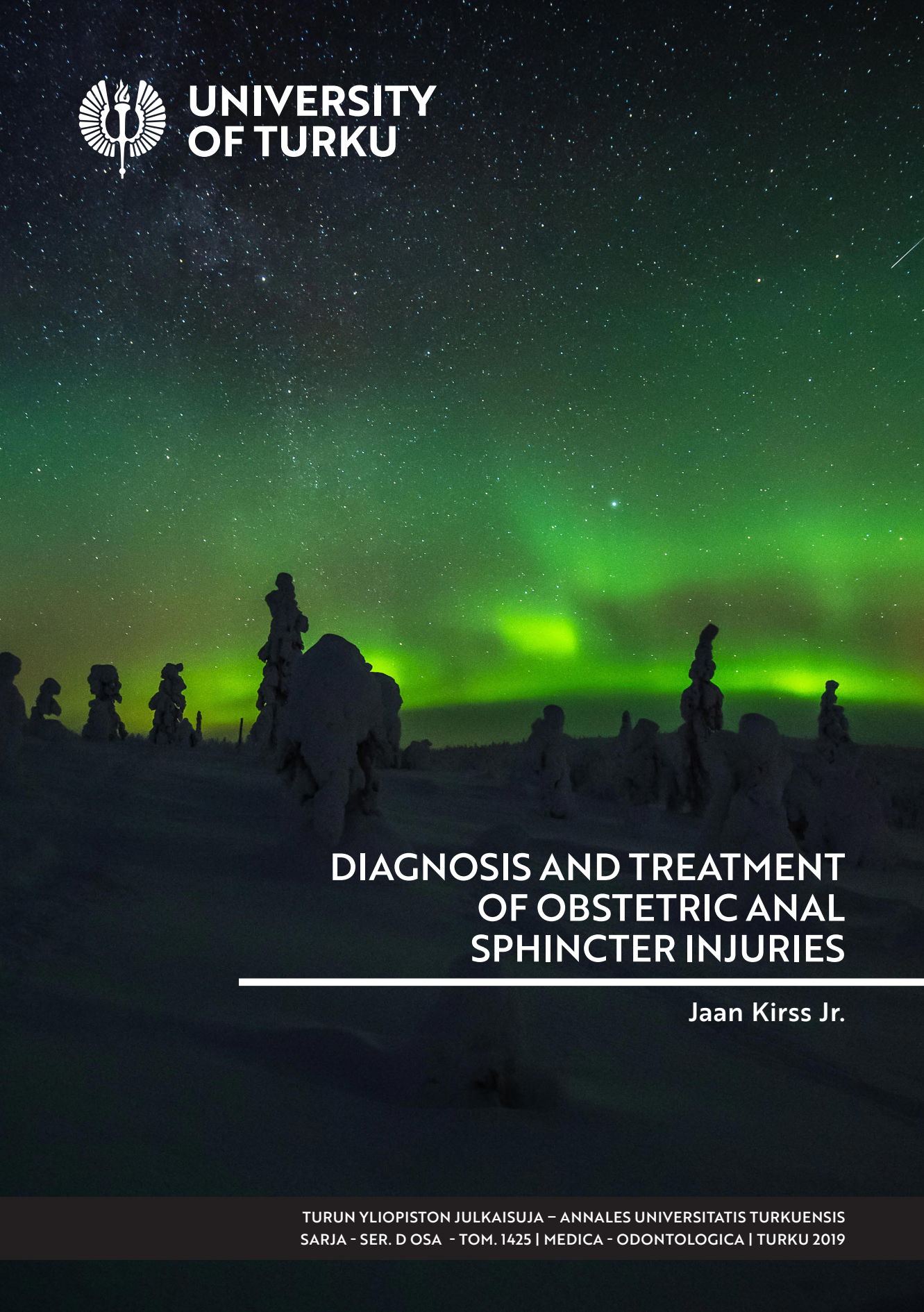

UNIVERSITY OF TURKU

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Jaan Kirss Jr.

TURUN YLIOPISTON JULKAISUJA – ANNALES UNIVERSITATIS TURKUENSIS
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To my grandfather- Heimar Peremees

ABSTRACT

Jaan Kirss Jr.
Diagnosis and Treatment of Obstetric Anal Sphincter Injuries (OASI)
University of Turku, Faculty of Medicine, Department of Surgery, Doctoral Programme in Clinical Research, The Division of Digestive Surgery and Urology, Turku University Hospital, Turku, Finland

Annales Universitatis Turkuensis
Painosalama OY, Turku, Finland 2019

Aims: The aims of this study were to identify the risk factors for a failed primary repair of obstetric anal sphincter injury (OASI), to determine whether external phased-array magnetic resonance imaging (MRI) is suitable for the diagnosis of residual obstetric anal sphincter injury (ROASI), and to evaluate the effectiveness of sacral neuromodulation (SNM) for the treatment of faecal incontinence (FI) in women with a history of OASI.
Patients and Methods: A total of 60 women with a history of OASI were analysed for factors influencing the failure of primary sphincter repair. Forty women who had been diagnosed with OASI underwent both MRI and three-dimensional endoanal ultrasound (3D EAUS) imaging 6–8 months postpartum. The results from these imaging studies were analysed. Data of all patients tested for SNM in Finland was gathered, patients with FI as the indication for SNM treatment were further analysed.
Results: The risk factors for a failed primary sphincter repair were repairs executed by inexperienced personnel ($p<0.001$), or during on-call hours ($p=0.039$), end-to-end suturing of the external anal sphincter ($p=0.030$), and failure to prescribe antibiotics or laxatives ($p<0.001$). External phased-array pelvic MRI is comparable to 3D EAUS in detecting external anal sphincter (EAS) lesions ($\kappa=0.510$). SNM treatment outcomes were more successful in patients with obstetric FI, compared to patients with other types of FI ($p=0.012$). The presence of a sphincter lesion or previous sphincter repair had no effect on the SNM treatment outcome ($p=0.425$).
Conclusions: There were clear risk factors that can affect the outcome of the primary repair of OASI. ROASI can be successfully imaged by external phased-array MRI. SNM treatment outcomes of patients with ROASI were comparable if not better than outcomes in patients with other causes of FI. A patent sphincter defect or previous sphincteroplasty (SP) had no effect on SNM treatment outcomes.

Keywords: obstetric anal sphincter injury, faecal incontinence, magnetic resonance imaging, sacral neuromodulation

TIIVISTELMÄ

Jaan Kirss Jr.
Diagnosis and Treatment of Obstetric Anal Sphincter Injuries (OASI)
Turun yliopisto, Lääketieteellinen tiedekunta, Kirurgian oppiaine, Turun kliininen tohtoriohjelma, Vatsaelinkirurgian klinikka, Turun yliopistollinen keskussairaala

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Tavoitteet: Tutkimuksen tavoitteena oli selvittää sulkijalihasrepeämän korjauksen pettämiseen liittyviä riskitekijöitä, magneettikuvauksen (MRI) soveltuvuutta sulkijalihasrepeämien diagnostiikassa ja sakraalihermomodulaation (SNM) sopivuutta sulkijalihasvaurioiden aiheuttaman ulosteenkarkailun (UK) hoidossa.
Aineisto ja menetelmät: Tutkimukseen kerättiin 60 sulkijalihasrepeämäpotilaan tiedot. Tämän potilasaineiston perustella selvitettiin, mitkä olivat sulkijalihaskorjauksen epäonnistumisen riskitekijät. Yhteensä 40 potilasta osallistui prospektiiviseen tutkimukseen, jossa verrattiin MRI:tä ja endoanaali ultraäänitutkimusta (EAUS) sulkijalihasrepeämien toteamisessa. Tutkimukseen kerättiin myös kaikki Suomessa SNM:lla hoidettujen potilaiden tiedot. Tutkimukseen otettiin mukaan potilaat, joilla oli SNM:n indikaationa UK.
Tulokset: Riskiä sulkijalihasrepeämän korjauksen epäonnistumiseen lisäsi se, että repeämän oli korjannut kokematon lääkäri tai kätilö ($p<0.001$), korjaus oli tehty päivystysaikana ($p=0.039$), repeämä oli korjattu pää päätä vasten ($p=0.030$) ja se, että potilaille ei ollut korjauksen jälkeen määrätty antibiootteja tai ulostuslääkettä ($p<0.001$). MRI oli yhtä tarkka kuin EAUS sulkijalihasrepeämien toteamisessa ($\kappa=0.510$). SNM:n tulokset olivat paremmat potilailla, joilla oli idiopaattinen UK tai UK:n syynä oli sulkijalihasrepeämä ($p=0.012$). Sulkijalihasrepeämä tai aiempi sulkijalihasten korjausleikkaus ei vaikuttanut SNM:n tuloksiin ($p=0.425$).
Johtopäätökset: Sulkijalihasrepeämän korjauksen epäonnistumiseen löytyi selviä riskitekijöitä. Sulkijalihasrepeämän voi todeta myös luotettavasti MRI:llä. SNM:n tulokset olivat sulkijalihasrepeämäpotilailla yhtä hyvät tai jopa paremmat kuin muilla karkailupotilailla. Sulkijalihasrepeämä tai aiempi sulkijalihasten korjausleikkaus ei vaikuttanut SNM:n tuloksiin.

Avainsanat: Sulkijalihasrepeämä, ulosteenkarkailu, magneettikuvaus, sakraalihermomodulaatio

TABLE OF CONTENTS

ABBREVIATIONS

3D EAUS	three-dimensional endoanal ultrasound
3DHRAM	three-dimensional high-resolution anal manometry
AM	anal manometry
EAS	external anal sphincter
EAUS	endoanal ultrasound
FI	faecal incontinence
FIQL	faecal incontinence quality of life index
FUI	faecal urge incontinence
GaI	gas incontinence
GI surgeon	gastrointestinal surgeon
IAS	internal anal sphincter
MRI	magnetic resonance imaging
OASI	obstetric anal sphincter injury
PNTML	pudendal nerve terminal motor latency
QoL	quality of life
QUALY	quality adjusted life year
ROASI	residual obstetric anal sphincter injury
SNM	sacral neuromodulation
SP	sphincteroplasty

LIST OF ORIGINAL PUBLICATIONS

This doctoral thesis is based on four original publications, which are numbered and referred to in the text by Roman numerals I–IV.

I. Kirss J. Jr., Pinta T., Böckelman C., Victorzon M. Factors predicting a failed primary repair of obstetric anal sphincter injury. Acta Obstetrica et Gynecologica Scandinavica 2016 Sept; 95(9):1063-1069. DOI:10.1111/aogs.120909

II. Kirss J. Jr., Huhtinen H., Niskanen E., Ruohonen J., Victorzon S., Kallio-Packalen M., Victorzon M., Pinta T. Comparison of 3D endoanal ultrasound and external phased-array magnetic resonance imaging in the diagnosis of obstetric anal sphincter injuries. European Radiology. Published ahead of print 2019 Mar. 26, DOI:10.1007/s00330-019-06125-8

III. Kirss J. Jr., Pinta T., Varpe P., Rautio T., Kairaluoma M., Hyöty M., Hurme S., Böckelman C., Kairaluoma V., Salmenkylä S., Victorzon M. Outcomes of treatment of faecal incontinence with sacral nerve stimulation - a Finnish multicentre study. Colorectal Disease. 2019 Jan; 21(1):59-65. DOI:10.1111/codi.14406

IV. Kirss J. Jr., Pinta T., Varpe P., Rautio T., Kairaluoma M., Hyöty M., Hurme S., Böckelman C., Kairaluoma V., Salmenkylä S., Victorzon M. Impact of sphincter lesions and delayed sphincter repair on sacral neuromodulation treatment outcomes for faecal incontinence. Results from a Finnish national cohort study. International Journal of Colorectal Disease 2018 Dec; 33(12):1709-1714, DOI: 10.1007/s00384-018-3161-0

1 INTRODUCTION

The principal aetiological factor for developing faecal incontinence (FI) in women is obstetric anal sphincter injury (OASI) (Jango et al. 2017a, Goldman et al. 2018). There were 52,000 births registered in Finland in 2016; 1.2% of the registered deliveries complicated in OASI (Heino et al. 2017). Although OASI is to some extent a preventable injury (Jango et al. 2014), it is not abolishable. As long as women are giving birth, there is a risk of developing perineal tears. In order to achieve the best possible outcomes for the treatment of this injury, physicians must be prepared to diagnose and treat OASI adequately. The cornerstone of a favourable outcome in the treatment of OASI is a well-executed primary repair. This is naturally coupled with adequate diagnosis of a postpartum sphincter injury (Oberwalder et al. 2004, Malouf et al. 2000a, Pinta et al. 2004a). Making a right diagnosis and repairing the defect can be challenging, due to the profuse bleeding, swelling, and extensive tissue damage that can result from vaginal delivery. The repair of OASI is a difficult surgical intervention in very unfriendly conditions. Postponing the repair until experienced personnel are available and the repair can be undertaken in operating room conditions has been deemed acceptable. A delay up to 24 hours will not have a negative effect on the outcome (Dudding et al. 2008a, Soerensen et al. 2008).

Follow-up after OASI is crucial for recognising residual tears and facilitating their timely repair (Soerensen et al. 2008).

Sphincter imaging is the only option for reliably evaluating residual sphincter defects (Dobben et al. 2006, Jeppson et al. 2012). For the last two decades, endoanal ultrasound (EAUS) has been the gold standard for imaging the anal sphincter complex and diagnosing anal sphincter lesions. Alternatively, endoanal magnetic resonance imaging (MRI) can be used to image the anal sphincter complex. Endoanal MRI has been shown to be as precise as three-dimensional endoanal ultrasound (3D EAUS) in diagnosing external anal sphincter defects (Deutekom et al. 2007, West et al. 2005). Both the endoanal MRI and 3D EAUS require specialised hardware, which is not widely available. The ever-improving quality of external phased-array pelvic MRI has facilitated imaging the anal sphincters without endoanal coils. This allows smaller centres where pelvic MRI is available to conduct imaging of patients with a history of OASI.

After the diagnosis of a residual obstetric anal sphincter injury (ROASI), most women are referred to a physiotherapist for biofeedback therapy. Simultaneously they are prescribed fibre supplements and, if needed anti-diarrhoeal agents such as loperamide. Women with no visible perineal defects are mostly treated conservatively with considerable success (Duelund-Jakobsen et al. 2016, Benezech et al. 2016, Ribas and Munoz-Duyos 2018). When diagnosed early, the sphincter defect can still be repaired surgically with acceptable short- and medium-term outcomes (Pinta et al. 2001, Molander et al. 2007, Soerensen et al. 2014). This only applies to women with symptomatic FI. Sphincteroplasty (SP) years from the initial injury is associated with poor treatment outcomes, though evidence on this matter is somewhat contradictory. A study by Pinta et al. (2001) showed patients age to have a negative effect on secondary SP outcomes. Published material on this matter has been contradictory, with some studies showing age not to have an effect on the success or failure of secondary SP (Malouf et al. 2000a, Johnson et al. 2010) and other studies showing age to have a negative impact on the outcomes of secondary SP (Pinta et al. 2001, Engel et al. 1994, Sitzler and Thomson 1996, Nikiteas et al. 1996, Bravo et al. 2004, Lamblin et al. 2014).

The treatment of ROASI has been a subject of debate in recent years. Currently, SNM has been advocated for patients with FI unresponsive to conservative treatment. Previous studies suggest that SNM treatment can be successful even in the presence of a patent sphincter lesion. SNM was conceived in 1982 as a treatment modality for urinary incontinence (Tanagho and Schmidt 1982). Since then the implications for SNM have evolved, and it has become the first line surgical treatment for FI (Goldman et al. 2018).

The aim of this doctoral thesis is to determine the risk factors for failure of primary repair of OASI, evaluate the possibility of imaging the anal sphincter complex with external phased-array pelvic MRI, and determine the effectiveness of SNM treatment for FI in patients with a history of OASI. Additionally, we shall evaluate the effect of a patent obstetric sphincter lesion or previous attempts at sphincter repair on SNM treatment.

2 REVIEW OF LITERATURE

2.1 History of obstetric anal sphincter injuries

The oldest evidence of OASI dates back to 2050 BC in ancient Egypt. The mummy of one of King Menuhotep II's wives was found to have an extensive perineal tear involving the bladder and the rectum. This individual most probably perished from these wounds. Since then many notable names in the history of medicine such as Celsus, William Harvey, and Ambroise Paré have expressed opinions on perineal injuries. Paré, the father of surgical obstetrics, was the first to describe suturing of the sphincter laceration. Paré went on to found a school for midwives in Paris (Ellis 2009, Drife 2002, Dunn 1994, Vinchon 2009).

In 1930 Royston described a method of approximation of the anal sphincter tear with sutures. The current method of end-to-end SP was described in 1955 by Cunningham. The overlapping SP with a separate internal anal sphincter (IAS) repair was first described by Parks and McPartlin (1971) as a method of secondary SP. The same method for sphincter repair immediately postpartum was described in 1999 by Sultan et al.

2.2 Anatomy

2.2.1 Anatomy of the female pelvis

The female pelvis consists of the bony pelvis, which forms the pelvic ring, and a muscular pelvic floor. The sides of the bony pelvis form the lateral walls of the pelvic cavity. The pelvic floor, which is comprised of muscular structures, forms the base of the pelvic cavity. The bony pelvis has a cylindrical structure. The ends of the cylinder form the pelvic inlet and the pelvic outlet. The pelvic inlet is bordered by the sacral promontory posteriorly, the arcuate lines of the iliac bones laterally, and the superior margin of the pubic rami anteriorly. The pelvic outlet is bordered by the coccyx posteriorly, the tuberositas of the ischial bone, and the lower ramus of the pubic bone (Figure 1) (Thomas and Au-Yong 2011, Craig and Billow 2018).

The pelvic floor is formed of several layers of muscles and ligaments. Its primary function is to support the load of the visceral organs and contain them in their proper positions. Pelvic floor musculature is also responsible for controlling continence. Both the rectal and the urogenital openings lie on the pelvic floor and are controlled by its muscles.

The posteriolateral part of the female pelvic floor is composed of the levator ani and coccygeus muscles. Both muscles attach to the inner spine of the ischium, the coccyx, and the anococcygeal ligament. The transverse perineal muscles also arise from the inner spine of the ischium but attach more anteriorly to the anterior aspect of the anus. The anterior part of the female pelvic floor is formed by the bulbocavernosus and ischiocavernosus muscles. Both of these muscles converge from the inner margin of the ischial bone to the lower aspect of the symphysis (Agur et al. 2013).

