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Short- and long-term outcome of surgical sphincteroplasty for anal incontinence

A cohort study based on prospective data from the Norwegian Register for Anal Incontinence

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Master's thesis in Medicine (MED 3950)

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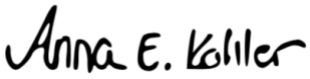
Preface

I was introduced to gastroenterology during my first year of medical school when I started working at the Department of Gastroenterological surgery at the University Hospital North of Norway (UNN) in Tromsø. Since then, my fascination for the field has only increased. I knew I wanted to write about gastroenterological surgery for my master thesis, so I asked professor and senior surgeon at UNN, Stig Norderval, who had previously helped me with a different assignment, to be my advisor. He suggested writing about surgical treatment for anal incontinence, a field he himself has dedicated much of his time to.

Before I started this project, my knowledge about the incontinence was limited. As I spent time immersing myself in the literature, and was surprised to learn that despite being a very common condition, research was sparse and established treatment options were relatively few. Even in our modern society, incontinence is still a taboo topic. I can only imagine the distress this condition entails those affected, and I hope that this thesis can be a small contribution to this field that is in need of further research and awareness.

Finally, I wish to acknowledge and extend my gratitude to all those who have helped me complete this thesis. Thank you to my supportive parents Jack and Elisabeth for valuable advice and guidance throughout the entire process at all hours, I am truly grateful. Thank you to my friend and fellow student Mathilde and my partner Oskar, both of whom were extraordinarily helpful regarding statistics and graphs. Thank you to Tone, manager of the register for anal incontinence, for helping me with the data and always thoroughly answering my numerous emails. Lastly, thank you to my dedicated advisor Stig. Between being head of department, a professor and researcher, I expect you don´t have very much free time. I greatly appreciate the time you have taken to provide feedback as well as the enthusiasm you have shown regarding the project.



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Abbreviations

ΔSMS	Delta St. Mark´s score
ΔQol	Delta quality of life
AI	Anal incontinence
EAS	External anal sphincter
IAS	Internal anal sphincter
No. of hrs.	Number of hours
NRA	Norsk register for anal inkontinens (Norwegian register for anal incontinence)
OASIS	Obstetric anal sphincter injuries
Qol	Quality of life
REK	Regionale komiteer for medisinsk og helsefaglig forskningsetikk (Regional committee for medical research ethics)
SNM	Sacral nerve modulation
SPSS	Statistical Package for the Social Sciences
UNN	University Hospital of North Norway

Abstract

Objective Anal incontinence (AI) is an underreported and burdensome condition, often associated with reduced quality of life in those affected. Despite the introduction of newer and less invasive therapies, surgical sphincteroplasty remains an important treatment option. The purpose of this study was to assess the 1- and 5-year outcome in patients who had undergone surgical sphincteroplasty for AI in Norway.

Methods This retrospective cohort study is based on prospectively recorded data from the Norwegian Register for Anal Incontinence. Data was available for baseline, year 1 and year 5. Patients with available results at baseline and year 1 were deemed the short-term group, while patients with results at baseline, year 1 and year 5, the long-term group. St. Mark´s score was used to determine degree of AI, and quality of life score (Qol) for evaluating well-being. Primary outcome was reduction in St. Mark´s score at year 1 and year 5, while secondary endpoints involved considering various baseline characteristics and their impact on outcome.

Results There were 83 patients in the short-term group and 19 in the long-term group. Between baseline and year 1 there was a mean decrease in St. Mark´s score of 3.7 points in the short-term group and 7.1 points in the long-term group. There was a mean increase in the Qol of 0.59 and 1 points in each of the groups, respectively. Between year 1 and year 5 the mean St. Mark´s score increased by 2.5 points and the mean Qol decreased by 1.4 points. Comparing baseline with year 5, there was still a mean decrease in the St. Mark´s score of 4.6 points, and 14 of the patients (74%) reported a lower St. Mark´s score and less symptoms than at baseline. The mean Qol decreased by 0.5 points. A low St. Mark´s score at baseline was found to be statistically significantly associated with less reduction in the St. Mark´s score short-term. Neither age, menopause or extent of sphincter injury were prognostic of outcome.

Conclusion. Surgical sphincteroplasty is successful in improving symptoms of AI. Few patients achieved complete continence, but there was a significant improvement in symptoms and in the QoL at year 1. By year 5 most patients had experienced an increase in symptoms, however, 75% of the patients still had a lower St. Mark´s score than before the surgery. The results suggest that despite there being a time-dependent decline in success, sphincteroplasty was worthwhile for most patients. The only factor predictive of outcome was the baseline St. Mark´s score, which was significantly associated with poorer short-term result in patients with a low pre-operative score. Our results suggest that patients with a baseline St. Mark´s score of 12 or less have little to no benefit from surgical sphincteroplasty.

1. Introduction

1.1 Anal incontinence

1.1.1 Definition

Anal incontinence (AI) is the inability to control bowel movements, resulting in involuntary leakage of intestinal content. Fecal and anal incontinence are often used interchangeably; however, fecal incontinence refers to involuntary loss of solid or liquid feces, while AI also includes the loss of flatus control (1). Fecal incontinence can further be classified as either:

- Passive incontinence or soiling, where the person is unaware of passing fecal discharge
- Urge incontinence, which is characterized by an urge to defecate before leakage (2).

Loss of bowel control can be socially and emotionally devastating, and is an important cause of reduced quality of life (3, 4). AI is common, but because many avoid seeking medical attention due to the surrounding stigma, the condition remains underdiagnosed and its true prevalence difficult to assess (5, 6). Furthermore, the numbers vary strongly depending on what definition of AI is used, as well as the population being studied. The prevalence increases with age, being the highest among nursing home residents, as well as 10-20 times higher in females than in males (2, 7, 8).

1.1.2 Pathophysiology

Continence is a result of a balanced interaction between the internal anal sphincter (IAS) and the external anal sphincter (EAS) and puborectalis muscle, as well as normal neurological innervation for rectal sensation and distention (9). The sphincter complex provides most of the anal resting pressure; however, hemorrhoidal tissue also contributes around 15% (4). Alterations to any of these components to an extent where other mechanisms are unable to compensate may result in clinical symptoms of AI.

The IAS is a continuation of the muscularis propria of the rectum. It consists of smooth muscle and is therefore entirely involuntary. This sphincter is contracted most of the time and responsible for maintaining over half of the anal resting pressure. Distention of the rectal ampulla causes the IAS to relax, requiring voluntary contraction of the puborectalis and EAS if defecation is not convenient (10). Dysfunction of the IAS is associated with passive incontinence (4).

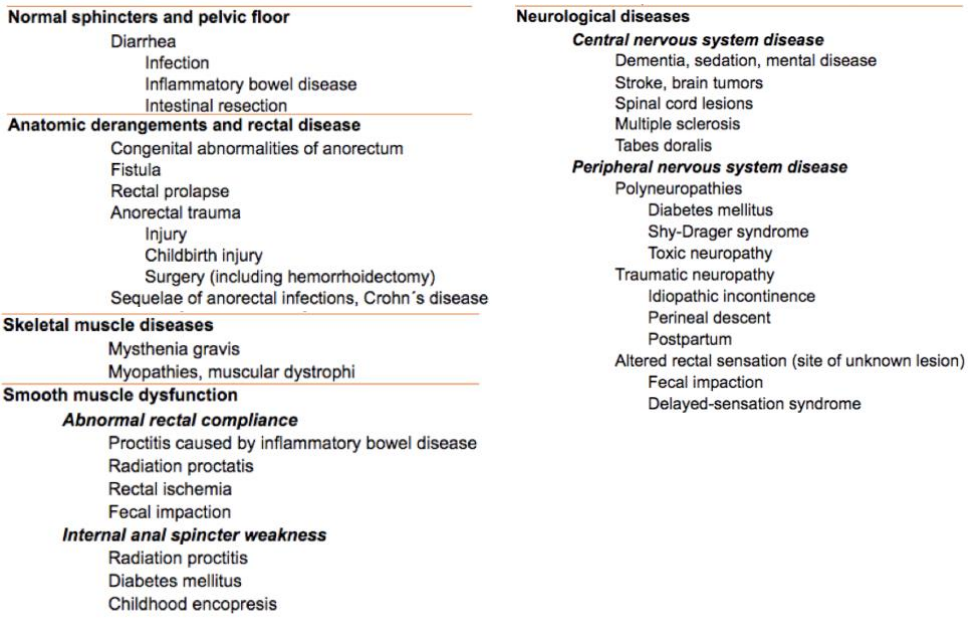
The puborectalis and the EAS surround the anal canal and are made up of striated muscle. These muscles contribute about 30-40% of the anal resting pressure, and provide the voluntary sphincter contraction. Injury to the EAS is associated with urge incontinence, while a weakened puborectalis can cause incontinence through widening of the anorectal angle (4). The pelvic floor and EAS are innervated by inferior rectal branches of the pudendal nerve and by branches directly from the anterior ramus of S4 (11). The pudendal nerves have both sensory and motoric function, and allow retention of stool and gas by initiating contraction of striated muscle (12). Higher level nervous control is maintained by the central nervous system, although the exact mechanism for this remains unclear (13).

1.1.3 Causes

The most important cause of AI in adult females is perineal injury in relation to childbirth. These are known as obstetric anal sphincter injuries (OASIS) and may occur spontaneously during vaginal delivery, or following an iatrogenic episiotomy. Disruption of the anal sphincter complex occurs with third and fourth degree perineal tears, with third degree tears resulting in partial or complete injury to one or both of the sphincters, while fourth degree tears also involve the anal mucosa (14). Furthermore, the pudendal nerve is susceptible to injury by either compression, stretch or direct trauma, which increases the likelihood of neuropathy (13).

Clinically recognized sphincter tears occur in up to 6% of all vaginal deliveries; however, the incidence of occult injuries can be as high as 35% (2, 6, 15). Despite immediate recognition and repair, 30-50% of these women will eventually develop AI. If there are larger residual defects, onset can be immediate, but symptoms may also not present until decades later, often in relation to menopause (6, 7, 16). The risk of AI also increases with use of instruments, prolonged labor, large infant birth weight, occipito-posterior presentation and multiple vaginal deliveries, regardless of anal sphincter injury (2, 8, 17). Other causes of AI are perianal abscesses and iatrogenic injuries after anorectal surgeries, such as low anterior resections for cancer and ileo-pouch-anal anastomosis for ulcerative colitis (7). Additional causes are listed in Table 1.

Table 1. Causes of AI (from Netter´s Gastroenterology (9)).



- **Normal sphincters and pelvic floor**
  - Diarrhea
    - Infection
    - Inflammatory bowel disease
    - Intestinal resection
- **Anatomic derangements and rectal disease**
  - Congenital abnormalities of anorectum
  - Fistula
  - Rectal prolapse
  - Anorectal trauma
    - Injury
    - Childbirth injury
    - Surgery (including hemorrhoidectomy)
  - Sequelae of anorectal infections, Crohn´s disease
- **Skeletal muscle diseases**
  - Mysthenia gravis
  - Myopathies, muscular dystrophi
- **Smooth muscle dysfunction**
  - ***Abnormal rectal compliance***
    - Proctitis caused by inflammatory bowel disease
    - Radiation proctatis
    - Rectal ischemia
    - Fecal impaction
  - ***Internal anal spincter weakness***
    - Radiation proctitis
    - Diabetes mellitus
    - Childhood encopresis
- **Neurological diseases**
  - ***Central nervous system disease***
    - Dementia, sedation, mental disease
    - Stroke, brain tumors
    - Spinal cord lesions
    - Multiple sclerosis
    - Tabes doralis
  - ***Peripheral nervous system disease***
    - Polyneuropathies
      - Diabetes mellitus
      - Shy-Drager syndrome
      - Toxic neuropathy
    - Traumatic neuropathy
      - Idiopathic incontinence
      - Perineal descent
      - Postpartum
    - Altered rectal sensation (site of unknown lesion)
      - Fecal impaction
      - Delayed-sensation syndrome

1.2 Management

1.2.1 Alternative interventions to sphincteroplasty

1.2.1.1 Conservative management

Treatment of AI is often demanding. Most cases of mild incontinence can be managed adequately with a combination of conservative therapeutics such as pelvic floor exercises with or without biofeedback, pads and plugs, diet modification, stool modulating drugs and rectal irrigation (7, 18). Patients with AI that is refractory to conservative management should be considered for surgical treatment.

1.2.1.2 Surgical treatment

Sacral nerve modulation (SNM) is a minimally invasive treatment that in recent years has transformed the management of AI. SNM was originally developed as treatment for urinary incontinence, but was accepted for use in AI in Europe in 1994 (19). The method involves stimulating a sacral nerve, usually S3, using an electrode connected to a pacemaker. The results are encouraging, with most patients achieving significant improvement in symptoms, despite sphincter injury being present (20, 21). The effect appears to be sustained over time as well (4). A similar and newer approach is percutaneous tibial nerve stimulation. This method is less invasive than SNM and was thought to work by indirectly stimulating the sacral plexus through

the tibial nerve. Beneficial outcomes have been reported, but a randomized controlled trial by Knowles et al. (22) found no clinical benefit when compared to sham electrical stimulation, and its use in the treatment of AI has for this reason been limited.

