Gerandomiseerde studie naar de effecten van opereren met LigaSure System op het post-operatief herstel en functioneren van de bekkenbodem na abdominale uterus extirpatie.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20645

Source
NTR

Brief title
N/A

Health condition

Abdominal hysterectomy for benign disease.

Sponsors and support

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Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Postoperative pain.

Secondary outcome

1. Resuming normal daily activities;

2. postoperative pelvic floor function;

3. complications;

4. blood loss;

5. duration of surgery;

6. duration of hospitalisation.

Study description

Background summary

In the Netherlands every year 20 000 abdominal hysterectomies are performed. Most of these operations are performed for benign conditions causing menorrhagia, metrorrhagia, dysmenorrhoea or pelvic pain. Hysterectomy carries the risk of damaging pelvic autonomic nerves which may trigger the development of pelvic floor dysfunction, resulting in micturition symptoms, defecation symptoms and worsened sexual functioning. 1-3
Studies focusing on the distribution of autonomic nerves to the pelvic organs in the supportive ligaments of the uterus, observed that the cardinal ligaments contain more nerves in comparison to the sacro-uterine ligaments.4 Cross-sectional biopsies taken during simple and radical hysterectomy, showed the majority of nerve fibers to be situated in the more lateral parts of the uterine supportive ligaments.4 This finding provides an anatomical explanation for the observation that radical hysterectomy causes more pelvic floor dysfunction than simple hysterectomy.
Based on these findings, we developed the hypothesis that cutting the supportive ligaments as close to the uterus as possible during simple hysterectomy might well reduce autonomic

nerve damage, thus resulting in improved post-operative pelvic floor function. The introduction of vessel sealing techniques provided the surgical tools to reach this goal, and enabled us to study our hypothesis.

LigaSure is a bipolar vessel sealing system, which provides a combination of pressure and energy which reforms the collagen and elastin in vessel walls to form an autologous seal and thereby achieving complete haemostasis. It permanently fuses vessels up to and including seven mm in diameter and tissue bundles without dissection or isolation. It is stated that vessel sealing systems have the potential to replace the use of conventional suture bounding.

Several advantages of the use of vessel sealing during hysterectomy like reduced post-operative pain, less blood loss and shorter admission stay have been documented.5-9 The reduced post-operative pain may be explained by the fact that the amount of traction applied to the tissue, during operation, is reduced when using vessel sealing. However, the mentioned studies all address vaginal hysterectomy, whereas reducing morbidity in patients undergoing abdominal hysterectomy appears to be more clinically relevant based on the fact that abdominal hysterectomy causes more morbidity than vaginal hysterectomy.10
Only one randomised trial has compared conventional suturing and vessel sealing in patients undergoing abdominal hysterectomy for benign disease.11 In this trial no differences with respect to duration of surgery, amount of blood loss and complications were observed. However, only 30 patients were included and the trial did not report on postoperative pain and pelvic floor function.

Reference List

1. Thakar R, Manyonda I, Stanton SL, Clarkson P, Robinson G. Bladder, bowel and sexual function after hysterectomy for benign conditions. A review. Br J Obstet Gynecol 1997; 104:983-987;

2. Virtanen H, Makinen J, tenho T, Kiilholma P, Pitkanen Y, Hirvonen T. Effects of abdominal hysterectomy on urinary and sexual symptoms. Br J Urol 1993; 72:868-872;

3. van Dam JH, Gosselink MJ, Drogendijk AC, Hop WCJ, Schouten WR. Changes in bowel function after hysterectomy. Dis Colon Rectum 1997; 40:1342-1347;

4. Butler-Manuel SA, Buttery LDK, A'Hern RP, Polak JM, Barton DPJ. Pelvic nerve plexus trauma at radical hysterectomy and simple hysterectomy: the nerve content of the uterine supporting ligaments. Cancer 2000; 89:834-841;

5. Hefni MA, Bhaumik J, El-Toukhy T, Kho P, Wong I, Abdel-Razik T et al. Safety and efficacy of using the LigaSure vessel sealing system for securing the pedicles in vaginal hysterectomy: randomised controlled trial. Br J Obstet Gynecol 2005; 112(3):329-333;

6. Cronje HS, de Coning EC. Electrosurgical bipolar vessel sealing during vaginal hysterectomy. Int J Gynaecol Obstet 2007; 91(3):243-245;

7. Douay N, Belot F, Bader G, Guyot B, Heitz D, Fauconnier A. Postoperative pain after hysterectomy through vaginal routes using electrosurgical bipolar vessel sealing versus conventional suture ligature. Gynecol Obstet Fertil 2007;Jun 21;

8. Ding Z, Wable M, Rane A. Use of LigaSure bipolar diathermy system in vaginal hysterectomy. J Obstet Gynaecol 2005; 25(1):49-51;

9. Levy B, Emery L. Randomized trial of suture versus electrosurgical bipolar vessel sealing in vaginal hysterectomy. Obstet Gynecol 2003; 102(1):147-151;

10. Van Den Eeden SK, Glasser M, Mathias SD, Colwell HH, Pasta DJ, Kunz K. Quality of life, health care utilization, and costs among women undergoing hysterectomy in a managed-care setting. Am J Obstet Gynecol 1998;178:91-100;

11. Hagen B, Eriksson N, Sundset M. Randomised controlled trial of LigaSure versus conventional suture ligature for abdominal hysterectomy. Br J Obstet Gynecol 2005; 112:968-70.

Study objective

Use of vessel sealing reduces postoperative pain and improves postoperative pelvic floor function.

Study design

1. Preoperative;

2. six weeks postoperative;

3. six months postoperative.

Intervention

1. Conventional surgery using suturing and clamps;

2. Vessel sealing using LigaSure.

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Eligibility criteria

Inclusion criteria

Patients undergoing abdominal hysterectomy.

Exclusion criteria

1. Indication for hysterectomy is gynaecologic malignancy;

2. Indication is genital prolapse;

3. Patients undergoing concomitant surgical procedures.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	48
Type:	Actual

Ethics review

Positive opinion

Date:	25-10-2007
Application type:	First submission

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
NTR-new	NL1072
NTR-old	NTR1105
Other	AMC Amsterdam :
ISRCTN	wordt niet aangevraagd/retrospectieve trial

Study results

Summary results

J Minim Invasive Gynecol. 2008 Sep-Oct;15(5):547-53. Epub 2008 Jul 10.