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Health-related quality of life after robotic-assisted laparoscopic hysterectomy for women with endometrial cancer — A prospective cohort study

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HIGHLIGHTS

• RALH does not have a prolonged negative effect on general health.
• Ability to perform work or hobbies was still negatively affected at 5 weeks.
• Fatigue, pain and gastrointestinal symptoms were negatively affected short term.

ARTICLE INFO

ABSTRACT

Objective. The aim of this prospective cohort study using patient-reported outcome measures (PROMs) was to detect short term changes in functioning, symptoms and health-related quality of life (HRQoL) after robotic-assisted laparoscopic hysterectomy (RALH) for endometrial cancer or atypical complex hyperplasia.

Methods/materials. A total of 139 women answered the EORTC C-30, EN-24 and EQ-5D-3L preoperatively (baseline) by face to face interview and again 1 week, 5 weeks and 4 months postoperatively by telephone interview. The women furthermore reported their level of activity compared to their habitual level in a diary during the first 5 weeks after surgery.

Results. We found a clinically relevant decrease in HRQoL after 1 week. At 5 weeks postoperatively, HRQoL was again at the preoperative level. Fatigue, pain, constipation, gastrointestinal symptoms, and appetite were all negatively affected 1 week postoperatively, but back to baseline level at 5 weeks. Ability to perform work or hobbies and change of taste were still affected at 5 weeks.

Conclusions. HRQoL and postoperative symptoms were overall back to the preoperative level 5 weeks after RALH. These findings indicate fatigue, pain, constipation, gastrointestinal symptoms, appetite, ability to perform work and hobbies, change of taste and sexually related problems should be addressed in future research and in the pre- and postoperative care for women undergoing RALH.

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1. Introduction

Patient-reported outcome measures (PROMs) are increasingly recognized as important for evaluation of treatment effectiveness and patient progress [1–4]. PROMS provide insight into patients' perspectives on health, symptoms and care without the interpretation of a clinician or anyone else [5]. PROMs should include an assessment of symptoms, function (physical, sexual or emotional) as well as health-related quality of life (HRQoL) [6]. PROMs are relevant and in demand in clinical practice [1], in cancer research in general [7] and in research concerning women with endometrial cancer [3,8].

Endometrial cancer is the most common cancer in the female genital tract in the developed world and the incidence is rising due to sedentary lifestyle and obesity in high income countries [3]. Annually, 750 women are diagnosed with endometrial cancer in Denmark [9]. Endometrial cancer has the highest incidence in women between 60 and 69 years of age. These women often have multiple medical comorbidities such

as diabetes, cardiovascular disease (CVD) and obesity [10]. The five-year survival rate is 80% for all stages of endometrial cancer [10].

Hysterectomy and bilateral salpingo-oophorectomy is the basic treatment of endometrial cancer [10]. Since 2005 it has been possible to perform hysterectomy by robotic-assisted laparoscopy (RALH) and throughout the last decade this treatment option has spread rapidly in high income countries. Diminished surgical trauma facilitates rapid recovery after RALH. There is, however, scarce evidence both concerning HRQoL immediately after RALH and the time needed to regain habitual level of activity postoperatively [3]. In general, we have minimal knowledge of HRQoL in women with endometrial cancer [3,8]. Studies have previously focused on postoperative complications [11], length of surgery [12], blood loss [11,13], learning curves for surgeons [14], length of stay (LOS) [11] and costs [15]. Following surgery for endometrial cancer, gastrointestinal, urinary, and sexual functions are potentially affected, perhaps especially in elderly women with comorbidities [3]. Knowledge of the recovery period is important to clinicians to tailor preventions, information and follow-up adequately.

The primary aim of the study was to prospectively examine HRQoL, symptoms and functional level in the immediate postoperative period defined as the first 4 months after surgery. Secondly, the aim was to examine potential associations between socio demographic variables and HRQoL over time in women treated by RALH for endometrial cancer or atypical complex hyperplasia (ACH).

2. Material and methods

2.1. Study population

We included 139 women treated with RALH (total hysterectomy) for endometrial cancer or ACH from January 1. 2013 to September 1. 2014 at Copenhagen (University Hospital, Herlev). Exclusion criteria were: radical hysterectomy, adjuvant treatment (chemotherapy or radiation), non-proficient in Danish, not cognitively able to fill in questionnaires and impaired hearing (not able to answer questions per telephone).