Apart from the obvious differences in the pelvic floor organs and musculature, the female bony pelvis, particularly the pelvic outlet, is wider and shorter than the male pelvis. The diameter of the pelvic outlet can widen even further during delivery and remain wider postpartum (Garagiola et al. 1989).

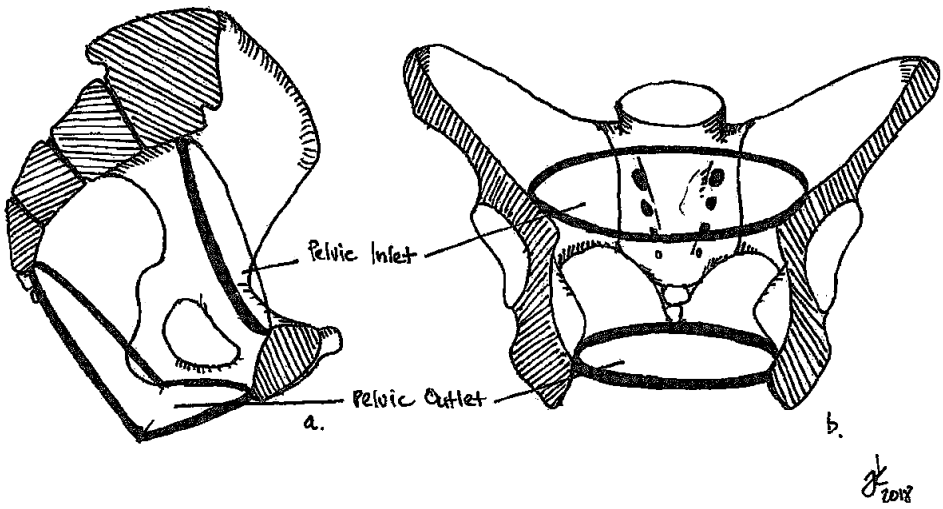

Figure 1 The bony pelvis. a- saggital view; b- coronal view. The rings represent the pelvic inlet and outlet

2.2.2 Anatomy of the anal sphincters

The anal sphincter complex is comprised of two circular sphincter muscles: the external and the internal anal sphincter (EAS and IAS). In the proximal part, the EAS evolves into *m. puborectalis,* which envelops the rectum in its posterior aspect and attaches to the pubic symphysis anteriorly, forming a horseshoe-like arc. The EAS and *m. puborectalis* are comprised of striated muscle fibres and the IAS of smooth muscle fibres. IAS tone accounts for most (≈80%) of the anal resting pressure. Typically, an EAS defect or loss of EAS function results in urge incontinence while impaired IAS function results in involuntary loss of stool (Thomas and Au-Yong 2011, Craig and Billow 2018, Agur et al. 2013).

The anal sphincter complex is innervated by the puborectalis and pudendal nerves, which arise from the S3 and S4 nerve roots (Agur et al. 2013).

2.2.3 Anatomy and physiology of the sacral nerves

The pelvic floor musculature is innervated by nerves originating from the sacral plexus. There are five sacral nerve roots (S1–S5) that exit from the corresponding sacral foramina. Of these, S2–S4 divide to form the pudendal nerve and give off parasympathetic fibres to the colon, rectum, bladder, anus and urogenital sphincters (Agur et al. 2013, Shafik 1995). The pudendal nerve itself carries only sympathetic fibres and has both afferent and efferent functions. It innervates the penis, the scrotum, the clitoris, and the labia. The pudendal nerve is also responsible for the afferent pathways of penile and clitoral erection as well as ejaculation. Its branches also supply sensation to the anal canal. Pudendal nerve branches, particularly the inferior anal branch, innervate the muscles of the perineum, the pelvic floor, and the external anal and urethral sphincters.

2.2.4 Physiology of continence

In adults, continence is maintained by a complex sequence of neuromuscular signals. The pelvic floor muscles and *m. puborectalis* are normally at a constant state of contraction, also known as the postural reflex (Barleben and Mills 2010). This reflex arises from the sacral plexus. The puborectalis muscle plays a key role in achieving passive continence. Its tone creates a

steep angle between the anus and the rectum, which inhibits faeces from evacuating spontaneously. The anal sphincters comprise the active continence system. The IAS is responsible for the resting pressure of the anal canal. IAS is innervated by sympathetic motor neurons arising from the hypogastric nerves derived from the L5 nerve root and inhibitory parasympathetic innervation derived from the sacral plexus (S2-4) (Gordon 2001, Mathews et al. 2013). When the rectum fills, the rising intrarectal pressure causes the inhibition of the postural reflex and thus relaxation of the puborectalis muscle. The rise of intrarectal pressure causes the IAS to relax. During rectal filling continence is maintained by active contraction of the EAS, which is innervated by the pudendal nerves. When the relaxation of the pelvic floor and sphincter muscles is not coordinated, normal defecation does not occur (Palit et al. 2012).

The fine sensory discrimination of the content of the rectum is achieved by receptors around the dentate line. Some sensory function is also attributed to the IAS, EAS and *m. puborectalis*, as the rectum is only sensitive to distention (Gordon 2001).

2.3 Introduction to faecal incontinence (FI)

Obstetric anal sphincter injures (OASI) often result in faecal incontinence (FI). As the treatment of OASI is in close conjunction with the treatment of FI, this chapter will give a short overview of the epidemiology, causes, diagnosis and general treatment options of FI.

2.3.1 Epidemiology and causes of FI

It is estimated that 2-5% of the adult population of Western countries suffers from FI (Hayden and Weiss 2011, Ruiz and Kaiser 2017, Sharma et al. 2016). According to a population-based study conducted in Finland, the incidence of FI among Finnish adults is 10.6% (Aitola et al. 2010). A more recent, large-scale study conducted in the United States revealed the prevalence of FI among adults to be 8.26% (Ditah et al. 2014). FI is more common among women, with two thirds of patients being female. FI is also more prevalent in the elderly population, with up to 50% of nursing home clients suffering from incontinence. (Aitola et al. 2010, Ruiz and Kaiser

2017, Hayden and Weiss 2011). The true incidence of FI is hard to evaluate and could in fact be even higher than reported.

The commonest cause of FI is history of obstetric injury, which explains why the majority of the patients suffering from FI are female (Chatoor et al. 2007, Ruiz and Kaiser 2017, Ditah et al. 2014). Other causes such as neurologic disease, inflammatory bowel disease, etc. can also contribute to the development of FI. The different causes of FI are listed in Table 1 (Ruiz and Kaiser 2017, Chatoor et al. 2007, Hayden and Weiss 2011).

Table 1 Aetiologic factors contributing to FI

Mechanism of FI	Aetiologic factors
Trauma	Obstetric injury, sexual abuse, anorectal trauma
Iatrogenic	Internal sphincterotomy, fistulotomy, haemorrhoidectomy, low anterior resection
Congenital	Spina bifida, meningomyelocele, Hirschsprung's disease, imperforate anus
Neurologic	Spinal trauma (other spinal pathologies), pudendal nerve atrophy, multiple sclerosis, diabetes mellitus
Functional	Crohn's disease, ulcerative colitis, proctitis malabsorption syndromes, chronic diarrhea, rectal prolapse/intussusception
Anorectal diseases	Haemorrhoidal disease, rectal prolapse, cancer

2.3.2 Diagnosis of FI

Since standards of hygiene, odors, etc. vary greatly among the general population, the quantification of the symptoms of FI is paramount in establishing an adequate diagnosis. This can be facilitated by using specific symptom severity scores. In addition, a thorough and detailed patient history will reveal the severity of FI and the impact it has on the individual's quality of life.

One of the first scores used to quantify the symptoms of FI was developed by Browning et al. This scoring system, though easy to use, was unable to

evaluate the severity of FI. It only assessed whether the patient was continent or not (Browning and Parks 1983).

Currently the most commonly used incontinence scoring systems in Finland and in Europe are the Wexner Incontinence Scale, alternatively known as the Cleveland Clinic Incontinence Score (Table 2), and the Vaizey score, also known as the St. Mark's score. In addition of being easy to use, these questionnaires can help evaluate the severity of symptoms of FI and alterations in lifestyle due to FI (Vaizey et al. 1999, Jorge and Wexner 1993, Frudinger et al. 2003).

Alternatively, the visual analogue score (VAS) can also be used to quantify FI symptom severity. Studies have shown the results of the VAS correlate well with specialised FI questionnaires. The VAS itself is not specific enough to replace specialised scoring tools (Paka et al. 2016, Devesa et al. 2013, Hussain et al. 2014, Harvie et al. 2018).

Table 2 The Wexner incontinence score (Jorge and Wexner 1993)

Type of incontinence	**Frequency of incontinence**				
	Never	Rarely	Sometimes	Usually	Always
Solid stool incontinence	0	1	2	3	4
Liquid stool incontinence	0	1	2	3	4
Gas incontinence	0	1	2	3	4
Use of pads	0	1	2	3	4
Lifestyle alterations	0	1	2	3	4

Sum of the points: 0- perfect continence; 20- total incontinence

2.3.3 Treatment of FI

There is a plethora of different treatment modalities for FI. The choice of treatment modality depends on the aetiology of FI and severity of symptoms. The treatment modalities specific to treatment of FI arising from OASI will be discussed in chapter 2.5.3 (Pages 39-42).

Treatment of FI starts by identifying the underlying cause of FI. Treatment of the underlying cause is essential in recovering optimum continence (Norton et al. 2007, Ruiz and Kaiser 2017). The initial treatment strategies of FI are conservative pharmacologic interventions as well as methods that address the dietary and behavioral aspects of bowel emptying. The goal is to slow down bowel motility and control the consistency of stools and times of bowel emptying (Figure 2) (Ruiz and Kaiser 2017, Bochenska and Boller 2016).

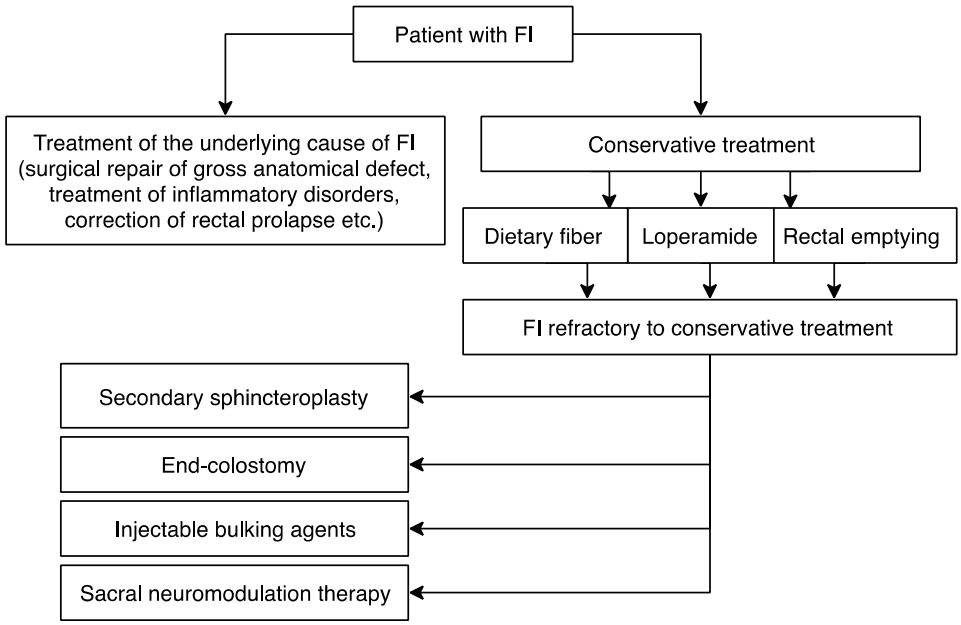

Figure 2 General treatment algorithm of FI

It has been shown that conservative treatment options such as dietary fibre supplementation decrease FI episodes (Forte et al. 2016, Paquette et al. 2015). Once conservative treatment has been deemed unsuccessful, other more invasive procedures are considered. The different treatment options and their effectiveness are presented in Table 3.

Table 3 Treatment options of FI and their relative effectiveness (Forte et al. 2016, Ruiz and Kaiser 2017, Paquette et al. 2015)

Type of intervention	Effect on FI
Dietary fibre supplementation	Reduces FI episodes by 2.5 times, no effect on QoL
Antidiarrheal medication	Reduces FI episodes by 10-30%. Side effects such as abdominal pain and constipation
Pelvic floor physiotherapy	Pelvic floor physiotherapy alone is not effective in reducing FI episodes. Effective when used in conjunction with other conservative treatment options.
Rectal irrigation	Shown to resolve FI in up to 44% of patients (van der Hagen et al. 2012)
Injectable bulking agents	No proven long-term efficacy. A minor effect on FI in the short term.
Sacral neuromodulation	Once implanted with a permanent stimulator 51-100% of the patients experience complete continence.
Posterior tibial nerve stimulation	Up to 40% of patients have shown improved continence
Sphincteroplasty	A majority of patients experience a marked improvement of FI postoperatively. Continence deteriorates over time.
End-colostomy	All patients achieve total continence.

2.3.4 FI and quality of life (QoL)

The impact of FI on quality of life (QoL) is a clearly negative one. Patients with FI are often constrained to their homes and unable to work or move freely. In less drastic cases patients will need to map out their routes in order to have toilet facilities close by to avoid accidents (Ratto et al. 2012, Meyer and Richter 2015). FI also has a marked negative impact on sexual

function (Imhoff et al. 2012). Patients with FI tend to suffer more often from major depression, compared to the general population (Heymen 2004).

Since the impact of FI on QoL is experienced differently by each individual, standardized questionnaires are helpful in quantifying the effect of FI on QoL (Bols et al. 2013). General QoL questionnaires, such as the SF-36 questionnaire, are not sensitive enough to register changes of QoL for specific conditions such as FI. Disease-specific questionnaires will yield a more specific result and should be used whenever possible (Rockwood 2004). The first FI-specific QoL tool developed, which is perhaps the most widely used, is the faecal incontinence quality of life index (FIQL). This questionnaire comprises of 29 questions and assesses the impact of FI on lifestyle, embarrassment, depression and behavior. The results of FIQL correlate well with incontinence scores such as the Wexner score (Bols et al. 2013, Meyer and Richter 2015). The FIQL score cannot be used to evaluate treatment success as it assesses only the impact of FI on QoL and not the severity of FI symptoms. Additionally, the FIQL questionnaire is rather cumbersome to fill out, especially compared to the Vaizey and Wexner questionnaires, which limits its use in clinical practice (Bols et al. 2013).

2.4 Obstetric anal sphincter injuries (OASI)

2.4.1 Epidemiology of OASI

The incidence of obstetric anal sphincter injuries (OASI) varies from country to country and is somewhat dependent on the traditions of obstetric care.

There are numerous studies on the incidence of OASI. The reported incidence varies and has been estimated to be as high as 11% of all births (Dudding et al. 2008b). More recent studies have revealed that the true incidence of OASI is probably around 0.5–3% of all registered births. Incidence of OASI is much higher among primiparous women (Laine et al. 2009, Gurol-Urganci et al. 2013, Thiagamoorthy et al. 2014). The incidence of OASI has been steadily rising in Scandinavia and the UK in the past two decades. The reasons for this are unclear, but the rise could be attributed to increasing maternal age and birthweight of the children. Recent changes

in methods of preventing OASI have brought a slight decline in the incidence of OASI in Sweden, Denmark, and Norway (Marschalek et al. 2018, Laine et al. 2009, Thiagamoorthy et al. 2014).

Studies where women were evaluated postpartum with EAUS revealed that the incidence of OASI could be as high as 35% in all primiparas (Sultan et al. 1993). The incidence of OASI in Finland was 1.2% of all births registered in 2016. OASI was found to be around three times more common among primiparous women than in multiparas. The same study revealed OASI to be related to instrumental delivery (Heino et al. 2017). Other risk factors, such as Asian ethnicity, large birthweight, and prolonged second stage of labour, have also been associated with the development of OASI (Ramm et al. 2018, Smith et al. 2013a).

2.4.2 Classification of OASI

Perineal injuries can be classified according to severity into four degrees or grades, as described by Sultan et al. in 1999 (Sultan 1999a).

The first-degree perineal tear involves only the perineal skin and vaginal mucosa.

In second-degree tears the injury is constrained to the perineum involving perineal muscles but not the anal sphincters.

A third-degree perineal tear involves the anal sphincter complex and is further subcategorised as a Grade 3a tear, where less than 50% of the thickness of EAS is torn; a Grade 3b, where more than 50% of EAS thickness is torn; and a Grade 3c tear, where the tear involves the full thickness of the EAS and also the IAS, with the rectal mucosa intact.

A fourth-degree tear involves the EAS, IAS, and the wall of the rectum. In a fourth degree tear the injury penetrates the anorectal mucosa.

Both third- and fourth-degree tears involve the anal sphincters, and due to that are classified as obstetric anal sphincter injuries (Table 4).

Table 4 Grading of perineal tears, according to Sultan et al.

Grade 1	Superficial tear of the vaginal mucosa
Grade 2	Tearing of the vaginal mucosa and perineal muscles
Grade 3 a	Tear of EAS, with <50%of the muscle thickness involved
Grade 3 b	Tear of EAS, with >50%of the muscle thickness involved
Grade 3 c	Complete EAS and IAS tear
Grade 4	Tear involving the rectal mucosa

OASI can also manifest in the form of an occult injury. In the case of an occult injury, there is no clear perineal defect detectable postpartum or the injury is diagnosed as a second-degree tear. Occult sphincter injuries can be detected only by imaging studies. The incidence of this type of injury has not been studied thoroughly. Studies that have been conducted on the matter have revealed the incidence of occult sphincter injury to be from 1.2% to 23% in all deliveries. Probably the true incidence of occult injury is well below 5% (Pinta et al. 2004b, Andrews et al. 2006, Fowler 2009).

2.4.3 Risk factors for OASI

The main risk factors for OASI are instrumental delivery (particularly forceps delivery), high birthweight, primiparity, Asian ethnicity, and prolonged second stage of labour (Donnelly et al. 1998, Smith et al. 2013b, Staric et al. 2017, Rosen et al. 2015). A short perineal body has also been associated with an increased risk of OASI (Geller et al. 2014, Lane et al. 2017). According to some researchers, the use of epidural analgesia also contributes to the development of OASI (Kapaya et al. 2015, Groutz et al. 2011).

The effect of mediolateral episiotomy on the incidence of OASI has been a matter of debate (Revicky et al. 2010, Dahl and Kjolhede 2010). A large registry-based study conducted in Finland found the incidence of OASI increased as the rates of episiotomy declined (Raisanen et al. 2013b). Other studies have shown episiotomy to be a risk factor for OASI (Ramm et al.

