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Original Research Article

## A study to compare the efficacy, acceptability and side effect of combined contraceptive vaginal ring with the combined oral contraceptive pills in a tertiary health centre located in central India

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### ABSTRACT

**Background:** A study to compare the efficacy, acceptability and side effect of combined contraceptive vaginal ring with the combined oral contraceptive pills in a tertiary health centre (RKDF Medical College and Research Centre, Bhopal) located in central India.

**Methods:** This prospective randomized comparative trial enrolled hundred women aged between 20 to 40 years seeking for contraception with no contraindication to hormonal contraception. After proper counseling and informed consent, women divided into two groups, study group (50) includes women using contraceptive vaginal ring and control group (50) include women using combined oral contraceptives. The contraceptive efficacy, acceptability, tolerability and adverse events were recorded at each follow-up visit at RKDF Medical College and Research Centre, Bhopal.

**Results:** Vaginal ring and combined oral contraceptives were found to have comparable contraceptive efficacy. In study group no pregnancy reported during study period while one pregnancy reported in control group, which was statistically insignificant. Satisfaction, continuation and recommendation to others were more with vaginal ring which were not significant statistically. Cycle control is superior with vaginal ring. Incidence of adverse effects was same in both groups.

**Conclusions:** Combined contraceptive vaginal ring is an effective and reliable contraception with excellent cycle control, well-tolerated and highly acceptable to most women.

**Keywords:** Combined oral contraceptive pills, Contraceptive vaginal ring, Efficacy

### INTRODUCTION

Contraception is the prevention of conception. Combined oral contraceptive is widely accepted and effective method of fertility control.<sup>1</sup> Combined oral contraceptives are being used in patient of abnormal uterine bleeding. Combined oral contraceptive are associated with side effects like nausea, vomiting, breakthrough bleeding. It has disadvantages like requirement for daily administration, hepatic first pass metabolism.<sup>2</sup> The

vaginal ring is a flexible transparent ring first approved in Netherland.<sup>3</sup> The ring contain 2.7 milligram of ethinyl estradiol and 11.7 milligram of etonogestrel.<sup>4</sup> After insertion into vagina, it releases 120 micrograms etonogestrel and 15 microgram of ethinyl estradiol per 24 hours over a period of 3 weeks.

Its single application allows long-term dosing increase compliance and avoidance of fluctuations in hormone level decrease side effects.<sup>5</sup> Number of randomised

control trial have shown lower systemic ethinyl estradiol exposure, same contraceptive efficacy, superior cycle control, comparable adverse events and higher degree of satisfaction with vaginal ring as compared to combined oral contraceptives.

This study was carried out to compare contraceptive efficacy and safety of vaginal ring versus oral contraceptive pill along with acceptability of each method.

## METHODS

It is prospective comparative randomized trial. The present study was conducted in department of obstetrics and gynecology, RKDF Medical College and Research Centre, Bhopal over a period of 6 month.

A total 100 cases were selected which comply with selection criteria. The study approved by research ethics committee at hospital. Informed consent was obtained from all women.

### Inclusion criteria

- Women should be in age group of 20 to 40 years seeking for contraception.

### Exclusion criteria

- Include known hypersensitivity to oestrogen or progestin, lactating women up to 6 months, non-lactating up to 3 months of delivery,
- Within one month of medical or surgical abortion, suspected breast malignancy, cervical malignancy, endometrial malignancy, vaginal malignancy
- History of venous thrombo embolism and cardiovascular accidents, hypertension, diabetes and liver diseases.

After proper counselling women were categorised into 2 groups with their consent.

- Group I (study group) women willing for insertion of vaginal ring
- Group 2 (control group) women willing for combined oral contraceptives.

*Insertion technique:* Vaginal ring is a flexible plastic ring. It is inserted in vagina between day 1 and day 5 of menstrual period and remains in place for 3 weeks. A new Ring is inserted at the end of one-week ring free interval.

*Use of oral pills:* Women were instructed to start taking pills from first day of menstrual cycle for 21 days.

*Follow-up visits:* Women of both groups were followed at 1 month, 3 months and 6 months

### Monitoring

*Contraceptive efficacy:* It is determined by occurrence of pregnancy during study

*Continuation rate:* Determined by number of women report back at each follow-up.

*Acceptability:* Assessed by questionnaire at each follow-up visit.

*Side effects:* Monitored at each follow-up visit.