Anal injections are another minimally-invasive treatment option. They are easily performed and can be done ambulatorily, without anesthesia (7). The evaluations of anal injections were initially optimistic, but studies have found that its efficacy is clearly inferior to SNM, which leaves its role in treatment of AI uncertain (23).

Colostomy is a last resort, but may be a good alternative if all other therapies fail (7, 9). Other surgical options, such as artificial bowel sphincter or electro-stimulated graciloplasty, are associated with high morbidity rates, and have for that reason been more or less abandoned (5, 7).

1.2.2 Sphincteroplasty

Surgical sphincteroplasty is a secondary reconstruction of the anal sphincters, and aims to restore the normal circular configuration of the muscle surrounding the anal canal (4). It was first described in the early 1920s, and later gained popularity following a publication in 1971 by Parks et al. (24), who were the first to introduce the overlapping sphincteroplasty as an alternative to the traditional end-to-end sphincteroplasty. With the patient under general anesthesia, an incision is made in the perineum and the two ends of the disrupted EAS are identified and repaired in an overlapping configuration. It is crucial that both ends have adequate perfusion and that the suture is not under excessive tension, which may promote dehiscence (5). Any injury to the IAS must also be identified and repaired. The procedure carries a low post-operative complication rate, with the most common complications being wound infection and suture dehiscence (5, 7).

The short-term outcome of sphincteroplasty is generally satisfactory. The success-rate varies, but most studies report an improvement in 70-80% of patients within the first year following treatment. Perfect continence is rarely achieved, but there is a general improvement in quality of life and patients are overall satisfied with the results. (25-28). As time passes, however, the initial good results appear to deteriorate, with the success-rate falling to under 50% within a few years (29-31). For a long time sphincteroplasty was the only treatment option for patients

with larger sphincter injuries, but with the long-term outcome in doubt and the introduction of newer, less invasive treatment options, this practice is now being challenged (29, 30).

2. Research objective

The objective of this study is to assess the outcome in patients who have undergone elective sphincteroplasty for AI in Norway after one year and five years.

1. The primary outcome is to evaluate reduction in incontinence score following sphincteroplasty.
2. Secondary outcomes are to evaluate reduction in incontinence score related to the severity of symptoms and ultrasonographic extent of sphincter injury prior to surgery. Furthermore, the efficacy of treatment will be related to various characteristics in order to identify factors associated with a favorable outcome.

3. Material and methods

3.1 Study design

This study was conducted as a retrospective cohort study on data from the National Register for Anal Incontinence (NRA), a consent-based national register that contains data describing treatment and outcome of surgical intervention for AI in Norway. It was initiated in 2013 with the intention to oversee and improve the quality of treatment of AI. As of today, there are no national guidelines for surgical management of AI, and as a consequence, the options offered to this group have been inconsistent. The aim is for the NRA to serve as a resource for creating a more standardized practice for treatment nationally (32). It currently includes surgical treatment with secondary sphincteroplasty and SNM.

National registers are advantageous as they collect uniform data on a population over time, and form useful material for research. Especially the Nordic countries have a long-standing tradition of utilizing registry data for quality monitoring and research. (33). Data in the NRA is provided through cooperation between the four healthcare regions in Norway; Helse Nord, Helse Midt-Norge, Helse Vest and Helse Sør-Øst, while the administrative responsibility lies with the

University Hospital of North Norway (UNN). As far as we are aware, no similar register exists internationally, and the NRA is in this sense unique (32).

The NRA includes all patients over the age of 18 who have undergone surgical sphincteroplasty for AI in Norway since 2013. The NRA defines AI as any involuntary leakage of gas and/or stool. Those excluded from participation in the register are those who:

- Are under 18 years of age or do not wish to consent
- Are unable to read or speak Norwegian
- Are unable to give consent because of their cognitive function
- Suffer from severe psychiatric illness (34)

3.2 Data collection and follow-up

Data collection begins during the first consultation. Participating patients fill out a symptom-related questionnaire (Form 1A), while the treating physician fills out a separate form (1B) describing clinical features after an examination. Another form (2A or 2B) describing surgical details is later filled out by the treating physician after the operation is completed. These comprise the baseline data of the study.

Another symptom-related questionnaire (Form 3B) is later sent to the participating patients by postal mail at year 1 and year 5 with questions considering the patient's burden of symptoms, quality of life, and improvement in health after treatment. Results from these questionnaires form the follow-up data.

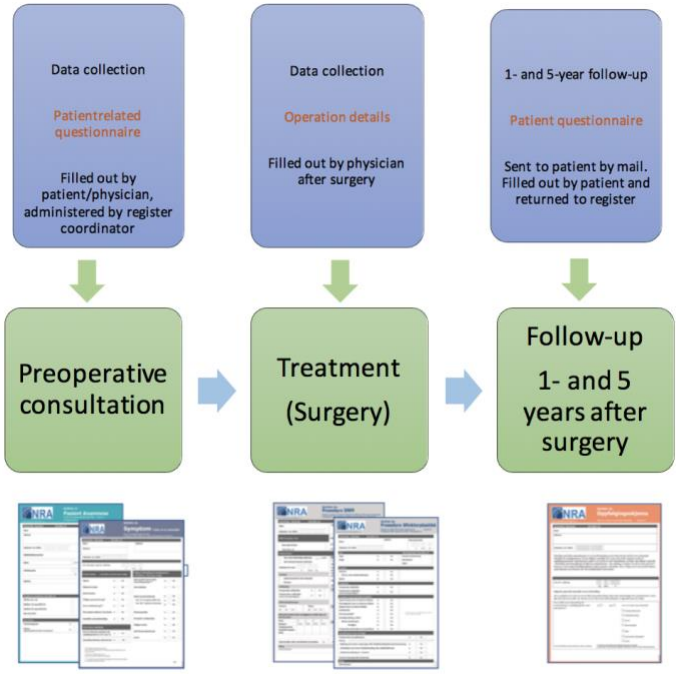


Figure 1. *Flow-chart illustrating data collection process (from the NRA user manual (34), translated).*

3.3 Research population

All patients who had available baseline data were included in the population description. However, only those with available results at year 1 were included in the group we defined as the short-term group. Only patients with available results at baseline, year 1 and year 5 were included in the long-term analysis, the long-term group. Four patients were excluded as they underwent surgical sphincteroplasty for other reasons than AI, and one patient was excluded because of incomplete baseline data. Three patients passed away before year 1 follow-up.

3.4 Variables

3.4.1 St. Mark´s score and general quality of life as means of evaluating treatment

Determining the degree of AI is beneficial for customizing treatment as well as for assessing outcome by comparing the severity of incontinence before and after intervention. An absence of objective methods has resulted in the development of severity scales. These are based on the patient's own perception of symptoms and have proved to correlate well with the clinician's impression of degree of severity.

The St. Mark´s score (Table 2) is a validated questionnaire and among the most widely used. It limits symptoms to the last four weeks, and considers frequency, type of incontinence, impact on lifestyle, use of pads and stool-modulating drugs, and urge. The result is summarized as a total score of 0 – 24. A score of zero indicates perfect continence, while a score of 24 absolute incontinence. The St. Mark´s score is what will be used in the present study, although several other severity scales also exist, including Wexner´s, AMS and Pescatori (16, 35). The disadvantage with St. Mark´s score is that it doesn´t include the patient's perception of general quality of life. For that reason, the quality of life (Qol) will be added as a variable in addition to St. Mark´s score when evaluating outcome. Patients scored their own Qol at baseline, year 1 and year 5 on a scale from 0 – 10, where zero indicated poor Qol, while 10 was the best imaginable Qol.

Table 2. *The St. Mark´s score.*

	Never	Rarely	Sometimes	Weekly	Daily
Incontinence for solid stool	0	1	2	3	4
incontinence for liquid stool	0	1	2	3	4
Incontinence for gas	0	1	2	3	4
Alteration in lifestyle	0	1	2	3	4
				No	Yes
Need to wear pad or plug				0	2
Taking constipating medication				0	2
Lack of ability to defer defecaton for 15 min (fecal urgency)				0	4

Never: No episodes in the past four weeks.
Rarely: One episode in the past four weeks.
Sometimes: More than one episode in the past four weeks but fewer than one a week.
Weekly: One or more episodes a week but fewer than one a day.
Daily: One or more episodes a day
Summed score from each row: 0 = perfect continence, 24 = complete incontinence

3.4.2 Other included variables

Other relevant variables included in the baseline data were gender, age, menopause status, etiology, duration in symptoms, treating hospital, and severity of sphincter injury. Sphincter injury was evaluated during the first consultation through endoanal ultrasound. It was assessed separately for the IAS and EAS, and classified as either partial tear or complete tear. In cases of complete tear, the circumferential extent was measured in number of hours (no. of hrs.) 0 – 12. Only injury to the EAS was included in analysis.

3.5 Non-responders

Non-responders were defined as patients who had not responded to the variable being assessed in the questionnaire. Patients with missing variables at baseline or year 1 were excluded from year 1 analysis, and similarly for year 5.

3.6 Statistical methods

Data were tabulated and processed using Microsoft Excel, while statistical analyses were completed using IBM Statistical Package for the Social Sciences (SPSS) version 28.0 for Mac. Descriptive statistics such as frequency (n), percentage (%), mean and median were used to present results. Change in mean was determined using one-sample T-test, and presented with 95% confidence interval (CI) and standard deviation (SD). When comparing means between groups, the paired T-test was used. Linear regression with a significance level of $p < 0.05$ was used to investigate correlation between variables and presented with unstandardized beta (B) and CI. All data was assumed to be normally distributed. Figures and tables were made using Microsoft Excel and Microsoft Word, while scatterplots were made in SPSS.

A favorable outcome was defined as a negative change in St. Mark´s score between two points in time, while an unfavorable outcome was defined as a positive change in St. Mark´s score. When evaluating Qol, a favorable outcome was defined as a positive change in score between two points in time, while an unfavorable outcome was defined as a negative change. Change in St. Mark´s score was expressed as delta St. Mark´s score (ΔSMS), and change in Qol as delta quality of life (ΔQol). When evaluating long-term outcome, only numbers from the long-term group was used. When investigating patterns in the ΔSMS between year 1 and baseline, and year 1 and year 5 separately in relation to different variables, the short-term group was used mainly for baseline and year 1 and the long-term group for year 1 and year 5. When presented in figures, baseline will be abbreviated as BL, year 1 as Y1 and year 5 as Y5.

3.7 Ethics

Participation in the NRA is voluntary and does not affect the quality of treatment the patient receives. Those who wish to participate give their written consent, allowing their patient pathway to be registered in the database as well as allowing data to potentially be retrieved at

a later point in time for research purpose. Consent may be withdrawn at any time without specifying a reason.

The thesis advisor applied to the Regional Committee for Medical Research Ethics (REK) for permission to access the data needed to complete this project. All patient-sensitive information was encrypted before the data was retrieved. Access to data was given 30 June 2021, and an updated version was acquired 7 January 2022.

4. Outcome

4.1 Population characteristics

There were 138 patients with available baseline data. The mean age in the population was 42.7 years, with 93 of the patients (67.4%) between the ages of 30 – 50 years old. 136 of the 138 patients (98.6%) were female, and 101 of them (74.3%) were premenopausal. 79 patients (57.2%) were incontinent for solid stool, liquid stool and gas. 42 (30.4%) for either liquid stool or solid stool and gas. 15 (10.9%) had pure gas-incontinence, while two (1.5%) had pure stool-incontinence. 121 patients (87.7%) suffered from urge-incontinence. The mean St. Mark´s score at baseline was 15 and the median duration of symptoms was 5-10 years. 117 cases (84.8%) were related to OASIS and 12 (8.7%) to OASIS and previous sphincterotomy.

Data was available from five different hospitals in Norway: Diakonhjemmet, Sykehuset Innlandet (Innlandet), St. Olavs, UNN and Sykehuset Østfold (Østfold). Of the different hospitals, Innlandet had the highest number of patients at baseline and year 1, with 63 (45.7%) and 62 (50.8%) patients, respectively, while St. Olavs had the most patients at year 5, with 15 (53.6%) (Figure 9). The mean baseline St. Mark´s score was highest at St. Olav at 17. The mean baseline St. Mark´s score for Diakonhjemmet, Innlandet, UNN and Østlandet were 13, 15, 16 and 14, respectively.

Some 29 patients experienced one or more post-operative complications (21%); there was one case of bleeding, 16 wound infections, and 17 wound dehiscences. The complication rate was highest at Østfold (60%), but Østfold also had the fewest number of operated patients (five). Diakonhjemmet had the lowest complication rate with three cases out of 26 operated patients (11.5%).

4.2 Non-responders

4.2.1 St. Mark´s score and Qol

In the short-term group, there were 39 non-responders for St. Mark´s score and 58 for Qol, leaving 83 and 64 eligible patients, respectively. In the long-term group, there were nine non-responders for both St. Mark´s score and Qol, resulting in 19 eligible patients.