2018). A Cochrane Review found there to be no evidence that routine episiotomy will protect against perineal trauma. In selected cases, where instrumental delivery is anticipated, the use of episiotomy will help to prevent severe perineal trauma. Routine use of episiotomy is not recommended. In cases where there is no need for instrumental delivery, routine episiotomy will increase the risk of OASI (Jiang et al. 2017, Marschalek et al. 2018).

2.4.4 Prevention of OASI

The first documented technique for the prevention of obstetric tears was described by DeWees in 1889. It is known as the flexion technique. The manoeuvre involves applying pressure on the foetal head, with one hand to maintain it in flexion until crowning. The other hand applies pressure to the perineum.

In 1903 Ritgen described a manoeuvre where two fingers were placed in the anus of the woman. Simultaneous forward and upward pressure was applied to the foetus's head between contractions. This manoeuvre was later modified by placing the two fingers on the perineum instead of inserting them in the anus (Cunningham 2008).

A modification of the Ritgen's manoeuvre was described in 1976. The modified manoeuvre was performed during a contraction. There were no other differences between the modified manoeuvre and the original.

The Finnish manoeuvre was described by Pirhonen et al. in 1998. In this manoeuvre, the speed of crowning is controlled by applying pressure on the head of the foetus. The first and second finger are then used to support the perineum while the flexed third finger is used to grip the foetus's chin. After achieving control of the foetus's chin, the woman is instructed to stop pushing and the midwife slowly delivers the foetus's head manually through the perineal ring (Pirhonen et al.).

Observational studies conducted in Scandinavia show that implementation of the Finnish method can reduce the incidence of OASI (Poulsen et al. 2015). Most publications on these manoeuvres' effects on the incidence of OASI have been large registry-based studies. A prospective randomised trial on the effectiveness of the Ritgen manoeuvre was unable to show any decrease in the incidence of OASI (Jönsson et al. 2008).

Focusing on risk factors associated with obstetric injury is of key importance in reducing the incidence of OASI. Unfortunately, there are no measures available to completely prevent OASI from occurring during vaginal delivery (Kapaya et al. 2015, Räisänen et al. 2012).

2.4.5 Primary diagnosis of OASI

Diagnosis of OASI is done immediately postpartum. The vaginal tear is inspected and a rectal examination is performed. The postpartum assessment must be carried out with proper lighting and anaesthesia, preferably in an operating room setting. The patient must be positioned in a way that the perineum is visible and accessed easily. Bleeding and oedema can make the primary diagnosis of OASI rather challenging (Samuelsson et al. 2000). Palpation of the sphincter muscles via the rectum is the single most important diagnostic tool in diagnosing sphincter lesions postpartum (Harvey 2015, Baghestan et al. 2010). The diagnosis of OASI requires experience. Training programmes on the detection of OASI have shown to increase knowledge on the surgical repair of OASI. Currently there are no publications on the effect of these training programmes on treatment outcomes of OASI (Vieillea et al. 2014, Zimmo et al. 2017, Patel et al. 2010). The use of EAUS immediately postpartum does not increase the accuracy of the diagnosis of OASI. The use of EAUS will help to identify occult anal sphincter injuries, which, as discussed earlier, can occur in up to 23% of vaginal deliveries (Pinta et al. 2004b, Andrews et al. 2006). In a Cochrane Review from 2015, the use of EAUS prior to repair of OASI was shown to improve continence outcomes (Walsh and Grivell 2015).

2.4.6 Primary repair of OASI

In Finland, the primary repair of OASI is conducted by a gynaecologist or a gastrointestinal surgeon. Regardless of the speciality of the attending physician, the repair of OASI requires experience or supervision by a physician experienced in the field. It is recommended that the primary repair of OASI be postponed if experienced personnel are unavailable. Postponing the repair up to 24 hours is acceptable and has no negative effect on the outcome (Dudding et al. 2008a). One study has even suggested that a delay of up to 72 hours will not have any negative long-term results compared to immediate repair; these result have not since been replicated (Soerensen

et al. 2008). Surgical repair of OASI must be conducted in operating room conditions, under adequate lighting and with proper instrumentation. The patient must be anaesthetised. Either general or epidural analgesia is recommended for the repair (Harvey 2015, Abdou and al 2007, Aigmueller et al. 2015).

2.4.6.1 Technique

It is currently recommended that when attempting a primary repair of OASI, the EAS must be sutured using the overlapping technique. This technique was first described by Parks and McPartlin (1971) for the secondary repair of sphincter defects. Later, this method was adopted to be used in the primary repair of OASI (Sultan 1999b) (Figures 3 and 4). If possible, the IAS must be approximated using interrupted stiches (Roos et al. 2010,

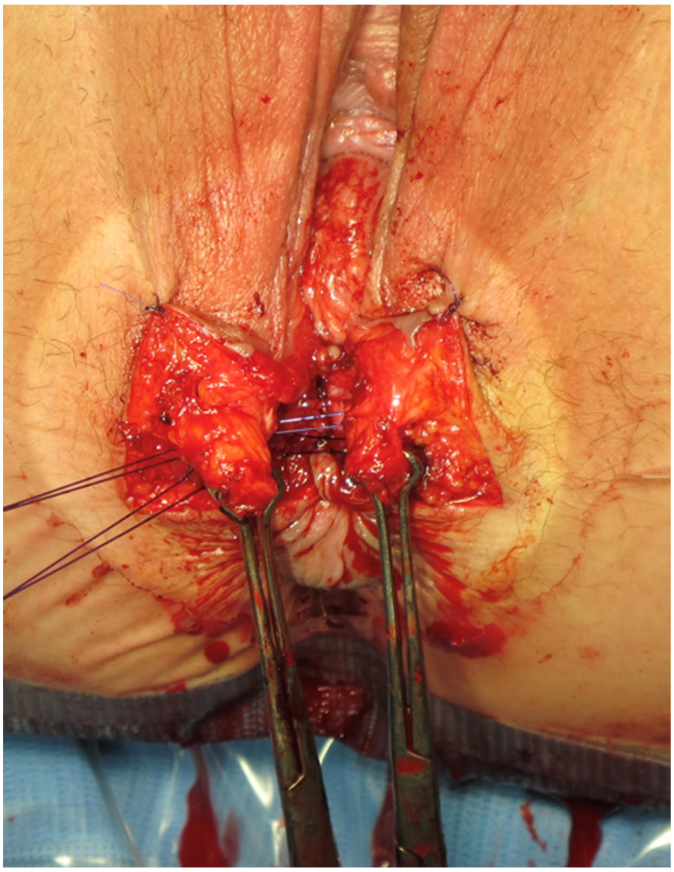

Figure 3 Intraoperative image of overlapping SP

Sultan 1999b). Studies have shown the overlapping technique to be superior to end-to-end suturing of the EAS (Rygh and Korner 2010, Lepisto et al. 2008, Fernando et al. 2013).

The repair technique depends on the grade of the tear. In Grade 4 tears the anal mucosa is first repaired using rapidly absorbable interrupted sutures. Then the IAS is sutured, if identified, using interrupted 3-0 monofilament sutures. In Grade 3a sphincter injuries, the approximation of the torn sphincter muscles is sufficient. In Grade 3b and c injuries, an overlapping repair using 2-0 monofilament U-shaped sutures is recommended. The overlapping repair requires the mobilisation of the muscle fibres, so that a 0.5–1cm overlap is achieved (Fernando et al. , Sultan 1999b, Williams et al. 2006, Abdou and al 2007, Aigmueller et al. 2015, Temtanakitpaisan et al. 2015).

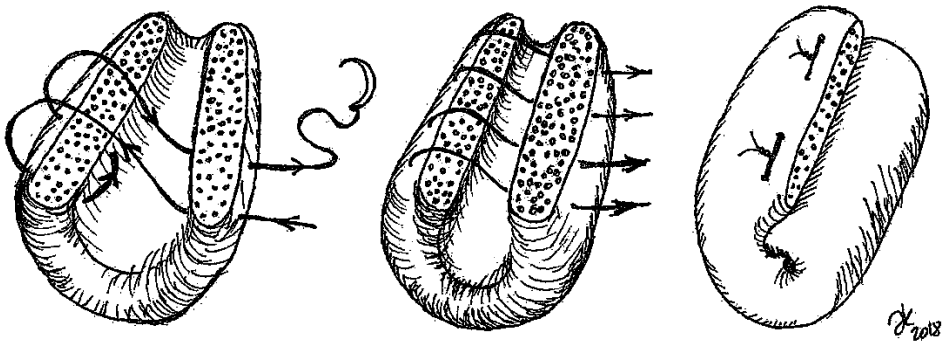

Figure 4 Schematic representation of the overlapping sphincteroplasty

2.4.6.2 Suture materials

There is scarce evidence on the effect of different suture materials on the outcome of the repair of OASI. Current guidelines recommend the use of slow absorbable sutures, such as polydioxanone (PDS) or polyglactin (Vicryl®) (Harvey 2015, Abdou and al 2007, Aigmueller et al. 2015). These recommendations are based on a single randomised controlled trial comparing PDS with Vicryl® in repairing OASI. The results of this trial showed no statistical difference in wound healing between the two suture materials (Williams et al. 2006).

2.4.6.3 Postoperative management

Postoperative antibiotics have been shown to reduce the risk of wound complications after surgical repair of OASI (Buppasiri et al. 2014). There is no consensus on the duration of the antibiotic regime nor on which antibiotic should be prescribed. One randomised trial on the length of the antibiotic regimen post-OASI showed that a seven-day antibiotic treatment decreased perineal wound complications compared to a single dose of preoperative antibiotic prophylaxis (Duggal et al. 2008).

In Finland women diagnosed with OASI are prescribed an antibiotic regimen similar to the one described by Duggal et al. They receive intravenous antibiotics for the duration of the hospital stay, which is followed by a seven-day oral regimen after discharge.

Laxatives should be prescribed to women with OASI to prevent unnecessary straining and pressure on the anal sphincter (Sultan 1999b). There have been no studies on the long-term effects of laxative use after the repair of OASI. A randomised controlled trial found that the use of lactulose after SP reduced the pain of the first bowel movement postpartum (Mahony et al. 2004a).

Not prescribing laxatives or antibiotics after the repair of OASI can lead to the failure of primary SP. Lactulose is prescribed to all women following the repair of OASI in Finland.

Most patients who have been diagnosed with OASI in Finland are referred to a physiotherapist for pelvic floor physiotherapy and biofeedback. There is little evidence on the effect of biofeedback therapy following OASI. Studies on the subject are mostly based on women with existing symptoms of FI and ROASI. It has been shown that biofeedback improves the symptoms of women with ROASI (Kairaluoma et al. 2004b, Mahony et al. 2004b), though a Cochrane Review from 2012 found neither biofeedback nor pelvic floor physiotherapy effective enough to be recommended as a sole treatment modality for FI (Norton and Cody 2012). In a more recent Cochrane Review, pelvic floor physiotherapy alone was found to have no effect on the symptoms of FI postpartum (Woodley et al. 2017). Biofeedback therapy in conjunction with other treatment modalities, such as antidiarrhoeal agents and physiotherapy, may have a synergic effect in preventing symptoms of FI postpartum (Scott 2014).

2.4.7 Outcomes of the primary sphincter repair

One of the reasons why evaluation of the treatment success of OASI is so challenging is the fact that the majority of women experience some form of incontinence postpartum. This has been attributed to pudendal nerve neuropathy due to the nerve being subjected to shearing forces during vaginal delivery (Snooks et al. 1984). Usually, in the absence of OASI, these symptoms subside (Johannessen et al. 2018, Borello-France et al. 2006, Rusavy et al. 2016, Lo et al. 2010, Fonti et al. 2009).

The short-term outcomes of the repair of OASI show that as many as 75% of women have a persistent sphincter defect detected on sphincter imaging. About the same percentage of women have reported either FI or faecal urgency (FU) (Pinta et al. 2004a, Lohuis and Everhardt 2014). Gas incontinence (GaI) can occur in up to 61% of patients (Pinta et al. 2004a). It would seem that the symptoms of incontinence subside over time. Medium-term results indicate that the incidence of FI and GaI after the repair of OASI is around 20–30% (Molander et al. 2007, Marsh et al. 2011, Dickinson et al. 2013). This suggests that the symptoms of FI could indeed subside over time, though only a few studies on this matter have been published, with contradicting results (Barisic et al. 2006, Salim et al. 2014, Lo et al. 2010).

FU seems to be a much more common symptom than FI, occurring in 35% of women after medium-term follow up (Marsh et al. 2011)

Long-term follow-up of patients with OASI suggests that symptoms of incontinence persist in 29–59% of women. Most of them complain of GaI and FU rather than FI. Studies where patients with OASI were compared to women without OASI revealed that 3–24% of the women in the control group also reported symptoms of FI (Samarasekera et al. 2008, Bharucha et al. 2012, Sundquist 2012).

The symptoms of FI seem to be dependent on the initial severity of OASI. Patients with a more severe perineal tear are more likely to have longer-lasting symptoms of FI. According to Jangö et al. (2017) women with a Grade 4 perineal tear had more expressed symptoms of FI than patients with Grade 3a and Grade 3b tears (Evers et al. 2012, Roos et al. 2010, Salim et al. 2014, Jango et al. 2017b, Barisic et al. 2006, Cornelisse et al. 2016, Soerensen et al. 2013, Sundquist 2012).

In addition to poorer continence, women with a history of OASI reported suffering more from stress urinary incontinence, dyspareunia, and pain

during defecation (Marsh et al. 2011). Although the effect of OASI on quality of life has yielded somewhat contradictory results, it can be said that OASI has a general and profound negative effect on the quality of life. According to studies conducted with healthy controls, up to 82% of women with a history of OASI reported deteriorated quality of life (Evers et al. 2012, Cornelisse et al. 2016, Sundquist 2012, Tucker et al. 2013, Fodstad et al. 2016, Kumar et al. 2012, Palm et al. 2013, Raisanen et al. 2013a). Women with a history of OASI are reported to have deteriorated sexual function postpartum compared to healthy individuals (Visscher et al. 2014, Fodstad et al. 2016). A study by Fodstad et al. (2016) revealed that women with a history of OASI will postpone coitus longer than controls without OASI.

2.4.8 Reasons for repair failure

According to previously published research, up to 75% of women with a history of OASI have a persistent EAS or IAS defect detected upon imaging (Pinta et al. 2004a, Lohuis and Everhardt 2014). Long-term outcome studies have shown that only a fraction of women with a persistent sphincter defect are in fact incontinent (Frudinger et al. 2008).

The reasons for these poor outcomes can be dependent on the factors influencing the repair of OASI, such as the use of end-to-end repair instead of the overlapping technique, use of inappropriate suture materials, or failure to prescribe antibiotics and laxatives postoperatively.

It has been shown conclusively that the use of the overlapping SP technique improves the primary outcomes of the repair (Rygh and Korner 2010, Fernando et al.). The dissection of the EAS to facilitate the overlapping repair may cause deinnervation of the muscle and contribute to a poorer functional outcome of the repair (Malouf et al. 2000a); however, according to Fernando et al., patients who have undergone the overlapping primary SP have a slower deterioration of symptoms compared to those who have undergone an end-to-end SP (Fernando et al. 2013).

As discussed earlier, the grade of the perineal tear on diagnosis seems to influence the functional outcome of primary SP. Due to more excessive bleeding and tissue damage, the severity of the tear has a direct influence on the complexity of the repair (Roos et al. 2010). Reasons for failure of primary SP have not been studied in great depth. Studies published on this matter to date have not been able to identify any patient-dependent factors

that could contribute to the failure of the primary SP (Glasgow and Lowry 2012).

It has been shown that proper diagnosis and treatment of OASI is essential in achieving adequate long-term continence. Following educational programmes, physicians have displayed better theoretical knowledge and a more adequate detection of OASI than before the training, but currently there is no evidence available on the effects of these programs on the outcomes of OASI repair (Vieillea et al. 2014, Krissi et al. 2015).

2.5 Residual obstetric anal sphincter injuries (ROASI)

2.5.1 Definition

Despite adequate repair of OASI, women with a history of such an injury can have defects of the anal sphincter detected on postpartum imaging studies. As discussed before, a small proportion of OASI can manifest as occult sphincter injuries, with no direct sphincter defect detected on postpartum clinical examination (Pinta et al. 2004b, Andrews et al. 2006).

In this paper, we will define these tears as residual obstetric anal sphincter injuries (ROASI). The aetiology of ROASI is heterogeneous: it involves women with missed OASI, occult OASI, and those who have undergone appropriate primary repair of OASI, but have a sphincter defect detected upon follow-up imaging.

The repair of OASI can be defined as primary repair, which occurs immediately postpartum, or secondary repair. The secondary repair occurs months if not years after the initial injury. Alternatively, secondary repair can be defined as repair of ROASI.

2.5.2 Diagnosis of ROASI

Diagnosis of ROASI is challenging. As discussed earlier, postpartum FI occurs often and is not always caused by a sphincter injury. Evaluation of continence status using designated questionnaires at the maternal outpatient clinic is usually the first modality of diagnosis.

The diagnosis of ROASI relies heavily on imaging of the anal sphincter musculature. Currently no method other than ultrasound or MRI has been able to adequately detect ROASI (Faltin et al. 2005, Sultan et al. 1994). There is a variation of ultrasound and MR imaging modalities available that can be used to image the anal sphincter complex. Each of these modalities has its own limitations. EAUS has been the gold standard for diagnosing ROASI; alternatively, MRI with either endoanal or endovaginal coils, external phased-array MRI, or transperineal ultrasound can be used (Eisenberg et al. 2018).

Anorectal physiology testing is important in evaluating the neuromuscular function of the sphincter complex. Anal manometry (AM) and pudendal nerve terminal motor latency (PNTML) are the methods of choice for evaluating the contractile strength and the innervation of the anal sphincters (Dudding et al. 2008b, Roos et al. 2012).

2.5.2.1 Clinical evaluation of ROASI

The clinical evaluation of ROASI begins with the taking of patient history. It is important to retrieve a detailed obstetric anamnesis. History taking will give additional information on the severity of symptoms and the patient's expectations of possible treatment outcomes (Dudding et al. 2008b, Sultan et al. 1994).

Clinical evaluation of the perineum is essential in determining whether the patient has a patent rectovaginal fistula, which is a definite indication for SP and surgical closure of the fistula (Saclarides 2002, Hibbard 1978). Perineal scarring and shortening of the perineal body can also be an indication of a possible sphincter lesion (Frudinger et al. 1997, Lane et al. 2017).

