.7 | 67.3 ± 9.2 | 0.53 |

[1] body mass index. The nominal variables are reported as counts and percentages (in parentheses); the continuous variables are reported as means and standard deviations. Published with permission from Wolters Kluwer.

Study II comprised all elective end ostomy PSH repairs that were performed in nine participating hospitals from January 1, 2007 to December 31, 2017 (Fig. 3, Table 10). Study III consisted of all the elective PSH repairs that were performed in six of the nine participating hospitals from January 1, 2007 to December 31, 2017 (Fig. 3, Table 11). The systematic review (Study IV) resulted in six RCTs and one cohort study that reported the PSH and IH rates after surgical treatment for Hinchey III–IV diverticulitis (Table 12).

**Table 10. Study II patient characteristics.**

| Character | Total (n) | Keyhole (n = 37) | Sugarbaker (n = 91) | Sandwich (n = 37) | Modified keyhole (n = 20) | *P*-value ($x^2$) |
|---|---|---|---|---|---|---|
| Age (years) | 235 | 67.1 ± 9.9 | 68.4 ± 10.6 | 70.0 ± 12.3 | 64.6 ± 9.9 | 0.30 |
| Gender | 235 | | | | | 0.060 |
| Female | | 21 (53.8) | 49 (53.8) | 19 (51.4) | 17 (85.0) | |
| Male | | 18 (46.2) | 42 (46.2) | 18 (48.6) | 3 (15.0) | |
| BMI[1] | 174 | 28.3 ± 5.8 | 28.8 ± 5.7 | 28.6 ± 4.4 | 25.4 ± 4.5 | 0.17 |
| Stoma type | 235 | | | | | 0.20 |
| Colostomy | | 25 (64.1) | 71 (78.0) | 23 (62.2) | 15 (75.0) | |
| Ileostomy | | 14 (35.9) | 20 (22.0) | 14 (37.8) | 5 (25.0) | |
| Indication for stoma | 235 | | | | | 0.13 |
| Cancer | | 20 (51.3) | 53 (58.2) | 21 (56.8) | 8 (40.0) | |
| Inflammatory bowel disease | | 9 (23.1) | 19 (20.9) | 13 (35.1) | 3 (15.0) | |
| Diverticulosis | | 0 | 4 (4.4) | 0 | 3 (15.0) | |
| Anal incontinence | | 4 (10.3) | 7 (7.5) | 1 (2.7) | 3 (15.0) | |
| Other | | 6 (15.4) | 8 (8.6) | 2 (5.4) | 3 (15.0) | |
| Follow-up (months) | 235 | 53.3 ± 37.1 | 33.2 ± 28.7 | 49.2 ± 29.0 | 49.5 ± 37.8 | 0.002 |

[1] body mass index. The nominal variables are reported as counts and percentages (in parentheses); the continuous variables are reported as means and standard deviations.

**Table 11. Study III patient characteristics.**

| Character | Total (n = 28) | Intra-abdominal keyhole (n = 18) | Sugarbaker (n = 10) | *P*-value ($x^2$) |
|---|---|---|---|---|
| Age (years) | 28 | 70.4 ± 9.2 | 76.9 ± 6.1 | 0.053 |
| Gender | 28 | | | 0.430 |
| Female | | 10 (55.6) | 4 (40.0) | |
| Male | | 8 (44.4) | 6 (60.0) | |
| BMI[1] | 22 | 28.4 ± 5.3 | 27.7 ± 3.9 | 0.737 |
| Follow-up (months) | 28 | 48.7 ± 34.2 | 27.4 ± 20.8 | 0.051 |

[1] body mass index. The nominal variables are reported as counts and percentages (in parentheses); the continuous variables are reported as means and standard deviations.

**Table 12. Study IV patient characteristics.**

| Source | Intervention | Age (SD[6] or range) | BMI (SD or range) | Female:male (%) | ASA[8] ≥ 3 (%) | Previous diverticulitis (%) | Previous abdominal surgery (%) | Gastrointestinal surgeon participating (%) |
|---|---|---|---|---|---|---|---|---|
| Kronborg | PR[1] | 73 (37–89) | NR[7] | 68:32 | NR | NR | NR | 100 |
| | SR[2] | 71 (38–88) | NR | 45:55 | NR | NR | NR | 100 |
| Zeitoun | PR | 66 (16) | NR | 49:51 | NR | NR | NR | NR |
| | SR | 67 (13) | NR | 54:46 | NR | NR | NR | NR |
| Vennix | LL[3] | 62.3 (12.7) | 27.6 (6.2) | 43:57 | 18 | 32 | 9 | 80 |
| | PR | 64.0 (12.3) | 27.0 (4.4) | 40:60 | 36 | 26 | 7 | 86 |
| Kohl | LL | 64 (50–76) | 25.6 (25–28) | 51:49 | 21 | 12 | 47 | NR |
| | HP[4] | 68 (56–79) | 24.9 (23–28) | 60:40 | 38 | 13 | 33 | NR |
| Schultz | LL | 68.5 (13.4) | 26.6 (4.8) | 52:48 | 38 | 19 | 29 | NR |
| | PR | 64.9 (15.0) | 26.2 (4.4) | 49:51 | 46 | 25 | 36 | NR |
| Lambrichts | HP | 61.7 (11.4) | 28.0 (4.7) | 38:62 | 37 | 18 | 5 | 86 |
| | PRA[5] | 62.4 (13.1) | 26.3 (4.8) | 36:64 | 24 | 19 | 2 | 91 |
| Pizza | HP | 76 (68–91) | 26 (23–37) | 54:46 | 66 | NR | 24 | NR |
| | PRA | 60 (44–71) | 27 (25–41) | 51:49 | 31 | NR | 22 | NR |