4.2.2 Other variables

For assessment of injury to the EAS, both non-responders and those without ultrasound results were excluded. 55 patients in the short-term group were excluded from these analyses due to being non-responders or because of unavailable ultrasound results, leaving 67 eligible patients. In the long-term group 12 patients were excluded for the same reasons, leaving 16 patients. When investigating menopause in the short-term group, the two men were excluded from analysis, in addition to the 39 other patients who were non-responders for St. Mark´s score, leaving 81 eligible patients. As there were no males in the long-term group, only the nine non-responders were excluded.

4.3 Primary outcome

4.3.1 St. Mark´s score and Qol

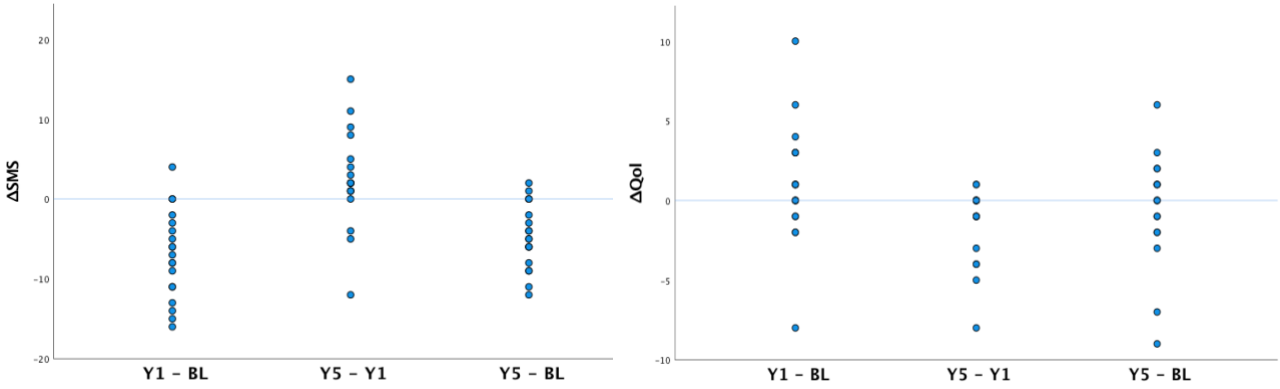
Between baseline and year 1, most patients had an improvement in symptoms, as deduced from a reduction in St. Mark´s score. The mean reduction in St. Mark´s score in the short-term group was 3.7 points (95% CI: -5.18 – -2.24, SD 6.71). 58 (70%) of the patients reported a reduction in St. Mark´s score, two patients (2%) reported no change, while 23 patients (28%) reported an increase in St. Mark´s score at year 1. The long-term group had a mean decrease of 7.1 points (95% CI: -9.70 – -4.41, SD 5.49). 16 of the patients (84%) reported a reduction in St. Mark´s score at year 1, while two patients (11%) reported no change and one patient (5%) reported an increase.

Between year 1 and year 5, most patients in the long-term group reported increasing symptoms. The mean increase in St. Mark´s score was 2.5 points (95% CI: -0.38 – 5.33, SD 5.93), with 15 (79%) patients reporting an increase in St. Mark´s score, one person (5%) reporting no change, and the remaining three patients (16%) reporting a further decrease. When compared with

baseline, there was still a mean decrease in St. Mark´s score of 4.6 points at year 5 (95% CI: -6.55 – -2.61, SD 4.10), with 14 of the 19 patients (74%) in the group reporting lower scores than before the surgery. Three patients had no change in St. Mark´s score while the remaining two had an increase of 1 and 2 points.

Between baseline and year 1 the mean change in the Qol was an increase by 0.59 points (95% CI: -0.17 – 1.36, SD 3.05) for the short-term group and 1 point for the long-term group (95% CI: -0.75 – 2.75, SD 3.64). Between year 1 and year 5, the mean Qol decreased by 1.4 points (95% CI: -2.55 – -0.29, SD 2.34). Comparing baseline with year 5, the mean change in Qol was a reduction of 0.5 points (95% CI: -2.05 – 1.21, SD 3.39).

There was a weak inverse correlation between ΔSMS and ΔQoL between baseline and year 1 (B=-0.15, 95% CI: -0.26 – -0.47, p=0.005), and a significant inverse correlation between year 1 and year 5 (B=-0.25, 95% CI: -0.41 – -0.10, p=0.003). There was no correlation between baseline and year 5 (B=-0.32, 95% CI: -0.69 – 0.43, p=0.08).



a) *b)*

Figure 2*. ΔSMS and ΔQol for the long-term group between different points in time. Baseline is abbreviated as BL, year 1 as Y1 and year 5 as Y5 on X-axis. A) ΔSMS. Points below the blue line indicate a reduction in St. Mark´s score over time and a favorable outcome, while points above the blue line indicate an increase in St. Mark´s score and an unfavorable outcome. B) ΔQol. Points above the blue line indicate an increase in Qol over time and a favorable outcome, while points below the blue line indicate a decrease in Qol and an unfavorable outcome.*

4.4 Secondary outcomes

4.4.1 Severity in baseline symptoms

A higher St. Mark´s score at baseline was statistically significantly associated with a larger decrease in St. Mark´s score between baseline and year 1 in the short-term group (B = -0.57, 95% CI: 0.88 – -0.26 p < 0.001). No correlation was found between year 1 and year 5 (B = 0.30, 95% CI: -0.53 – 1.12, p = 0.46).

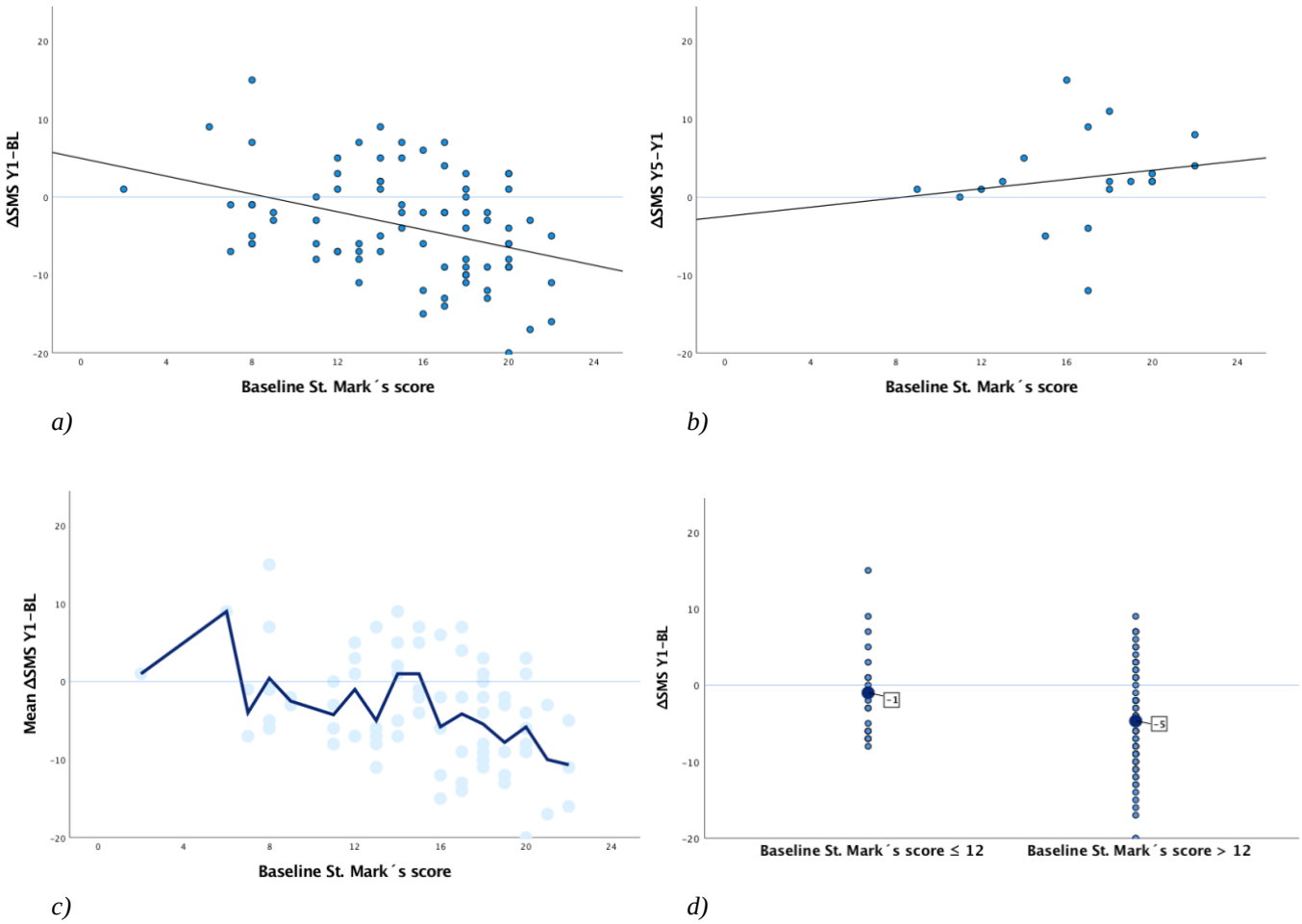
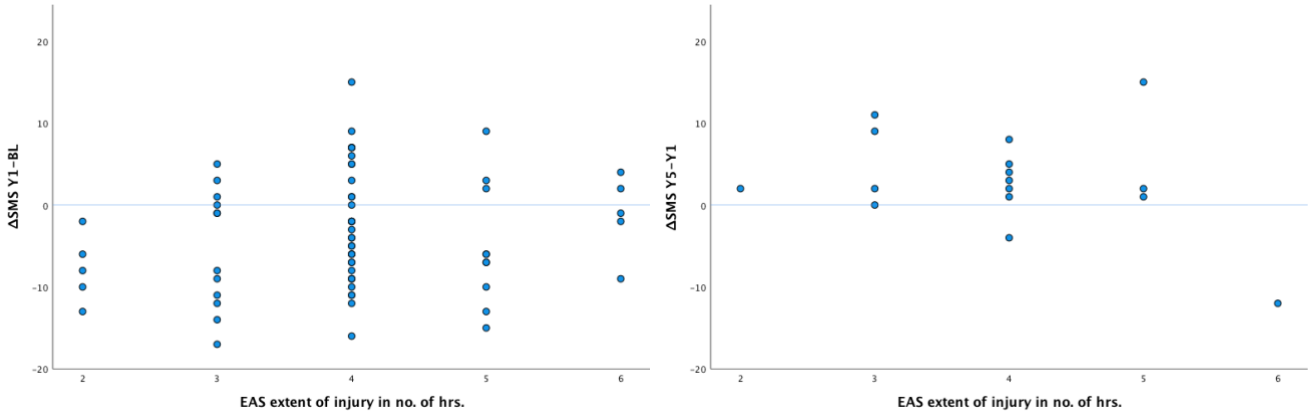


Figure 3. *ΔSMS and St. Mark´s score at follow-up compared with baseline. Baseline is abbreviated as BL, year 1 as Y1 and year 5 as Y5 on Y-axis. Points below the blue line indicate a reduction in St. Mark´s score over time and a favorable outcome, while scatters above the blue line indicate an increase in St. Mark´s score and an unfavorable outcome. A) ΔSMS between baseline and year 1 in relation to St. Mark´s score at baseline in the short-term group. A high St. Mark´s score at baseline was significantly association with a larger reduction in St. Mark´s score. B) ΔSMS between year 1 and year 5 in relation to St. Mark´s score at baseline in the long-term group. There was no significant association between ΔSMS and the St. Mark´s score at baseline. C) ΔSMS between baseline and year 1 in relation to St. Mark´s score at baseline in the short-term group. Interpolation line shows mean ΔSMS fo various baseline St. Mark´s scores on X-axis. D) ΔSMS between baseline and year 1 in group with baseline St. Mark´s score ≤ 12 (n=22) and group with baseline St. Mark´s score > 12 (n=61). Points in darker blue show mean ΔSMS for each group, respectively.*

4.4.2 Severity in sphincter injury

120 of the patients had complete tears in the EAS, while 16 of the patients had partial tears. The mean circumferential extent for the complete tears in no. of hrs. was four.

There was no correlation between extent of injury and the St. Mark´s score, neither between baseline and year 1 (B = 1.18, 95% CI: -0.56 – 2.94, p = 0.19) or between year 1 and year 5 (B = -1.94, 95% CI: -5.30 – 1.42, p = 0.24).

