The short and longterm effects of posterior colporrhaphy; the role of levator sutures.

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To determine the long and short term outcomes of posterior colporrhaphy with and without levator sutures. To compare both groups and maybe give a scientifically proven answer to the question which one has a better outcome. Then we can offer our...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49473

Source
ToetsingOnline

Brief title
The effects of levator sutures in posterior colporrhaphy

Condition

- Other condition
- Obstetric and gynaecological therapeutic procedures

Synonym
proctocele, Prolapse

Health condition

Bekkenbodem aandoeningen(verzakkingen)

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Het management van de vakgroep Vrouw en Kind van het Haga Ziekenhuis financieert de financiële bijdrage aan het wetenschapsbureau van het Haga Ziekenhuis. DIt betreft 250 euro voor het monitoren van de studie. Er zijn geen andere kosten aan het onderzoek verbonden.

Intervention

Keyword: Levator sutures, Long term effects, Posterior colporrhaphy, Short term effects

Outcome measures

Primary outcome

Primary outcome:

Recurrence rate of posterior wall prolapse

Secondary outcome

Secundary outcomes:

- Short term: postoperative pain (0-10), micturition (+/-), duration of the

surgery, bloodloss and bowel fysfunction (+/-, if so, what type of dysfunction)

- Long term: prolapse symptoms (+/-, PGI-I score), resume daily

activities,(time in weeks) recurrence of prolapse (vaginale examination),

postoperative wound or urinarytract infection (+/-), dyspareunia (+/-)

The data will be gathered by a combination of desk and fieldresearch.

- Deskresearch will be done to determine the shortterm effects. Data research

in the hospitals data system will be performed where surgery reports and

postoperative checks will be included.

- Fieldresearch will be done with interviews where the long term effects will be determined with a questionairre. This questionairre was formulated in cooperation with the clinic of psychosomatic gynaecology and sexology of the LUMC. Patients can decide to take this questionairre at home (digitally or on paper) or to come to the clinic. In addition to the interviews we will try to see patients in our clinic to do a physical and vaginal exam, so we can determine whether or not the is a recurrence of the prolapse.

Study description

Background summary

Prolapse of the pelvic organs is a very common problem. 50% of parous women above 50 have a prolapse of one of the pelvic organs. These prolapses are mostly asymptomatic. However 11,1% of women with a prolapse experience such heavy symptoms that surgical correction is indicated. A defect in the posterior vaginal wall can lead to a rectocele(prolapse of the rectum) or a enterocele(prolapse of the small bowel). These prolapses can cause symptoms like difficult defeacation and 'feeling like there is a ball between your legs'. Surgical correction with a posterior colporrhaphy can relief the symptoms. During this surgery the defect in the posterior vaginal wall is corrected. Posterior colporrhaphy reliëfs the symptoms in 86% of all cases.

There are 2 different methods for the posterior colporrhaphy; with or without certain 'levator sutures'. With these sutures you can create a anterior plication of the levator ani muscles. The common idea behind this method is that it should lead to fewer recurrences. However previous research indicates that this technique may cause more dyspareunia and more bowel dysfunction. Systematic research to compare both techniques is however lacking. Therefore there is no golden standard and the surgeons preference determines which method is chosen.

Therefore we formulated the following research question: Does the use of levator sutures significantly improve the short and longterm outcomes in posterior colporrhaphy?

The PICO we formulated is:
P: Patiënts who had posterior colporrhaphy surgery between 01-01-2010 and

31-12-2019 in the Haga hospital in The Hague.
I: Posterior colporrhaphy with levator sutures
C: Posterior colporrhaphy without levator sutures
O: Short term: postoperative pain, micturition and bowel dysfunction
Long term: resume daily activities, recurrence rate of prolapse, postoperative wound or urinarytract infection, dyspareunia

Study objective

To determine the long and short term outcomes of posterior colporrhaphy with and without levator sutures. To compare both groups and maybe give a scientifically proven answer to the question which one has a better outcome. Then we can offer our patients the best treatment and patient care.

Study design

It is a observational study in the form of a retrospective cohort study. Prospective randomised research is ideal, however that takes up a lot opf time. Therefore we chose a retrospective design to compare both groups and to see if further prospective research is necessary and indicated.

Study burden and risks

Patients can choose the extent of the burden they put themselves under.
- Data research can be done without the help of the patients, they don't have to do anything.
- Interviews; the patient can choose whether or not to cooperate with the study. If they do; the interviews will be about 10 minutes long and patients can answer the questions from home or come to the clinic to take the questionairre.
- Physical examination in the clinic: the appointment will be about 20 minutes long, people have to travel to the appointment and they will get a physical and vaginal exam. Which can cause discomfort or sometimes some pain. During this exam we can possibly observe a recurrence of the prolapse or other abnormalities for which we may want to do further research or suggest a treatment.

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

Patients who had posterior colporrhaphy surgery between 01-01-2010 and 31-12-2019 in the Haga hospital in The Hague.

Exclusion criteria

- Patients whose contact info are outdated
- Patients who don't want to participate in the research(they are excluded for the interviews, not the data research)
- Patients where postoperative data is missing
- Patients where it is unclear which operation method was used

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-10-2020
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	21-07-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL73134.058.20

Study results

Date completed: 05-04-2022

Summary results
Trial ended prematurely