[1] primary resection, [2] secondary resection, [3] laparoscopic lavage, [4] Hartmann procedure, [5] primary anastomosis, [6] standard deviation, [7] not reported, [8] American Society of Anaesthesiologists

**Table 13. Clinical outcome at five-year follow-up in Study I.**

| Variable | Intervention group (n = 20) | Control group (n = 15) | Difference (95% CI) | *P*-value |
|---|---|---|---|---|
| Parastomal hernia (clinical evaluation) | 4 (20.0) | 5 (33.3) | -13.3 (-41.0–14.9) | 0.45 |
| Incisional hernia | 4 (20.0) | 1 (6.7) | 13.3 (-12.7–35.6) | 0.37 |
| Perineal hernia | 3 (15.0) | 1 (6.7) | 8.3 (-16.8–30.1) | 0.62 |
| Incisional hernia of abdominal wound | 0 | 1 (6.7) | -6.7 (-29.8–10.4) | 0.43 |
| Episodes of small-bowel obstruction | 3 (15.0) | 3 (20.0) | -5.0 (-32.0–19.7) | > 0.90 |
| Surgery due to small-bowel obstruction | 0 | 2 (13.3) | -13.3 (-37.9–5.4) | 0.18 |
| Patients with stoma-related complications | 5 (25.0) | 5 (33.0) | -8.3 (-36.9–20.1) | 0.47 |
| Number of complications | | | | |
| Prolapse | 0 | 3 (20.0) | -20.0 (-45.2–0.7) | 0.070 |
| Stomal granulation | 1 (5.0) | 1 (6.7) | -1.7 (-25.2–17.7) | > 0.90 |
| Stricture/stenosis | 2 (10.0) | 1 (6.7) | 3.3 (-20.9–24.2) | > 0.90 |
| Retraction | 1 (5.0) | 0 | 5.0 (-15.8–23.6) | > 0.90 |
| Skin inflammation | 2 (10.0) | 3 (20.0) | -10.0 (-36.2–13.9) | 0.63 |
| Mesh erosion | 0 | n/a | | |
| Fistula | 0 | 0 | 0 (-20.4–16.1) | > 0.90 |
| Parastomal hernia operated on | 1 (5.0) | 2 (13.3) | -8.3 (-33.2–12.6) | 0.57 |

The nominal variables are reported as counts and percentages (in parentheses). The differences between the groups are reported as percentages with 95% confidence intervals (95% CIs). Published with permission from Wolters Kluwer.

PSH found by CT scan was present in 45% (9/19) of the patients in the mesh group and 58% (7/12) of the patients in the control group ($p = 0.719$; Table 14). The content or size of the PSH as determined by CT scan did not differ between the groups (Table 14). All nine PSH found by CT scan in the intervention group were classified as type I according to the EHS classification system. One PSH in the control group was classified as type II with concomitant IH (cIH).

Due to the 50% dropout rate, the data of all patients who initially enrolled in the study were retrieved from the patient records. Clinical PSH was diagnosed in 46% (16/35) of the patients in the mesh group and 26% (9/35) of the patients in the control group ($p = 0.103$). In the mesh group, one patient underwent PSH repair, while six patients in the control group underwent operation for PSH ($p = 0.030$). All repairs were performed within 2 years after the primary APR and were indicated by symptoms—mainly pain, prolapse and intermittent episodes of incarceration and small-bowel obstruction.

**Table 14. Radiological findings at five-year follow-up.**

| Variable | Intervention group (n = 19) | Control group (n = 12) | Difference (95% CI) | *P*-value |
|---|---|---|---|---|
| Stomal hernia at CT scan | 9 (47.4) | 7 (58.3) | -11.0 (-41.0–22.7) | 0.72 |
| Parastomal hernia content | | | | 0.67 |
| Small bowel or colon | 1 (5.3) | 2 (16.7) | | |
| Omentum | 3 (15.8) | 2 (16.7) | | |
| Both omentum and bowel | 5 (26.3) | 3 (25.0) | | |
| Stomal hernia sac volume mean (SD), $cm^3$ | 203 (250) | 205 (419) | -2 (-405–402) | > 0.90 |
| European Hernia Society classification | | | | 0.44 |
| Type I (≤ 5 cm, no cIH[1]) | 9 (47.4) | 6 (50.0) | | |
| Type II (≤ 5 cm, with cIH) | 0 | 1 (8.3) | | |
| Type III (> 5 cm, no cIH) | 0 | 0 | | |
| Type IV (> 5 cm, with cIH) | 0 | 0 | | |

The nominal variables are reported as counts and percentages (in parentheses). [1] concomitant incisional hernia. Published with permission from Wolters Kluwer.

