Laparoscopic hysterectomy in benign gynaecological conditions

Outcomes after total laparoscopic hysterectomy and laparoscopic supracervical hysterectomy, a comparison of surgical procedures

PhD thesis by Espen Berner, MD - 2014 Department of Gynaecology, Oslo University Hospital, Ullevål and University of Oslo, Faculty of Medicine, Norway

The PhD Thesis was publicly defended at Oslo University Hospital, Ullevål, Dec 15th 2014.

The official opponents:

1st Opponent: **Jon Ivar Einarsson**, Associate Professor Obstetrics and Gynecology, Harvard Medical School, Boston, MA, USA

2nd Opponent: **Marie Ellström Engh**, Professor Institutt for klinisk medisin, Universitetet i Oslo

3rd Opponent (Leader of the committee): Professor **Tom Tanbo**, Institutt for klinisk medisin, Universitetet i Oslo

Main Supervisor:

Førsteamanuensis Marit Lieng, Institutt for klinisk medisin, Universitetet i Oslo

Correspondence:

espen.berner@ous-hf.no or espen.berner@gmail.com

Summery of the thesis

There has been a continued debate for decades regarding methods of hysterectomy. The disagreement has both been related to the surgical approach and the removal of cervix in women suffering from benign conditions. After the implementation of the laparoscopic approach, the rate of supracervical hysterectomy has increased. The preference of total laparoscopic hysterectomy (TLH) or laparoscopic supracervical hysterectomy (LSH) follows the corresponding discussion as for abdominal hysterectomy. Arguments in favor of LSH have been a reduced risk of complications and a more rapid recovery without compromising the long-term outcome compared to TLH. In contrast, a risk of vaginal bleeding and pelvic pain after LSH has been documented. Cervical stump symptoms after a supracervical hysterectomy might cause patient distress and repeated surgery. In addition, the risk of complication caused by tissue extraction using the morcellator during the LSHprocedure has become the focus of this debate, recently.

Inadequate amputation of the cervix during LSH may cause remnant endometrial tissue in the upper cervix. Consequently, a modification of the surgical technique might reduce the occurrence of vaginal bleeding after this procedure. For this purpose, we developed a monopolar device for a reverse loop electrosurgical excision procedure (LEEP) of the endocervix during LSH.

The risk of a persistent cyclic pelvic pain after LSH has also been recognized. Especially, this risk is evident in women with endometriosis. Therefore, various gynecologists have claimed that supracervical hysterectomy should not be performed in women with endometriosis, pelvic pain or dysmenorrhea. Other gynecologists state that endometriosis and pelvic pain should not be contraindications for performing supracervical hysterectomy, unless leaving the cervix compromises the removal of endometriosis.

In the decision of performing a total or supracervical hysterectomy in minimal invasive surgery (MIS), the benefits of LSH must be weighed up against the risk of complications and persistent cervical stump symptoms after the procedure. Unfortunately, there is a lack of prospective randomised trials (RCT) to evaluate outcomes after different methods of MIS hysterectomy.

The persistent debate regarding methods of MIS in hysterectomy encouraged us to carry out the trials included in this PhD thesis. The aims of this thesis were to explore and compare the outcomes of different techniques of laparoscopic hysterectomy. Firstly, we intended to compare the occurrence of vaginal bleeding and patient satisfaction 12 months after LSH performed with and without the use of a reverse LEEP of the endocervix (Paper 1). Secondly, we wanted to evaluate the occurrence, intensity and reduction of cyclic pelvic pain and patient satisfaction 12 months after LSH (Paper 2). In particular, we aimed for a subgroup analysis of cyclic pelvic pain in study participants with or without perioperative detection of endometriosis and in women with or without histological confirmed adenomyosis in this trial. Finally, we wanted to compare cyclic pelvic pain, patient satisfaction and quality of life 12 months after TLH and LSH, respectively (Paper 3). An additional subgroup analysis of women with or without perioperative detection of endometriosis and in women with or subjective detection of endometriosis and in women with or without perioperative detection and quality of life 12 months after TLH and LSH, respectively (Paper 3). An additional subgroup analysis of women with or without perioperative detection of endometriosis and in women with or without perioperative detection of endometriosis and in women with or without perioperative detection of endometriosis and in women with or without perioperative detection of endometriosis and in women with or without perioperative detection of endometriosis and in women with or without perioperative detection of endometriosis and in women with or without perioperative detection of endometriosis and in women with or without perioperative detection of endometriosis and in women with or without histological confirmed adenomyosis was conducted in this trial as well.