## RESULTS

The present study was conducted in the department of obstetrics and gynaecology RKDF Medical College Bhopal, Madhya Pradesh, India.

**Table 1: Distribution of cases according to age.**

Age group in years	Study group		Control group	
	No. of cases	Percentage	No. of cases	Percentage
21-25	11	22%	12	24%
26-30	19	38%	18	36%
31-35	10	20%	11	22%
36-40	10	20%	9	18%
Total	50	100%	50	100%
Mean±SD	30.01±26.05		29.83±29.11	

Majority of women in the study group where of 26 to 30 years age group (38% i.e. 19 cases) followed by 21 to 25 years (22% i.e. 11 cases) and then 31 to 35 years (20% i.e. 10 cases) and 36 to 40 years (20% i.e. 10 cases) (Table 1). Mean age in study group was

30.01±26.05years.majority of women in control were of 26 to 30 year age group (36% i.e. 18 cases) followed by 21 to 25 years (24% i.e. 12 cases) and followed by 31 to 35 years (22% i.e. 11 cases) and then 36 to 40 years age group (18% i.e. 9 cases). Mean age in combined oral contraceptive group was 29.83±29.11 year.

**Table 2: Distribution of cases according to parity.**

Parity	Study group		Control group	
	No. of cases	Percentage	No. of cases	Percentage
Nulligravida	20	40%	22	44%
Nulliparous	24	48%	23	46%
Multiparous	6	12%	5	10%
Total	50	100%	50	100%

**Table 3: Distribution of cases according to socio-economic status. (Modified B. J. Prasad Classification).**

Class (per capita income per month)	Study group		Control group	
	No. of cases	Percentage	No. of cases	Percentage
>10000	1	2%	-	-
5000-9999	13	26%	12	24%
3000-4999	18	36%	19	38%
1500-2999	10	20%	11	22%
500-1499	8	16%	7	14%
<500	-	-	1	2%
Total	50	100%	50	100%

**Table 4: Mean body weight per assessment for study and control group.**

Assessment	Study group mean body weight in kg	Control group mean body weight in kg
Base line	52.4	50.8
After cycle 1	52.2	52.6
After cycle 3	52.1	52.7
After cycle 6	52.4	52.7
After cycle 9	52.5	52.9
After cycle 13	52.7	53.3
Last assessment	52.8	52.8

**Table 5: Incidence of withdrawal bleeding in combined contraceptive vaginal ring and combined oral contraceptive treatment groups.**

Cycle control parameter	Study group		Control group		p value
	No. of cycle	Percentage	No. of cycle	Percentage	
Incidence of withdrawal bleeding	643	99%	637	98%	>0.05
Incidence of cycle with intended bleeding pattern	455	70%	318	50%	<0.05
Incidence of early withdrawal bleeding	78	12%	65	10%	>0.05
Incidence of late withdrawal bleeding	104	16%	143	22%	<0.05
Incidence of irregular bleeding	13	2%	52	8%	<0.05

Most of the cases in study group 48% (24 cases) were nulliparous followed by nulligravida 40% (20 cases) and then multiparous 12% (6 cases).

Most of the cases in control group were nulliparous 46% (23 cases) followed by nulligravida 44% (22 cases) and then multiparous 10% (five cases) (Table 2).

Maximum number of cases in study group (18 cases i.e. 36%) and control group (19 cases i.e. 38%) belong to class III according to their social economic status. 13

cases (26%) in study group and 12 cases (24%) and control groups belong to class II (Table 3). 10 cases (20%) in the study group and 11 cases (22%) in control groups belong to class IV. 1 case (2%) in study group belong to class I. 1 case (2%) in control group belongs to class-V.

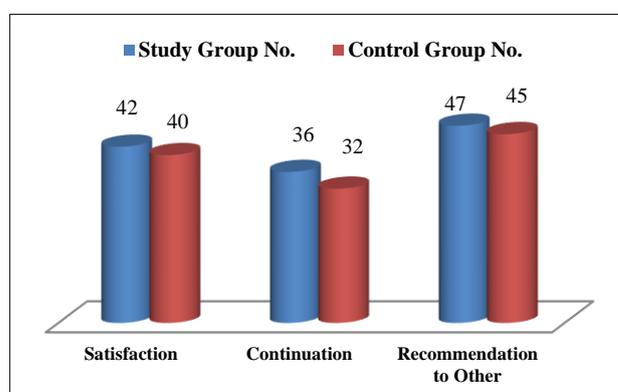
In the study group the observed mean changes in body weight was  $\pm 0.4$  kg. In control group, the observed mean change in body weight was +2 kg. The p value was 0.25 which was statistically insignificant (Table 4).