## 4.2 Study II

In study II, 235 patients were operated on for primary PSH in the nine participating hospitals from January 1, 2007 to December 31, 2017. Most of the patients had end colostomy (165/235, 69%). The repairs were performed using the keyhole (n = 39), Sugarbaker (n = 91), sandwich (n = 37) and modified keyhole (n = 20) techniques. Other non-specified techniques were used in 20% (48/235) of all the PSH repairs, including 12 suture repairs, 10 stoma location changes with a preventive mesh and 12 without a preventive mesh, 6 retrorectus mesh repairs, 2 onlay mesh repairs and 6 non-specified mesh repairs. These operations were not included in the analysis due to the heterogeneity of their technical details.

The repairs were performed by 85 surgeons. After the mean follow-up time of 45 months (0–146, SD 35 months), the recurrence rates were 36%, 22%, 14% and 15% after the keyhole, Sugarbaker, sandwich and modified keyhole repairs, respectively ($p = 0.11$). The complication rate was 26% (see Table 15 for a detailed description of complications). After the keyhole, Sugarbaker, sandwich and modified keyhole repairs, the rate of reoperation was 23%, 19%, 14% and 15%, respectively ($p = 0.03$), mainly because of recurrence. The laparoscopic technique was found to lead to the worst outcome (Table 16).

**Table 15. Parastomal hernia repair results (Study II).**

| Variable | Keyhole (n = 39) | Sugarbaker (n = 91) | Sandwich (n = 37) | Modified keyhole (n = 20) | *P*-value | Other (n = 48) |
|---|---|---|---|---|---|---|
| Recurrence | 14 (35.9) | 20 (22.0) | 5 (13.5) | 3 (15.0) | 0.11 | 16 (33.3) |
| Reoperation | 9 (23.1) | 17 (18.7) | 3 (8.1) | 3 (15.0) | 0.03 | 16 (33.3) |
| Parastomal hernia recurrence | 3 (33.3) | 11 (68.8) | 0 | 2 (66.7) | | 8 (50.0) |
| Prolapse | 1 (11.1) | 0 | 0 | 0 | | 4 (25.0) |
| Fistula | 1 (11.1) | 0 | 0 | 0 | | 1 (6.3) |
| Infection, mesh removed | 0 | 0 | 2 (66.7) | 0 | | 0 |
| Stricture | 0 | 1 (5.9) | 0 | 1 (33.3) | | 0 |
| Seroma | 0 | 0 | 1 (33.3) | 0 | | 0 |
| Unknown | 5 (55.6) | 5 (29.4) | 0 | 0 | | 3 (18.8) |
| Complications | | | | | 0.53 | |
| Complications in 30 days | | | | | | |
| Surgical site infection | 4 (10.3) | 11 (12.1) | 5 (13.5) | 0 | | 2 (4.2) |
| Other infection | 3 (7.7) | 6 (6.6) | 2 (5.4) | 0 | | 2 (4.2) |
| Bleeding complication | 2 (5.1) | 5 (5.5) | 0 | 0 | | 3 (6.3) |
| Cardiovascular complication | 1 (2.6) | 2 (2.2) | 0 | 0 | | 0 |
| Thromboembolic complication | 1 (2.6) | 3 (3.3) | 0 | 0 | | 0 |
| Complications during follow-up | | | | | | |
| Small-bowel obstruction | 2 (5.1) | 6 (6.6) | 3 (8.1) | 3 (15.0) | | 6 (12.5) |
| Fistula | 3 (7.7) | 3 (7.7) | 0 | 0 | | 1 (2.1) |

The nominal variables are reported as counts and percentages (in parentheses). The *p*-values were calculated by comparing the results only of the keyhole, Sugarbaker, sandwich and modified keyhole techniques due to the heterogeneity of the procedures in the "other" category.

**Table 16. Results of the parastomal hernia repair: laparoscopic versus open surgery (Study II).**

| Variable | Keyhole (n = 39) | Sugarbaker (n = 91) | Sandwich (n = 37) | Modified keyhole (n = 20) | *P*-value | Other (n = 48) |
|---|---|---|---|---|---|---|
| Laparoscopic | 11 (28.2) | 68 (74.7) | 31 (83.8) | 6 (30.0) | | 7 (14.6) |
| Open | 24 (61.5) | 14 (15.4) | 4 (10.8) | 12 (60.0) | | 40 (83.3) |
| Recurrence | | | | | 0.659 | |
| Laparoscopic | 8 (72.7) | 17 (25.0) | 4 (12.9) | 1 (16.7) | | 2 (28.6) |
| Open | 5 (20.8) | 1 (7.1) | 0 | 2 (16.7) | | 14 (35.0) |
| Reoperation | | | | | 0.072 | |
| Laparoscopic | 5 (45.5) | 14 (20.6) | 3 (9.7) | 1 (16.7) | | 2 (28.6) |
| Open | 3 (12.5) | 1 (7.1) | 0 | 2 (16.7) | | 14 (35.0) |

