Anorectal function and clinical symptoms in patients with a third degree anal sphincter rupture: longterm follow-up

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- to establish the long-term alteration of anorectal function in women after promary repair of a third degree obstetrical anal sphincter rupture- to evalute the following complaints in women in late postpartum period after 3rd degree rupture:...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anal and rectal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON32951

Source
ToetsingOnline

Brief title
Anorectal function in patients with third degree rupture

Condition

- Anal and rectal conditions NEC

Synonym
sphincter injury, third degree anal sphincter rupture

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Research Budget MDL VUmc

Intervention

Keyword: anal canal/ injuries, anorectal function, pregnancy, third degree anal sphincter rupture

Outcome measures

Primary outcome

a) Changes of anorectal function assessed by anal manometry, rectal compliance

measurement and anal endosonography

b) Clinical symptoms:

o faecal symptoms measured by Vaizey and Wexner scores:

o urinary incontinence (urge/ stress/ mixed) measured by ICIQ-SF

o sexual complaints measured by BIQ, PSHQ, MMQ, FSDS, FSFI, SPEQ

Secondary outcome

- quality of life measured by QLQ-FS 36

Study description

Background summary

Third-degree obstretric tear is a vaginal tear with clinical disruption of the perineum with total separation of the anal sphincters, with or without a breach of the anal epithelium. In the literature, the incidence of third degree rupture is reported between 0.6-6%.

Faecal incontinence is a frequent problem after childbirth. This can be due to damage of the anal sphincter (third degree rupture) or stretch injury of pudendal nerve. Often these two factors both play a role. After delivery, some improvement can be expected in the first months. This is due to partial recovery from the overstretching of the muscles in the pelvic floor and of the pudendal nerve. However, many women will develop complains of faecal incontinence later in life, attributed to aging or subsequent deliveries with nerve damage or sphincter atrophy.
The literature about the incidence of faecal incontinence is not clear. Furthermore, awareness of the importance of a good sphincter repair postpartum

has increased and is performed in the operative room and not in the obstetric ward.

Sexual complaints are associated with anal sphincter injury as well and it seems that the complaints become even more severe two decades after delivery. However, other study with the same follow-up time of 18 to 20 years, found no significant association of anal sphincter injury with sexual complaints.

In summary, studies have shown that a third degree rupture may lead to incontinence and sexual complaints and warrant increase attention because the complaints are hidden by patients.
Most of the studies with a long term follow-up were only based on questionnaires and no anal function tests were performed. Long-term follow-up of such women will be necessary to determine whether they are at risk for incontinence and sexual complains later in life.

Study objective

- to establish the long-term alteration of anorectal function in women after promary repair of a third degree obstetrical anal sphincter rupture
- to evalute the following complaints in women in late postpartum period after 3rd degree rupture:
faecal incontinence
sexual complaints
urinary incontinence
- to relate the anal endosonography and anorectal manometry findings with the clinical outcome

Study design

Since 1998, 71 patients who experienced a 3rd degree anal sphincter rupture in our department of Obstetrics were seen for anorectal function evaluation in our department of Gastroenterology. After a 3rd degree anal sphincter rupture, all women had an overlapping sphincter repair under general anaesthesia in the operation room. Anal manometry and anal endosonography were performed 3 to 4 months after their delivery.

During their referral, all patients were already informed that they might be contacted in the future for follow-up and all agreed. Their addresses are retrieved from the electronic patient files. If women have moved from the last known address, the current address will be traced with the help of the family doctor.

All patients will be asked to fill in questionnaires regarding anorectal complaints, urinary symptoms and sexual function. Furthermore, they will be invited to undergo anorectal function tests again. The actual complaints and

the results of present anorectal function tests will be compared with the results of the anorectal function test of the last referral.

Study burden and risks

No specific ethical problems exist. The anorectal examinations are easy to perform and well tolerated by patients. It requires no bowel preparation. The investigation takes only a few minutes. The use of hydrogen can be considered as a safe, economic and accurate procedure to assess fistulas. Furthermore, all patients were already informed that they might be contacted in the future for follow up and all agreed. In addition, all patients had these test previously.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Diagnosis of 3rd degree anal sphincter rupture confirmed by gynaecologist during repair
-Evaluation of anorectal function 3-4 months after 3rd degree anal sphincter rupture

Exclusion criteria

females who had a delivery < 6 months

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-11-2009
Enrollment:	71
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL28159.029.09