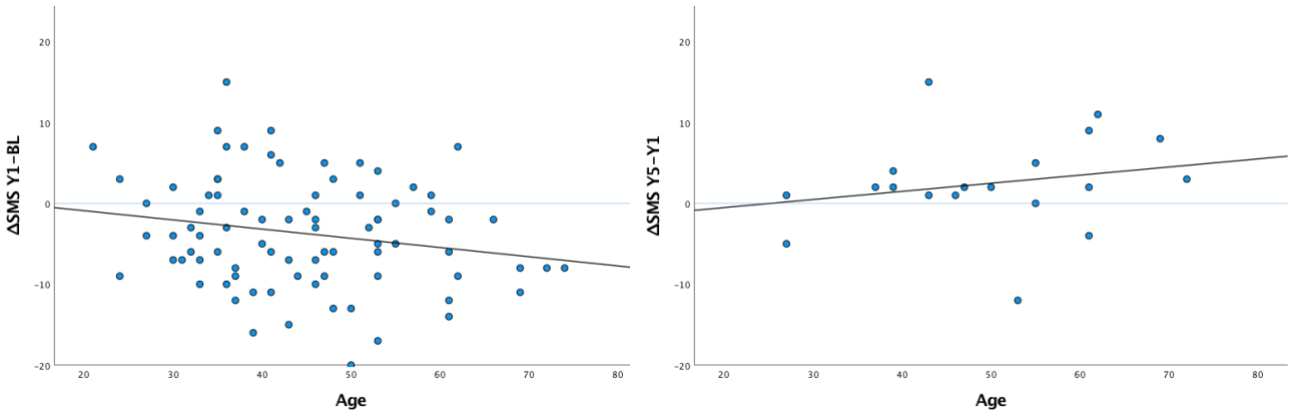


a) *b)*

Figure 4. *ΔSMS and EAS injury extent in no. of hrs.. Baseline is abbreviated as BL, year 1 as Y1 and year 5 as Y5 on Y-axis. Points below the blue line indicate a reduction in St. Mark´s score over time and a favorable outcome, while points above the blue line indicate an increase in St. Mark´s score and an unfavorable outcome. A) ΔSMS between baseline and year 1 in relation to EAS extent of injury in no. of hrs. in the short-term group. B) ΔSMS between year 1 and year 5 in relation to EAS injury extent in no. of hrs. in the long-term group.*

4.4.3 Age

There was no correlation between age and outcome, neither between baseline and year 1 (B = -0.11, 95% CI: -.0.24 – 0.01, p = 0.07) or between year 1 and year 5 (B = 0.10, 95% CI: -0.13 – 0.33, p = 0.37).



a) *b)*

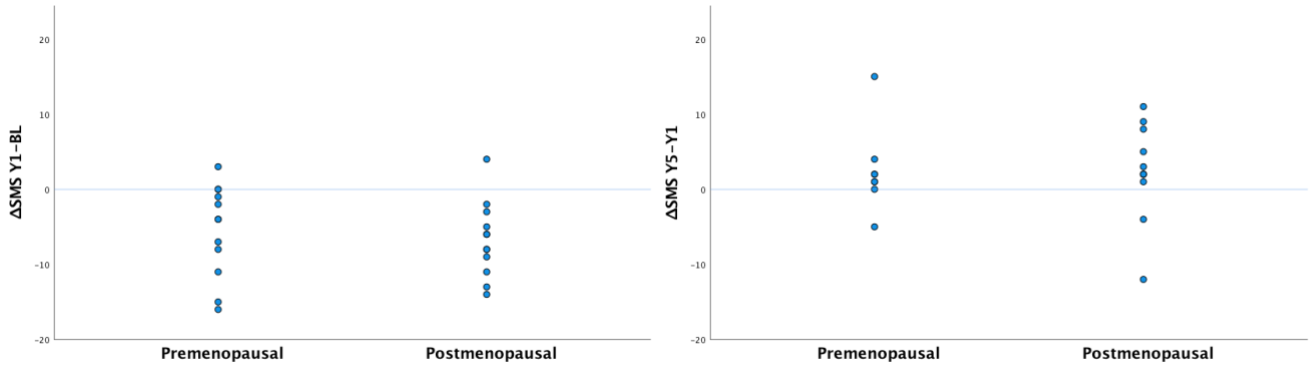
Figure 5*. ΔSMS and age. Baseline is abbreviated as BL, year 1 as Y1 and year 5 as Y5 on Y-axis. Points below the blue line indicate a reduction in St. Mark´s score over time and a favorable outcome, while points above the blue line indicate an increase in St. Mark´s score and an unfavorable outcome. A) ΔSMS between baseline and year 1 in relation to age in the short-term group. B) ΔSMS between year 1 and year 5 in relation to age in the long-term group.*

4.4.4 Menopause

In the short-term group, 54 of the patients were premenopausal while 27 were postmenopausal. The mean change in St. Mark´s score between baseline and year 1 was -3.2 points in the premenopausal group (95% CI: -5.11 – -1.30, SD 6.98), and -4.8 points in the postmenopausal group (95% CI: -7.28 – -2.35, SD 6.23).

In the long-term group, eight of the women were premenopausal while 11 were postmenopausal. There was a mean reduction of 7.6 points in the St. Mark´s score in the premenopausal group (95% CI: -12.78 – -2.47, SD 6.16) and 6.6 points in the postmenopausal group (95% CI: -10.14 – -3.13, SD 1.57) between baseline and year 1. Between year 1 and year 5 there was a mean increase by 2.5 points in the St. Mark´s score in both the premenopausal and the postmenopausal group (95% CI: -2.25 – 7.25, SD 5.68) (95% CI: -1.82 – 6.74, SD 6.38).

No statistically significant correlation between menopause status and outcome was found for any of the groups at any points in time.



a) *b)*

Figure 6*. ΔSMS and menopausal status. Baseline is abbreviated as BL, year 1 as Y1 and year 5 as Y5 on Y-axis. Points below the blue line indicate a reduction in St. Mark´s score over time and a favorable outcome, while points above the blue line indicate an increase in St. Mark´s score and an unfavorable outcome. A) ΔSMS between baseline and year 1 in relation to menopausal status in the short-term group. B) ΔSMS between year 1 and year 5 in relation to menopausal status in the long-term group.*

4.4.5 Participating hospitals

Table 3. *ΔSMS between baseline and year 1 in the short-term group for participating hospitals. A more negative ΔSMS indicates more favorable outcome.*

Hospital	n	Mean ΔSMS	95% CI	SD
Diakonhjemmet	11	-2.91	-7.27 – 1.45	6.49
Innlandet	35	-2.00	-4.69 – 0.69	7.83
St. Olav	20	-4.85	-7.26 – -2.44	5.14
UNN	14	-6.36	-9.48 – -3.24	5.40
Østfold	3	-6.67	-19.41 – 6.08	5.13

Table 4. *ΔSMS between year 1 and year 5 in the long-term group for participating hospitals. A more negative ΔSMS indicates more favorable outcome.*

Hospital	n	Mean ΔSMS	95% CI	SD
St. Olav	12	0.92	-2.93 – 4.76	6.05
UNN	6	4.67	-0.91 – 10.25	5.32
Østfold	1	8.00	-	-

5. Discussion

The present study summarizes the first findings from the NRA on surgical sphincteroplasty for AI. The main objective was to assess the short- and long-term outcome in patients who had received treatment, while secondary endpoints involved considering various factors and their impact on outcome.

With regards to short-term results, most of the participating patients reported a notable improvement in symptoms in the first year following surgery. There was a mean reduction in St. Mark´s score of 3.7 points in the short-term group and 7.1 points in the long-term group. Few patients achieved complete continence; only three of the 83 patients in the short-term group had scores of 0 or 1 by year 1, and in the long-term group only one patient had a score of 1. There was nevertheless an improvement in the Qol as the St. Mark´s score decreased.

In terms of the five-year outcome, the long-term group in the NRA is at present time relatively small, but the first results are as expected: Between year 1 and year 5 almost all patients in the long-term group reported an increase in AI symptoms with a mean rise in St. Mark´s score of 2.5 points, as well as a decrease in the Qol. This pattern is consistent with the findings in existing literature and further supports the theory that the initial good results after surgical sphincteroplasty are not sustained over time (29, 30). Although most patients improved their continence for solid and liquid stool, only one patient was fully continent for gas at year 5, and urge-symptoms persisted in nearly all. It is also worth mentioning that four of the seven patients who responded having perfect continence for solid stool at baseline, developed incontinence for solid stool by year 5. Despite the apparent poor outcome between year 1 and year 5, the majority of patients reported lower St. Mark´s scores at year 5 than at baseline with the mean reduction being 4.6 points. This suggests that overall, most patients improved symptomatically and benefited from the surgery at year 5 compared with baseline. The Qol was inversely correlated with the St. Mark´s score, further emphasizing the impact continence has on well-being. Surprisingly, the mean Qol was lower at year 5 compared with baseline. A possible explanation for this paradox could be considerable disappointment and increasing distress with reoccurrence of symptoms after an initial improvement.

Of the five participating hospitals, St. Olav had the largest decrease in St. Mark´s score between baseline and year 1, and the lowest increase in St. Mark´s score between year 1 and year 5. St.

Olav also had the highest baseline St. Mark´s score at 17. Innlandet had the highest number of operated patients out of all the hospitals. It also had the second highest complication rate at 46%, and the poorest ΔSMS between baseline and year 1. As there were large variations in the number of operated patients, comparing results has limited value. The general trend regarding the St. Mark´s score was, however, present in the data from all hospitals.

It is still unclear why the success rate declines following a seemingly successful sphincteroplasty. The sphincter complex is not the only component involved in continence; other factors, such as the rectal reservoir function, neurological innervation and elasticity, are also crucial. A hypothesis is that injury, despite repair, can accelerate the degeneration process, which with time could alter any of these aspects (4). Furthermore, excessive repairs may in fact disrupt the innervation and vascularation of the EAS leading to worse outcome (36). This could be of greater significance in women, where there also is a natural decline in striated muscle strength and innervation with age, due to the fall in estrogen levels (16, 29). Disrupted innervation may also be a result of over-stretching of the pelvic floor and the pudendal nerves, as can occur during a prolonged or difficult vaginal delivery. The majority of patients who undergo sphincter repair have various degrees of pudendal neuropathy (13). Pudendal neuropathy can be investigated clinically using a glove mounted electrode which measures nerve conduction time. Unfortunately, the method has been found to be inaccurate, and is therefore not used routinely (16, 37). Several studies have explored the possibility that pudendal neuropathy can be used as a predictor of failure after sphincteroplasty, but the results of these studies are conflicting (36, 38-41). This could, however, explain why surgery alone may fail as treatment in certain types of sphincter injuries, although it is uncertain whether the etiology of the sphincter lesion can affect the outcome (3, 5, 29). Similar to in previous studies (27), there was poorer improvement in incontinence for gas compared with liquid or solid stool in our population. Control of flatus requires fine tuning and discriminatory function of the anus, and the results suggest that this ability is difficult to regain through sphincter repair alone (4). Grey et. al (36) actually found that sphincter repair did not improve the function of the striated EAS, instead attributing improvement in symptoms mainly to the stenosing effect of the procedure. The validity of this finding is uncertain however as the literature surrounding anal manometry results is inconsistent (27).

Determining factors associated with successful outcome is advantageous as it allows for identification and selection of patients likely to benefit from sphincteroplasty. This has been

attempted in previous studies, but so far, no certain factors have been identified. A complicating aspect is the lack of heterogenic measures, which makes comparison of previous studies for assessment of outcome and success difficult (36). Of the variables considered in this present study, only severity in symptoms at baseline was found to be correlated with outcome. Patients with a low St. Mark´s score prior to surgery had significantly lower reduction in St. Mark´s score between baseline and year 1 compared with patients with a high St. Mark´s score. As deduced from Figure 3d, significant improvement appears unlikely if the baseline St. Mark´s score is twelve or lower. Furthermore, the mean ΔSMS was zero when the pre-operative St. Mark´s score was nine or less (Figure 3a), implying that these patients were as likely to worsen from the surgery as they were to improve. There was no significant association between year 1 and year 5, but there instead appeared to be an opposite pattern of increasingly worse outcome with higher baseline St. Mark´s score (Figure 3b). If this observed tendency is relevant, then it would indicate that patients with high St. Mark´s score at baseline initially have a greater decrease in St. Mark´s score short-term, but also have a greater rebound in symptoms long-term. The trend is, however, weak and there are scatters which makes interpretation uncertain. A similar pattern was seen for age. Both advanced age and menopause have been mentioned as variables associated with worse outcome (42). Although neither were correlated with outcome in our analysis, there is a tendency of larger decrease in St. Mark´s score with increasing age between baseline and year 1 (Figure 5a). Between year 1 and year 5 an opposite trend is observed with increasingly more positive St. Mark´s score with increasing age year 1 (Figure 5b). This would similarly imply that patients with higher age initially have a greater decrease in symptoms short-term, but also a greater worsening in symptoms between year 1 and year 5. However, a larger population is needed to determine if these observed tendencies are true associations or simply incidental.

One could presume that more extensive sphincter injury would result in more severe AI. A large enough disruption of the circular configuration of the sphincter muscle will certainly alter the ability to constrict the anal canal, as it will result in the muscle acquiring more of a crescent shape when contracted. Even so, most previous studies have found no correlation between the two, and no such association was found in our analysis either (42). There was, however, an apparently poorer outcome, i.e. greater ΔSMS with increasing no. of hrs. in damage between baseline and year 1. This pattern only appears to apply up until four hours in circumferential extent, after which there is no further increase in the ΔSMS (Figure 4a). The extent of sphincter injury in itself likely has only limited impact on the degree of AI, as the function of the sphincter

muscle will be impaired when the degree of injury reaches a certain extent. However, advanced injury to the sphincter complex also suggests more extensive injury to adjacent neuromuscular structures of the pelvic floor. We still have no good way of investigating and systemizing injury extent to these structures, nor do we have the competence to cure them. This is further complicated by the fact that often, many occult impairments coexist, and it is impossible to determine the proportion each factor contributes to the clinical picture (36). This is one of the aspects that makes treatment so challenging.

