The place of pelvic floor complaints and sexual abuse in the gastroenterology practice: a cross-sectional study in colonoscopy patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual dysfunctions, disturbances and gender identity disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37852

Source
ToetsingOnline

Brief title
GEPfSa

Condition

- Sexual dysfunctions, disturbances and gender identity disorders

Synonym
treatment and assessment of the gastroenterologist regarding sexuality and sexual abuse

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: pelvic floor, sexual abuse

Outcome measures

Primary outcome

The primary outcome measure will be the survey results.

Secondary outcome

We will provide for a standardized questionnaire for new patients consuling a

gastroenterologist and make referral to a sexuologist or psychologist easier.

If proven necessary we will provide a list with sexologist and urologist in the

area, this can make referral easier.

Study description

Background summary

Dysfunction of the pelvic floor may lead to a wide range of symptoms, involving the urinary and gastrointestinal tract as well as sexual function. Only a small minority of the patients visiting a pelvic floor-clinic has just one symptom. There is a strong relationship between pelvic floor dysfunction and a history of SA. In the population consulting a gastroenterologist, the prevalence of SA history is much higher than in the general population (30-56%). The association between SA and GI-symptoms relates to a raised tonus of the pelvic floor muscles, an altered stress-induced mucosal immune function and impaired ability of the central nervous system to down-regulate incoming visceral and somatic afferent signals. Patients who (had to) deal with SA have a much poorer health status, they are more likely to report other symptoms such as depressive symptoms and fatigue, and they have a high risk of developing Irritable Bowel Syndrome (IBS).
In the majority of cases, patients consulting a specialist do not mention complaints in other areas of their body if they are not specifically asked about them. Understanding the importance of doctors* inquiry about symptoms

relating to their own area of expertise, we recently evaluated whether Dutch gastroenterologists address pelvic floor related symptoms in their daily practices. Furthermore we studied the awareness among Dutch gastroenterologists concerning SA. The results showed that most GE doctors are aware of the associated symptoms; the majority inquires about micturition and sexual function in patient presenting with complaints such as constipation and chronic abdominal pain. Sixty-eight percent of the GE-doctors ask about SA if a female patient presents with specific complaints. Nevertheless, only 36% of the doctors think about it when a male patient presents with specific symptoms such as fecal incontinence.
It is known that performing invasive physical examination, such as colonoscopy, can provoke intense emotional responses, dissociation or refusal to endure the procedure. This can be manifested by a startle response to touching, unanticipated tearfulness before or during the procedure, or cognitive or emotional dissociation. However, almost none of the GE-doctors ask about SA before performing a colonoscopy, only 0.6% in male patients and 2.4% in females.

Study objective

The purpose of this study is to evaluate patients consulting gastroenterologists regarding their perspectives concerning delicate matters such as sexuality. Would it be helpful if the doctor brings up the subject of SA? And how many patients would wish to be referred to a sexologist or a physiotherapist? Furthermore, how do patient are like to be treated prior and during endoscopic procedures? We are interested in patient*s perspectives on the treatment received by their gastroenterologists concerning pelvic floor complaints and sexual abuse inquiry.

Study design

Study design:
We will perform an anonymous, cross-sectional survey study and include all patients that underwent a colonoscopy in the HAGA teaching hospital in the past 12 month. Inclusion criteria will be: Age above 18 years old and the ability to fill out a 34-item questionnaire in the Dutch or English (Appendix) language. Exclusion criteria: Age beneath 18 years old, legally incapability and/or the inability to understand and fill out a Dutch or English questionnaire. There will be no maximum age limit for inclusion in this survey, as many elderly people tend to consider sexuality an important aspect of life.
Before sending the questionnaires, a letter explaining the objectives of the study and a consentform will be sent. Patients that are willing to participate have to return the consentform and state their willingness to participate, a questionnaire will be send or emailed to those patients in return (as well as a prepaid return envelope). For patients unwilling to participate, we will provide an option in the consentform in which they can state their

unwillingness to participate. If this option is marked, we will not approach the patient again. Non-responders will receive a reminder letter and a consentform one more time after a month. Data will be handled anonymously; the main researcher will not be in the possession of the names and addresses corresponding with the respondents.
This study will be perfomed accordingly in the Zuwe Hofpoort Hospital and in the Leiden University Medical Center. Ethical approval will be obtained.

Materials; Questionnaire:
In the 34-item questionnaire (Appendix) the different domains of the pelvic floor will be evaluated. Furthermore it will address the beliefs and overall impression of patients that visited the gastroenterologist, regarding their treatment and their experience with colonoscopy.
Demographic data will include gender, age, country of origin and the reason for consulting the gastroenterologist. Many of the questions are from The Pelvic Floor Inventories Leiden (PelFI*s), which is validated in both Dutch and English. A small pilot study among 5 to10 non-medical volunteers will be performed to investigate whether the questionnaire is comprehensive and easy to fill in.

Data management:
All data will be collected anonymously. Each consentform will get a number, by means of which a second letter can be send out in case of unresponsiveness and the respondents that stated not willing to participate can be removed from of the mailing list. The data will be analyzed anonymously and the questionnaires will be stored safely. The main researcher will not be in the possession of the names and addresses corresponding with the respondents.

Statistical analysis:
Data analysis will be performed using SPSS release 17. Bivariate associations between demographic information and the type of answers will be calculated using the Pearson*s chi-square procedure. A two-sided P value of < 0.05 will be considered statistically significant. Questions with more than one possible answer and with open answers will be grouped together for analysis.

Ethics:
Because of the personal character of the questions, ethical approval will be required. We will ask the Medical Ethical Committee for advice.
We will give the respondents with a history of SA the opportunity for referral to the physician-sexologist (M.P.) at the HAGA teaching hospital or to a psychologist, because the questionnaire may provoke emotional distress. This referral will be realized by providing a letter for the General Practitioner; this letter will explain the reason for the referral and the General Practitioner just has to sign it in order to arrange a referral to a sexologist or a psychologist.

Study burden and risks

The questionnaire may provoke emotional distress.

We will give the respondents with a history of SA the opportunity for referral to the physician-sexuologist (M.P.) at the HAGA Teaching Hospital. Participation in the study will contribute to the better healthcare towards invasive procedures such as colonoscopy and towards holistic patientcare.

Contacts

Public
Leids Universitair Medisch Centrum

albinusdreef 2
2333 ZA, Leiden
NL
Scientific
Leids Universitair Medisch Centrum

albinusdreef 2
2333 ZA, Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age>18 years old with the capability to understand and fill in a dutch, english or turkish

questionnaire.
Patients that underwent a colonoscopy at the HAGA medical centre the Hague in the past 12 month.

Exclusion criteria

-Age under 18 years old.
-legaly incapable people
-mentaly disabled people (IQ<70), including people suffering from dementia.
-unable to master the dutch, english or turkish language.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2012
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	25-04-2012

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL38471.098.11

Study results

Date completed:	20-12-2012
Actual enrolment:	785