Though it has been shown that palpation and clinical evaluation are not diagnostic in determining sphincter lesions, this will give the physician the first impression of sphincter tone and possibly even rule out sphincter injury as the cause of FI. A well-conducted primary clinical evaluation will aid in the planning of further diagnostic procedures if necessary (Jeppson et al. 2012, Dobben et al. 2006).

Patients over 50 years of age should also undergo colonoscopy to rule out possible adenomas or cancerous lesions of the colon and rectum. Presence of such lesions could affect planned treatment strategies for ROASI.

2.5.2.2 FI questionnaires and symptom scoring

To facilitate adequate evaluation of the severity of symptoms, it is essential that the symptoms of FI be objectified. The use of standardised FI symptom scoring questionnaires is one of the means to achieve this. Standardised scoring can help to determine the severity of the symptoms of FI, which could be difficult for some patients to adequately verbalise. FI questionnaires can also help in identifying patients who require further imaging studies and possible surgical treatment.

Some treatment modalities such as SNM rely on FI questionnaires to evaluate the feasibility and success of treatment.

The commonly available scores were discussed earlier in chapter 2.3.2 (Page 19).

A study published by Frudinger et al. (2003) showed that the sensitivity of FI symptom severity questionnaires was 57.1% in detecting EAS defects. Though FI questionnaires cannot be considered a diagnostic tool per se, they can detect deterioration of FI symptoms and help guide and plan further diagnostic studies.

2.5.2.3 Endoanal ultrasound (EAUS)

The first paper on the use of EAUS was published in 1989 by Law et al. The first EAUS images were two-dimensional. The length of the defect was determined by moving the probe manually along the anal canal (Law et al. 1991, Law and Bartram 1989). Later developments saw the creation of 3D EAUS, which is much less operator-dependent imaging modality and allows for post hoc evaluation of the images in multiple planes. These features allowed for a more detailed evaluation of the structures of the anal canal (Gravante and Giordano 2008, West et al. 2005).

Before the development of EAUS, there were no methods available for imaging the anal sphincters. Since its introduction EAUS has rapidly evolved to be the gold standard for diagnosing OASI (Solan and Davis 2013, Albuquerque 2015).

The 3D EAUS imaging procedure is performed with the patient in the lateral prone or the jack-knife position. The endoanal probe is inserted into

the anal canal, and after initiation of the imaging process, a rotating ultrasound transducer moves in the proximal-distal direction inside the probe to obtain images. Using specialised software, the 3D image of the anal canal is created in real time. Though this is a quick and reliable imaging modality, it can cause some discomfort to the patient during the insertion of the probe (Figure 5). The imaging procedure itself, depending on the type and manufacturer of the hardware, usually takes no more than a minute (Brillantino et al. 2015).

Figure 5 3D EAUS device. The imaging probe is marked with an arrow

3D EAUS imaging produces a volumetric cube (Figure 6), where the IAS appears as a hypoechogenic circular structure; the EAS in contrast appears as a hyperechogenic structure. 3D EAUS allows for the imaging of the anal canal, EAS, and the most cranial aspect of *m. puborectalis* (Abdool et al. 2012). The levator plate and other aspects of the pelvic floor cannot be imaged using 3D EAUS (Gravante and Giordano 2008). 3D EAUS is unsuitable for evaluating sphincter atrophy. A study by West et al. demonstrated

this convincingly (West et al. 2005). In the case of a rectovaginal fistula, 3D EAUS may be used to gain more information about the fistula tract.

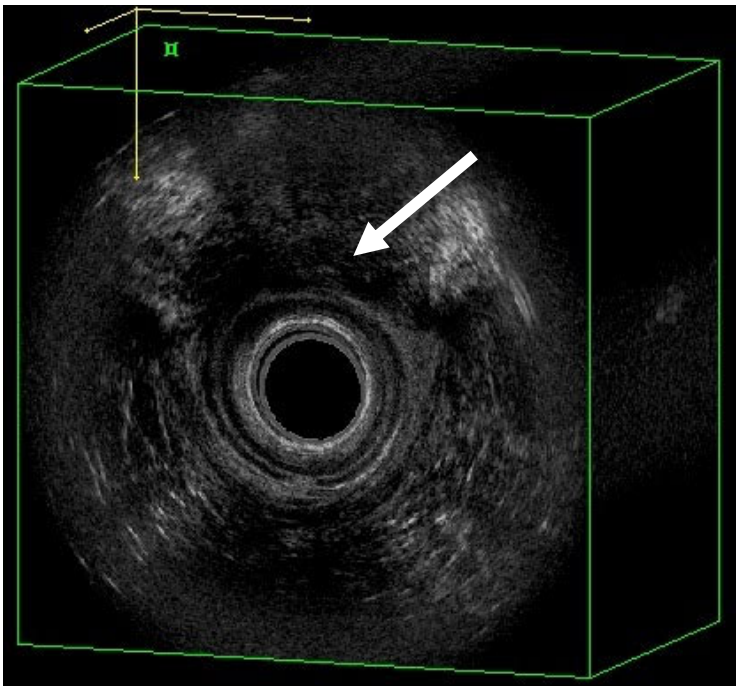

Figure 6 3D EAUS image of an anterior EAS defect (marked with a white arrow)

2.5.2.4 Magnetic resonance imaging (MRI)

The use of magnetic resonance to produce images of the human body was first described by Paul Lauterbur in 1973. In 2003 Lauterbur and Mansfield were awarded the Nobel Prize for the development of MRI. MR images are produced when the patient lies in a strong and static magnetic field. This magnetic field causes the alignment of all the hydrogen atoms or protons in the body. A radio frequency impulse is used to excite the protons, which then spin out of alignment. Different receiver coils are used to detect the energy released as the protons realign with the magnetic field. The improvement in MR image quality has been enormous in the past decade. Developments such as the introduction of high field-strength superconducting magnets and phased-array coils allow for the acquisition of very precise images of various tissues (Edelman 2014).

MRI was first used to image obstetric injuries in the 1990s (Aronson et al. 1990). The quality of the earlier images did not allow for the imaging of the sphincter complex without endoanal coils. Studies comparing 3D EAUS and MRI with endoanal coils have shown that endoanal MRI is as precise as 3D EAUS in diagnosing EAS defects (Hussain et al. 1996). Some of these studies revealed 3D EAUS to be superior in detecting IAS defects (Tan et al. 2008a, Malouf et al. 2000b, West et al. 2005).

External phased-array MRI has been found to be comparable to MRI with endoanal coils in detecting IAS and EAS lesions (Figure 7). A study comparing the two modalities found that there was no difference between them in the accuracy of detecting sphincter defects (Terra et al. 2005).

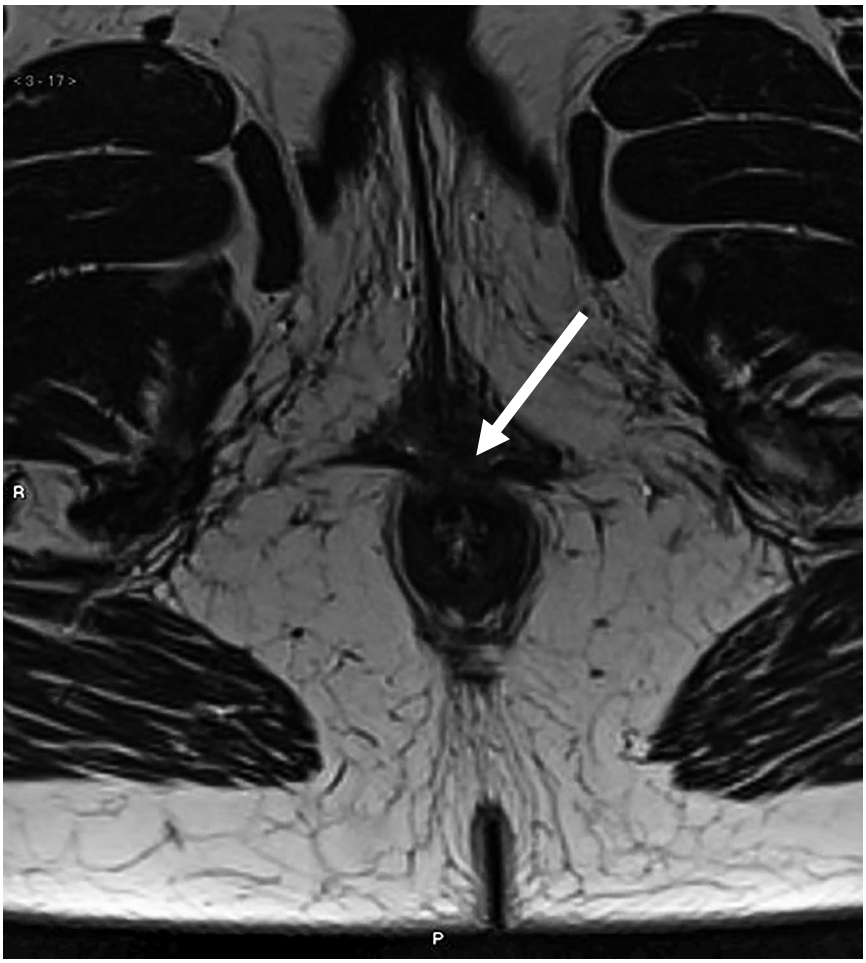

Figure 7 MR image of an EAS defect. The defect is marked with an arrow

Though MRI performed using either the endoanal or the external phased-array coils allows for the precise imaging of the anal sphincters, it is an expensive imaging method, especially compared to EAUS. Additionally, the imaging procedure is lengthy and cannot be performed on individuals with metallic implants, implanted electronic devices, or severe claustrophobia.

2.5.2.5 Anal manometry

Anal manometry (AM) is a useful tool for evaluating sphincter function. Previously, the standard method for evaluating sphincter function was water perfused AM. This method gives an adequate estimate of the squeeze and resting pressures of the anal canal, though it is unable to identify the exact location of the low-pressure areas. Decreased squeeze pressure indicates a defect in EAS function. A drop in the resting pressure usually indicates a loss of function of the IAS (Corsetti et al. 2010, Pedersen and Christiansen 1989). Though AM is currently the method of choice for evaluating anal sphincter function, studies have not shown a clear connection between the decreased squeeze and resting pressures and the symptoms of FI (Roos et al. 2012, Nordenstam et al. 2010).

Recent years have seen the development of AM hardware. Three-dimensional high-resolution AM (3DHRAM) enables the evaluation of rectal pressures in more detail. Three-dimensional modelling of the pressure readings produces a pressure topogram of the anal canal (Lee et al. 2013). The pressure topogram allows for the localisation of low-pressure areas. The use of 3DHRAM has been proposed for the detection of sphincter defects, though its accuracy is not comparable to 3D EAUS (Vitton et al. 2013b, Vitton et al. 2013a).

2.5.3 Treatment of ROASI

The treatment of ROASI depends largely on the continence status of the patient. In Finland, the primary treatment of patients with ROASI is conservative medical treatment in combination with biofeedback therapy and pelvic floor physiotherapy. If patients are symptomatic immediately postpartum or not responsive to conservative treatment, other more invasive treatment options are considered.

2.5.3.1 Conservative treatment

The first line of treatment of patients with ROASI and symptomatic FI is conservative. The medical treatment regimen is comprised of antidiarrhoeal agents and dietary fibre supplements. Though no studies have been conducted exclusively on patients with ROASI, there is evidence that dietary fibre reduces the frequency of FI episodes. (Bliss et al. 2001). In a randomised controlled trial conducted by Bliss et al. (2001), it was found that only supplements containing psyllium reduced the frequency of FI episodes.

Antidiarrhoeal agents such as loperamide can also be used to treat FI. Loperamide is a synthetic μ-receptor agonist that is not resorbed in the bowel. Loperamide has shown to reduce episodes of FI. Treatment with loperamide can have notable side effects such as constipation and abdominal pain (Omar and Alexander 2013, Norton et al. 2007).

Rectal irrigation can also offer alleviation of the symptoms of FI. Studies have shown this method to have some effect in alleviating symptoms, but the effect is limited compared to more invasive procedures (Sturkenboom et al. 2018, Crawshaw et al. 2003).

As discussed earlier the effectiveness of biofeedback and physiotherapy on FI is somewhat unclear. There have been studies published that show effectiveness of biofeedback therapy regardless of the presence of sphincter defects (Norton et al. 2003, Norton and Kamm 1999). The same authors later concluded in a Cochrane Review that there is insufficient evidence to advocate biofeedback therapy for FI (Norton and Cody 2012). A study of patients with a history of OASI showed a marked decrease in the Wexner scores after a period of biofeedback treatment (Ghahramani et al. 2016). A recent randomised trial, though not conducted on patients with ROASI, showed that the combination of physiotherapy, medical, and biofeedback treatment was effective in reducing symptoms of FI (Sjödahl et al. 2015).

2.5.3.2 Sphincteroplasty

Secondary SP for ROASI has been the gold standard of treatment for patients with sphincter defects and symptomatic FI (Fernando et al. 2006, McNicol et al. 2010). This mode of treatment has been challenged in the past decade by Sacral Nerve Modulation (SNM) treatment.

The technique of secondary SP was first described in 1971 by Parks et al. (Parks and McPartlin 1971). Repair of ROASI should be attempted no earlier than 3 months from delivery (Barisic et al. 2006). The technique involves the opening of the skin with a semi-circular incision above the suspected injury site, which is usually anteriorly between the anus and the vagina. From there the sphincter defect is explored and the ends of the EAS dissected free of the surrounding tissues. If applicable and possible, the IAS defect is also explored. Usually the IAS cannot be identified intraoperatively. The EAS is repaired using the overlapping technique (McNicol et al. 2010). A diverting stoma is not recommended as it does not improve wound healing or the functional results of the secondary repair (Hasegawa et al. 2000).

Outcomes of secondary SP have been somewhat disappointing. A systematic review on the matter published by Glasgow et al. concluded that the symptoms of FI in patients who have undergone secondary SP deteriorate over time (Glasgow and Lowry 2012). The reasons for these poor outcomes are unclear, although age has been suggested as one of the factors contributing to an unsatisfactory outcome. Results from studies published on this matter have been contradictory (Pinta et al. 2001, El-Gazzaz et al. 2012). Other studies have proposed atrophy of the EAS as a reason for a poor outcome of secondary SP (Briel et al. 1999).

There are absolute indications for secondary SP, such as a patent rectovaginal fistula or other visible perineal defects (Saclarides 2002, Hibbard 1978). Currently, the mere presence of a sphincter defect detected upon imaging is not an indication for secondary SP. Recent evidence suggests that symptomatic patients with a patent sphincter lesion have benefitted more from SNM treatment than from SP (Rodrigues et al. 2017).

2.5.3.3 Sacral Nerve Modulation (SNM) Therapy

The method of SNM was first described by Tanagho et al. in 1982. The method was first used for the treatment of urinary incontinence and retention (Tanagho and Schmidt 1982). Since then SNM treatment has established itself as the first line of surgical treatment for FI (Goldman et al. 2018).

With the initial successful experiences of SNM treatment, the necessity of surgical sphincter repair has been questioned. If patients have a patent

sphincter defect detected upon imaging, SP prior to SNM treatment is not necessary. Studies have shown that a patent sphincter lesion does not affect the outcome of SNM treatment (Ramage et al. 2017, Boyle et al. 2009, Rodrigues et al. 2017, Noblett and Cadish 2014).

The history, surgical technique, and outcomes of SNM treatment will be described in more detail below.

2.6 Sacral neuromodulation therapy for faecal incontinence

2.6.1 History

The first SNM implantation was done by Tanango and Schmidt in 1982 in California. The method was initially described as an open technique, where an electrode was implanted adjacent to the sacral nerve root. Evaluating treatment feasibility requires testing patients with temporary SNM. The testing was initially conducted with a test electrode, which was explanted after test cessation regardless of the test outcome. Since then the implantation technique has evolved and currently uses a tined lead that is left in place after SNM testing and later used for permanent SNM.

In 1995 a study was published by Matzel et al. describing the effects of SNM on the symptoms of FI. SNM was approved by the European drug administration in 1994 for the treatment of urgency urinary incontinence. Approval of the Federal Drug Administration (FDA) followed in 1997. In 2010 the FDA approved the use of SNM for treatment of FI (Matzel et al. 1995).

The first SNM devices were implanted in Finland in 1996 for UI. The first implantation for FI was conducted in 1999. Since then there have been around 90 devices implanted in Finland annually (Kirss et al. 2018).

2.6.2 SNM mechanism of action

The exact mechanism of the effect of SNM on FI is unknown. There are several hypotheses of a possible mechanism of action.

S2-4 nerve roots are comprised of different nerve fibers: autonomic, somatic, efferent, and afferent sensory fibers. SNM has an effect on all of these fibers, with the most probable target being the large afferent sensory fibers. One possible mechanism of action might be the inhibition of a somatovisceral reflex mediated by the afferent fibres. This results in a decreased colonic motility and activation of IAS contractility. Though shown on animal models, this mode of action has not yet been conclusively proven in human trials (Dinning et al. 2007, Gourcerol et al. 2011, Vitton et al. 2008). A second possible mechanism of action is the activation of cortical centres associated with faecal continence control via afferent somatic fibres. Another suggested mode of action could be the inhibition of the ascending defecation reflex via the same afferent fibres (Gourcerol et al. 2011, Amend et al. 2011).

A study by Lundby et al. suggested that the mechanism of action of prolonged SNM treatment of at least two weeks could be associated with changes in the regions of the brain associated with learning. These changes are also mediated via the afferent fibres of the sacral nerve roots (Lundby et al. 2011).

2.6.3 SNM implantation technique

Currently SNM treatment relies on testing all patients with a temporary SNM. Studies have not been able to identify any predictive factors for the success of SNM treatment. Thus, a test phase is required to evaluate the feasibility of SNM treatment (Roy et al. 2014, Gourcerol et al. 2007). Prior to test phase initiation, the patient fills out all the relevant symptom severity questionnaires and keeps a diary of bowel habits and FI episodes for at least two weeks prior to test initiation.

The implantation technique involves the implantation of a tined electrode, which stays in place after the test phase and can be removed in case of an unsuccessful test or used for permanent SNM if testing proved successful (Janssen et al. 2017).