To summarize, the findings in the present study appear to be in accordance with the existing literature. The short-term outcome is generally acceptable, but the results worsen with time. There is at present time no planned follow-up after year 5 in the NRA, so it is uncertain how the St. Mark´s score will continue to progress after this point in time. One could argue that even with the decrease in St. Mark´s score the short-term outcome is disappointing seeing as very few patients achieved complete continence. It is likely that full continence is an unrealistic goal for most of these patients, and that symptom- and Qol improvement should be the main ambition. Seeing as most cases are related to OASIS, more awareness surrounding birth injuries and how to limit them is of great importance. Such measures include more restrictive use of instruments, and avoiding midline episiotomies, as both have been shown to be associated with anal sphincter damage (15). The main finding of a high baseline St. Mark´s score being associated with a more significant improvement suggest that as sphincteroplasty is most advantageous in patients with considerable symptoms, it should mainly be reserved for such cases. Patients with low St. Mark´s scores at baseline are unlikely to achieve significant improvement, and should as a rule be offered other less invasive treatment options. Treatment of AI is generally challenging. Our understanding of the pathophysiology of the condition is still lacking in many aspects and this must be further explored in order to optimize treatment.

6. Strengths and limitations

An important strength of this study is that it is based on data from a national register. Register-based research differs from sample-based studies in that it contains information from all people in a defined population. The unselected inclusion of the entire patient cohort reduces the risk of selection bias and ensures representativeness. Furthermore, using prospectively registered data minimizes the risk of recall bias (33). The study is however limited by the current quantity of patients in the NRA. As the register was initiated in 2013, the patient population has not yet reached the size necessary for transferability. Especially at year 5 the size results in low statistical power as the margin of error greatly increases. It is also well known that studies of non-randomized are more susceptible to systematic- and confounding biases.

7. Conclusion

In conclusion, surgical sphincteroplasty is successful in improving symptoms of AI. Few patients achieved complete continence, but there was a significant improvement in symptoms and in the QoL at year 1. By year 5 most patients had experienced an increase in symptoms, however, 75% of the patients still had a lower St. Mark´s score than before the surgery. The results suggest that despite there being a time-dependent decline in success, sphincteroplasty was worthwhile for most patients. The only factor predictive of outcome was the baseline St. Mark´s score, which was significantly associated with poorer short-term result in patients with a low pre-operative score. Our results suggest that patients with a baseline St. Mark´s score of 12 or less have little to no benefit from surgical sphincteroplasty.

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Appendices

Appendix 1: Tables

Table 5. *Statistics for domains in St. Mark´s score for short-term group at baseline and year 1.*

	baseline		year 1	
Domain	**Mean**	**SD**	**Mean**	**SD**
Solid stool	1.71	1.44	1.37	1.56
Liquid stool	2.12	1.45	1.57	1.41
Gas	3.63	0.76	2.88	1.39
Lifestyle alteration	2.64	1.53	1.78	1.60
Pad/plug	1.28	0.97	0.84	0.99
Stool modulating drugs	0.31	0.73	0.36	0.77
Urge	3.47	1.36	2.66	1.90
St. Mark´s score	15.16	4.46	11.45	6.50

Table 6. *Statistics for domains in St. Mark´s score for long-term group at baseline, year 1 and year 5.*

	baseline		year 1		year 5	
Domain	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Solid stool	1.68	1.49	0.84	1.21	1.47	1.35
Liquid stool	2.26	1.52	1.16	1.34	1.47	1.17
Gas	3.37	1.07	2.42	1.61	3.00	1.25
Lifestyle alteration	3.74	0.73	1.05	1.51	2.11	1.73
Pad/plug	1.26	0.99	0.95	1.03	0.53	0.90
Stool modulating drugs	0.63	0.96	0.12	0.46	0.21	0.63
Urge	3.79	0.92	3.16	1.68	3.37	1.50
St. Mark´s score	16.74	3.63	9.68	5.20	12.16	4.62

Appendix 2: Relevant figures

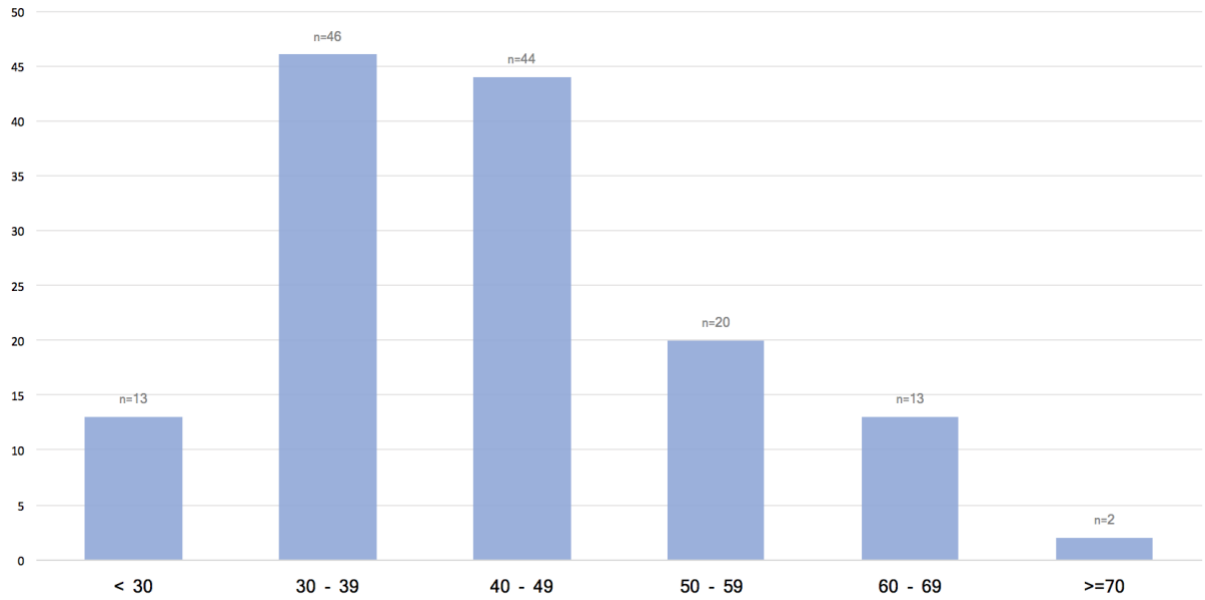


Figure 7. *Age distribution among participants. Age groups are on the x-axis and number of patients on the y-axis.*

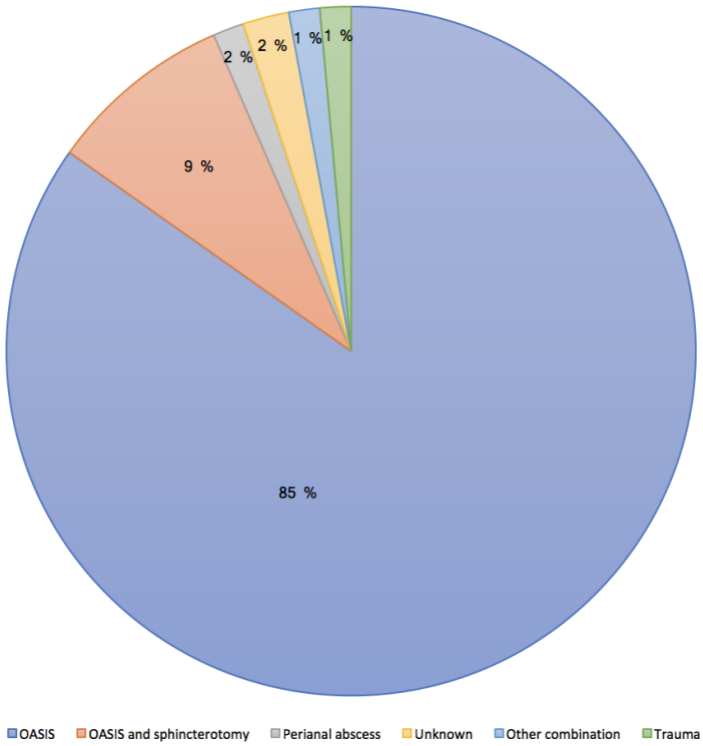


Figure 8. *Pie-chart illustrating etiologies in % among participants.*

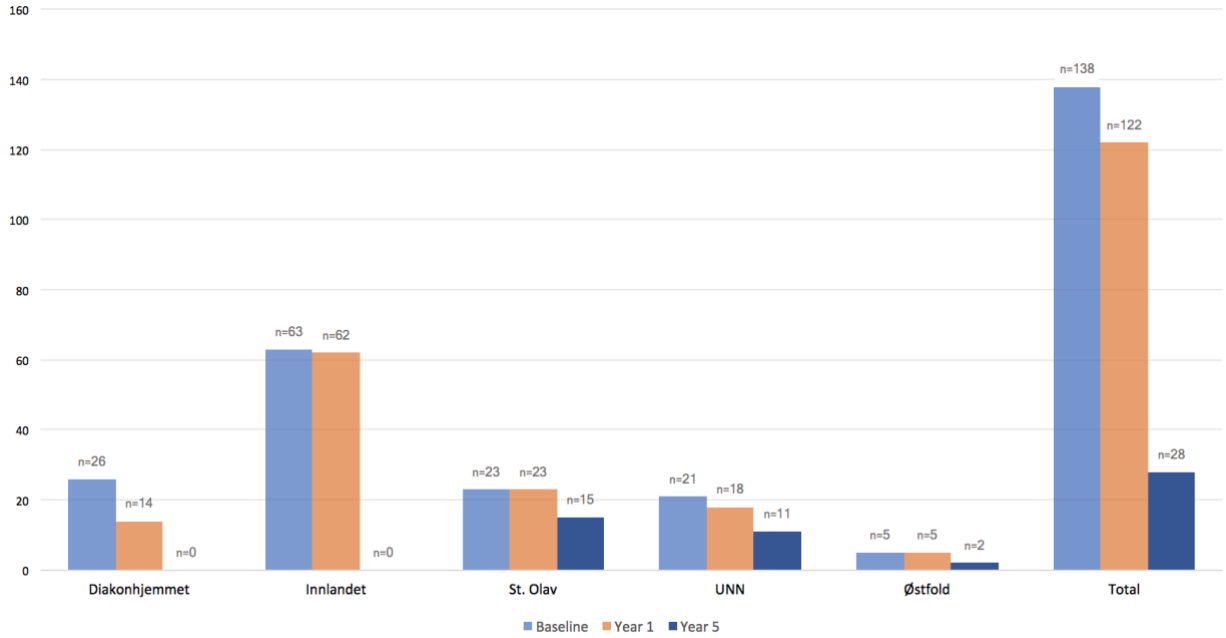


Figure 9. *Distribution of patients at the different hospitals at the different points in time. Hospitals are on the x-axis and number of patients are on the y-axis.*

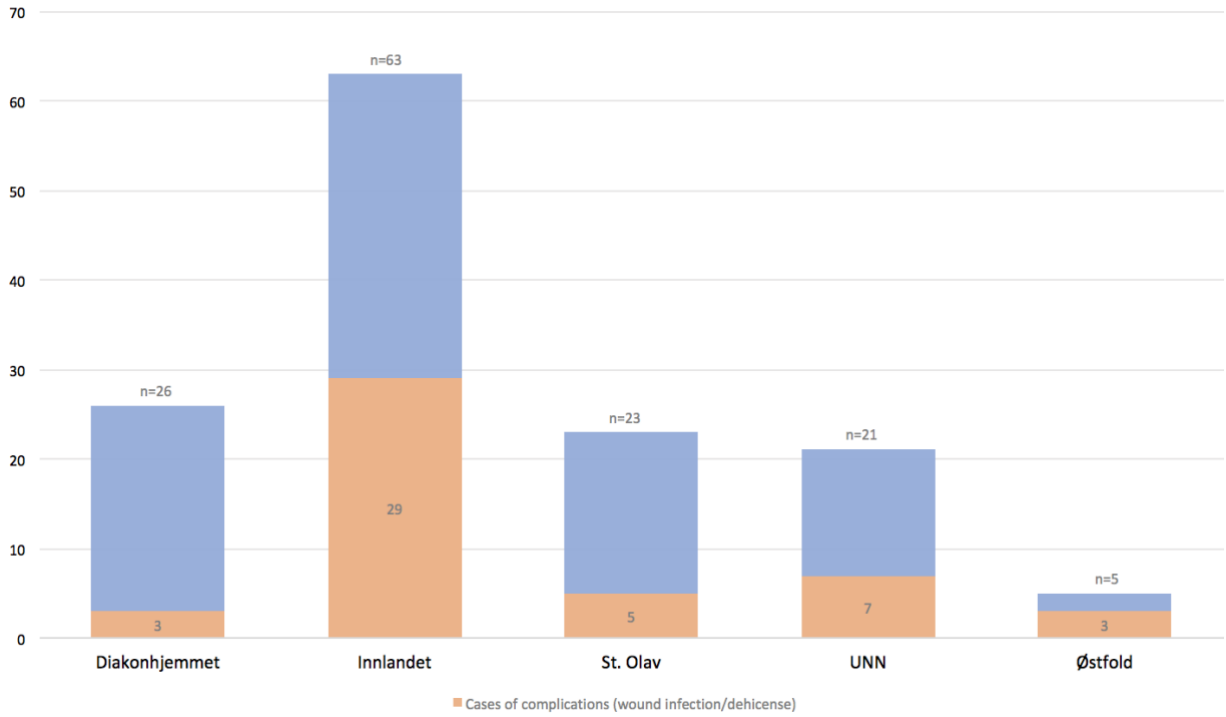


Figure 10. *Cases of complications in relation to total number of operated patients. Hospitals are on the x-axis and number of patients on the y-axis.*

Appendix 3: NRA forms

NRA consent form

Samtykkeerklæring

Norsk Register for Analinkontinens

Epost: nra@unn.no
Hjemmeside: www.analinkontinensregisteret.no

Versjon 3.0

Til deg som blir behandlet for analinkontinens
På oppdrag fra Helsedirektoratet har Universitetssykehuset Nord-Norge HF opprettet Norsk Register for Analinkontinens, (NRA), som er et nasjonalt medisinsk kvalitetsregister. Formålet med registeret er å overvåke kvaliteten og effekten av behandlingen, som blir tilbudt på de ulike sykehus i Norge. Universitetssykehuset Nord-Norge HF v/administrerende direktør er databehandlingsansvarlig.