2.2. Outcomes

The primary outcome was HRQoL measured by the European Organization for Research and Treatment of Cancer (EORTC) QLQ C-30 (cancer specific) and EN-24 (endometrial cancer specific) [16]. Secondary outcomes were HRQoL measured by Euroqol-5D (EQ-5D-3L) [17], self-rated health (5 levels) [18], and postoperative level of activity as a percentage of the patients' habitual level of activity.

2.3. Tools and single item questions

To assess generic HRQoL we used EQ-5D-3L [17] in the Danish translation. This is a standardised, generic instrument developed to describe and rate health [19] and it is increasingly used in gynaecology [20,21]. Each of the five domains comprising the EQ-5D-3L is assessed by a single question with three levels of response describing the severity of a patient's problems in the domain. The domains are mobility, self-care, usual activities, pain/discomfort and anxiety/depression. In addition, participants were asked to rate their general health on a visual analogue scale (EQ-5D-VAS) from 1 to 100, with 1 representing the worst state and 100 representing the best imaginable state. To assess illness-specific HRQoL, we used the EORTC QLQ C-30 and EN-24 [16] originally developed for cancer patients, and the EN-24 specifically for endometrial cancer. Participants were asked to rate their physical, psychological and social well-being in the preceding week. Together, the two questionnaires contained 54 items, the majority of which were rated on a scale from 1 to 4 where 1 "is not at all" and 4 is "very much". The EORTC QLQ C-30 and EN-24 are validated [22] and translated into Danish. Raw scores were converted to a 0–100 scale according to the scoring

manual of the EORTC Quality of Life Group [23]. Missing values were handled as suggested in the manual [23], i.e. if sub-scales had less than half of the items missing, the mean value of the sub scale was imputed and no single item measures were imputed. Higher scores on the QLQ C-30 functioning and the global quality of life (QoL) scale indicated better functioning or QoL, whereas higher scores on the symptom scales represented a higher level of symptoms. A higher score on items related to sexuality (sexual interest, sexual activity and sexual enjoyment) in the QLQ EN-24 module indicated better sexual functioning. Questions (51–54) related to sexuality presume sexual activity and were therefore optional. For these items only scores from sexually active women were computed. Questions concerning sexuality (Questions 49–54) were only included at baseline (the last week day before surgery) and at 4 months as the women were advised to abstain from intercourse for the first 6–8 weeks after surgery.

The women were furthermore asked at baseline and 4 months postoperatively to rate their level of health with the single item question: "In general, how would you rate your health today?" with the options "Very bad", "Bad", "Moderate", "Good" or "Very good" [18]. Finally, during the first 5 postoperative weeks, the women were asked to assess their level of daily activity compared to their habitual preoperative level once a week in a diary.

2.4. Procedure for data collection

Two research assistants (instructed by the first author) approached eligible women in the hospital in connection with the planning of surgery. They informed eligible patients orally and in writing about the study. The first author or the research assistants obtained informed consent to participate from the women who wished to do so. Baseline variables and patient demographics were collected face to face on the last weekday before surgery. The first author or the research assistants collected follow-up data on participants' HRQoL at 1 week, 5 weeks and 4 months after RALH by telephone interviews.

2.5. Data analysis and statistics

Double data entry was done and we compared the two datasets for any discrepancies. Potential differences between included women and those not included/excluded were explored.

Mean scores and standard deviations (SD) were calculated for the multi-item and single-item scales.

Changes in HRQoL in the EORTC C-30 and EN −24 within 4 months postoperatively were examined using a Linear Mixed Model analysis. This analysis is relevant when analysing unbalanced data with repeated measures (correlated data) [24]. We considered differences in EORTC scale scores of 10 points or more clinically relevant [25].

EQ-5D-3L scores were reported as a binary outcome – stating no problem or problems in each of the 5 domains and reported as numbers and percentages of the sample. A 10% change in distribution was considered clinically relevant [26]. EQ-VAS scores were reported as means with SDs and mean differences from baseline and were analysed by Linear Mixed Model Analysis. Differences in the EQ-5D-VAS scores over time were tested for subgroups of women. The subgroups were: age > 70 years, BMI > 40, pelvic lymphadenectomy performed, ASA score 3, single women, women with <9 years of school and women with >4 years of education. The test was an analysis of the interaction between subgroups and time points of measurement.

Self-rated health was analysed using the non-parametric Wilcoxon Signed Rank test for differences. For differences between levels of activity we used Linear Mixed Model analysis. All calculated p values were two sided and we considered p < 0.05 statistically significant. Data was analysed using SPSS version 19. 9 (Inc., Chicago, Il, USA).