Trial 2012: Surgical Procedures (Hysterectomy)

The effect of hysterectomy or levonorgestrel-releasing intrauterine system on premenstrual symptoms in women treated for menorrhagia: secondary analysis of a randomized controlled trial

Link: https://pubmed.ncbi.nlm.nih.gov/22168810/

Year published: 2012

Pubmed classification: Randomised Controlled Trial.

Further trial: ***information****Secondary* analysis.

Objective: To study the effect of hysterectomy or levonorgestrel-releasing intrauterine system (LNG-IUS) on premenstrual symptoms in women treated for menorrhagia.

Randomised? Yes.

Placebo? No.

Participant information: A cohort of 236 women in Finland, aged 35-49 years (mean 43 years) referred for menorrhagia between 1994 and 1997. The women were not diagnosed with premenstrual syndrome.

Trial length: Assessments after the treatment at 6 months, 12 months, and 5 years after the randomisation.

Drug and dosage: Hysterectomy (117); or LNG-IUS (119).

Measuring scales: The occurrence of premenstrual symptoms evaluated by questionnaires at baseline and at follow-up visits 6 and 12 months after the treatment and 5 years after the randomization.

Methodology further information: Analyses were performed using the intention-to-treat and actual treatment principles. Women using estrogen therapy and women who underwent bilateral salpingo-oophorectomy were excluded from the analyses.

Efficacy outcomes: Premenstrual symptoms decreased significantly in both groups by six months ($p \leq 0.028$) without significant differences between the groups, except that in the LNG-IUS group the decrease of breast tenderness was seen first by 12 months ($p=0.048$).

Even though 42% of the women assigned to treatment with LNG-IUS were hysterectomized during the follow-up period, the results of intention-to-treat and actual treatment analyses were comparable.

Conclusion: Both hysterectomy and LNG-IUS seem to alleviate premenstrual symptoms of women treated for menorrhagia, while the effect of these treatments on premenstrual syndrome remains unsettled.

Trial 2011: Surgical Procedures (Novasure)
Improved premenstrual syndrome symptoms after NovaSure endometrial ablation

Link: https://pubmed.ncbi.nlm.nih.gov/21872168/

Year published: 2011

Trial information: Prospective, single-arm cohort study.

Objective: To evaluate the change in premenstrual syndrome (PMS) symptoms in women with heavy periods who underwent endometrial ablation.

Participant information: 36 women with heavy periods who were to undergo endometrial ablation, had PMS symptoms and completed all surveys at baseline and follow-up. The mean age was 41.4 years, with a mean body mass index of 26.7. Most (27/36, 75%) had failed hormonal management.

Trial length: Follow-up surveys at 4 to 6 months.

Measuring scales: A brief baseline survey was done to evaluate menstrual bleeding and baseline PMS symptoms, and two 30-day prospective validated measures of PMS were used. Follow-up surveys were sent at 4 to 6 months and included both the brief survey questions and the validated measures of PMS (Daily Symptoms Report and Daily Record of Severity of Symptoms).

Efficacy outcomes: All measures of PMS showed significant improvement after endometrial ablation. Self-rating of PMS symptoms on a scale of 0 (none) to 10 (severe) improved from a baseline of 7.4 to a follow-up rating of 3.2 ($p < .05$).

The vast majority of women (35/36, 97%) reported improvement in PMS after undergoing endometrial ablation. Both validated measures of PMS, Daily Symptoms Report and Daily Record of Severity of Symptoms, showed statistically significant improvement in PMS symptoms.

Conclusion: Women with heavy menses and associated PMS symptoms who undergo NovaSure endometrial ablation showed improvement in PMS symptoms, as well as reduced menstrual bleeding.

Trial 2004: Surgical Procedures (Hysterectomy and Oophorectomy)
Hysterectomy and bilateral oophorectomy for severe premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/15229203/

Year published: 2004

Objective: To evaluate the effectiveness and patient satisfaction with total abdominal hysterectomy/bilateral salpingo-oophorectomy (TAH/BSO) in PMS sufferers; and assessing the post-operative HRT continuation.

Participant information: 47 women undergoing TAH/BSO for severe PMS (1994-2000). Median age was 42 years (interquartile range 39.8-46.6) at the time of surgery. They had suffered with PMS for a mean of 9.68 years (SD 6.8) and received treatment for a mean of 3.57 years (SD 2.0) prior to referral to a gynaecologist. 52% were treated with estradiol patches and 48% with estradiol implants prior to TAH/BSO.

Measuring scales: Interviews; responses recorded by structured questionnaire.

Efficacy outcomes: 96% of women were 'satisfied' or 'very satisfied' with TAH/BSO, and 93.6% declared complete resolution of their cyclical symptoms; 93.6% were continuing with HRT, usually by implants of estradiol and testosterone, for a mean duration of 3.8 years (SD 1.86) post-operatively.

Conclusion: Despite few reports of TAH/BSO as a treatment for severe PMS, we have found surgery, coupled with appropriate HRT, to be an extremely effective and well-accepted permanent cure for PMS.