To achieve the aims mentioned above, two blinded RCTs were conducted. In

addition, a prospective observational study was performed. Premenopausal women referred for hysterectomy on the basis of a benign condition were eligible for study recruitment. In the first RCT, the study participants were either allocated to the standardized LSH operative technique at our department or LSH performed with a laparoscopic LEEP of the endocervix in a reverse cone pattern. In the second RCT, the study participants were randomised to either TLH or LSH. In this RCT, the LSH was performed with the standardized operative technique without excision of the endocervix. In both RCTs, the allocated treatment was concealed for study participants throughout the 12 months follow up period. The observational trial was recruited among study participants from the first RCT and included only women with preoperative cyclic pelvic pain treated by LSH.

During planning of the trials, a power analysis for the primary outcome was conducted for each of the RCTs. The test power was set to be 90 % and the level of significance was 0.05. In accordance to the results of the power calculations, 140 and 62 women were included in the two trials, respectively. The data of the two RCTs were analyzed according to the principle of intention to treat. The prospective observational was an open trial of women treated by LSH. Therefore, this trial was analyzed per protocol.

This PhD thesis concludes that an additional reverse LEEP of the endocervix during LSH do not reduce bleeding 12 months after the procedure compared to the standard LSH-technique. Vaginal bleeding after LSH occurs quite frequently, but the bleeding episodes are minor and do not affect patient satisfaction.

Secondly, this PhD thesis confirms a very high patient satisfaction after LSH and TLH, respectively. There is a significant and comparable improvement in Quality of life (Qol) 12 months after both procedures. There are no differences in patient satisfaction and Qol 12 months after TLH compared to LSH.

Finally, the PhD thesis demonstrates that cyclic pelvic pain is reduced to a minimum 12 months after LSH and TLH, respectively. There is no difference in cyclic pelvic pain 12 months after TLH compared to after LSH. Women with minimal, mild or moderate endometriosis detected and treated during the procedures, should anticipate the same reduction of cyclic pelvic pain 12 months after LSH or TLH compared to women without endometriosis. The same pattern should be anticipated for women with adenomyosis confirmed in the specimen from hysterectomy compared to women without adenomyosis in specimen after TLH and LSH, respectively.

The findings in this PhD will be used to individualize the preoperative counselling before MIS hysterectomy in women with benign conditions. If vaginal hysterectomy is not feasible, the laparoscopic approach is recommended. The method of LSH and TLH appears to demonstrate comparable clinical outcomes, also in women with minimal, mild or moderate endometriosis and in women with adenomyosis. If there are no documented differences in the essential outcomes in benign conditions, the safest procedure should be preferred. In addition, patient preferences must also always be taken into account. To evaluate the benefits and risks of the treatment options, an individual risk analysis should be presented to the women, preoperatively. In spite of the current recommendations, abdominal hysterectomy continues to be a frequently used method worldwide. Compared to LSH, the TLH-technique requires more advanced laparoscopic skills. Therefore, to safely accomplish a total hysterectomy in women with fibroids, laparotomy might be the only feasible method for many gynaecologists. Consequently, to avoid laparotomy in selected women, the gynaecologist should consider performing LSH. Therefore, a more extent recommendation of LSH might reduce abdominal hysterectomy worldwide.