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Comparison of combined hormonal vaginal ring and low dose combined oral hormonal pill for the treatment of idiopathic chronic pelvic pain: a randomised trial☆

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ABSTRACT

Objective: To compare the efficacy and acceptability of combined hormonal vaginal ring with combined oral hormonal pill in women with idiopathic chronic pelvic pain.
Study design: Randomised prospective interventional trial conducted in 60 women with idiopathic chronic pelvic pain. Women were randomised into two groups of 30 each. In each group, treatment was given for 84 days using either combined vaginal ring or combined oral hormonal pill. Hormonal vaginal ring releases 15 mcg of ethinyl estradiol and 120 mcg of the etonogestrel per day while the hormonal pill contained 30 mcg of ethinyl estradiol and 150 mcg of levonorgestrel. There was no ring or pill free week. After every 28 days, pain relief was measured using visual analogue scale (VAS), and verbal rating score (VRS) calculated by summing dysmenorrhea, non-cyclic pelvic pain (NCCP) and deep dyspareunia scores. Side effects, compliance, satisfaction, and user acceptability were also measured. Data was analyzed using various parametric and non-parametric tests.
Results: Reduction in mean VAS score at end of treatment in ring group was 6.23 (95% confidence interval [CI], 5.45–7.01; $p < 0.001$) as compared to 5.53 in pill group (95% CI, 4.83–6.23; $p < 0.001$). Reduction in mean VRS score was 5.63 in ring users (95% CI, 4.84–6.42; $p < 0.001$) versus 4.36 in pill users (95% CI, 3.63–5.10; $p < 0.001$). A significantly higher persistent relief in NCPP score was observed in vaginal ring group as compared to oral pill group at end of one month after stopping treatment. Compliance, satisfaction, and user acceptability were higher in ring users (80%) than pill users (70%) and a higher incidence of nausea was seen in pill group.
Conclusion: Present study demonstrates for first time that both vaginal and oral hormonal therapy are effective in treatment of idiopathic chronic pelvic pain and vaginal ring may be a better choice with higher satisfaction rate and fewer side effects.

Introduction

Chronic pelvic pain (CPP) is defined as intermittent or constant pain of six or more months duration that localizes to the anatomic pelvis, anterior abdominal wall at or below the umbilicus, the lumbo-sacral back or the buttocks that is severe enough to cause functional disability or requiring medical or surgical treatment [1]. It is a symptom, not a diagnosis and dysmenorrhea, deep dyspareunia and non-cyclic pelvic pain constitute its main symptom complex [2]. The prevalence rates of various entities in CPP are: dysmenorrhea—1.7%–97%, dyspareunia—1.3%–45.7% and non-cyclic pelvic pain—4.0%–43.4% [3].

Prevalence of chronic pelvic pain is estimated to be 38 per 1000 in women aged 15–73 years [4]. In South-East Asian countries it varies from 5.2% in India, 8.89% in Pakistan to 43.2% in Thailand [3]. It accounts for 10–15% of office visits to gynecologists, general clinics, and about a quarter of outpatient consultations in general gynecologic practice [5]. In roughly 40% of women undergoing diagnostic laparoscopy, no obvious etiology is found [5,6]. In various studies, hormonal therapies like combined oral hormonal pills, injections, implants and hormone releasing intrauterine devices have been reported to relieve symptoms in chronic pelvic pain associated with endometriosis, interstitial cystitis, irritable bowel syndrome, pelvic congestion syndrome, ovarian retention

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syndrome, and ovarian remnant syndrome [7–12]. Hormonal therapy suppresses ovarian activity, reduces growth of endometrial tissue, decreases both menstrual flow and prostaglandin production, and accelerates apoptosis in the eutopic endometrium, however, long term daily oral therapy is restricted by poor compliance and unacceptable side effects. Newer methods like injections, implants and intrauterine devices require administration by a trained personnel and have side effects like unpredictable bleeding patterns and loss of bone density [13–16]. Recently the vaginal ring has been developed, which releases 15 mcg of ethinyl estradiol and 120 mcg of etonogestrel per day. Vaginal administration has the advantage of once-a-month administration, avoidance of hepatic first pass metabolism and gastrointestinal side effects [17,18]. In addition, estrogen and progestogen are administered at a lower dosage compared to oral therapy. With this background, the present trial was planned to study the efficacy of vaginal versus oral hormonal therapy in women with idiopathic chronic pelvic pain.