| Variable | Keyhole (n = 39) | Sugarbaker (n = 91) | Sandwich (n = 37) | Modified keyhole (n = 20) | *P*-value | Other (n = 48) |
|---|---|---|---|---|---|---|
| Complications in 30 days | | | | | 0.897 | |
| Laparoscopic | | | | | | |
| Surgical site infection | 3 (27.3) | 18 (26.5) | 7 (22.6) | 1 (16.7) | | 0 |
| Other infection | 0 | 6 (8.8) | 2 (6.5) | 0 | | 0 |
| Bleeding | 1 (9.1) | 4 (5.9) | 0 | 0 | | 0 |
| Cardiovascular complication | 0 | 1 (1.5) | 0 | 0 | | 0 |
| Thromboembolic complication | 0 | 3 (4.4) | 0 | 0 | | 0 |
| Open | | | | | | |
| Surgical site infection | 3 (12.5) | 3 (21.4) | 1 (25.0) | 0 | | 2 (5.0) |
| Other infection | 3 (12.5) | 2 (14.3) | 0 | 0 | | 1 (2.5) |
| Bleeding | 1 (4.2) | 0 | 0 | 0 | | 3 (7.5) |
| Cardiovascular complication | 0 | 1 (7.1) | 0 | 0 | | 0 |
| Thromboembolic complication | 1 (4.2) | 0 | 0 | 0 | | 0 |
| Complications during follow-up | | | | | | |
| Laparoscopic | | | | | | |
| Small-bowel obstruction | 1 (9.1) | 3 (4.4) | 2 (6.5) | 1 (16.7) | | 0 |
| Fistula | 0 | 0 | 0 | 0 | | 0 |
| Open | | | | | | |
| Small-bowel obstruction | 0 | 3 (21.4) | 0 | 2 (16.7) | | 6 (15.0) |
| Fistula | 3 (12.5) | 2 (14.3) | 0 | 0 | | 1 (2.5) |

The nominal variables are reported as counts and percentages (in parentheses). The percentages were calculated as proportions of a given technique. The *p*-values were calculated by comparing the results only of the keyhole, Sugarbaker, sandwich and modified keyhole techniques due to the heterogeneity of the procedures in the “other” category.

## 4.3 Study III

A total of 47 patients were operated on for ileal conduit PSH in six of the nine participating hospitals from January 1, 2007 to December 31, 2017. The patients underwent 18 intra-abdominal keyhole repairs and 10 Sugarbaker repairs. Of the patients, 18 were operated on using various other techniques, but these procedures were excluded from the final analysis due to their heterogeneity.

After a mean follow-up time of 54.6 months (0–133 months, SD 39.7 months), the recurrence rate was 22% (4/18) after keyhole repair and 10% (1/10) after Sugarbaker repair ($p = 0.626$). Reoperation was done in 17.9% (5/28) of the patients who had undergone keyhole repair and in none of the patients who had undergone Sugarbaker repair ($p = 0.265$). One reoperation had small-bowel perforation classified as a Clavien-Dindo 4 complication of primary surgery as its indication. The indication for the other four reoperations was recurrence. A complication occurred in 15% (4/28) of the patients, and in some of them, more than one complication occurred. Overall, six complications occurred after keyhole repair while only one complication occurred after Sugarbaker repair. The results are presented in Table 17.

**Table 17. Results of the techniques used to repair ileal conduit PSH (Study III).**

| Variable | Intra-abdominal keyhole (n = 18) | Sugarbaker (n = 10) | *P*-value |
|---|---|---|---|
| Recurrence | 4 (22.2) | 1 (10.0) | 0.626 |
| Reoperation | 5 (27.8) | 0 | 0.265 |
| Parastomal hernia recurrence | 4 (22.2) | 0 | |
| Complications | | | 0.999 |
| Clavien-Dindo 4 small-bowel perforation | 1 (5.6) | 0 | |
| Clavien-Dindo 3b bleeding | 1 (5.6) | 0 | |
| Clavien-Dindo 2 surgical site infection | 0 | 1 (5.6) | |
| Clavien-Dindo 2 urinary infection | 1 (5.6) | 0 | |
| Clavien-Dindo 2 pneumonia | 3 (16.7) | 0 | |

The nominal variables are reported as counts and percentages (in parentheses).

## 4.4 Study IV

The systematic review of the current literature resulted in the inclusion of six RCTs and one retrospective cohort study in the analysis (Fig. 4). Both IH and PSH were rarely reported. The PSH incidence was reported by three studies and varied from 0–85% depending on the type of stoma. The PSH incidences were found to be 15.2% and 46.0% following the Hartmann procedure (Lambrichts et al., 2019; Pizza, D'Antonio, Arcopinto, Dell'Isola, & Marvaso, 2020). Schultz et al. reported a 4% PSH incidence following sigmoid resection, either through the Hartmann procedure or through primary anastomosis (Schultz et al., 2017).

