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Bridging the gap: pelvic floor physical therapy in the treatment of chronic anal fissure

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PART III

CHAPTER 9

Summary of results and general discussion

Chapter 1

General introduction

Anorectal disorders are common in general practice and the incidence of chronic anal fissure is 2.5 cases per 1000 persons in the Netherlands.¹

This thesis covers the anatomical and pathophysiological aspects of CAF faced during clinical practice with the focus on treatment by pelvic floor physical therapy alongside current management.

In chapter 1 we outlined the symptoms, pathogenesis, diagnostics, and management of CAF. A chronic anal fissure (CAF) refers to a longitudinal ulcer or tear in the squamous epithelium, generally located in the posterior midline with symptoms present for longer than 4-6 weeks or recurrent fissures.^{2,3} The classical symptom is pain during defecation, which may persist for hours,^{4,5} and has a significant impact on quality of life.⁶

Although some debate exists on the pathogenesis of CAF, it is assumed that pain causes an increased anal sphincter tone leading to ischemia which inhibits fissure healing, generating a vicious circle of pain and constipation.⁷⁻¹⁰

Pelvic floor dysfunction e.g., dyssynergia and/or increased pelvic floor muscle tone may also be an underlying cause and part of the pathophysiology and a reason for unresponsiveness to treatment.

We described the importance of performing a digital rectal examination including examination of the pelvic floor muscles and a comprehensive evaluation of the pelvis and surrounding structures to determine the underlying cause of pain and pelvic floor dysfunction.^{11,12}

Recent technological advances (electromyography and anorectal manometry) were described in this thesis. Electromyography can be used to assess motor control patterns, coordination, and pelvic floor muscle function.¹³ Manometry can be used as a component of clinical evaluation for patients in whom additional management strategies are considered.¹⁴

According to current guidelines, the initial conservative management is comprised of fibre intake and/or use of laxatives, toilet behaviour, lifestyle advice, sitz baths, and ointments.

Pelvic floor physical therapy (PFPT) is an important part of a multidisciplinary treatment approach and could be added to conservative management.

When conservative treatment fails, botulinum toxin can be applied.^{15,16} which is a safe alternative to surgery.¹⁷ Various surgical procedures are possible such as fissurectomy and lateral internal sphincterotomy. Although lateral internal sphincterotomy is the

preferred surgical treatment in guidelines,^{15,16} there is a potential risk of incontinence.¹⁸⁻²¹ Therefore the need for conservative management cannot be overemphasized.

Chapter 2

Management of chronic anal fissure, results of a national survey among gastrointestinal surgeons in the Netherlands

The knowledge among clinicians across medical community concerning the pelvic floor and pelvic floor disorders and regarding when and how to refer to pelvic floor physical therapy (PFPT) varies.²² Our aim was to evaluate current practice in the management of CAF amongst gastrointestinal surgeons in the Netherlands. A 21-item questionnaire was sent by email to Dutch gastrointestinal surgeons and residents between June 2021 and September 2021.

The questionnaire consisted of questions concerning work experience, physical examination, diagnostic- and surgical techniques and follow-up. Overall, 106 (33%) surgeons completed the survey and 59% had at least 10 years of experience in treating CAF. Only 23% always addressed pelvic floor complaints. Fifty-one percent performed digital rectal examination and 22% always, or almost always, examined the pelvic floor muscles. Most respondents started treatment with fibers and/or laxatives and ointment (96%) and diltiazem was in 90% the preferred ointment. Twenty-two percent referred patients for PFPT. Botulinum toxin was in 54% performed under general- or spinal anesthesia or sedation. The first surgical procedure of choice was fissurectomy (71%) followed by lateral internal sphincterotomy (27%). Fissurectomy was in 51% always combined with botulinum toxin. Fifty-seven percent of the respondents preferred a physical follow-up appointment.

Guideline recommendations are largely followed in the Netherlands, starting with conservative measures followed by surgical procedures. Surgeons do not consistently assess pelvic floor complaints, nor do they routinely examine the pelvic floor muscles. Awareness of pelvic floor dysfunctions is important to refer patients for pelvic floor physical therapy.

