Nociceptive and stress hormonal state during hysterectomy as an index of pain perception: a prospective study.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Observational invasive

Summary

ID

NL-OMON32268

Source
ToetsingOnline

Brief title
Indexes of pain perception in hysterectomies.

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
excision of the uterus, hysterectomy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,subsidie wordt aangevraagd

Intervention

Keyword: hysterectomy, nociceptive status, pain perception, stress hormones

Outcome measures

Primary outcome

Pulse transit time measures, catecholamine-levels, VAS-scores from the three

study groups.

Secondary outcome

N.A.

Study description

Background summary

Hysterectomy is the most frequently performed major gynaecologic surgical procedure annually throughout the world. The annual number of women undergoing hysterectomy in the Netherlands is about 15.000.
The most common indication for hysterectomy is uterine fibroids, followed by dysfunctional uterine bleeding and endometriosis. The three types of hysterectomy are now used - abdominal, vaginal, and laparoscopic.
Traditionally, abdominal hysterectomy (AH) has been used for gynaecological malignancy or if the uterus is enlarged. Vaginal hysterectomy (VH) was originally used only for prolapse, but it is now also used for menstrual abnormalities when the uterus is of fairly normal size. Laparoscopic hysterectomy (LH) has been introduced in 1989 as an alternative to abdominal hysterectomy. However, LH requires other technical skills than the vaginal or abdominal method.
Several studies compared the three methods stated above in detail. Significantly improved outcomes suggested that VH should be performed in preference to AH whenever possible. LH can avoid the abdominal approach and shows benefits in lower intraoperative blood loss, smaller drop in hemoglobin level, shorter duration of hospital stay, speedier return to normal activities, fewer wound or abdominal wall infections, fewer unspecified infections, however, at the cost of longer operating time and more urinary tract (bladder or ureter) injuries. In contrast, according to relative elevated IL-6 and CRP serum levels found in AH, this abdominal approach is repeatedly associated with inclined tissue damage.

Still a debate is continuing concerning the method of preference in hysterectomies when a vaginal approach is contraindicated. A recent Dutch preference study concluded that patients prefer the safest as well as the laparoscopic method. Although after surgery LH patients report to be pain free in a significant shorter period of time compared to AH, recent studies observed that laparoscopic surgery is associated with higher pain scores in the first hours postoperatively. Due to minimal access, the laparoscopic approach is proved to cause less tissue damage. Still patients appear to report heavier pain immediately after the procedure. In addition, as minimal invasive surgery is associated with minimal (tissue) damage, should it therefore cause minimal pain impulses during and after the intervention? A novel approach in measuring nociceptive impulses as an index of pain perception during surgery has recently been validated.
To our knowledge no research on evaluation of stress hormone levels in patients undergoing the different modes of hysterectomy has been published yet. Measured stress hormones (e.g. catecholamine) might be accompanying predictors of experienced intraoperative pain. Previous research indicated that a minimal invasive approach in surgery is associated with lower intraoperative stress hormone levels. According to one recent study the depth of anesthesia does not influence the endocrine-metabolic response to pelvic surgery, thus suggesting that the results from the three different to be studied approaches should be fairly comparable.

Study objective

This study primarily aims to get insight in the intraoperative nociceptive state of the patient as an index of the amount of pain stimuli comparing the three modes of hysterectomy. Next to this, by measuring pre-, intra- and postoperative stress hormone levels this study aims to emphasize whether these levels differ between the three modes of hysterectomy.

Study design

In this prospective single center study every consecutive hysterectomy (vaginal, abdominal or laparoscopic) will be included.

Nociceptive state monitoring
In order to compute the nociceptive state the pulse transit time (PTT, defined as the time between the R-wave of the ECG and the arrival of the pulse wave in the periphery (e.g. finger tip)) is measured as an index of pain perception. Previous studies show that PTT gives a better indication of the nociceptive state than commonly used parameters, such as blood pressure, heart rate and processed EEG monitoring.

Hormonal state monitoring
Pre-, intra- and postoperatively blood samples will be collected in order to

measure stress hormone levels. In total six blood samples will be collected, of which three will be taken during regular control moments (see figure 1) The remaining three samples will be collected during surgery. Plasma catecholamine concentration (C-CAMI; norepinephrine and epinephrine levels) will be measured. Each obtained sample consists of 4 ml blood and will be kept in an EDTA-fuse, stored in a minus 20 degrees Celsius environment for further analysis.

Postoperative pain reporting
As an extra check every patient will be asked to assess her pain level using a VAS (1-10) preoperatively (before pre-medication has been administered) and one hour postoperatively, provided she self-rates herself awake (>4-10 VAS). Otherwise attempts will be made by the PACU physician or nurse, every 15 minutes until awake.
Pain-medication of each patient will be registered.

Power calculation
Provided patients undergoing a LH will experience more pain durante operationem and
during the first 4 hours postoperatively compared to the AH-group we want to assess a
30% mean difference (α = 0.05) in PTT during surgery, with SD 0.2. Based on the results from the pilot study, we need 15 patients in each group to achieve a power of 0.98. The VH-group will primarily act as a control group, as unfortunately no adequate comparable research on pain perception in vaginal surgery is available yet.

Informed consent
As in this study several blood samples will be collected and participation of the patient is needed, regarding her cooperation in assessing pain intensities using the VAS pre- and postoperatively, an informed consent is a requisite.

Study burden and risks

N.A.

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

Hysterectomy for benign or premalign uterine pathology

Exclusion criteria

Exclusion criteria include disturbances of the central nervous system or psychiatric diseases, chemical substance abuse, chronic use of analgesics, chronic pain, cardiovascular, hepatic or renal insufficiency, pregnancy, extended accompanying prolapse or oncologic surgery, and age < 18 years

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (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	NL23404.058.08