The IH incidence was reported by all seven included studies, but with a wide variation. The IH incidences are presented in Table 18. Due to the apparent underdiagnosis of both PSH and IH and their absence in the predefined outcomes, no meta-analysis was conducted.

**Table 18. IH incidence reported by the studies and type of operation.**

| Source | Laparoscopic lavage | Hartmann procedure | Primary anastomosis | Primary resection | Secondary resection |
|---|---|---|---|---|---|
| Zeitoun | - | - | - | 14 (25.5%) | 22 (45.8%) |
| Kronborg | - | - | - | 1 (3.2%) | 5 (16.1%) |
| Vennix | 5 (11.1%) | - | - | 5 (11.9%) | - |
| Kohl | 2 (4.7%) | 2 (5.0%) | - | - | - |
| Schultz | 2 (2.7%) | - | - | 6 (8.6%) | - |
| Lambrichts | - | 5 (7.8%) | 3 (4.5%) | - | - |
| Pizza | - | 43 (38.1%) | 22 (27.2%) | - | - |

The nominal variables are reported as counts and percentages (in parentheses).

# 5 Discussion

## 5.1 Study I

Study I was designed in the initial years of PSH prevention. Since then, several RCTs have been published with short-term results. Based on the results of these RCTs, the use of preventive meshes was recommended. However, while many studies have been published with short-term results, long-term outcomes have rarely been published (Jänes et al., 2009; Lambrecht et al., 2015). Thus, study I provided valuable information on the long-term efficiency and safety of the intra-abdominal keyhole technique.

Study I presented a reliable assessment of PSH incidence through both clinical evaluation and imaging via CT scan. Additionally, the patients, who were alive and fit enough to attend a follow-up visit, were reliably reached for evaluation. Radiologists who evaluated the secondary outcome (i.e., the PSH on CT scan) remained blinded to the study group. The proportion of patients who were evaluated both clinically and through a CT scan was high.

Although the intra-abdominal keyhole mesh significantly prevented clinically evident PSH at the 12-month follow-up (Vierimaa et al., 2015), significant differences were not noticed in the long-term follow-up, either for clinically detected PSH or PSH detected via CT scan. However, the results indicated that the mesh might have prevented stomal prolapse. Additionally, the patients in the mesh group underwent fewer PSH repairs during the long-term follow-up compared to the patients in the control group. The reasons behind this remain unknown, but fewer reoperations may indicate less symptomatic PSH.

The advantages of PSH prevention have been questioned recently by studies (Correa Marinez et al., 2020; Odensten et al., 2019; Prudhomme et al., 2021) and a published meta-analysis (Prudhomme et al., 2020). Most of the previous studies on PSH prevention used the keyhole technique; only a few studies investigated the other techniques (Köhler et al., 2016; López-Borao et al., 2019; López-Cano et al., 2016). The keyhole technique resulted in a significant rate of recurrence in both studies II and III and in previously published meta-analyses of PSH repair (DeAsis et al., 2015; Hansson et al., 2012). Therefore, the intraperitoneal or retrorectus keyhole technique may also not be an optimal PSH prevention method.

Lopez-Cano et al. studied the use of the modified Sugarbaker technique for PSH prevention in an RCT setting and reported a 25% PSH recurrence rate (compared to 64% in the control group). Additionally, the modified keyhole technique with a specific funnel-shaped mesh was shown to be promising for PSH prevention in a case series (Köhler et al., 2016; López-Borao et al., 2019). Therefore, not the possibility of PSH prevention but the effectiveness of the methods that are used for this prevention should be questioned. PSH often occurs following end colostomy. Therefore, the aim to find better means of preventing PSH is justified.

## 5.2 Study II

Study II was designed when hardly any studies comparing the different PSH repair methods had been published. The keyhole technique was hypothesised to be inferior to the Sugarbaker technique according to a previously published meta-analysis (DeAsis et al., 2015; Hansson et al., 2012), and the results of the sandwich and modified keyhole repair techniques were widely unknown outside highly specialised tertiary centres.

Study III revealed high recurrence, complication and reoperation rates, even for laparoscopic PSH repair, especially when the intra-abdominal keyhole technique was used. These results may have reflected the technical complexity of laparoscopic PSH repair and showed that the keyhole technique should not be a primary option for PSH repair. Due to the small number of patients in the study, no further conclusions could be drawn.

The strength of the study was its wide extraction of patients across the country. Therefore, the results of the study likely reflected the realities of PSH repair in Finland. Previously published results in the United Kingdom and Sweden were similar in terms of results of PSH repair (Aslam, Rubio-Perez, Smart, & Singh, 2019; Odensten et al., 2020). However, the study results were clearly inferior to the reports of excellent PSH repairs at highly specialised tertiary centres (Ayuso et al., 2020; Berger & Bientzle, 2007; Fischer et al., 2017; Köhler et al., 2014; Pauli et al., 2016). The reasons behind this worse outcome remain unknown.

The study patients (n = 235) were operated on by 85 surgeons who used nine different techniques in nine hospitals; this led to an average of 2.6 repairs per surgeon during the 10-year study interval. The choice of the technique used for PSH repair likely reflected the preferences of the operating surgeons and the hospital rather than unique tailoring for each patient. Therefore, study II did not provide any information on the techniques that should be used for PSH repair for particular types of patients.