Chapter 3

Pelvic floor physical therapy for pelvic floor hypertonicity1: a systematic review of treatment efficacy

Increased pelvic floor muscle tone (non-neurogenic hypertonicity) is a disabling condition with urological, gynaecological, and gastrointestinal symptoms, sexual

problems, and chronic pelvic pain. Increased tone of the pelvic floor may be a cardinal factor contributing to delayed healing and pain in patients with CAF.^{23,24} To gain more knowledge on the effect of treatment on increased pelvic floor muscle tone, we systematically reviewed the treatment efficacy of PFPT. The outcome measures were pelvic floor muscle tone and function, pain reports, sexual function, pelvic floor symptom scores, quality of life and patient's perceived effect.

The literature search resulted in 10 eligible studies published between 2000 and 2019. Most studies had a high risk of bias associated with the lack of a comparison group, insufficient sample sizes and non-standardized interventions. Six studies were of low and 4 of medium quality. All studies were narratively reviewed. Three of 4 RCTs found positive effects of PFPT compared to controls on 5 out of 6 outcome measures. The prospective studies found significant improvements in all outcome measures that were assessed. PFPT seems to be efficacious in patients with chronic prostatitis, chronic pelvic pain syndrome, vulvodynia, and dyspareunia. Smallest effects were found in patients with interstitial cystitis and painful bladder syndrome. No studies were found in patients with a chronic anal fissure and the use of PFPT. The findings of this systematic review suggest that PFPT can be beneficial in patients with increased pelvic floor muscle tone.

¹An update on the terminology by the International Continence Society was conducted and published in 2021 after this systematic review. 'Hypertonicity' is changed into 'increased pelvic floor muscle tone' and is further used in this thesis.

Chapter 4

To what extent are anorectal function tests comparable? A prospective study comparing digital rectal examination, anal electromyography, 3-dimensional high resolution anal manometry and transperineal ultrasound

Anorectal function tests are helpful objectivizing anorectal (dys)functions, but there is no recommendation when to perform which test. The aim of our prospective study was to examine the correlation of anal pressures and diagnosing pelvic floor dyssynergia between digital rectal examination (DRE) and several anorectal function tests.

Between January 2020 and April 2022, all men and women aged 18 till 80 years, treated in the Proctos Clinic, who were referred to PFPT by the surgeon and underwent anorectal function tests in their diagnostic work-up, were included. Digital rectal examination was performed to establish the anal pressure in rest, and during squeeze and straining. Anorectal function tests included 3D-High resolution anal

manometry (3D-HRAM), balloon expulsion test, transperineal ultrasound and surface electromyography (s-EMG).

A total of 50 patients, 37 (74%) females, were included with a median age of 51 years. Twenty-three (62%) females had two or more vaginal deliveries in the past. Most frequent indication for referral for PFPT was fecal incontinence in 54% of the patients. The assessed pressures and pelvic floor function measured with digital rectal examination by the surgeon and the pelvic floor physical therapist during rest, squeeze and straining correlated in 78%, 78% and 84%, respectively. Correlation between digital rectal examination and 3D-HRAM or s-EMG, was better for squeeze pressures than resting pressures. The correlation between surface electromyography and 3D-HRAM was better during squeeze- than in rest with an agreement of 59% and 37% respectively. Digital rectal examination by an experienced investigator is of sufficient value for daily clinical practice to detect dyssynergia and measuring sphincter tone. Commonly performed anorectal function tests do not correlate with digital rectal examination, nor with other anorectal function tests. Although anorectal function tests can allay anxiety, these tests are invasive to the patient and expensive for health insurances.²⁵ They can however give some clarity in specific complex combined incontinence and obstructive defecation complaints. Perhaps we should reserve anorectal function tests for these kinds of patients and to those who are refractory to conservative treatments, where more invasive procedures, surgery, botulinum toxin e.g., are considered. Furthermore, these tests are valuable when evaluating new (surgical) therapies.