Method

In this randomized prospective interventional study, we compared combined hormonal vaginal ring (CVR) and low dose combined oral hormonal pills (CHP) in women with chronic pelvic pain when no definite cause was found on history, examination, transabdominal, transvaginal ultrasonography and laparoscopy. The study was carried out in Gynaecology Department of University College of Medical Sciences & Guru Teg Bahadur Hospital, New Delhi over a total duration of 18 months from October 2011 to April 2013. A total of 60 sexually active women aged between 18–45 years with pelvic pain duration of more than six months were included in the study. Pelvic pain comprised of non-cyclic pelvic pain, cyclic progressive dysmenorrhea and deep dyspareunia and women who had all the three components for more than six months were considered eligible for the study. Women with gynaecologic disorders like endometriosis, adenomyosis, fibroids, ovarian remnant syndrome, chronic PID or cervical stenosis, gastrointestinal disorders (inflammatory bowel disease), urinary problems (interstitial cystitis, urethral syndrome), musculoskeletal disorders (pelvic floor myalgia, fibromyalgia, neuralgia of iliohypogastric, ilioinguinal or genitofemoral nerve), or neurological diseases (abdominal cutaneous nerve entrapment in surgical scar), and psychosocial issues like depression were excluded.

Every effort was made to exclude endometriosis as a cause of chronic pelvic pain. In women with history suggestive of endometriosis namely progressive severe dysmenorrhea, dyspareunia, dyschezia and dysuria and/or pelvic examination findings of a retroverted uterus with decreased uterine mobility, and tender uterosacral nodularity, ultrasonography was done. If ultrasonography was normal, laparoscopy was done and case was included if no pathology was found. Women with ovarian endometriomas on ultrasonography were excluded. Postmenopausal women, treatment other than NSAIDs upto three months before study entry, women planning pregnancy and those with contraindications to use of estrogens and progestins were excluded. Written informed consent was obtained from all women and institutional ethical committee approved the study. A total of 96 women with CPP were assessed. A detailed history and examination of all women with chronic pelvic pain were done and recorded in a predesigned form. Routine blood biochemistry, urine routine and culture, transabdominal and transvaginal ultrasound were done in all the women. Laparoscopy was done in 31 women in whom endometriosis was suspected. In 15 women, no pathology was found on laparoscopy and were included in the study. Women were randomly allocated into two groups in 1:1 ratio, using computer generated random numbers; CVR (study group) or CHP (control group), as depicted in consort flow chart (Fig. 1). Depending on

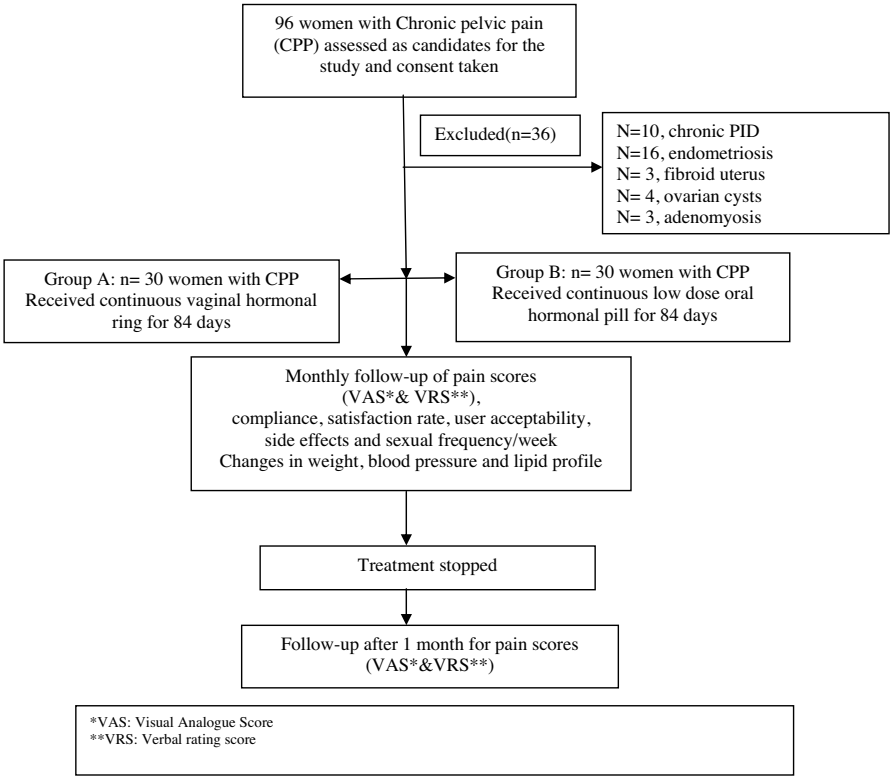

Fig. 1. Consort diagram.