## 5.3 Study III

Study III was one of the first cohort studies that reported the results of the repair of a PSH that developed following ileal conduit urinary diversion. It was also one of the first to compare the outcomes of the keyhole and Sugarbaker techniques. The outcome of the keyhole technique was far below optimal, as it had high recurrence and complication rates. Thus, the keyhole technique may not be optimal for repair either of end colostomy PSH or of ileal conduit PSH. However, as only 10 patients were operated on using the Sugarbaker technique, no firm conclusions can be made with regard to the technique's superiority.

The posterior attachment of ureters may cause potential difficulties in the lateralisation of the ileal conduit. Therefore, the Sugarbaker technique was previously considered potentially unsuitable for the repair of PSH that developed following ileal conduit urinary diversion (Narang et al., 2017). Study III, however, provided the results of 10 successful PSH repairs using the Sugarbaker technique. Still, this technique may not be optimal for all PSH repairs, and further research is needed to broaden the spectrum of treatment options.

The study also showed a rare elective repair of a PSH that developed following ileal conduit urinary diversion. Records of only 47 PSH repairs were in the registries of the nine participating hospitals. Therefore, expertise in ileal conduit PSH repair is unachievable in the current practice.

## 5.4 Study IV

Patients operated on for acute diverticulitis may have an increased risk of developing both PSH and IH compared to those operated on for colorectal cancer (Perez et al., 2020; Pogacnik et al., 2014; Shao et al., 2020). Despite the large number of recently published studies on the surgical treatment of acute diverticulitis, hernias were mainly ignored in the outcomes. Diverticulitis may reflect a predisposition to the development of hernias due to connective tissue abnormalities (Broad et al., 2019; Schafmayer et al., 2019). Combined with peritonitis, diverticulitis may pose a higher risk for developing hernia (Moussavian et al., 2010). However, the reported IH incidences were surprisingly low (Table 18). This may have been due to inadequate hernia diagnosis methods. Additionally, the hernia rate was not defined as an outcome in most of the studies.

Since hernias that develop after surgery for acute diverticulitis are not recognised, they are unlikely to be prevented. However, IH prevention may be beneficial during the emergency laparotomy closure (Burns, Heywood, Challand, & Lee, 2020). The use of the correct suture technique is likely to prevent hernias to a large extent (Deerenberg et al., 2015; Thorup, Tolstrup, & Gögenur, 2019); preventive mesh may be necessary only for patients with increased risk of developing IH (Borab et al., 2017; Burns et al., 2020; Depuydt, Allaeys, de Carvalho, Vanlander, & Berrevoet, 2021; Gignoux et al., 2021; Nachiappan, Markar, Karthikesalingam, Ziprin, & Faiz, 2013).

Although permanent colostomy is a frequent complication of emergency surgery for diverticulitis (Cirocchi et al., 2018; Ryan et al., 2020), PSH is an ignored problem, and PSH prevention during emergency surgery is still a widely unexplored topic.

# 6 Limitations

## 6.1 Study I

Study I had the limitations of a small study population (n = 35) and a high dropout rate, mainly due to the deaths of the study patients (50%). The value of the clinical evaluation was limited by the unblinded assessment of the primary outcome (i.e., clinical PSH). Additionally, the significance of PSH diagnosis was weakened by the lack of patient-reported outcomes.

## 6.2 Study II

Study II had the limitations of having a retrospective nature and a small number of patients operated on using different techniques. The patients who were operated on using the modified Sugarbaker technique had a shorter follow-up time, which created difficulty in comparing the results with those of the other techniques. Additionally, due to the retrospective registry data, the indications of PSH repair and the decisions for choosing the technique were unknown. Moreover, the clinical significance of recurrence was unclear due to the lack of patient-reported outcomes. Finally, the severity of the complications was also unknown due to the non-reporting of the complications' Clavien-Dindo classification.

## 6.3 Study III

Study III had the limitations of a small number of patients, the retrospective manner of data collection and a short follow-up time after Sugarbaker repair. Therefore, no firm conclusion could be made regarding the applicability of the Sugarbaker technique for the repair of PSH at the ileal conduit.

## 6.4 Study IV

Study IV had the limitation of the underreporting of PSH and IH in the context of diverticular disease. Additionally, PSH and IH were not defined as outcomes, which limited the trustworthiness of the data available on hernia incidence. The follow-up methods that were chosen in the RCTs were also not suitable for reliable hernia diagnosis, and the hernia definitions and diagnostic methods were unclear.

# 7 Clinical significance

## 7.1 Study I

Study I was one of the first studies to report the results of a long-term follow-up on PSH prevention. Based on recently published studies, the keyhole technique is not an effective way to prevent PSH. Additionally, the study confirmed that some hernias could be detected only via CT scan at short-term follow-up and could be subsequently detected as clinically significant at long-term follow-up. However, despite the equal incidence of CT-confirmed PSH in the mesh and control groups, the use of a preventive mesh decreased the need for further surgery for PSH repair in both cases. Additionally, the results showed that the preventive mesh might prevent clinically diagnosed stoma prolapse. The preventive keyhole IPOM also was found to be safe in the long term, without any mesh-related complications.

