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# Efficacy of combined hormonal vaginal ring in comparison to combined hormonal pills in heavy menstrual bleeding

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ABSTRACT

*Objective:* To compare the efficacy, acceptability and compliance of combined hormonal vaginal ring (CVR), with combined hormonal pills (CHP) in patients with heavy menstrual bleeding (HMB).
*Study design:* This prospective study was conducted in 50 women with HMB in age group of 25–40 years. Patients were divided in two groups of 25 each and followed for six treatment cycles. In each group, cycle comprised of three weeks of CVR (releases 15 μg of EE and 120 μg of the etonogestrel per day) or CHP (containing 30 μgm of EE and 150 μgm of LNG) use, followed by one ring or pill free week. After each cycle, patients were evaluated about the amount of blood loss and duration of bleeding by the pictoral blood assessment chart (PBAC), early bleeding (EWB), continued bleeding (CWB), intermenstrual bleeding, intended bleeding, compliance, and user acceptability. The collected data were analyzed using the Chi square test, *t*-test and ANOVA test.
*Result:* Reduction in PBAC score for CVR (70.73%) and CHP group (70.02%), duration of bleeding and incidence of EWB was comparable among the two groups. The incidence of intermenstrual bleeding was lower in CVR than in CHP group in cycle 3 and 4 with significant *p* value. The incidence of CWB was significantly lower and the incidence of intended bleeding pattern in CVR group was significantly higher in cycle 3, 4, 5 and 6, signifying better cycle control. Compliance was also higher in CVR (88%) than CHC (75.33% of all cycles).
*Conclusion:* This trial suggests that both the CVR and CHP are very effective short-term treatments for HMB in reproductive age group. However, women had better cycle control and compliance with CVR. This may be an attractive option among the wide variety of medications used to treat HMB.


## Introduction

Heavy menstrual bleeding (HMB) is defined as menstrual bleeding that is abnormally heavy (>80 ml) or of prolonged duration lasting more than seven days [1].

In women with HMB, different medications and conservative surgical management option are being used such as combined hormonal pills (CHP), only progesterone, non-steroidal anti inflammatory drugs, androgenic synthetic steroid, laser endometrial ablation and hysteroscopic resection of endometrium. But there is a need for newer, more convenient method. New products such as injections or implantable rods and hormone releasing intrauterine devices have several disadvantages, that affects their acceptability, including the need for administration by trained personnel and the unpredictable bleeding patterns associated with progesterone only formulations. Because of such disadvantages, other approaches have been investigated, which led to the development of combined hormonal vaginal ring (CVR) to administer hormonal steroids [2,3].

More recently, a CVR that releases 15 μg of EE and 120 μg of the etonogestrel (ENG) per day, at constant rates, has been developed [3]. This is a flexible, transparent ring made of evatane (ethinyl vinyl acetate), with an outer diameter of 54 mm and a cross-section of 4 mm. This hormonal vaginal ring is being used as a contraceptive method, and is reported by Oddsson [4], Roumen et al. [5] in their studies. This study was planned to compare the efficacy, acceptability and compliance of CVR, with CHP in patients with HMB.

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*Method*

This prospective study was conducted in 50 women having HMB in age group from 25 to 40 year attending OPD in the department of Obstetrics & Gynaecology, Pandit B.D. Sharma Post Graduate Institute of Medical Sciences, Rohtak. Ethical clearance was obtained from the Institutional Board of Studies.

The inclusion criteria were patients in reproductive age group (18–50 years), fibroid <4 cm, no other pelvic pathology and not on hormonal therapy for the last 6 months. Women with known or suspected malignant condition of genital tract or breast, lactating women, any liver or heart disease, arterial or venous thrombosis, headache with focal neurological symptoms, severe hypertension, personal or family history of any bleeding disorder, vaginal/cervical infection, cervical descent, chronic constipation, were excluded from the study. A pre informed consent was obtained from every woman.

A detailed, presenting menstrual history of the last six months (including duration of bleeding, passage of clots, cycle length) was noted down. Assessment of menstrual blood loss was done with pictorial blood assessment chart (PBAC) developed by Higham et al. [6]. A PBAC score of more than 100 was considered diagnostic of heavy menstrual bleeding. The present alteration in menstrual cycle was compared to previous menstrual cycles. Any history of treatment was recorded for each patient. General physical examination and detailed systemic examination were done. Pelvic examination was done to rule out any pelvic pathology.

Baseline work up for each patient was done. Transvaginal sonography was done to note endometrial thickness and to rule out any pelvic pathology. In women above 35 years of age, endometrial sampling was done.

Ninety patients with HMB who presented to outpatient department were screened for enrollment. Forty of them were excluded: Thirty five did not meet inclusion criteria, 5 declined to give consent. The remaining 50 patients were randomized to the two groups of 25 each (CVR, CHP group) as per computer generated random numbers table (Fig. 1). Allocation concealment was done with opaque sealed envelops. The number and allocation concealment was assigned by third person not linked to study. Fifty patients enrolled for study, were given treatment for 6 cycles. Bleeding in each menstrual cycle was assessed by pictoral blood assessment chart (PBAC). In each group, cycle comprised of three weeks of ring or pill use, followed by one week ring or pill free week. In first group (study group), CVR (Nuva ring by Organon India Ltd.) inserted on day 5 of the menstrual cycle and this ring was removed after 3 weeks. The patient had withdrawal bleeding after removal of vaginal ring. Next vaginal ring inserted after 1 week of previous ring removal (treatment free period of 1 week). In the second group (control group), low dose CHP containing 30 μgm of EE and 150 μgm of LNG (Mala-N by Indian Drugs and Pharmaceuticals Ltd.) started from day 5 of the menstrual cycle and same was continued for 3 weeks followed by pill free period of 1 week. Next pack was started after 1 week pill free period. Treatment was given for a total duration of 6 cycles.