Chapter 5

Pelvic floor physical therapy in the treatment of chronic anal fissure (PAF-study): study protocol for a randomized controlled trial

Prolonged persistence of symptoms and recurrence in patients with CAF indicate that present treatment modalities are not always sufficient. Currently, there is a gap in treatment modalities between conservative management and surgery. We aim to provide a management protocol for PFPT to bridge this gap. The protocol prescribes the rationale, design, and methodology of a randomized controlled trial investigating PFPT as a treatment option for patients with CAF. The Pelvic Floor Anal Fissure study (PAF-study) is a single-centre, two armed, randomized controlled trial. The PAF-study aims to determine the efficacy and effectiveness of PFPT on improvement

on pelvic floor muscle tone and function, pain, healing of the fissure, quality of life and complaint reduction in patients with CAF. Patients with CAF and pelvic floor dysfunction will be recruited by surgeons of the Proctos Clinic. Exclusion criteria included abscess, fistula, Crohn's disease, ulcerative colitis, anorectal malignancy, prior rectal radiation, and pregnancy. A total of 140 patients are randomized for either PFPT or postponed treatment of PFPT. The primary outcome is tone at rest during electromyographic registration of the pelvic floor before and after therapy. Secondary outcomes consist of healing of the fissure, pain ratings, improvement of pelvic floor function, complaint reduction and quality of life. Primary and secondary endpoints are measured at 8 -and 20 week and at 1-year follow-up.

Chapter 6

Pelvic floor physical therapy in patients with chronic anal fissure: a randomized controlled trial

This chapter outlines the results of the PAF-study at 8- and 20-week follow-up.

Between December 2018 and July 2021, at the Proctos Clinic in the Netherlands, patients with chronic anal fissure and pelvic floor dysfunction were randomly assigned to an intervention group, receiving 8 weeks of PFPT including electromyographic biofeedback or assigned to a control group receiving postponed PFPT.

Endpoints were measured at 8- and 20-week follow-up. 140 patients were included in the study, 68 men (48.6%) and 72 women (51.4%) with a mean age of 44.5 ± 11.1 (range 19-79) years. Mean resting electromyographic values of the pelvic floor in the intervention group significantly improved from pre-to post-treatment ($p < 0.001$) and relative to controls (mean estimated difference between groups $-1.88 \mu V$; 95% CI, -2.49 to -1.27 ($p < 0.001$) at first follow-up and remained significant from baseline at 20-week follow-up ($p < 0.001$).

The intervention group performed better compared to the control group on all secondary outcomes i.e., healing of the fissure (55.7% of the patients vs 21.4% in control, pain ratings ($p < 0.001$), diminished dyssynergia ($p < 0.001$), complaint reduction ($p < 0.001$) and decrease of pelvic floor muscle tone ($p < 0.05$) at first follow-up.

The findings of this study provide strong evidence that PFPT is effective in patients with CAF and pelvic floor dysfunction and supports its recommendation as adjuvant treatment besides regular conservative treatment.

Chapter 7

Pelvic floor physical therapy in the treatment of chronic anal fissure (PAF-trial): outcome of Quality of Life

CAF is associated with reduced quality of life.⁶ This chapter outlines the results of the effects of PFPT on quality of life in patients with CAF who were included in the PAF-trial using the Short-Form 36 Health Survey (RAND-36). Quality of life and pain ratings were outcomes of the study and were measured at 8- and 20-week follow-up. Between December 2018 and July 2021, 100 patients, (50 women and 50 men, with a median age of 44.6 years [range 19-68]), completed the RAND-36 questionnaire and visual analog (VAS) pain score at admission. A significant improvement was found at 20-week follow-up in all domains of the RAND-36; physical functioning, pain, health change ($p < 0.001$); physical role, vitality, general health, social functioning, emotional role, mental health ($p < 0.05$). VAS pain was significantly reduced at 8 weeks (mean estimated difference 1.98; 95% CI. 1.55 to 2.42, $p < 0.001$) and remained significant at 20-week follow-up ($p < 0.001$). The difference between the groups as regards change in the mean pain intensity scores at 8 weeks was 2.48 (95% CI. -3.20 to -1.75; $p < 0.001$). Compared to the reference values of the general Dutch population, the patients in our study with a CAF and pelvic floor dysfunction reported an impaired quality of life in 8 of 9 domains of the RAND-36. After treatment significant lower scores were found in 2 out of 9 domains.

The results of this study provide evidence that treatment by PFPT improves quality of life and reduces pain, making it an important tool in management of CAF and concomitant pelvic floor dysfunction.