Currently the SNM implantation technique has been standardised and all centres in Finland use the technique described by Matzel et al. (2017). One of the key steps of this technique is the identification of the medial edge of the sacral foramina and the lower edge of the iliosacral junction. These landmarks are identified using intraoperative X-ray and marked on the pa-

tient's skin. This so-called H-marking facilitates the fast and easy identification of the correct sacral foramina. (Matzel et al. 2017). After a needle is inserted into the sacral foramina, electrical current is passed along the needle to achieve a motor response of the pelvic floor. The desired effect is the "bellowing" of the pelvic floor upon stimulation with low-voltage electricity. After confirming a satisfactory motor response, the electrode is implanted adjacent to the sacral nerve root which yields the best motor response with the lowest voltage. Electrode implantation is then carried out using the Seldinger technique. The electrode is guided adjacent to the sacral nerve root via a stylus under X-ray control.

Implantation is followed by a test phase with a temporary stimulator. The test phase lasts 2-4 weeks, during which patients return to normal daily activities. They are asked to keep a diary of FI episodes during the test phase. At the end of the test phase, patients fill out once more the symptom severity scoring questionnaires. If there is a 50% reduction in either FI episodes or FI scores, the patient is eligible for permanent SNM implantation. The consensus of Finnish SNM specialists is that the patient's subjective opinion of the treatment effect should also be taken into account when considering permanent SNM implantation. This in effect means that upon careful consideration, some patients are implanted with permanent SNM without reaching a 50% reduction in FI symptoms during testing.

2.6.4 Outcomes of SNM treatment for FI

Matzel et al. (1995) were the first to report successful SNM treatment results for patients with FI. Since then, other authors have published similar short-term outcome results (Matzel et al. 1995, Melenhorst et al. 2007). A multicentre study published by Altomare showed that SNM treatment had lasting long-term effects on the symptoms of FI (Altomare et al. 2015). Wexner et al. were able to show in a small retrospective trial that the outcomes of SNM were superior to secondary SP (Rodrigues et al. 2017).

Evaluation of SNM treatment success is somewhat challenging. There is no universal measure how the test phase or final treatment success should be evaluated. Currently test phase success is determined by at least a 50% reduction in either FI episodes or specific FI severity scores (Goldman et al. 2018). After implantation of a permanent device the same methods are used to objectify treatment success. QoL questionnaires may be used to evaluate SNM treatment's effect on QoL, which requires obtaining baseline

values from patients prior to test initiation. QoL changes should be measured by specialised questionnaires, such as the FIQL. QoL scores are cumbersome to obtain, which is why their use is limited to clinical research (Bols et al. 2013).

In a review article published in 2015, 13-88% (average 36.5%) of all patients tested for SNM implantation achieved total continence after permanent stimulator implantation (Mirbagheri et al. 2016). A much higher percentage of patients had a more moderate positive response (59-100%; average 88%). Outcomes of this study are presented in more detail in Table 5

Table 5 SNM treatment result for patients with FI (Mirbagheri et al. 2016)

Study (year published)	Sample size	Partial responders (%)	Total responders (%)
Matzel *et al.* (1995)	3	3 (100%)	2 (67%)
Vaizey *et al.* (1999)	9	8 (89%)	7 (78%)
Ganio *et al.* (2001)	19	17 (89%)	14 (74%)
Ganio *et al.* (2001)	25	22 (88%)	11 (44%)
Leroi *et al.* (2001)	9	8 (89%)	1 (11%)
Kenefick *et al.* (2002)	15	15 (100%)	11 (73%)
Matzel *et al.* (2004)	37	37 (100%)	12 (32%)
Leroi *et al.* (2005)	34	34 (100%)	5 (15%)
Jarret *et al.* (2005)	59	46 (78%)	19 (32%)
Kenefick *et al.* (2006)	19	19 (100%)	14 (74%)
Oz-Duyos *et al.* (2008)	47	28 (59%)	14 (30%)
Tjandra *et al.* (2008)	59	54 (91%)	25 (42%)
Altomare *et al.* (2009)	52	38 (73%)	9 (17%)
Boyle *et al.* (2011)	50	37 (74%)	8 (16%)
George *et al.* (2012)	25	23 (92%)	12 (48%)
Santoro *et al.* (2012)	28	28 (100%)	19 (68%)
Hull *et al.* (2013)	72	64 (89%)	26 (36%)
Oom *et al.* (2014)	46	37 (80%)	8 (17%)

SNM treatment has relatively low complication frequencies. The commonest complications are pain and infection at the implantation site. A study by Bielefelt et al. (2016) found that 20% of the patients treated with SNM in the United States undergo additional surgery due to complications. Explantation of the SNM device because of infection occurs in 1.6–1.97% of cases (Lee et al. 2017, Myer et al. 2018, Bielefeldt 2016).

SNM treatment has been shown to be successful in patients with patent sphincter lesions. The circumference of the sphincter lesion does not influence treatment outcome (Melenhorst et al. 2008, Chan and Tjandra 2008).

Currently SNM is accepted as the first line of surgical treatment for FI in Europe (Goldman et al. 2018).

The results of SNM treatment for patients with constipation and pelvic pain have not been comparable to treatment results for FI. Currently, the only official non-urologic indication for SNM treatment is FI (Thaha et al. 2015, Tirlapur et al. 2013)

3 AIMS OF THE STUDY

The aims of the present study were:

1) To identify the risk factors for a failure of the primary repair of OASI.
2) To compare external phased-array MRI to 3D EAUS imaging in diagnosing residual OASI.
3) To assess the outcomes of SNM treatment for FI in the Finnish national cohort and determine factors that could predict treatment outcome.
4) To analyse the effect of a patent sphincter lesion or previous secondary sphincter repair on SNM treatment results.

4 MATERIALS AND METHODS

This thesis consists of four papers based on three data sets. Study I is a retrospective study, based on data collected from Seinäjoki Central Hospital patient archives. Study II is a prospective study including patients from two Finnish central hospitals. Studies III and IV are based on a national data set collected from all centres in Finland that have provided or provide SNM treatment.

The methodology of each study will be discussed below. Since studies III and IV are based on the same data set, the methods of these two studies will be described in the same chapter

4.1 Factors predicting a failed primary repair of obstetric anal sphincter injury (study I)

The data for this study was collected retrospectively from Seinäjoki Central Hospital patient archives. Data of all patients who had been diagnosed with OASI or had undergone secondary SP from 2004 to 2015 was collected. Patients who had undergone imaging of the sphincter complex postpartum were selected for further analysis. Exactly 104 patients met the search criteria; of these 60 were included in the study (Figure 8).

All patients included in the study had been followed up at two weeks postpartum by a gynaecologist and at three months by a gastrointestinal (GI) surgeon. At the three-month follow-up, patients underwent imaging of the sphincters by either 3D EAUS or external phased-array MRI. Upon follow-up, all patients filled out a Wexner incontinence questionnaire and were asked to evaluate the severity of their symptoms using the visual analogue score (VAS).

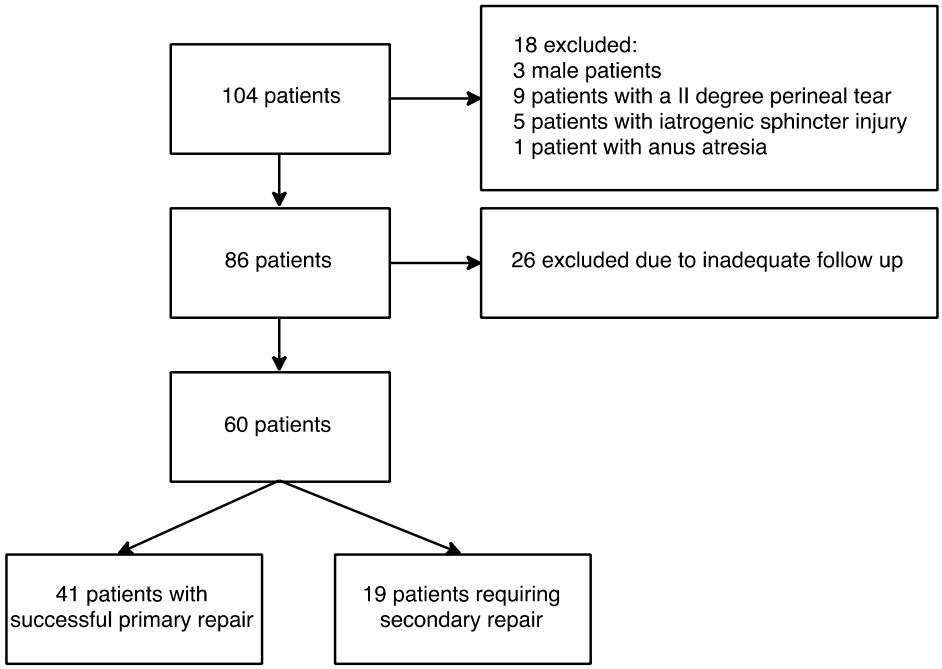

Figure 8 A diagram depicting the inclusion of patients (study I)

The patients who met the inclusion criteria were divided into two groups: those with a successful primary SP and those with a failed primary SP. These two groups were compared for patient-dependent characteristics such as BMI, age, and parity. Also, delivery characteristics such as the use of episiotomy, instrumental delivery, use of pain relief during labour, medical induction of labour, and lengths of different stages of labour were compared between groups. Patients were also compared on the basis of types of SP and time from partum to SP. The time of day the repairs were undertaken and by whom the repairs were conducted were also compared.

The majority (n=58) of the women underwent 3D EAUS imaging of the sphincters. Two of the women were imaged using external phased-array pelvic MRI. Anal manometric studies were conducted using the water perfused pull-through technique. A total of 45 women were examined for squeeze and resting pressures.

All patients in the failed primary SP group later underwent secondary SP conducted by a GI surgeon in Seinäjoki Central Hospital.

Since the study in question was a retrospective register-based study, no approval of the ethical board was required. Permission to conduct the study was granted by the Chief Doctor of Seinäjoki Central Hospital.

4.2 External phased-array magnetic resonance imaging (MRI) in the diagnosis of obstetric anal sphincter injury (study II)

Study II is a prospective study, which compares 3D EAUS and MRI in diagnosing ROASI. The study population was comprised of women who had given birth in Seinäjoki and Vaasa Central hospitals.

An initial power analysis revealed that there was a strong correlation (r=0.788) between the results of the two imaging modalities. Initial power analysis indicated that 40 women would be needed to prove with a power of 90% that a moderate to strong (r>0.6) correlation exists between the two imaging modalities (Kirss et al. 2016).

The first patients were enrolled in January 2014 and the study was terminated in August of 2017 upon reaching 40 patients.

4.2.1 Patients

All women who had been diagnosed with OASI in Seinäjoki and Vaasa Central Hospitals were asked to participate in the study. Women with a suspicion of an undiagnosed OASI were also included in the study. Patients completed a Wexner incontinence questionnaire upon consenting to participate in the study. All women were followed up at 2 weeks and 3 months postpartum by an obstetrician. All participants were imaged with MRI at least 3 months postpartum. Patients were followed up at least 8 months postpartum by a GI surgeon; during this follow-up, the 3D EAUS study was conducted. Participants were informed of the MRI and 3D EAUS study results after the 3D EAUS imaging procedure. Women with symptoms of FI received biofeedback therapy and pelvic floor physiotherapy. When symptoms persisted after 6-8 weeks of physiotherapy, women were seen again by a GI surgeon for possible SP or SNM treatment.

The 3D EAUS imaging was conducted by the two investigating GI surgeons. All images were analysed post hoc by both of the GI surgeons. The MRI images were analysed by two experienced radiologists, specialised in gastrointestinal radiology. The parameters analysed were: extent of the sphincter lesion, circumference of the tear in degrees and EAS thickness at different locations. The extent of the sphincter lesion, if present, was documented by patients having an isolated EAS or IAS defect or a combined EAS and IAS defect. The thickness of the EAS was measured at positions 3

and 9 on the proctologic clock face. This data was analysed for interrater reliability and intraclass correlation.

4.2.2 Ethical aspects of study II

Ethical approval was obtained from the Hospital District of Southwest Finland Ethics committee (ETMK 66/1801/2015). The current study was registered in the ClinicalTrials.com portal, identification number NCT 03039374.

The ethical committee required the researchers to guarantee that all women would receive equal follow-up, regardless of their participation in the study. Women who declined to participate in the study would still have been followed up using the same protocol as described above, but the data from these investigations would not have been collected. All women who were offered the chance to participate in the study did so.

4.3 SNM treatment results in patients with FI (studies III and IV)

Studies III and IV are based on the Finnish national cohort of SNM patients. There are seven centres that offer SNM treatment in Finland. Data of all patients implanted from January 1999 to April 2017 with SNM for non-urologic indications, such as FI, constipation, or pelvic pain, was collected from all centres that provide or have provided SNM treatment in Finland. Patient demographic data along with pre-implantation, SNM implantation, and follow-up data was collected from electronic patient archives from each of the participating centres. Data was analysed for possible factors that could influence the success or failure of SNM treatment.

Data of patients who had been evaluated with EAUS or MRI were analysed for effects of a patent sphincter lesion or previous SP on SNM treatment outcomes. Patients who had been imaged previously were divided into groups according to imaging results. The first three groups included patients with an IAS defect, with an EAS defect, and with a combined IAS and EAS defect. The fourth group was formed of patients with normal sphincter musculature. The groups were compared for demographic data,

SNM implantation parameters and surgical procedure details, Wexner incontinence scores, anal physiology test results, and aetiology of FI. Patients with a history of secondary SP were compared to patients with no history of SP for the parameters listed above.

4.3.1 Evaluation of SNM treatment success

All patients implanted with a permanent SNM device in Finland are followed up at 1, 6, and 12 months postoperatively. After the 12-month follow-up, patients are only followed up if problems occurred with the SNM device or the device needed servicing. Since there are no uniform evaluation criteria used for the success of SNM treatment in Finland, universally applicable criteria for treatment success or failure was needed to analyse results. The success of the test phase was easily interpretable, with patients advancing to permanent stimulator implantation and unsuccessful tests ending with no implantation. Permanent SNM treatment was defined as successful when patients had a working permanent stimulator implanted with subjective alleviation of symptoms of FI. SNM treatment was deemed unsuccessful either when the SNM device had been explanted or the patient reported no subjective positive effect on symptoms of FI.

4.3.2 Ethical aspects of studies III and IV

Although these studies were retrospective, ethical approval from the Ethics Committee of the Hospital District of Southwest Finland was obtained (ETMK: 163/1801/2015). The main ethical considerations of these studies were with the protection of sensitive personal data from multiple centres across Finland. Collection of patient data from multiple centres required additional approval from the governing body of each of the participating hospitals.

4.4 Statistical analysis

The statistical analyses of all of the studies were done in cooperation with the Turku Clinical Research Centres Department of Biostatistics. All patient data was analysed using Microsoft Excel for MAC version 15.13.1 and IBM SPSS software Version 23.

All continuous data was tested for normality using the Shapiro-Wilk test. Normally distributed data was analysed using the independent samples *t*-test. The Mann-Whitney U or the Kruskal-Wallis independent samples tests were used to compare non-normally distributed data. Where indicated, *p*-values were corrected using Bonferroni´s method. Either Pearson's chi-squared test or the Fisher's exact test was used to compare nominal values. The interrater reliability was calculated using the intraclass correlation (ICC) for continuous variables and Cohen's kappa for categorical variables. The ICC values from 0.0 to 0.2 indicated a slight agreement, values from 0.21 to 0.40 a fair agreement, values from 0.41 to 0.60 a moderate agreement, values from 0.61 to 0.80 a substantial agreement, and values from 0.81 to 1.0 a perfect agreement (Hallgren 2012). Spearman's correlation coefficient was used to calculate correlations between ordinal data.

5 RESULTS

5.1 Risk factors for developing ROASI (study I)

A total of 60 women were included in the study, of whom 19 (31.7%) had a ROASI diagnosed with 3D EAUS or MRI upon follow-up. As discussed earlier, data of women with a ROASI (n=19) was compared to those with a successful primary repair (n=41) to determine the possible risk factors for developing ROASI.

5.1.1 Demographic factors influencing the outcome of the primary repair

There was no difference between the two groups in age or BMI of the women. Neither was there a difference in the demographic data of the children. There was no difference in the length, weight, or head circumference between the children of the women in the two groups. The details of these findings are presented in Table 6.

Table 6 The demographic data of the mothers and newborns in the ROASI and the successful primary SP group.

	Successful primary SP	**ROASI**	***p*-value**
	Mean (SD)	Mean (SD)	
Age of women (years)	28.7 (4.2)	23.7 (5.9)	0.407[1]
BMI[3] of women (kg/m^2)	23.1 (5.7)	22.8 (3.6)	0.710[2]
Weight of the child (grams)	3738 (425.9)	3646 (517.8)	0.467[2]
Length of the child (mm)	509 (19.8)	510 (22)	0.934[2]
Head circumference of child (mm)	352 (14.6)	353 (14.8)	0.701[2]

1- Mann-Whitney U test, 2- two sampled T-test, 3- Body Mass Index of mothers measured before pregnancy

5.1.2 *Risk factors contributing to ROASI*

Analysis of the two groups revealed possible risk factors that could contribute to ROASI (Table 7).

Table 7 Factors contributing to the failure of primary SP

	Successful primary SP	**Failed primary SP**	***p*-value**
	n (%)	*n* (%)	Fisher's exact test
Pain relief			
No pain relief	2 (4.9)	1 (5.9)	0.003
EA only	5 (12.2)	5 (29.4)	
PNB only	2 (4.9)	0 (0.0)	
N_2O only	6 (14.6)	3 (17.6)	
EA and N_2O	25 (61)	3 (17.6)	
EA, PNB and N_2O	1 (2.4)	5 (29.4)	
Grade of tear			
Grade 3a tear	3 (7.3)	1 (5.9)	0.563
Grade 3b tear	22 (53.7)	6 (35.3)	
Grade 3c tear	14 (34.1)	3 (17.6)	
Grade 4 tear	2 (4.9)	2 (11.8)	
Tear repaired by:			
Specialist gynaecologist	18 (43.9)	5 (29.4)	<0.001
Specialist GI surgeon	23 (56.1)	6 (35.3)	
Gynaecology resident	0 (0.0)	2 (11.8)	
Midwife	0 (0.0)	4 (23.5)	
On-call repair	17 (42.5)	12 (75)	0.039
Working hours repair	23 (57.5)	4 (25)	
Tear not recognized	0 (0.0)	6 (31.6)	<0.001
Overlapping SP	39 (95.1)	9 (47.4)	0.025
End-to-end SP	2 (4.9)	4 (21)	
Antibiotics prescribed	40 (97.6)	10 (62.5)	<0.001
Antibiotics not prescribed	1 (2.4)	6 (37.5)	
Laxatives prescribed	35 (85.4)	5 (31.3)	<0.001
Laxatives not prescribed	6 (14.6)	11 (68.8)	

There was a higher number of women who were administered a combination of analgetics in the ROASI group, compared to the successful primary SP group (p=0.003). The majority of the tears in the successful primary SP group were repaired using the overlapping technique (p=0.025). The primary repairs in the ROASI group were more often conducted by a midwife or a specialising gynaecologist (p<0.001). There was a significant difference in the times of the repairs between the two groups. There were more repairs undertaken during the on-call hours in the ROASI group, compared to the successful primary SP group (p=0.039). We found that the time from delivery to repair had no influence on the outcome of the primary repair (p=0.828). There was a significant difference in the use of postoperative antibiotics and laxatives between the two groups. There was no difference in the incidence of postoperative infections between the two groups (p=0.696), although patients in the ROASI group were not prescribed antibiotics (p<0.001) nor laxatives (p<0.001) as often as in the successful primary SP group. There was no difference in the delay to initial repair between the two groups (Table 8).