Hva skal registreres?
Ditt navn og fødselsnummer, opplysninger om diagnosen, antatt årsak til helseplagene, eventuell tidligere behandling, hvilke symptomer du opplever, forhold knyttet til livskvalitet og hvilken behandling du får. Det vil bli gjort nye registreringer dersom tilstanden krever ny behandling.

Hvor skal opplysningene i registeret hentes fra?
Opplysningene samles inn både før og etter behandling. Før behandling registreres skjemaet som vi nå ber deg fylle ut, samt skjema som din behandler fyller ut. Etter ett og fem år vil du få tilsendt skjema hjem i posten med spørsmål om symptomer, livskvalitet og tilfredshet med behandlingstilbudet. Det jobbes med løsninger for at pasienter i fremtiden kan gi opplysninger elektronisk. Dette betyr i så fall at spørreskjemaet kan komme elektronisk i stedet for på papir.

Hvem kan få tilgang til opplysningene?
Det er ønskelig at de som behandler deg (leger og annet helsepersonell) får kjennskap til sine behandlingsresultater. Dette for å vurdere effekten av behandlingen de tilbyr på en systematisk måte. Samtlige opplysninger som samles inn gjøres derfor tilgjengelig for den sykehusavdeling som behandlet deg. Opplysningene behandles konfidensielt og de som har tilgang til dem har taushetsplikt. Samtlige behandlende sykehus vil i tillegg får rapportert uten identifiserbare data.

Forskning og kvalitetssikring
Registeret vil kunne benyttes til å evaluere hva som har betydning for gode eller dårlige behandlingsresultater, komplikasjoner eller hvilken betydning behandlingen har i relasjon til sosialmedisinske og helseøkonomiske forhold. Ved å samtykke til å delta i NRA aksepterer du at registrerte opplysninger kan benyttes både til kvalitetssikring og forskningsformål, og du samtykker til at du kan kontaktes på nytt utenom sykehuskontroller. Du samtykker også til sammenstilling av relevante helseopplysninger gjennom kobling med andre registre, under forutsetning av at det foreligger behandlingsgrunnlag/tillatelser for dette, gitt av de instanser loven krever. Forskningsprosjekter skal godkjennes av Regional komité for medisinsk forskningsetikk.

Koblinger mot Norsk pasientregister vil bli gjort regelmessig for å måle dekningsgrad og validitet i NRA. Det vil bli utarbeidet årlige nasjonale rapporter over omfang, resultat og sikkerhet. Resultater vil også publiseres fortløpende på fagmøter, i nasjonale og internasjonale medisinske tidsskrifter. Resultater basert på analyser fra registeret vil ikke kunne tilbakeføres til enkeltindivider.

Snu arket!

Rettigheter
Spørreskjemaene oppbevares i et arkiv ved sykehuset. De vil bli makulert senest etter to år. Opplysningene i skjemaet lagres også elektronisk i en database som er tilrådd av personvernombudet ved UNN. Opplysninger i databasen lagres på en trygg måte som ivaretar personvernet. De vil bli lagret uten tidsbegrensning. Alle data vil bli slettet dersom tilrådningen opphører.

Å bidra med opplysninger til registeret er frivillig. Hvis du velger å ikke skrive under på samtykkeerklæringen vil det ikke få noen konsekvenser for behandlingen du får nå eller i fremtiden. Du har rett til å få vite hva som står om deg i registeret, og du har rett til å kreve at eventuelle feil blir korrigert eller at opplysninger blir slettet fra registeret. Informasjon om registeret finner du på www.kvalitetsregistre.no, der du også kan finne informasjon om hvordan du kan kreve sletting eller retting av opplysninger.

Det kan være aktuelt å kople sammen informasjon fra NRA med følgende offentlige registre og befolkningsundersøkelser:

- Medisinsk Fødselsregister
- Norsk Pasient Register
- Kreftregisteret
- NAV
- Dødsårsaksregisteret
- Statistisk Sentralbyrå
- Befolkningsundersøkelsene som inngår i Conor (Cohort of Norway)
- Befolkingsundersøkelsen som inngikk i Statens Helseundersøkelser
- Helse Undersøkelsen i Nord Trøndelag 3

Samtykke til deltagelse i Norsk Register for Analinkontinens

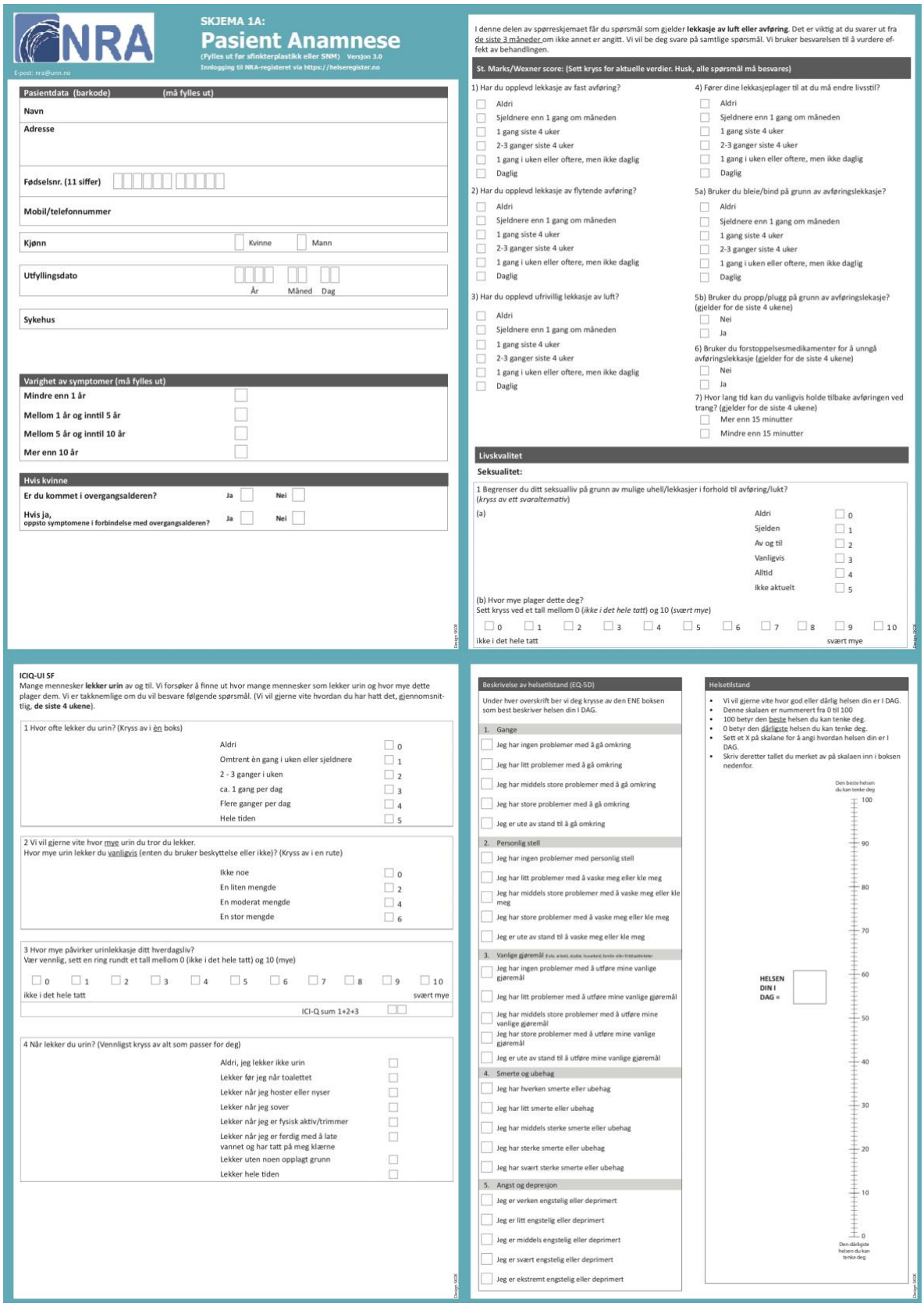
Jeg har lest informasjonen ovenfor og samtykker i at de nevnte opplysningene registreres i pasientdatabasen og gjøres tilgjengelig for kvalitetssikring og forskning.

Navn:_____ Fødselsdato:_____

Sted: _____Dato: _____ Underskrift:_____

NRA- Norsk Register for Analinkontinens – Samtykkeerklæring

Form 1A, history



SKJEMA 1A:

Pasient Anamnese

(Fylles ut før sfinkterplastikk eller SNM) Versjon 3.0

Innlogging til NRA-registeret via https://helseregister.no

E-post: nra@unn.no

Pasientdata (barkode) (må fylles ut)

Navn

Adresse

Fødselsnr. (11 siffer)

Mobil/telefonnummer

Kjønn ☐ Kvinne ☐ Mann

Utfyllingsdato ☐☐☐☐ År ☐☐ Måned ☐☐ Dag

Sykehus

Varighet av symptomer (må fylles ut)

Mindre enn 1 år ☐

Mellom 1 år og inntil 5 år ☐

Mellom 5 år og inntil 10 år ☐

Mer enn 10 år ☐

Hvis kvinne

Er du kommet i overgangsalderen? Ja ☐ Nei ☐

Hvis ja, oppsto symptomene i forbindelse med overgangsalderen? Ja ☐ Nei ☐

Design NORE

I denne delen av spørreskjemaet får du spørsmål som gjelder **lekkasje av luft eller avføring**. Det er viktig at du svarer ut fra de siste 3 måneder om ikke annet er angitt. Vi vil be deg svare på samtlige spørsmål. Vi bruker besvarelsen til å vurdere effekt av behandlingen.

St. Marks/Wexner score: (Sett kryss for aktuelle verdier. Husk, alle spørsmål må besvares)

1) Har du opplevd lekkasje av fast avføring?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

2) Har du opplevd lekkasje av flytende avføring?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

3) Har du opplevd ufrivillig lekkasje av luft?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

4) Fører dine lekkasjeplager til at du må endre livsstil?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

5a) Bruker du bleie/bind på grunn av avføringslekkasje?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

5b) Bruker du propp/plugg på grunn av avføringslekkasje? (gjelder for de siste 4 ukene)
- ☐ Nei
- ☐ Ja

6) Bruker du forstoppelsesmedikamenter for å unngå avføringslekkasje (gjelder for de siste 4 ukene)
- ☐ Nei
- ☐ Ja

7) Hvor lang tid kan du vanligvis holde tilbake avføringen ved trang? (gjelder for de siste 4 ukene)
- ☐ Mer enn 15 minutter
- ☐ Mindre enn 15 minutter

Livskvalitet

Seksualitet:

1 Begrenser du ditt seksualliv på grunn av mulige uhell/lekkasjer i forhold til avføring/lukt? (*kryss av ett svaralternativ*)

(a)
- Aldri ☐ 0
- Sjelden ☐ 1
- Av og til ☐ 2
- Vanligvis ☐ 3
- Alltid ☐ 4
- Ikke aktuelt ☐ 5

(b) Hvor mye plager dette deg?
Sett kryss ved et tall mellom 0 (*ikke i det hele tatt*) og 10 (*svært mye*)

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

ikke i det hele tatt — svært mye

Design NORE

ICIQ-UI SF

Mange mennesker **lekker urin** av og til. Vi forsøker å finne ut hvor mange mennesker som lekker urin og hvor mye dette plager dem. Vi er takknemlige om du vil besvare følgende spørsmål. (Vi vil gjerne vite hvordan du har hatt det, gjennomsnittlig, **de siste 4 ukene**).