Chapter 8

Pelvic floor physical therapy in patients with chronic anal fissure: long term follow-up of a randomized controlled trial

The optimal management of CAF is quite challenging, mainly because of its recurrent nature. Our aim was to determine the outcomes of the PAF-trial and fissure recurrence in patients who completed the 2 months of PFPT at 1-year follow-up.

The treatment protocol was followed by 133 patients. 97 patients (71%) completed the 1-year follow-up, 48 women (49.5%) and 49 men (50.5%) with a mean age of 44.4 \pm 11.6 years (range 19-68). In the total group of patients, mean resting electromyographic values of the pelvic floor significantly improved from baseline to follow-up at 1 year (mean estimated difference 2.20 μ V; 95% CI, 1.79 to 2.61; $p < 0.001$).

After 1 year, the fissure recurred in 15 patients (15.5%). VAS-pain significantly decreased from baseline to follow-up (mean estimated difference 4.16; 95% CI, 3.75 to 4.58; $p < 0.001$). Dyssynergia was found in 72.9% at baseline and decreased to 14.4% at 1-year follow-up ($p < 0.001$). Complaint reduction measured with the Proctoprom, significantly improved from baseline to 1-year follow-up ($p < 0.001$). Quality of life (RAND-36) significantly improved in eight of nine domains at 1-year follow-up. No significant improvement was found in the domain vitality.

In the PAF-trial, we demonstrated that PFPT yields a significant and clinical benefit in the time course and should be advocated as adjuvant conservative treatment in patients with chronic anal fissure.

Discussion and recommendations

Conservative treatment is the first step in patients with CAF. It includes dietary adaptations, the use of (extra) fibers and/or laxatives, toilet behaviour, lifestyle advice, ointment and PFPT.

A selective approach is recommended based on the patient's medical history and physical examination. We strive for a greater understanding and recognition of CAF leading to, at an early stage, a better outcome for the patient.

Digital rectal examination including investigating of the pelvic floor muscles should be performed in routine clinical practice in the chronic phase, to distinguish between different causes of anorectal pain²⁶ aiming to adequately refer patients for PFPT.

To make the correct diagnosis and to reduce various treatment options, a local and/or regional partnership between a general practitioner (and collective) and a pelvic floor physical therapist is a desirable future perspective. The pelvic floor physical therapist as a practice assistant could be a possibility. But we also see a further development of 1.5-line care with the pelvic floor physical therapist in a one-off consultation in the role of consultant specialist as a renewed option to optimize the care for this anorectal disorder.

In this thesis we have proven the effect of PFPT in patients with CAF and concomitant pelvic floor dysfunction. Pelvic floor physical therapists are trained to diagnose and treat a wide range of diagnoses related to pelvic floor dysfunctions. The personal contact and skills of the therapist are pivotal for the effect of conservative management in this debilitating disease. In addition, to optimize the outcome, it is essential to actively listen to the patient to identify patients concerns, to provide education about CAF and the use of ointment (when, how and why), to set realistic goals,²⁷

manage comorbid conditions that may interfere with therapy compliance and manage expectations.²⁵ The success rate of PFPT depends on a careful diagnosis and patient selection,²⁸ evaluation concerning patients' motivation and commitment to treatment. The use of behaviour training with biofeedback was effective and durable in our study, but it should be mentioned that it is a labour-intensive treatment, treatment protocols vary among centers, and it is not universally available.

Brown et al.²⁹ found that adherence and completion of the treatment are critical for maintaining effectiveness. Monitoring sessions could be performed after the PFPT sessions to verify correct performance of exercises. Studies on effective implementation are the next step.