Table 8 Delay of initial repair of OASI. p-value calculated using the two-sampled t-test

		Successful primary SP	**Failed primary SP**	***p*-value**
	Median (range)	Mean (SD)	Mean (SD)	
Delay to initial repair (h:min)	01:30 (0- 123:56)	06:58 (3:43)	05:56 (02:25)	0.828

As expected, the mean Wexner score was significantly higher in the ROASI group compared to the successful primary SP group (p<0.001).

As expected, the maximum squeeze pressures were significantly lower in the failed primary SP group measured at 1 and 2 centimetres (Table 9). This is also the average length of the anal canal in females (Nivatvongs et al. 1981).

Table 9 Anomanometric study results of the two groups

	Successful primary SP (n=30)	**Failed primary SP (n=15)**	***p*-value**
	Mean (SD)	Mean (SD)	Mann-Whitney U test
Anomanometry findings			
Maximum squeeze pressure at 1 cm (mmHg)	82.6 (30.6)	61.7 (31.5)	0.046
Maximum squeeze pressure at 2 cm (mmHg)	83.3 (34.9)	56.0 (28.9)	0.01
Mean resting pressure at 1 cm (mmHg)	67.8 (30.3)	45.0 (26.2)	0.028
Mean resting pressure at 2 cm (mmHg)	67.3 (33.9)	45.0 (26.2)	0.02

5.2 Comparison of 3D EAUS and external phased-array MRI in the diagnosis of ROASI (study II)

As per initial power analysis, 40 women were imaged with both 3D EAUS and MRI. The majority of the women participating were primiparous (n=25; 62.5%). The mean BMI of the women was 24.82 kg/m^2 (SD: 4.729). The mean age at delivery was 29.97 years (SD: 4.386). The children born were mostly full term, with the median time of birth of 40+2 (range: 37+0;42+6) weeks. The majority of the deliveries were spontaneous (n=21; 52.5%). Nineteen of the deliveries were vacuum assisted.

5.2.1 3D EAUS imaging results compared to MRI

The mean time from delivery to MRI was 7 months 14 days (235.8 days; SD: 138.16 days). 3D EAUS was performed on average 7 months 1 day post-partum (211.27 days; SD: 145.9 days; p<0.001). Details of the primary diagnosis of the OASI and immediate outcomes are outlined in Table 10.

Table 10 Results of the immediate diagnosis of OASI postpartum

Grade of Tear	Grade 3A	13	32.5%
Upon initial evaluation	Grade 3B	20	50.0%
	Grade 3C	5	12.5%
	Grade 2	2	5.0%
Repaired by	Consultant Gynaecologist	22	55.0%
	Consultant GI surgeon	12	30.0%
	Resident Gynaecologist	3	7.5%
	Midwife	3	7.5%
Type of Sphincter Repair	No repair	2	5.0%
	Overlapping SP	20	50.0%
	End-to-End SP	18	45.0%
Antibiotic prophylaxis	No antibiotic prophylaxis	5	12.5%
	Antibiotic prophylaxis given	35	87.5%
Complications postpartum	No complications	31	77.5%
	Wound infection	4	10.0%
	Pain	2	5.0%
	Pain & Wound infection	3	7.5%
Incontinence postpartum	No incontinence	22	55.0%
	Gas incontinence	10	25.0%
	Gas & Liquid stool incontinence	4	10.0%
	Urge incontinence	3	7.5%
	Solid stool incontinence	1	2.5%

More EAS tears were detected with the MRI (n=15) compared to 3D EAUS (n=13). A moderate interrater reliability was observed between 3D EAUS and MRI in diagnosing the extent (κ=0.510) and the circumference (κ=0.506) of the EAS tear. Details of the imaging results are presented in Tables 11 and 12.

Table 11 MRI and 3D EAUS findings on the extent of the sphincter injury

		No tear	IAS tear	EAS tear	IAS&EAS tear
3D EAUS	n	13	1	13	13
	%	32.5	2.5	32.5	32.5
MRI	n	10	2	15	13
	%	25	5	37.5	32.5
Kappa[1]			0.510		

1-Interrater reliability value

Table 12 MRI and 3D EAUS measurements on the circumference of the EAS, the size of the EAS defect in degrees, and the thickness of the EAS at position 3 and 9 on the proctologic clock face

		Tear in Deg.	EAS thickness at 9[2]	EAS thickness at 3[3]
MRI	Mean	63.75	2.693	2.753
	St. Deviation	51.375	0.786	1.078
3D EAUS	Mean	48.11	2.698	2.838
	St. Deviation	38.901	0.794	0.762
Kappa[1]		0.506	0.336	0.320

1-Intra-class correlation value; 2-Position 9 on the proctologic clock face, right lateral aspect of the EAS; 3-Position 3 on the proctologic clock face, left lateral aspect of the EAS

5.3 Predictive factors of SNM treatment outcome (study III)

Study III is a national register-based study outlining the results of patients treated with SNM for FI in Finland. Additionally, we aimed to determine factors that could predict SNM treatment outcome. There were 701 SNM tests conducted for non-urologic indications in Finland from 1999 until April 2017. A total of 462 patients were tested for FI.

5.3.1 SNM treatment results for FI

There was sufficient data to conduct analysis of outcomes for 432 of the 462 patients. The median time from SNM implantation to the time of data collection was 858 days (2.4 years; range 8–4853 days). A total of 72.5% (n=313) patients had a successful SNM test outcome; 59.3% (n=256) of all the patients had a successful final treatment result. Explantation of the permanent SNM device occurred in 13.1% (n=41) of the cases. Demographic data of patients is presented in Table 13.

Wexner scores dropped significantly during the test phase from a median of 16 to 7. The Wexner scores remained low (median: 7.5) after permanent SNM implantation.

Table 13 Demographic data of patients treated with SNM for FI. Distribution of patients having a successful test phase and final treatment outcome according to sex and age.

	Overall (%)	Successful test phase (%)	p-value	Successful final treatment result (%)	p-value
Median Age	62.9	64.4	0.813	64.5	0.466
Male	68 (15.5)	33 (49.3)	<0.001	26 (38.8)	0.637
Female	368 (84.5)	280 (76.7)		230 (63.0)	

5.3.2 Predictive factors of SNM treatment outcome

Analysis of the data revealed factors that could predict SNM treatment outcome. The factors having a significant effect on SNM treatment outcome, such as aetiology of FI, are outlined in Table 14. Age had no effect on the SNM treatment outcomes. Sex of the patients did have a significant influence on the test phase outcome. A majority of the female patients (76.7%) had a successful test phase, whereas only 49.3% of the male patients experienced a successful test outcome. The sex of the patients had no effect on the final treatment outcome (p=0.637) (Table 13).

Table 14 Factors influencing SNM test phase and final treatment outcome.

	Successful test phase (%)	**p-value**	**Successful final treatment outcome (%)**	**p-value**
Aetiology of FI				
Obstetric FI	82 (75.2)		69 (63.3)	
Idiopathic FI	89 (84.0)		80 (75.5)	
Iatrogenic FI	57 (57.6)	<0.001	44 (44.4)	0.06
Neurologic FI	50 (71.4)		36 (51.4)	
FI post rectal prolapse & other FI	32 (72.7)		24 (54.4)	
Number of program changes during testing				
0	145 (72.9)		122 (61.3)	
1	42 (65.6)	0.297	38 (59.4)	0.053
>1	25 (62.5)		17 (42.5)	
Number of working electrodes during testing[1]				
4	139 (74.3)		122 (65.2)	
<4	68 (62.3)	0.031	54 (49.5)	0.114
First motor response				
<0.5V	198 (76.2)		167	
0.5-1V	61 (65.6)	0.098	47	0.306
>1	54 (68.4)		42	
Complications during test phase	40 (62.5)	0.046	33	0.991
Complications after stimulator implantation	-	-	14	<0.001

The cohort of patients with an OASI consisted naturally only of women. To evaluate whether in fact it was the sex of the patients, not the aetiology of FI, that influenced treatment outcome, the same analyses on treatment success were conducted excluding the patients with OASI as the aetiology of FI. We found that the when patients with OASI were excluded from the

analysis, only 48.5% of the male patients versus 76.7% of the female patients advanced to permanent SNM implantation (p<0.001). This indicated once more that sex of the patients has an effect on SNM test outcomes.

Complications occurred in 15% (n=65) of the patients during the test phase and in 4.4% (n=19) of the patients after permanent SNM implantation. The different complications and their rates are presented in Figure 9. The complications experienced during the test phase and after permanent SNM implantation had a negative effect on the treatment outcome (Table 14). In 25 cases the electrode was prematurely removed due to a complication during the test phase.

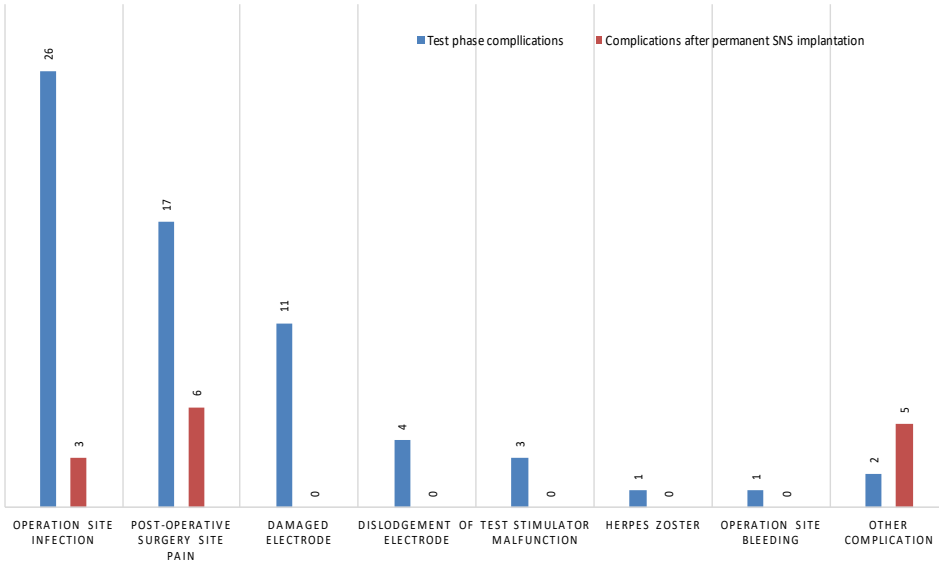

Figure 9 The different complications during the test phase and after permanent SNM implantation (study III)

A quadripolar tined lead was used for testing in the majority of cases (87.4%). A motor response from all of the four electrodes was a predictor of a successful test phase (p=0.031).

5.4 SNM treatment outcomes in patients with a patent sphincter lesion or previous SP (study IV)

In the Finnish national cohort of SNM patients, 237 had undergone EAUS imaging. The inclusion of patients in the study is outlined in Figure 10. Most of the patients included in the study were female (n=215; 91.1%). Not

surprisingly the commonest aetiology of FI was OASI, with 39.4% (n=93) patients having a history of obstetric injury. Of the patients included in the study, 73.1% (n=171) advanced to permanent SNM implantation and 60.6% (n=160) of the patients tested initially had a successful final treatment outcome.

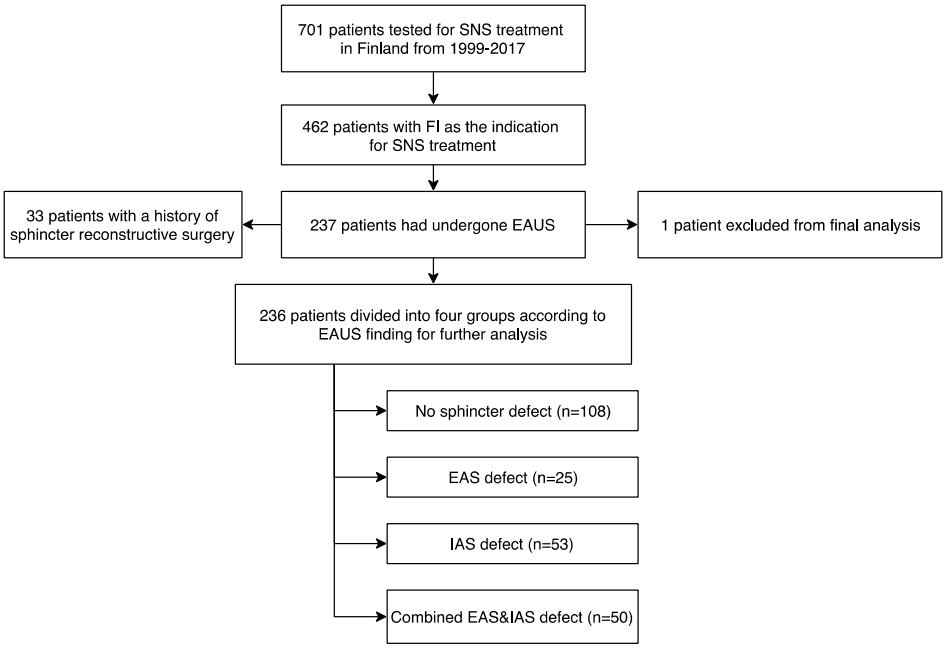

Figure 10 Inclusion of patients in study IV

5.4.1 EAUS findings in relation to SNM treatment outcome

Patients who had undergone EAUS imaging were divided into four groups: patients with no sphincter damage, patients with an EAS defect, patients with an IAS defect, and patients with a combined EAS and IAS defect (see Figure 10). There were more women in the group with an EAS defect and in the group with EAS and IAS defect ($p=0.008$), compared to the group with IAS defect. No other significant difference in the demographic data between the groups was noted. The Wexner scores dropped significantly during testing in all of the groups ($p<0.001$). The details of the Wexner scores are presented in Table 15.

Table 15 Median Wexner scores prior to testing and during the test phase.

	Median Wexner score before testing	Median Wexner scores during testing
Normal sphincters	15	7
Pathologic EAS	15.5	10
Pathologic IAS	17	14
Pathologic EAS&IAS	16	6
p-value	0.439	0.163

P-values obtained using the single sample t-test

The overall complication rate was 6.05%, with no difference between the rates of complications between the groups (p=0.194). The complications that occurred in different groups during testing are presented in Figure 11.

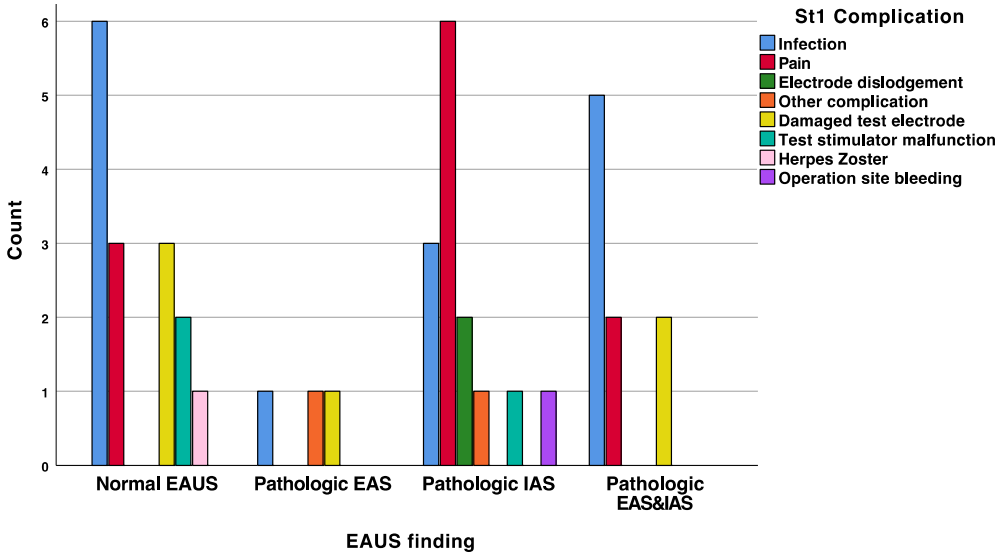

Figure 11 Rates of different complications occurring during the test phase (St1) according to the EAUS finding (study III)

5.4.2 The effect of previous SP on SNM outcomes

Of the 33 patients with previous SP, 2 had undergone a graciloplasty

and 31 an overlapping SP. One of the patients was male. In 87.9% (n=29) of the cases, the indication for SP was ROASI; the rest of the patients had a history of iatrogenic injury. There was no significant difference in patients with or without previous SP in having a successful test phase (p=0.425) or final treatment outcome (p=0.442). Of the patients with previous SP, 78.8% (n=26) advanced to permanent stimulator implantation and 66.7% (n=22) patients had a successful final treatment outcome.

Just over half of the patients (51.5%; n=17) with a history of previous SP had a patent EAS defect detected upon postoperative EAUS.

6 DISCUSSION

6.1 Risk factors for developing ROASI (study I)

Research on OASI has mainly concentrated on the long-term outcomes of the primary repair and on the risk factors for developing FI after primary SP. There is less evidence on the reasons for the failure of primary SP. In this study, we analysed the data of women with a history of OASI to determine the risk factors for developing ROASI. Previous studies have confirmed that a successful primary repair of OASI will yield better long-term results in regard to symptoms of FI compared to a secondary SP (Pinta et al. 2001, Barisic et al. 2006). In addition, a well-executed primary repair is cheaper per quality adjusted life year (QUALY) gained compared to secondary SP for ROASI (Tan et al. 2008b).