## 7.2 Study II

Study II highlighted the poor results of PSH repair outside highly specialised tertiary centres. As the patient volumes per centre and surgeon were low in Study II, the significance of the centralisation of PSH repairs should be further evaluated. The keyhole technique was found to be inferior to the other intra-abdominal techniques and should be avoided, especially in the laparoscopic technique. The results of Study II encouraged further evaluation of both the sandwich and modified keyhole techniques.

## 7.3 Study III

Study III suggested that the Sugarbaker technique is likely suited for repairing PSH at the ileal conduit. However, due to the small number of study patients, this finding should be further evaluated in larger studies. The study confirmed that ileal conduit PSH repair is seldom performed, thus limiting surgeons' ability to obtain sufficient experience with this repair. The data also revealed that many of the end ostomy PSH repair techniques that were thought to be abandoned were actually still being used to repair PSH at the ileal conduit.

## 7.4 Study IV

Study IV emphasised the missing data on the hernia rate after emergency surgery for diverticulitis. Although the importance of proper abdominal wall closure after laparotomy has been recognised (Deerenberg et al., 2015; Henriksen et al., 2018), and the high risk of developing hernia associated with emergency surgery is well-known (Burns et al., 2020), insufficient evidence exists for any recommendations regarding hernia prevention. Thus, the study encouraged further research on diverticular disease focusing on hernia incidence and prevention.

# 8 Future expectations

## 8.1 Study I

Recent relevant studies and meta-analyses have questioned the importance of PSH prevention. However, the problem is not the possibility of preventing PSH but the techniques that have been used to do so. Hopefully, the research community will acknowledge the justification for PSH prevention and will continue searching for better solutions instead of abandoning PSH prevention due to the pitfalls of the keyhole technique.

The rectorectus and intra-abdominal keyhole techniques should not be used for PSH prevention due to their limited ability to prevent the development of PSH. Future studies should concentrate on other techniques, such as the modified keyhole technique with a specific funnel-shaped mesh or the Sugarbaker technique, and they should include a more detailed cost analysis and a focus on patient-reported outcomes. Innovations in PSH prevention should follow the recommendations for modern hernia surgery to avoid using IPOM techniques. Most of the studies on PSH prevention involve patients with rectal cancer, so preventive indications should be broadened to patients requiring emergency surgery and those who require ileal conduit PSH prevention. The significance of temporary stoma enforcement with a mesh should also be evaluated.

## 8.2 Study II

The current studies could not provide a clear answer regarding how to determine if a PSH will develop if no symptoms are exhibited. Therefore, additional studies on surgical treatment indications are needed. Furthermore, no study has compared PSH repair techniques between elective and emergency settings. Therefore, comparative studies on tailored repair techniques using patient-reported outcomes and pre-operative PSH classification are needed. As the PSH recurrence rate is currently high, further research is also needed to guide the selection of the technique used for reoperation.

To draw firmer conclusions regarding the advantages of the sandwich technique and the use of the specific funnel-shaped mesh, RCTs with a larger number of patients and a longer follow-up should be conducted. Technically achievable and repeatable techniques that place the mesh outside the intra-abdominal space are still needed. As the new complex PSH and abdominal wall repair techniques are associated with a high complication rate (Tastaldi et al., 2017), PSH repair should be conducted only in specialised abdominal wall repair centres.

## 8.3 Study III

Evidence of the effectiveness of any technique for repairing PSH following ileal conduit urinary diversion is scarce. Because patients are followed up by urologists who are not dedicated to hernia surgery, the implementation of PSH repair is not always clear. Additionally, when ileal conduit PSHs are treated by surgeons not dedicated to hernia surgery, there is a risk of utilising outdated techniques once commonly used for end colostomy PSH repair. Already abandoned techniques for colostomy PSH repair (i.e., local repairs, suture repair, onlay meshes and probably the keyhole technique) should not be used to repair ileal conduit PSHs. Therefore, since PSH repair after urinary diversion is a rare operation in the elective setting, patients should be operated on by high-volume hernia surgeons. Additionally, international multicentre and registry studies with sufficient patient numbers that compare different PSH repair techniques are urgently needed to fill the wide research gap on ileal conduit PSH repair.

The significance of PSH prevention should also be studied, as the risk of developing a PSH after urinary diversion is remarkable, and the results of the existing repair techniques are poor. The traditional keyhole technique is unlikely to be optimal for preventing ileal conduit PSH, but both the Sugarbaker technique and a technically easy modified keyhole technique with funnel-shaped mesh placement are worth exploring in future RCTs.

## 8.4 Study IV

PSH and IH rates following emergency surgery for diverticulitis have been poorly reported. PSH is a frequent complication of end colostomy following surgery for rectal cancer, and end colostomy is a frequent complication of emergency surgery for diverticulitis. Therefore, PSH is likely a common, albeit underdiagnosed, complication of emergency surgery for diverticulitis. However, no preventive measures have been considered. Therefore, future studies should pay special attention to PSH incidence after emergency surgery for diverticulitis.