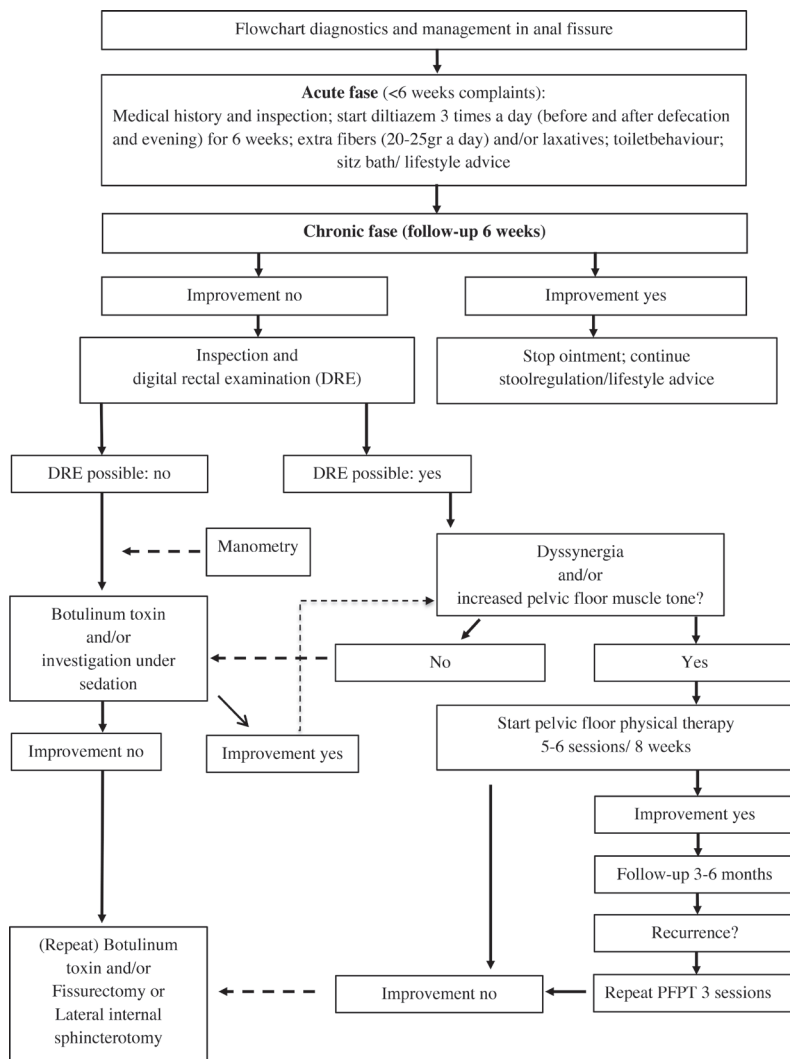
There is evidence of a strong and consistent relationship of sexual and/or physical abuse history in gastro intestinal disorders.³⁰⁻³³ Besides that, increased pelvic floor muscle tone is associated with sexual abuse.^{34,35} A history of sexual and/or physical abuse may play a role in the divergence between the symptoms patients report and objective measurements and may alter treatment recommendations.³⁶ Besides that, there is a high comorbidity of psychological disorders e.g. anxiety and depression in patients with CAF which could have a negative influence on quality of life and sexual function.^{6,37-39} More attention should be paid for addressing the issue of sexual health and other associated psychological factors in clinical practice and implementing questions concerning these topics and pelvic floor dysfunction in history taken. Further studies are needed to establish the effect of the underlying psychological mechanisms and the use of additional behavioral interventions including psychoeducation besides PFPT to identify targeted efficacious interventions in patients with CAF.

Although we did not perform an evaluation of the actual costs of each treatment including PFPT, we should take this into account. Treatment of CAF is a balance between efficacy, adverse events, risk of recurrence and costs. Improving daily functioning and reducing recurrence rates has cost implications and it is likely that the integrated nature of our conservative treatment is more cost-effective because of the diminishing need for surgery. A cost consideration study would be sensible calculating costs in time, effort, and finance for undergoing PFPT.

The findings of our study highlight the feasibility and effectiveness of a multidisciplinary treatment and points out the importance of integrating across health care professionals to improve the treatment in patients with CAF. The treatment of CAF should be sequential and tailored to the patients' needs and a holistic and multimodal approach is a requisite.

Referral to a gastrointestinal surgeon is essential when a digital rectal examination is not possible to perform, and when patients fail to respond to conservative measures including PFPT. A tailored approach is reflected in the proposed algorithm.

Although more high-quality studies are warranted to determine the effect of PFPT in patients with CAF and implementing these in guidelines, we are convinced that PFPT fills the gap between conservative treatment and surgery.



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