The overall success of the primary repair was comparable to other, previously published results (Lohuis and Everhardt 2014, Molander et al. 2007). As described earlier, we found risk factors that could help reduce the incidence of ROASI, the main one being the lack of expertise in diagnosing OASI, which will inevitably lead to treatment decisions based on inadequate information and to poorer treatment results. The results of this study were in line with previously published research, which has suggested that the delay of the primary SP of up to 24 hours has no effect on the outcome of the repair. In fact, repairs conducted during on-call hours seemed to be a risk factor for developing ROASI. Some studies have shown that the involvement of experienced colorectal surgeons in the primary repair process can benefit the outcome of the primary SP (McNicol et al. 2010, Krissi et al. 2015). In unclear cases, postponing the repair until experienced personnel are available will yield a more favourable outcome of the primary SP. Most of the injuries were diagnosed as grade 3B injuries; our data was not sufficient to indicate whether this was dependent on the lack experience of the attending physician in diagnosing OASI or due to the fact that grade 3B injuries are just most common. Results from study II indicate that grade 3B tear is probably the commonest type of OASI (see Table 10). It must be emphasised that an adequate diagnosis of OASI immediately postpartum is the of the utmost importance in achieving a successful repair. Failure to diagnose OASI will lead to wrong treatment choices and a poor end result. Another factor contributing to an unsuccessful outcome of the

primary repair was failure to prescribe antibiotics and laxatives postoperatively.

The Wexner scores were higher in patients with ROASI. There are studies that have indicated a correlation of Wexner scores with EAUS findings (Norderval et al. 2012). This suggests that FI questionnaires could be used as a primary diagnostic tool for the evaluation of ROASI.

As this was a single centre retrospective study, it had all the limitations of such a study, the main one being the heterogeneity of data quality. This study also highlighted that even though there are guidelines for the follow-up of patients with OASI, adherence to these guidelines was poor. All women diagnosed with ROASI were offered secondary SP as a treatment option. All of the women offered secondary SP underwent the procedure.

6.2 External phased-array MRI in diagnosing ROASI (study II)

This was a prospective study evaluating external-phased array MRI in diagnosing ROASI. Since its development, the gold standard of imaging the sphincter musculature has been the EAUS (Albuquerque 2015, Solan and Davis 2013). Though this is an easy and well tolerated method of imaging, it requires specialised hardware that is not readily available in all centres. The availability of 3D EAUS is particularly scarce in Finland. MRI hardware, on the other hand, is widely available, though the availability of specialised endoanal coils can be limited. Unlike 3D EAUS, the acquisition of MRI can be lengthy, and the endoanal coil can be difficult for patients to tolerate. Since clinical evaluation alone is not precise enough in evaluating sphincter defects, diagnosis of ROASI must rely on imaging studies (Jeppson et al. 2012, Dobben et al. 2006).

Studies comparing the diagnostic accuracy of endoanal MRI and 3D EAUS have concluded the two imaging modalities to be comparable in diagnosing sphincter lesions (Terra et al. 2006, Stoker 2008, Briel et al. 1999, Tan et al. 2008a). Previous research has shown endoanal MRI to be as sensitive as 3D EAUS in diagnosing EAS lesions, but 3D EAUS to be more accurate in diagnosing IAS lesions (West et al. 2005, Tan et al. 2008a, Deutekom et al. 2007). We are unaware of any previous studies having been published comparing 3D EAUS to external phased-array MRI.

Results of the current study found that external phased-array MRI is more precise in detecting EAS lesions compared to 3D EAUS. 3D EAUS was unable to differentiate scar tissue from viable muscle fibres. As shown in previously published research, scar tissue interferes with normal muscle contractility and may result in symptoms of FI (Terra et al. 2006). Results of this study indicate that external phased-array MRI is a valuable diagnostic tool in diagnosing EAS defects and is suitable for diagnosing ROASI. These results are similar to those published previously when comparing 3D EAUS and endoanal MRI results (West et al. 2005, Malouf et al. 2000b, Deutekom et al. 2007).

The increased sensitivity of external phased-array MRI compared to 3D EAUS could lead to the overdiagnosis of ROASI (Thomas et al. 2017). This may very well be, but as currently only patients with symptoms of FI are allocated for surgical treatment detecting more sphincter lesions will not increase the number of patients being treated unnecessarily. Additionally, previously presented evidence supports secondary SP to be reserved for patients with a short time from initial injury. Results of our study suggest that young, symptomatic patients with a recent history of OASI should undergo imaging of the anal sphincters. These patients could still benefit from a secondary SP (Pinta et al. 2001, Wald et al. 2014, Chatoor et al. 2007).

This study was limited by the absence of a control group of healthy individuals.

6.3 Results of SNM treatment for FI (study III)

This study was the largest of its kind and the first analysing SNM treatment results in a national cohort. Our results were comparable with results published earlier (Gallas et al. 2011, Leroi et al. 2011, Michelsen et al. 2010, George et al. 2012, Altomare et al. 2015).

6.3.1 Predictive factors for SNM treatment outcome

As discussed earlier, SNM treatment has become the first line of surgical treatment for patients with FI. There have been numerous studies published on the short- and long-term results of SNM treatment. The predic-

tive factors influencing treatment outcome have been less extensively studied (Hull et al. 2013, Mellgren et al. 2011, Hetzer et al. 2006, George et al. 2012, Altomare et al. 2015, Gallas et al. 2011, Roy et al. 2014, Dudding et al. 2008a).

The results of our study indicate that there are factors that influence SNM treatment outcome. A novel finding of this study was the influence that patient sex and the aetiology of FI had on the SNM treatment outcomes. Male patients had considerably worse test phase outcomes compared to female patients. There was no obvious reason for this outcome. The different aetiologic profile of male patients did not contribute to this finding; when patients with OASI were discarded from the analysis, male patients still had poorer test phase outcomes compared to females. There was no difference between male and female patients in the final treatment outcome. This finding does not suggest that male patients should be deferred from SNM treatment, but is definitely a subject for further research.

There was a disproportionally large number of patients with idiopathic FI. This group of patients was mostly female and probably had a history of obstetric injury.

Previously published studies have not shown aetiology of FI to influence treatment results (Hull et al. 2013, Mirbagheri et al. 2016, Dudding et al. 2008a, Roy et al. 2014). Results of this study seem to indicate the opposite. Aetiologic factors seemed to influence treatment outcome. Patients with a history of iatrogenic sphincter injury experienced worse treatment results compared to patients with other aetiologies of FI. When looking at the different types of iatrogenic injuries treated with SNM, including low anterior resection syndrome, post haemorrhoidectomy, and post fistulotomy FI, there was no difference in treatment outcomes between the groups. Since patients with OASI had considerably better treatment results, it would seem that a sphincter injury *per se* does not influence SNM treatment outcome. Since currently there is no other method for reliably predicting the SNM treatment outcome other than performing the test phase, it not feasible to deny SNM treatment to patients with iatrogenic injuries. These results indicate that patients with an iatrogenic injury should be informed of the poorer outcomes.

Contrary to some previously published studies, age did not seem to influence the outcome of SNM treatment (Govaert et al. 2009, Roy et al. 2014).

Cognitive function does play a role in selecting patients for SNM treatment. Patients are required to give adequate feedback about the effects of sacral nerve stimulation and be able to operate the patient controller. Our results indicate that age should not be a limiting factor for initiating SNM treatment, if the patient has adequate cognitive function.

The only stimulator dependent variable having a predictive value for treatment success was the number of electrodes in the quadripolar lead provoking a motor response. The number of responding electrodes is a clear indication of how the electrode is in contact with the nerve root, so it is not unexpected that this factor could influence treatment outcome (Elkelini et al. 2012, Su et al. 2017).

Another factor influencing treatment outcome were complications occurring either during the test phase or after permanent device implantation. The commonest complication was the infection of the operation site; the rates of complications were comparable to earlier published data (Lee et al. 2017, Noblett et al. 2017). Proper anti- and aseptic precautions must be taken to reduce the possibility of infection. In addition, all Finnish centres administer preoperative intravenous antibiotics, continued by a seven-day oral regimen. The data of this study was insufficient to draw any conclusions on which antibiotic regimen would be best to avoid complications. Results of this study suggest that aiming to reduce rates of complications can have a positive effect on SNM treatment outcomes.

The limitations of this study were characterised by its retrospective nature. The main limitations were the lack of data on postoperative symptom specific scoring and the fact that there is no uniform method in Finland for detecting a 50% improvement in symptoms of FI. This forced us to opt for defining the test phase and final treatment success as described above (see 4.3.1; page 50).

6.4 The effect of sphincter lesions and previous SP on SNM treatment results (study IV)

As with study III, this was the first study published on the effects of sphincter lesions on SNM treatment outcome in a national cohort. This study features a large cohort of patients who have undergone EAUS imaging prior to SNM treatment. As this was a retrospective study, it has its limitations. The limitations of this study are similar to the limitations of study III. The

main one being the lack of uniform criteria for evaluating test phase and treatment success.

As reported in previously published smaller studies, a sphincter lesion detected upon EAUS imaging had no effect on the outcome of the test phase or final treatment outcome (Boyle et al. 2009, Ramage et al. 2017). Though EAUS imaging is well tolerated and not associated with any adverse effects, it is not widely available in Finland. Results of this indicate that imaging studies prior to SNM treatment initiation are not necessary, because they do not influence treatment outcome.

As discussed earlier the outcomes of secondary SP have not been encouraging (Engel et al. 1994, Bravo et al. 2004, Nikiteas et al. 1996, Sitzler and Thomson 1996, Pinta et al. 2001). There is no compromise among researchers on the effectiveness of the secondary SP compared to SNM treatment (Altomare 2010, Goetz and Lowry 2005). Though data on the matter has been contradictory, there is evidence of SNM yielding better results compared to SP, particularly in a situation when the delay from initial injury is years or even decades. A small study conducted by Rodrigues et al. (2017) revealed SNM treatment to be superior to SP in the short term. The results of the current study found previous SP to have no effect on SNM treatment outcome. This finding supports the treatment of patients with a patent sphincter lesion primarily with SNM, though it must be mentioned that the basis of an adequate continence postpartum lies in a well-executed primary repair of OASI (Kairaluoma et al. 2004a).

The results of this study indicate that previous SP or a patent sphincter lesion have no effect on SNM treatment outcomes.

6.5 Future aspects

The results of these studies outlined some of the problems of treating patients with FI due to a history of OASI. One of the main questions raised was the indication of a secondary SP. As mentioned above, successful primary repair of OASI is paramount in achieving good long-term results. Currently it is unclear which patients, if any, should be treated with secondary SP and what the optimal timing is for SP. Is secondary SP a relevant treatment modality in the age of SNM? SNM treatment is very expensive, compared to a simple SP. It could be argued that a secondary SP will post-

pone the symptoms of FI, but will these patients achieve long-term continence without SNM? The answer to these questions is subject to future research.

The results of studies III and IV also highlighted the need for a centralised database of patients treated with SNM.

7 CONCLUSIONS

1) There are clear risk factors for the failure of the primary repair of OASI, such as inexperience of the attending physician, repairs conducted during on-call hours, and use of improper suturing techniques. Excessive use of pain medication during labour and failure to prescribe antibiotics and laxatives postoperatively can also contribute to the failure of the primary repair.

2) External phased-array MRI is a feasible imaging modality for imaging patients with suspected anal sphincter injuries. MRI is as precise as 3D EAUS in detecting EAS lesions. MRI also facilitates the differentiation of scar tissue from viable muscle fibres.

3) Outcomes of Finnish SNM treatment results are comparable to previously published results. Patient sex and aetiology of FI have an influence on SNM treatment outcomes.

4) Neither a patent sphincter lesion nor previous secondary sphincter repair has an effect on SNM treatment results.

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APPENDICES

Appendix 1: Wexner questionnaire and VAS used in Study II

Vasa centralsjukhus
Vaasan keskussairaala

ULOSTEEN PIDÄTYSKYVYN ARVIOINTI

Nimi: _____ Päivämäärä: _____

INKONTINENSSIN TYYPPI	ei koskaan	harvoin	joskus	usein	aina
Karkaako kiinteä uloste?/ Tuleeko isoja vahinkoja?	0	1	2	3	4
Karkaako uloste, kun se on löysää?	0	1	2	3	4
Karkaako ilma?	0	1	2	3	4
Käytättekö vaippaa/sidettä tämän takia?	0	1	2	3	4
Rajoittaako vaiva harrastuksia tai sosiaalista elämää?	0	1	2	3	4
Karkaako virtsa yskiessä, hyppiessä, nauraessa tai ponnistaessa?	0	1	2	3	4
PISTEET YHTEENSÄ					

harvoin = alle kerran/kuukausi
joskus = yli kerran/kuukausi
usein = kerran tai useammin/viikko
aina = joka päivä

Kuinka isoa haittaa koet 1-10 ulosteenkarkailusta?

1.....2.....3.....4.....5.....6.....7.....8.....9.....10

Vasa centralsjukhus Sandviksgatan 2–4, 65130 Vasa **www.**vasacentralsjukhus.fi **tfn / puh** 06–323 1111 **Banker / Pankit** Nordea 205218–7669
Vaasan keskussairaala Hietalahdenkatu 2–4, 65130 Vaasa **www.**vaasankeskussairaala.fi Aktia 497010–2800898 Sampo 800014–1722963

VASA SJUKVÅRDSDISTRIKT · VAASAN SAIRAANHOITOPIIRI

Vasa centralsjukhus
Vaasan keskussairaala

Utvärdering av avföringsinkontinens

Namn: _____ Datum: _____

INKONTINENSTYP	aldrig	sällan	ibland	ofta	alltid
Läcker fast avföring? Händer ”stora” olyckor?	0	1	2	3	4
Läcker avföringen om den är lös?	0	1	2	3	4
Läcker det luft?	0	1	2	3	4
Använder du blöja/skydd för det här?	0	1	2	3	4
Begränsar besvären ditt sociala liv/dina hobbyer?	0	1	2	3	4
Läcker urin när du hostar, hoppar, skrattar eller anstränger dig?	0	1	2	3	4
POÄNG SAMMANLAGT					

sällan = under en gång/månad
ibland = mer än en gång/månad
ofta = en eller flera gånger/vecka
alltid = varje dag

Hur stort besvär förorsakar avföringsinkontinens 1-10?

1.....2.....3.....4.....5.....6.....7.....8.....9.....10

Vasa centralsjukhus Sandviksgatan 2–4, 65130 Vasa **www**.vasacentralsjukhus.fi **tfn / puh** 06–323 1111 **Banker / Pankit** Nordea 205218–7669
Vaasan keskussairaala Hietalahdenkatu 2–4, 65130 Vaasa **www**.vaasankeskussairaala.fi Aktia 497010–2800898 Sampo 800014–1722963

VASA SJUKVÅRDSDISTRIKT · VAASAN SAIRAANHOITOPIIRI

Appendix 2: Consent forms filled out by women participating in Study II

VAASAN KESKUSSAIRAALA, Kirurgian klinikka
Hietalahdenkatu 2-4
65130 Vaasa
S-posti: jaan.kirss@utu.fi

SUOSTUMUS TUTKIMUKSEEN
Sopiiko lantiopohjan magneettitutkimus synnytykseen liittyvän peräaukon sulkijalihasvaurion toteamiseksi?

Olen saanut yllä mainittua tutkimusta koskevaa tietoa ja lukenut saamani kirjallisen potilastiedotteen, jossa on selvitetty tutkimuksen tarkoitus, luonne ja käytettävät tutkimusmenetelmät.
Minulla on ollut mahdollisuus esittää tutkijoille kysymyksiä tutkimuksesta ja siihen osallistumisesta sekä saada kysymyksiini vastaukset.

Minulle on selvitetty, että tutkimuksessa kerättävät tiedot käsitellään luottamuksellisesti. Tutkimustuloksia esitettäessä ja julkaistaessa tutkimushenkilön henkilöllisyyttä ei missään vaiheessa paljasteta.

Suostun vapaaehtoisesti tähän tutkimukseen, jossa selvitetään miten sulkijalihasrepeämä vaikuttaa elämänlaatuun ja miten magneettitutkimus sopii sulkijalihasvaurion toteamiseksi. Hyväksyn, että minusta otettuja radiologisia kuvia lähetetään tarvittaessa muihin Suomen keskussairaaloihin.
Tiedän, että voin halutessani milloin tahansa syytä ilmoittamatta perua tämän suostumukseni eikä kieltäytymiseni vaikuta oikeuteeni saada tarvitsemaani lääketieteellistä hoitoa.

Vahvistan saaneeni potilastiedotteen sekä kopion tästä vastaanotetusta suostumuksestani.

Suostumuksen antaja	Päiväys	Allekirjoitus
	Etunimi	Sukunimi
	Henkilötunnus	Osoite
	Postinumero	Postitoimipaikka
	Puh. koti/työ	Matkapuh.
Suostumuksen vastaanottaja	Päiväys	Allekirjoitus
	Nimen selvennys	
	Puhelin 06–323 1111	

VASA CENTRALSJUKHUS, Kirurgiska kliniken
Sandviksgatan 2-4
65100 VASA
Tel. (06) 323 1111
E-mail: jaan.kirss@utu.fi

SAMTYCKE TILL UNDERSÖKNING
Passar sig en magnetundersökning av bäckenbotten för att konstatera sfinkterskada uppkommen under en förlossning

Jag har fått information rörande ovannämnda undersökning och jag har läst den skriftliga patientinformationen, där undersökningens syfte, karaktär och de undersökningsmetoder som används är förklarade.

Jag har haft möjlighet att ställa frågor till undersökarna angående undersökningen och deltagandet i den samt få svar på mina frågor.

Man har förklarat för mig att de uppgifter som insamlas i undersökningen behandlas konfidentiellt. Vid presentation och offentliggörande av undersökningsresultat avslöjas inte undersökningspersonens identitet i något skede.

Jag samtycker frivilligt till att delta i undersökningen, i vilken man förklaras vilket sätt de påverkar livskvalitet och hur magnetundersökning passar sig för att konstatera sfinkterskada. Jag vet att om jag vill kan jag annullera mitt samtycke när som helst utan att uppge orsak och mitt avböjande inverkar inte på min rätt att få den medicinska behandling som jag är i behov av.

Jag bekräftar att jag har fått patientinformationen samt en kopia av detta mitt mottagna samtycke.

Samtyckesgivare	Datum	Underskrift
	Förnamn	Efternamn
	Personsignum	Adress
	Postnummer	Postanstalt
	Tel. hem/arbete	Mobiltel.
Mottagare av samtycke	Datum	Underskrift
	Titel/yrke	Namnförtydligande
	Tel. (06)- 323 1111	

Appendix 3: Information for patients asked to participate in Study II

Tiedote tutkittavalle (synnytyksen yhteydessä sulkijalihasvaurion saaneille)

Sopiiko lantiopohjan magneettitutkimus (MRI) synnytykseen liittyvän peräaukon sulkijalihasvaurion toteamiseksi?