After completion of each cycle in both group patients were evaluated about the amount of blood loss and duration of bleeding (by PBAC). Vaginal bleeding was classified as spotting (requiring <1 pad per day) or bleeding (>1 pad per day). Withdrawal bleeding was classified as any bleeding/spotting starting just before the ring/pill free week (Fig. 2). Any withdrawal bleeding/spotting just before the ring/pill free week was termed early withdrawal bleeding (EWB). Continued withdrawal bleeding (CWB)/late withdrawal bleeding was defined as any withdrawal bleeding/spotting that continues into the ring/pill period of the next cycle. All other bleeding/spotting was classified as intermenstrual/irregular bleeding. Intended bleeding pattern (IBP) was defined as a cycle with withdrawal bleeding in ring/pill free week, but without early or continued withdrawal bleeding and no irregular bleeding.

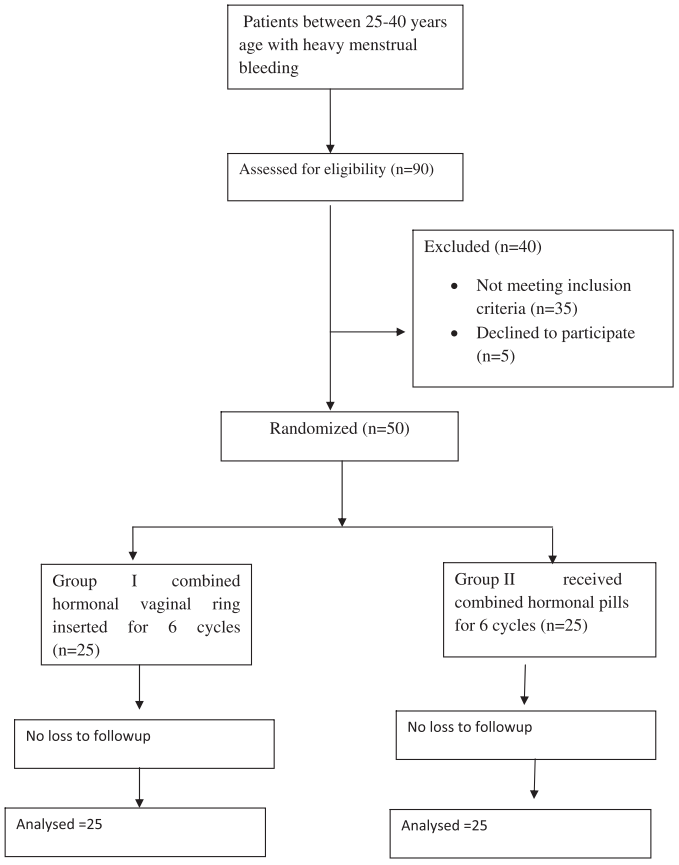


**Fig. 1.** Diagram showing the flow of patients.

Compliance of treatment was observed down in both groups. In the oral pill group, full compliance was defined as a cycle in which

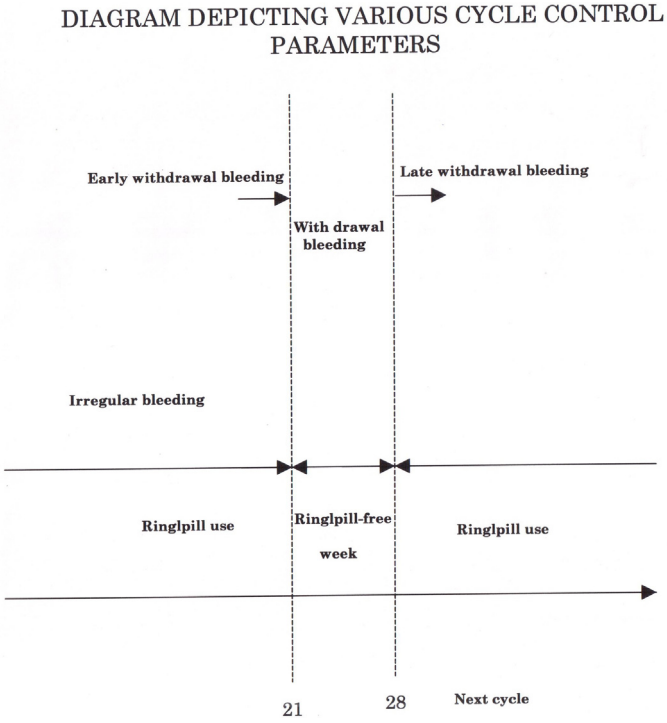


**Fig. 2.** Diagram depicting various cycle control parameters.