1 Hvor ofte lekker du urin? (Kryss av i èn boks)
- Aldri ☐ 0
- Omtrent èn gang i uken eller sjeldnere ☐ 1
- 2 - 3 ganger i uken ☐ 2
- ca. 1 gang per dag ☐ 3
- Flere ganger per dag ☐ 4
- Hele tiden ☐ 5

2 Vi vil gjerne vite hvor mye urin du tror du lekker.
Hvor mye urin lekker du vanligvis (enten du bruker beskyttelse eller ikke)? (Kryss av i en rute)
- Ikke noe ☐ 0
- En liten mengde ☐ 2
- En moderat mengde ☐ 4
- En stor mengde ☐ 6

3 Hvor mye påvirker urinlekkasje ditt hverdagsliv?
Vær vennlig, sett en ring rundt et tall mellom 0 (ikke i det hele tatt) og 10 (mye)

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

ikke i det hele tatt — svært mye

ICI-Q sum 1+2+3 ☐☐

4 Når lekker du urin? (Vennligst kryss av alt som passer for deg)
- Aldri, jeg lekker ikke urin ☐
- Lekker før jeg når toalettet ☐
- Lekker når jeg hoster eller nyser ☐
- Lekker når jeg sover ☐
- Lekker når jeg er fysisk aktiv/trimmer ☐
- Lekker når jeg er ferdig med å late vannet og har tatt på meg klærne ☐
- Lekker uten noen opplagt grunn ☐
- Lekker hele tiden ☐

Design NORE

Beskrivelse av helsetilstand (EQ-5D)

Under hver overskrift ber vi deg krysse av den ENE boksen som best beskriver helsen din I DAG.

1. Gange
- ☐ Jeg har ingen problemer med å gå omkring
- ☐ Jeg har litt problemer med å gå omkring
- ☐ Jeg har middels store problemer med å gå omkring
- ☐ Jeg har store problemer med å gå omkring
- ☐ Jeg er ute av stand til å gå omkring

2. Personlig stell
- ☐ Jeg har ingen problemer med personlig stell
- ☐ Jeg har litt problemer med å vaske meg eller kle meg
- ☐ Jeg har middels store problemer med å vaske meg eller kle meg
- ☐ Jeg har store problemer med å vaske meg eller kle meg
- ☐ Jeg er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)
- ☐ Jeg har ingen problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har litt problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har middels store problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har store problemer med å utføre mine vanlige gjøremål
- ☐ Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag
- ☐ Jeg har hverken smerte eller ubehag
- ☐ Jeg har litt smerte eller ubehag
- ☐ Jeg har middels sterke smerte eller ubehag
- ☐ Jeg har sterke smerte eller ubehag
- ☐ Jeg har svært sterke smerte eller ubehag

5. Angst og depresjon
- ☐ Jeg er verken engstelig eller deprimert
- ☐ Jeg er litt engstelig eller deprimert
- ☐ Jeg er middels engstelig eller deprimert
- ☐ Jeg er svært engstelig eller deprimert
- ☐ Jeg er ekstremt engstelig eller deprimert

Helsetilstand

- Vi vil gjerne vite hvor god eller dårlig helsen din er I DAG.
- Denne skalaen er nummerert fra 0 til 100
- 100 betyr den beste helsen du kan tenke deg.
- 0 betyr den dårligste helsen du kan tenke deg.
- Sett et X på skalane for å angi hvordan helsen din er I DAG.
- Skriv deretter tallet du merket av på skalaen inn i boksen nedenfor.

Den beste helsen du kan tenke deg

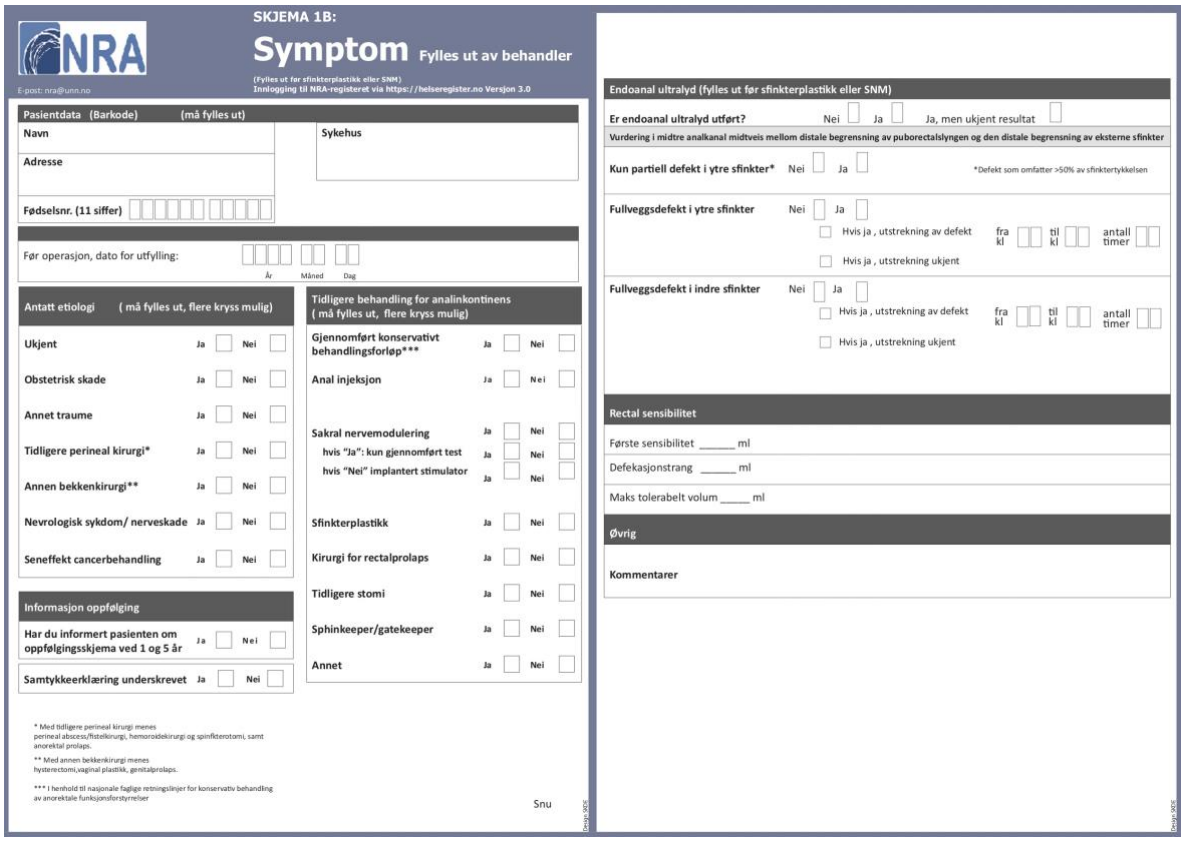
100 90 80 70 60 50 40 30 20 10 0

Den dårligste helsen du kan tenke deg

HELSEN DIN I DAG = ☐

Design NORE

Form 1B, symptoms



SKJEMA 1B:

Symptom Fylles ut av behandler

(Fylles ut før sfinkterplastikk eller SNM)
Innlogging til NRA-registeret via https://helseregister.no Versjon 3.0

E-post: nra@unn.no

Pasientdata (Barkode) (må fylles ut)

Navn | Sykehus

Adresse

Fødselsnr. (11 siffer)

Før operasjon, dato for utfylling: År Måned Dag

Antatt etiologi (må fylles ut, flere kryss mulig)

Ukjent	Ja	Nei
Obstetrisk skade	Ja	Nei
Annet traume	Ja	Nei
Tidligere perineal kirurgi*	Ja	Nei
Annen bekkenkirurgi**	Ja	Nei
Nevrologisk sykdom/ nerveskade	Ja	Nei
Seneffekt cancerbehandling	Ja	Nei

Informasjon oppfølging

Har du informert pasienten om oppfølgingsskjema ved 1 og 5 år	Ja	Nei
Samtykkeerklæring underskrevet	Ja	Nei

Tidligere behandling for analinkontinens (må fylles ut, flere kryss mulig)

Gjennomført konservativt behandlingsforløp***	Ja	Nei
Anal injeksjon	Ja	Nei
Sakral nervemodulering	Ja	Nei
hvis "Ja": kun gjennomført test	Ja	Nei
hvis "Nei" implantert stimulator	Ja	Nei
Sfinkterplastikk	Ja	Nei
Kirurgi for rectalprolaps	Ja	Nei
Tidligere stomi	Ja	Nei
Sphinkeeper/gatekeeper	Ja	Nei
Annet	Ja	Nei

* Med tidligere perineal kirurgi menes perineal abscess/fistelkirurgi, hemoroidekirurgi og spinkterotomi, samt anorektal prolaps.

** Med annen bekkenkirurgi menes hysterectomi,vaginal plastikk, genitalprolaps.

*** I henhold til nasjonale faglige retningslinjer for konservativ behandling av anorektale funksjonsforstyrrelser

Snu

Endoanal ultralyd (fylles ut før sfinkterplastikk eller SNM)

Er endoanal ultralyd utført? Nei Ja Ja, men ukjent resultat

Vurdering i midtre analkanal midtveis mellom distale begrensning av puborectalslyngen og den distale begrensning av eksterne sfinkter

Kun partiell defekt i ytre sfinkter*	Nei	Ja			*Defekt som omfatter >50% av sfinktertykkelsen
Fullveggsdefekt i ytre sfinkter	Nei	Ja	Hvis ja , utstrekning av defekt	fra kl / til kl / antall timer	
			Hvis ja , utstrekning ukjent		
Fullveggsdefekt i indre sfinkter	Nei	Ja	Hvis ja , utstrekning av defekt	fra kl / til kl / antall timer	
			Hvis ja , utstrekning ukjent		

Rectal sensibilitet

Første sensibilitet _____ ml

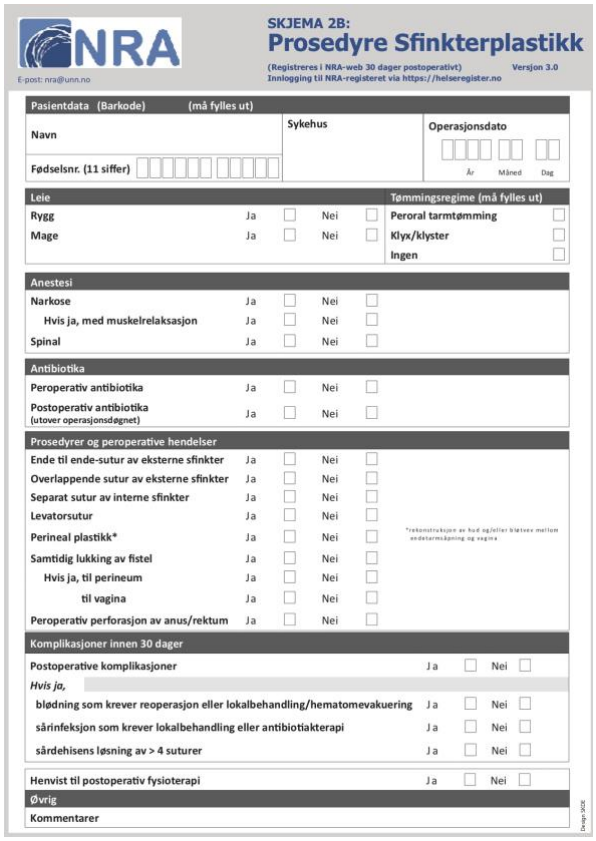
Defekasjonstrang _____ ml

Maks tolerabelt volum _____ ml

Øvrig

Kommentarer

Form 2B, procedure sphincteroplasty



SKJEMA 2B:

Prosedyre Sfinkterplastikk

(Registreres i NRA-web 30 dager postoperativt) Versjon 3.0
Innlogging til NRA-registeret via https://helseregister.no

E-post: nra@unn.no

Pasientdata (Barkode) (må fylles ut)

Navn | Sykehus | Operasjonsdato (År Måned Dag)

Fødselsnr. (11 siffer)

Leie				Tømmingsregime (må fylles ut)	
Rygg	Ja	Nei		Peroral tarmtømming	
Mage	Ja	Nei		Klyx/klyster	
				Ingen	

Anestesi			
Narkose	Ja	Nei	
Hvis ja, med muskelrelaksasjon	Ja	Nei	
Spinal	Ja	Nei	

Antibiotika			
Peroperativ antibiotika	Ja	Nei	
Postoperativ antibiotika (utover operasjonsdøgnet)	Ja	Nei	

Prosedyrer og peroperative hendelser				
Ende til ende-sutur av eksterne sfinkter	Ja	Nei		
Overlappende sutur av eksterne sfinkter	Ja	Nei		
Separat sutur av interne sfinkter	Ja	Nei		
Levatorsutur	Ja	Nei		
Perineal plastikk*	Ja	Nei		*rekonstruksjon av hud og/eller bløtvev mellom endetarmsåpning og vagina
Samtidig lukking av fistel	Ja	Nei		
Hvis ja, til perineum	Ja	Nei		
til vagina	Ja	Nei		
Peroperativ perforasjon av anus/rektum	Ja	Nei		