Teitä pyydetään mukaan tutkimukseen, jossa tutkitaan peräsuolen sulkijalihasvaurioihin liittyvää ulosteenkarkailua. Soveltuisitte mukaan tutkimukseen, koska Teillä on synnytyksen yhteydessä todettu repeämä ja sen yhteydessä on vaurioitunut muun muassa peräaukon sulkijalihakset. Tämä tiedote kuvaa tutkimusta ja Teidän osuuttanne siinä.

Osallistuminen tähän tutkimukseen on täysin vapaaehtoista. Voitte kieltäytyä osallistumasta tutkimukseen tai milloin tahansa keskeyttää osallistumisenne syytä ilmoittamatta.

Saamanne hoito ei ole riippuvainen osallistumisestanne tutkimukseen.

Lukekaa rauhassa tämä tiedote. Jos Teillä on kysyttävää, voitte olla yhteydessä tutkijalääkäriin tai tutkimuksen muuhun henkilökuntaan. Jos päätätte osallistua tutkimukseen, pyydämme Teitä allekirjoittamaan liitteenä olevan suostumuslomakkeen sekä kyselykaavakkeet.

Taustaa

Alatiesynnytykseen voi usein liittyä emättimen tai jopa peräsuolen sulkijalihaksen repeämiä. Repeämän vaikeusaste määritellään gynekologin toimesta heti synnytyksen jälkeen ja yleensä gynekologi tai vatsaelinkirurgiaan erikoistunut kirurgi korjaa repeämän saman tien. Noin 3-6 kk:n kuluttua synnytyksestä Teille järjestetään vatsaelinkirurgian poliklinikalla jälkikontrolli, jossa tarkastetaan miten sulkijalihasten korjaus on onnistunut.

Vaikka repeämä olisi korjattu parhaalla mahdollisella tavalla, voi peräsuolen sulkijalihasrepeämän saanut kärsiä ulosteen pidätysongelmista. Oireet voivat olla lieviä, kuten ilman karkailua tai vaikeampia, kuten kiinteän ulosteen karkailua. Oireet saattavat ilmaantua vasta myöhemmin, vuosien jälkeen.

Tutkimuksen tarkoitus

Tämän tutkimuksen tavoitteena on selvittää, miten peräaukon sulkijalihasrepeämän oireet vastaavat magneettikuvien, ultraäänikuvien ja peräaukon painemittausten löydöksiin. Tämän lisäksi tutkittavia pyydetään arvioimaan, miten sulkijalihasrepeämä on vaikuttanut elämänlaatuun ja ulosteen pidätyskykyyn.

Tämän tutkimuksen toteuttavat Vaasan ja Seinäjoen keskussairaalat yhteistyössä Turun Yliopistollisen sairaalan kanssa. Tutkimuksen rekisterinpitäjä on Vaasan keskussairaala, joka vastaa tutkimuksen yhteydessä tapahtuvan henkilötietojen käsittelyn lainmukaisuudesta.

Tutkimuksen kulku

Teille lähetetään postitse tiedote tutkimuksesta, kyselylomakkeet ja kirjallinen suostumuslomake. Mikäli haluatte osallistua tutkimukseen, pyydetään Teitä palauttamaan täytetyt kyselylomakkeet ja kirjallinen suostumus allekirjoitettuina tutkijalääkäreille.

Kun olette allekirjoittaneet suostumuksenne, Teille lähetetään aika lantionpohjan MRI-tutkimukseen, peräaukon sulkijalihasten painemittaukseen ja kirurgian poliklinikalle vatsaelinkirurgin vastaanotolle. Mikäli ette suostu osallistumaan tutkimukseemme, lähetetään Teille pelkästään aika kirurgian poliklinikalle.

Kirurgian poliklinikalla tapaatte tutkijalääkäri Tarja Pinnan tai Jaan Kirssin. Poliklinikkavastaanotolla Teille tehdään myös peräsuolen sulkijalihasten ultraäänitutkimus. Samalla käydään läpi Teidän MRI-tutkimuksenne tulokset, peräsuolen painemittaustulokset ja mahdolliset oireet.

Mikäli ilmenee, että Teillä on kirurgista hoitoa vaativa sulkijalihasrepeämä, Teille suunnitellaan asianmukaista jatkohoitoa.

Kutsu vastaanotolle lähetetään postitse, ja tarvittaessa tutkimuksen henkilökunta voi olla Teihin yhteydessä myös puhelimitse.

Peräaukon sulkijalihasten painemittaus (Anaalimanometriatutkimus)

Tutkimuksessa selvitetään peräsuolen ja sen sulkijalihaksen toimintaa sekä häiriöitä, kuten pidätyskyvyn puutetta. Tutkimus suoritetaan tutkittavan maatessa vasemmalla kyljellään. Mittausväline on ohut mittauskatetri, joka tutkimuksessa viedään peräsuoleen muutaman senttimetrin syvyyteen. Tutkimuksessa tehdään kaksi painemittausta kahdella eri katetrilla. Tutkimus on kivuton ja kestää noin puoli tuntia.

MRI-tutkimus

Magneettitutkimuksella saadaan tarkkoja kuvia elimistöstä radioaaltojen ja magneettikentän avulla. Tutkimuksessa ei käytetä röntgensäteilyä. Tutkimuksen ajan makaatte putkimaisessa laitteessa noin 20 minuuttia, jolloin Teistä otetaan muutamien minuuttien pituisia kuvasarjoja.

Saatu kuvamateriaali tallennetaan ja analysoidaan jälkikäteen.

Peräsuolen sulkijalihasten ultraäänitutkimus (endoanaaliultraäänitutkimus)

Peräsuolen sulkijalihasten ultraäänitutkimuksella saadaan kolmiulotteinen kuva Teidän sulkijalihaksestanne. Kuvat otetaan käyttämällä ultraäänianturia, joka laitetaan Teidän peräsuoleenne. Tutkimus kestää noin 2 minuuttia ja on kivuton.

Kuvat tallennetaan ja analysoidaan jälkikäteen.

Tutkimuksen mahdolliset hyödyt

Saatte tietoa sulkijalihasten tilanteesta, esimerkiksi siitä onko repeämä parantunut. Lisäksi selvitetään sulkijalihasten toimintaa ja sitä, miten repeämä on vaikuttanut elämänlaatuunne. Mikäli Teillä ilmenee hoitoa vaativa jälkirepeämä tai Teillä ilmenee vaikea-asteista ulosteen pidätyskyvyttömyyttä, tarjotaan Teille siihen hoitoa.

Voi olla, että synnytyksen yhteydessä saatu repeämä on parantunut hyvin ja Teillä ei ole sulkijalihasten toiminnallisia häiriöitä. Tutkimuksesta saatu tieto auttaa parantamaan sulkijalihasrepeämien hoitoa ja diagnostiikkaa tulevaisuudessa. Tutkimuksen yhteydessä saatte tietoa terveydentilastanne.

MRI-tutkimus, sulkijalihasten ultraäänitutkimus ja peräaukon painemittaus on todettu vaarattomiksi potilaalle.

Tietojen luottamuksellisuus ja tietosuoja

Tutkimuksessa henkilöllisyytenne sekä muut tunnistettavat tiedot ovat ainoastaan tutkimuksen henkilökunnan tiedossa, ja he kaikki ovat salassapitovelvollisia. Kaikkia Teistä kerättäviä tietoja käsitellään koodattuna siten, ettei yksittäisiä tietojanne pystytä tunnistamaan tutkimukseen liittyvistä tutkimustuloksista, selvityksistä tai julkaisuista.

Tutkimusrekisteriin tallennetaan vain tutkimuksen tarkoituksen kannalta välttämättömiä henkilötietoja. Teidän yksilöintitietonne (syntymäaika, yhteystiedot jne.) käsitellään ja myös tallennetaan tutkimustiedoista erillään. Tutkimustuloksissa ja muissa asiakirjoissa Teihin viitataan tarvittaessa vain tunnistekoodilla. Rekisteriä säilytetään Vaasan keskussairaalassa viisi vuotta tutkimuksen päätyttyä. Tutkimusrekisteristä on laadittu henkilötietolain 10 §:n mukainen rekisteriseloste, jonka saatte halutessanne nähtäväksi.

Terveydentilaanne koskevia ja tutkimuksen kannalta tarpeellisia tietoja voidaan luvallanne kerätä myös muista terveydenhuollon toimintayksiköistä. Tutkijalääkäri voi tällöin hankkia tarvitsemansa tiedot henkilötunnuksenne avulla. Teillä on oikeus tarkastaa omat henkilötietonne ja tarvittaessa pyytää niihin korjauksia.

Jos päätätte peruuttaa suostumuksenne tai osallistumisenne tutkimukseen keskeytyy jostain muusta syystä, keskeyttämiseen asti kerättyjä tietoja käytetään osana tutkimusaineistoa.

Tutkimuksen kustannukset ja taloudelliset selvitykset

Tutkimukseen liittyvät toimenpiteet kuuluvat kuntalaskutuksen piiriin. Tutkimukseen liittyvästä lääkärikäynnistä Teiltä peritään normaali poliklinikan käyntimaksu.

Tutkittavien vakuutusturva

Jos tutkimuksen takia tehdystä toimenpiteestä aiheutuu Teille henkilövahinko, voitte hakea korvausta.

Tutkimuksesta aiheutuneista vahingoista haetaan korvausta potilasvakuutuksesta. Se korvaa potilasvahinkolain mukaisesti terveyden- ja sairaanhoidon yhteydessä aiheutuneita henkilövahinkoja laissa tarkemmin säädellyin edellytyksin. Potilasvakuutuskeskus huolehtii potilasvahinkojen korvauskäsittelystä.

Jos Teillä on kysyttävää tutkimuksesta, voitte olla yhteydessä tutkijalääkäreihin.

Heidän kanssaan voitte keskustella kaikista tutkimuksen aikana mahdollisesti ilmenneistä haittavaikutuksista tai muista mieltänne askarruttavista asioista.

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Information till deltagare i undersökningen (förlossning med skador på ändtarmsöppningens slutmuskel)

Är en MRI-undersökning (Magnetisk resonanstomografi) av bäckenbotten lämplig för att konstatera eventuella skador på ändtarmsöppningens slutmuskel till följd av en förlossning?

Du bjuds in att delta i ett undersökningsprojekt där man undersöker förekomsten av analinkontinens i samband med skador på ändtarmens slutmuskel. Du skulle vara en lämplig person för undersökningen, eftersom du vid förlossningen konstaterades ha fått en bristning som bland annat skadade ändtarmsöppningens slutmuskel. Informationen som följer beskriver undersökningsprojektet och ditt deltagande i det.

Det är helt frivilligt att delta i den här undersökningen. Du kan vägra delta i undersökningen eller avbryta ditt deltagande i vilket skede som helst utan att uppge någon orsak.

Den vård du erhåller är inte beroende av att du deltar i undersökningen.

Forskningsläkaren kan bli tvungen att avbryta ditt deltagande. Om så skulle ske, kommer vi att samtala med dig om fortsatta åtgärder efter avslutandet.

Läs igenom detta informationsbrev i lugn och ro. Om du har frågor kan du kontakta forskningsläkarna eller någon annan i undersökningspersonalen. Om du beslutar dig för att delta i undersökningsprojektet ber vi dig underteckna den bifogade blanketten för samtycke.

Bakgrund

En vaginal förlossning kan ofta leda till bristningar i slidan eller till och med i ändtarmsöppningen. Svårhetsgraden på bristningen fastställs av gynekologen genast efter förlossningen och i allmänhet åtgärdas bristningen omedelbart av gynekologen eller en kirurg specialiserad på matsmältningsorgan och buk. Cirka 3-6 månader efter förlossningen kallas du på kontrollbesök till kirurgiska polikliniken för mag- och matsmältningsorgan, där man kontrollerar om resultatet av åtgärdandet av bristningen blev bra.

Även om bristningen skulle ha blivit åtgärdad på bästa möjliga sätt, kan den som fått en bristning lida av problem med läckage av avföring. Symptomen kan vara lindriga så som läckage av gaser eller svårare som läckage av fast avföring.

Syftet med undersökningen

Syftet med den här undersökningen är att klargöra i vilken grad symptomen på bristning i ändtarmsöppningens slutmuskel motsvarar det man kan få fram via magnet-, ultraljudsbilder och tryckmätning av ändtarmsöppningen. Dessutom ombeds undersökningsdeltagarna uppskatta hur bristningen i slutmuskeln har påverkat livskvaliteten och förmågan att stå emot tarmläckage.

Det här undersökningsprojektet genomförs av centralsjukhusen i Vasa och Seinäjoki i samarbete med Åbo universitets centralsjukhus. Registeransvarig för undersökningen är Vasa centralsjukhus som ansvarar för att hanteringen av personuppgifter i samband med undersökningen sker i enlighet med lagen.

Om undersökningen

Du kommer att få frågeformulären, information om undersökningen och blanketten för samtycke postad hem till dig. Om du vill delta i undersökningen ber vi dig skicka de ifyllda frågeformulären och den undertecknade blanketten för samtycke tillbaka till forskningsläkarna.

Efter att du har undertecknat blanketten för samtycke, kommer du att få en tid till MRI-undersökning av bäckenbotten, tryckmätning av ändtarmsöppningen och tid till mottagning på kirurgiska polikliniken för mag- och matsmältningsorgan. Om du inte vill delta i undersökningen kommer du endast att få en tid till kirurgiska polikliniken.

På kirurgiska polikliniken får du träffa någondera av forskningsläkarna Tarja Pinta eller Jaan Kirss. På poliklinikmottagningen utförs även en ultraljudsundersökning av ändtarmens slutmuskler. På samma gång går man igenom resultaten av MRI-undersökningen, tryckmätningen av ändtarmen och eventuella symptom.

Om det visar sig att du har sådana bristningar i slutmuskeln som kräver kirurgisk vård, planerar vi en fortsatt vård som är mest lämplig för dig.

Kallelsen till mottagningen skickas per post, men vid behov kan undersökningspersonalen även kontakta dig per telefon.

Tryckmätning av ändtarmsöppningens slutmuskel (Anorektal manometri)

Vid undersökningen klargör man hur ändtarmen och dess slutmuskler fungerar och om det finns eventuella störningar som oförmåga att hålla emot läckage. Under undersökningen ligger personen på sin vänstra sida. Trycket mäts med en tunn mätkateter som vid undersökningen förs in några centimeter i ändtarmen. Det görs två tryckmätningar med två olika katetrar vid undersökningen. Undersökningen är smärtfri och tar cirka en halv timme.

MRI-undersökningen

Med en magnetundersökning fås detaljrika bilder av organ och vävnader med hjälp av radiovågor och magnetfält. Ingen röntgenstrålning används vid undersökningen. När du undersöks ligger du inne i en tubliknande apparat i cirka 20 minuter medan några minuter långa bildserier tas.

Bildmaterialet som fås sparas och analyseras i efterhand.

Ultraljudsundersökning av ändtarmens slutmuskel (endoanal ultraljudsundersökning)

Genom en ultraljudsundersökning av ändtarmens slutmuskel fås en tredimensionell bild av din slutmuskel. Bilderna tas med hjälp av en ultraljudssond som förs in i ändtarmen. Undersökningen tar cirka 2 minuter och är smärtfri.

Bildmaterialet sparas och analyseras i efterhand.

Eventuell nytta av undersökningen

Du får information om vilket tillstånd slutmuskeln befinner sig i, exempelvis om bristningen har läkt. Dessutom utreds hur väl slutmuskeln fungerar och hur bristningen har påverkat din livskvalitet. Ifall det konstateras att du har en efterbristning som kräver vård eller det konstateras en svår analinkontinens, så kommer du att erbjudas vård.

Det kan hända att den bristning du fått i samband med förlossningen har läkts bra och att du inte har några funktionsstörningar i slutmuskeln. Informationen som fås från undersökningen förbättrar den framtida diagnostiseringen och vården av bristningar i slutmuskeln. I samband med undersökningen får du även information om ditt hälsotillstånd.

MRI-undersökningar, ultraljudsundersökning av slutmuskeln och tryckmätning av ändtarmsöppning har konstaterats vara ofarliga för patienten.

Uppgifternas konfidentialitet och integritetsskydd

I detta undersökningsprojekt finns din identitet och andra identifierbara uppgifter tillgängliga endast för undersökningspersonalen som alla har tystnadsplikt. All data som samlas in om dig och prover som tas hanteras kodade, vilket gör att dina enskilda uppgifter inte kan identifieras varken i undersökningsresultat, utredningar eller publikationer.

I undersökningsregistret sparas endast sådana personuppgifter som är nödvändiga för undersökningens syfte. Dina identifikationsuppgifter (födelsetid, kontaktuppgifter osv.) hanteras och sparas separat från undersökningsuppgifterna. I undersökningsresultaten och övriga dokument hänvisar man vid behov till dig enbart genom en identifieringskod. Registret uppbevaras på Vasa centralsjukhus i fem år efter att undersökningen avslutats. För undersökningsregistret finns en registerbeskrivning i enlighet med 10§ lagen om personuppgifter. Registerbeskrivningen kan du ta del av om du så önskar.

Uppgifter om ditt hälsotillstånd och uppgifter nödvändiga för undersökningen kan med din tillåtelse inhämtas även från andra verksamhetsenheter inom hälsovården. Forskningsläkaren kan då skaffa de uppgifter han/hon behöver med hjälp av ditt personnummer. Du har rätt att kontrollera dina egna personuppgifter och vid behov be om korrigeringar.

Om du beslutar dig för att dra tillbaka ditt samtycke eller ditt deltagande i undersökningen avbryts av någon annan orsak, kommer de ditintills insamlade uppgifterna att användas som en del av undersökningsmaterialet.

Kostnader och ekonomiska utredningar för undersökningen

Åtgärder som vidtas i anslutning till undersökningen täcks av den så kallade kommunfaktureringen. För läkarbesöket i anslutning till undersökningen debiteras du normal avgift för poliklinikbesök.

Försäkringsskydd för dig som deltar i undersökningen

Om någon åtgärd under undersökningen ger upphov till personskada hos dig, kan du ansöka om ersättning.

För skador som uppkommit under undersökningen söks ersättning från patientförsäkringen. Den ersätter i enlighet med patientskadelagen sådana personskador som uppkommit i samband med hälso- och sjukvård enligt vad som närmare stadgas i lagen. Patientförsäkringscentralen sköter behandlingen av patientskadeersättningar.

Om du har frågor om undersökningen kan du kontakta forskningsläkarna.

Med dem kan du diskutera alla biverkningar som eventuellt uppkommit under undersökningen, misstänkta symptom eller andra saker som du funderar över.

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