The risk of developing IH may increase in patients with diverticulitis compared to those with other indications for open surgery. The risk may be even further increased by peritonitis and surgical site infection, which is common after emergency laparotomy. The proper abdominal wall closure through suturing is recommended for hernia prevention in the emergency setting, and some patients may also benefit from the use of preventive meshes. Further research is needed to create a risk-scoring system to help select patients who are eligible for preventive-mesh placement combined with midline laparotomy for PSH prevention.

Altogether, little is known about the hernias that may develop following emergency surgery for diverticulitis. Thus, future research exploring both IH and PSH prevention in the emergency setting is encouraged.

# 9 Conclusions

Based on the findings of the present study, the following conclusions can be made:

1. The keyhole technique does not prevent either clinical or radiologically detected PHS over the long-term. However, the use of mesh decreases the need for PSH repair and prolapses.
2. The results of PSH repair for both end-ostomies and ileal conduits are far below optimal in terms of PSH recurrence, complications and re-operations.
3. The incidence of PSH and IH following surgery for Hinchey III–IV diverticulitis is likely underestimated in the current literature. Future studies are encouraged to pay attention to hernia incidence.

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# Original Publications

I Mäkäräinen-Uhlbäck, E. J., Klintrup, K., Vierimaa, M. T., Carpelan-Holmström, M. A., Kössi, J., Kairaluoma, M. V., … Rautio, T. T. (2020). Prospective, randomized study on the use of prosthetic mesh to prevent a parastomal hernia in a permanent colostomy: Results of a long-term follow-up. *Diseases of the Colon and Rectum, 63*(5), 678–684. https://doi.org/10.1097/DCR.0000000000001599

II Mäkäräinen-Uhlbäck, E., Vironen, J., Falenius, V., Nordström, P., Välikoski, A., Kössi, … & Rautio, T. (2021). Parastomal hernia: A retrospective nationwide cohort study comparing different techniques with long-term follow-up. *World Journal of Surgery*, 10.1007/s00268-021-05990-z. Advance online publication. https://doi.org/10.1007/s00268-021-05990-z

III Mäkäräinen-Uhlbäck, E., Vironen, J., Vaarala, M., Nordström, P., Välikoski, A., Kössi, J., Falenius, V., Kechagias, A., Mattila, A., Ohtonen, P., Scheinin, T., Rautio, T. (2021). Keyhole versus Sugarbaker techniques in parastomal hernia repair following ileal conduit urinary diversion: A retrospective nationwide cohort study. *BMC Surgery, 21*(1), 231. https://doi-org.pc124152.oulu.fi:9443/10.1186/s12893-021-01228-w

IV Mkäräinen, E., Rautio, T., Rintala, J., Muysoms, F., Kauppila, J. (2021). Parastomal and incisional hernias following emergency surgery for Hinchey III–IV diverticulitis: A systematic review. *Submitted.*



Original publications are not included in the electronic version of the dissertation.

1611. Gebre, Robel Kebede (2021) Computed tomography assessment of low-energy acetabular fractures in the elderly

1612. Siira, Heidi (2021) Ikääntyneiden näkövammaisten henkilöiden näönkuntoutus, terveyteen liittyvä elämänlaatu ja siihen yhteydessä olevat tekijät : kahden vuoden monimenetelmäinen seurantatutkimus

1613. Choudhary, Priyanka (2021) Early origins of cardiometabolic risk factors : life course epidemiology and pathways

1614. Raatikainen, Ville (2021) Dynamic lag analysis of human brain activity propagation : a fast fMRI study

1615. Knuutinen, Oula (2021) Childhood-onset genetic white matter disorders of the brain in Northern Finland

1616. Farrahi, Vahid (2021) Sedentary time, physical activity and cardiometabolic health : accelerometry-based study in the Northern Finland Birth Cohort 1966

1617. Savukoski, Susanna (2021) Metabolic effects of early-onset menopausal transition

1618. Vainio, Laura (2021) Neuronostatin, connective tissue growth factor and glycogen synthase kinase 3? in cardiac physiology and disease

1619. Karvonen, Risto (2021) Preterm birth and cardiovascular risk factors in young adulthood

1620. Kärmeniemi, Mikko (2021) The built environment as a determinant of physical activity : Longitudinal associations between neighborhood characteristics, urban planning processes, and physical activity

1621. Halonen, Harri (2021) Dental anxiety: a patient's personality traits and comorbidity with other psychiatric disorders

1622. Hietanen, Siiri (2021) Alcohol-related health problems in critically ill patients

1623. Laitakari, Kirsi (2021) Anatomic and functional long-term results of ventral rectopexy

1624. Koivisto, Katri (2021) Zoledronic acid for chronic low back pain associated with Modic changes : Efficacy for low back symptoms, effect on magnetic resonance imaging findings and serum biomarkers in a randomized placebo-controlled study

1625. Kummu, Maria (2021) Role of placental transporters in fetal exposure to toxic environmental chemicals

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