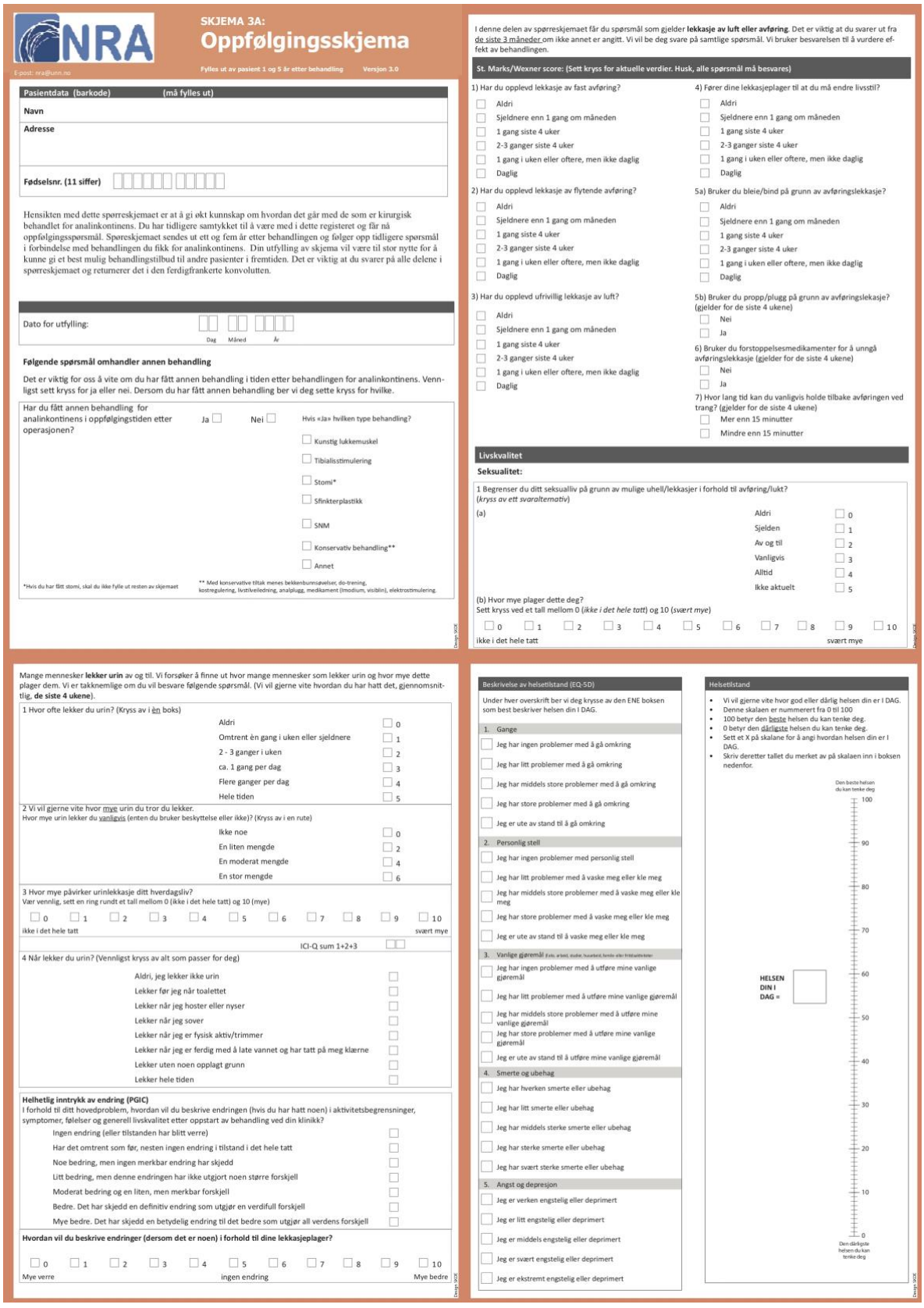
Komplikasjoner innen 30 dager		
Postoperative komplikasjoner	Ja	Nei
Hvis ja,		
blødning som krever reoperasjon eller lokalbehandling/hematomevakuering	Ja	Nei
sårinfeksjon som krever lokalbehandling eller antibiotiakterapi	Ja	Nei
sårdehisens løsning av > 4 suturer	Ja	Nei

Henvist til postoperativ fysioterapi Ja Nei

Øvrig

Kommentarer

Form 3A, follow-up



NRA

E-post: nra@unn.no

SKJEMA 3A:

Oppfølgingsskjema

Fylles ut av pasient 1 og 5 år etter behandling Versjon 3.0

Pasientdata (barkode) **(må fylles ut)**

Navn

Adresse

Fødselsnr. (11 siffer) ☐☐☐☐☐☐ ☐☐☐☐☐

Hensikten med dette spørreskjemaet er at å gi økt kunnskap om hvordan det går med de som er kirurgisk behandlet for analinkontinens. Du har tidligere samtykket til å være med i dette registeret og får nå oppfølgingsspørsmål. Spøreskjemaet sendes ut ett og fem år etter behandlingen og følger opp tidligere spørsmål i forbindelse med behandlingen du fikk for analinkontinens. Din utfylling av skjema vil være til stor nytte for å kunne gi et best mulig behandlingstilbud til andre pasienter i fremtiden. Det er viktig at du svarer på alle delene i spørreskjemaet og returnerer det i den ferdigfrankerte konvolutten.

Dato for utfylling: ☐☐ ☐☐ ☐☐☐☐ (Dag Måned År)

Følgende spørsmål omhandler annen behandling

Det er viktig for oss å vite om du har fått annen behandling i tiden etter behandlingen for analinkontinens. Vennligst sett kryss for ja eller nei. Dersom du har fått annen behandling ber vi deg sette kryss for hvilke.

Har du fått annen behandling for analinkontinens i oppfølgingstiden etter operasjonen? Ja ☐ Nei ☐

Hvis «Ja» hvilken type behandling?

- ☐ Kunstig lukkemuskel
- ☐ Tibialisstimulering
- ☐ Stomi*
- ☐ Sfinkterplastikk
- ☐ SNM
- ☐ Konservativ behandling**
- ☐ Annet

*Hvis du har fått stomi, skal du ikke fylle ut resten av skjemaet

** Med konservative tiltak menes bekkenbunnsøvelser, do-trening, kostregulering, livstilveiledning, analplugg, medikament (Imodium, visiblin), elektrostimulering.

Design NKK

I denne delen av spørreskjemaet får du spørsmål som gjelder **lekkasje av luft eller avføring**. Det er viktig at du svarer ut fra de siste 3 måneder om ikke annet er angitt. Vi vil be deg svare på samtlige spørsmål. Vi bruker besvarelsen til å vurdere effekt av behandlingen.

St. Marks/Wexner score: (Sett kryss for aktuelle verdier. Husk, alle spørsmål må besvares)

1) Har du opplevd lekkasje av fast avføring?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

2) Har du opplevd lekkasje av flytende avføring?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

3) Har du opplevd ufrivillig lekkasje av luft?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

4) Fører dine lekkasjeplager til at du må endre livsstil?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

5a) Bruker du bleie/bind på grunn av avføringslekkasje?
- ☐ Aldri
- ☐ Sjeldnere enn 1 gang om måneden
- ☐ 1 gang siste 4 uker
- ☐ 2-3 ganger siste 4 uker
- ☐ 1 gang i uken eller oftere, men ikke daglig
- ☐ Daglig

5b) Bruker du propp/plugg på grunn av avføringslekasje? (gjelder for de siste 4 ukene)
- ☐ Nei
- ☐ Ja

6) Bruker du forstoppelsesmedikamenter for å unngå avføringslekkasje (gjelder for de siste 4 ukene)
- ☐ Nei
- ☐ Ja

7) Hvor lang tid kan du vanligvis holde tilbake avføringen ved trang? (gjelder for de siste 4 ukene)
- ☐ Mer enn 15 minutter
- ☐ Mindre enn 15 minutter

Livskvalitet

Seksualitet:

1 Begrenser du ditt seksualliv på grunn av mulige uhell/lekkasjer i forhold til avføring/lukt? (*kryss av ett svaralternativ*)

(a)
- Aldri ☐ 0
- Sjelden ☐ 1
- Av og til ☐ 2
- Vanligvis ☐ 3
- Alltid ☐ 4
- Ikke aktuelt ☐ 5

(b) Hvor mye plager dette deg?
Sett kryss ved et tall mellom 0 (*ikke i det hele tatt*) og 10 (*svært mye*)

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

ikke i det hele tatt — svært mye

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Mange mennesker **lekker urin** av og til. Vi forsøker å finne ut hvor mange mennesker som lekker urin og hvor mye dette plager dem. Vi er takknemlige om du vil besvare følgende spørsmål. (Vi vil gjerne vite hvordan du har hatt det, gjennomsnittlig, **de siste 4 ukene**).

1 Hvor ofte lekker du urin? (Kryss av i én boks)
- Aldri ☐ 0
- Omtrent èn gang i uken eller sjeldnere ☐ 1
- 2 - 3 ganger i uken ☐ 2
- ca. 1 gang per dag ☐ 3
- Flere ganger per dag ☐ 4
- Hele tiden ☐ 5

2 Vi vil gjerne vite hvor mye urin du tror du lekker.
Hvor mye urin lekker du vanligvis (enten du bruker beskyttelse eller ikke)? (Kryss av i en rute)
- Ikke noe ☐ 0
- En liten mengde ☐ 2
- En moderat mengde ☐ 4
- En stor mengde ☐ 6

3 Hvor mye påvirker urinlekkasje ditt hverdagsliv?
Vær vennlig, sett en ring rundt et tall mellom 0 (ikke i det hele tatt) og 10 (mye)

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

ikke i det hele tatt — svært mye

ICI-Q sum 1+2+3 ☐☐

4 Når lekker du urin? (Vennligst kryss av alt som passer for deg)
- Aldri, jeg lekker ikke urin ☐
- Lekker før jeg når toalettet ☐
- Lekker når jeg hoster eller nyser ☐
- Lekker når jeg sover ☐
- Lekker når jeg er fysisk aktiv/trimmer ☐
- Lekker når jeg er ferdig med å late vannet og har tatt på meg klærne ☐
- Lekker uten noen opplagt grunn ☐
- Lekker hele tiden ☐

Helhetlig inntrykk av endring (PGIC)
I forhold til ditt hovedproblem, hvordan vil du beskrive endringen (hvis du har hatt noen) i aktivitetsbegrensninger, symptomer, følelser og generell livskvalitet etter oppstart av behandling ved din klinikk?
- Ingen endring (eller tilstanden har blitt verre) ☐
- Har det omtrent som før, nesten ingen endring i tilstand i det hele tatt ☐
- Noe bedring, men ingen merkbar endring har skjedd ☐
- Litt bedring, men denne endringen har ikke utgjort noen større forskjell ☐
- Moderat bedring og en liten, men merkbar forskjell ☐
- Bedre. Det har skjedd en definitiv endring som utgjør en verdifull forskjell ☐
- Mye bedre. Det har skjedd en betydelig endring til det bedre som utgjør all verdens forskjell ☐

Hvordan vil du beskrive endringer (dersom det er noen) i forhold til dine lekkasjeplager?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Mye verre — ingen endring — Mye bedre

Design NKK

Beskrivelse av helsetilstand (EQ-5D)

Under hver overskrift ber vi deg krysse av den ENE boksen som best beskriver helsen din I DAG.

1. Gange
- ☐ Jeg har ingen problemer med å gå omkring
- ☐ Jeg har litt problemer med å gå omkring
- ☐ Jeg har middels store problemer med å gå omkring
- ☐ Jeg har store problemer med å gå omkring
- ☐ Jeg er ute av stand til å gå omkring

2. Personlig stell
- ☐ Jeg har ingen problemer med personlig stell
- ☐ Jeg har litt problemer med å vaske meg eller kle meg
- ☐ Jeg har middels store problemer med å vaske meg eller kle meg
- ☐ Jeg har store problemer med å vaske meg eller kle meg
- ☐ Jeg er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)
- ☐ Jeg har ingen problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har litt problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har middels store problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har store problemer med å utføre mine vanlige gjøremål
- ☐ Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag
- ☐ Jeg har hverken smerte eller ubehag
- ☐ Jeg har litt smerte eller ubehag
- ☐ Jeg har middels sterke smerte eller ubehag
- ☐ Jeg har sterke smerte eller ubehag
- ☐ Jeg har svært sterke smerte eller ubehag

5. Angst og depresjon
- ☐ Jeg er verken engstelig eller deprimert
- ☐ Jeg er litt engstelig eller deprimert
- ☐ Jeg er middels engstelig eller deprimert
- ☐ Jeg er svært engstelig eller deprimert
- ☐ Jeg er ekstremt engstelig eller deprimert

Helsetilstand

- Vi vil gjerne vite hvor god eller dårlig helsen din er I DAG.
- Denne skalaen er nummerert fra 0 til 100
- 100 betyr den beste helsen du kan tenke deg.
- 0 betyr den dårligste helsen du kan tenke deg.
- Sett et X på skalane for å angi hvordan helsen din er I DAG.
- Skriv deretter tallet du merket av på skalaen inn i boksen nedenfor.

Den beste helsen du kan tenke deg: 100, 90, 80, 70, 60, 50, 40, 30, 20, 10, 0 (Den dårligste helsen du kan tenke deg)

HELSEN DIN I DAG = ☐

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