**Table 6: Proportion of cases with adverse events in combined contraceptive vaginal ring and combined oral contraceptive treatment groups.**

Adverse events	Study group		Control group	
	No. of cases	Percentage	No. of cases	Percentage
Acne	1	1.8%	1	2.5%
Breast tenderness	2	4.0%	2	4.1%
Decreased libido	3	5.2%	0	0%
Depression	0	0%	2	3.2%
Device related events	1	2.5%	-	-
Headache	1	2.4%	2	3.3%
Leucorrhoea	2	4.2%	1	2.5%
Nausea	2	3.2%	3	5.2%
Nervousness	1	2.5%	1	1.6%
Weight gain	1	1.6%	2	3.3%
Vaginitis	2	4.2%	1	1.7%
Total	16	31.6%	15	27.4%

Incidence of withdrawal bleeding was 99 percent (643 /650 cycles) In Study group and 98% (637 /650 cycles) in control group. The p-value was 0.93 which was statistical insignificant. Incidence of cycle with intended bleeding pattern was 70% (455/650 cycles) in study group and 50% (318 /650 cycles) in control group. The p-value was 0.0002 to which was statistically significant. Incidence of cycle with early withdrawal bleeding was 12% (78/650 cycles) in study group and 10% (65/650 cycles) in control group. the p-value was 0.33 which was statistically insignificant.

Incidence of cycle late withdrawal bleeding was 16% (104/650 cycles) in study group and 22% (143/650 cycles) in control group. The p-value was 0.02 which was statistically significant. Incidence of irregular bleeding was 2% (13/650 cycles) in study group and 8% (52/650) cycles in control group. The p-value was 0.0001 which was statistically significant.



**Figure 1: Distribution of cases according to the acceptability with both groups.**

Satisfaction with combined contraceptive vaginal ring observed in 84% of the cases (42 cases).

**Table 7: Distribution of cases according to the reason of discontinuation with combined contraceptive vaginal ring and combined oral contraceptive.**

Reason of discontinuation	Study group		Control group		p value
	No. of cases	Percentage	No. of cases	Percentage	
Unacceptable vaginal bleeding	1	2%	1	2%	>0.05
Felt ring during intercourse	2	4%	0	0%	<0.05
No further need for contraception	1	2%	2	4%	>0.05
Adverse events	6	12%	6	12%	>0.05
Not willing to cooperate	1	2%	2	4%	>0.05
Others reasons	2	4%	2	4%	>0.05
Total	13	26%	13	26%	

Satisfaction with combined oral contraceptives observed in 80% of cases (40 cases). The p-value was 0.88 which

was statistically insignificant. Continuation with combined contraceptive vaginal ring observed in 72% of

cases (36 cases). Continuation with combined oral contraceptive observed in 64% cases (32 cases). The p-value was 0.74 which was statistically insignificant. Recommendation of combined contraceptive vaginal ring to others observed in 94% of cases (47 cases) recommendation of combined oral contraceptive to others observed in 90% of the cases (45 cases). The p-value was 0.88 which was statistically insignificant.

In Study group, majority of women (12% i.e. 6 cases), discontinued combined contraceptive vaginal ring because of adverse events (p-value more than 0.05) 4% of cases (2 cases) because of felt ring during intercourse (p value less than 0.05). 2% of cases (one case) because of unacceptable vaginal bleeding (p value more than 0.05) (Table 8). 2% of cases (one case) because they were not willing to corporate (p value more than 0.05), 2% of cases (one case) because they had no further need for contraception and 4% of cases (2 cases) because of other reason (p value more than 0.05).

In control group, majority of women (12% i.e. 6 cases) discontinued combined oral contraceptive because of adverse events (p value more than 0.05). 4% of cases (2 cases) because of they had no further need for contraception (p value less than 0.05). 4% of cases (2 cases) because they are not willing to corporate (p value more than 0.05). 2% of cases (one case) because of unacceptable vaginal bleeding (p value more than 0.05). 4% of cases (two cases) because of other reasons (p value more than 0.005).

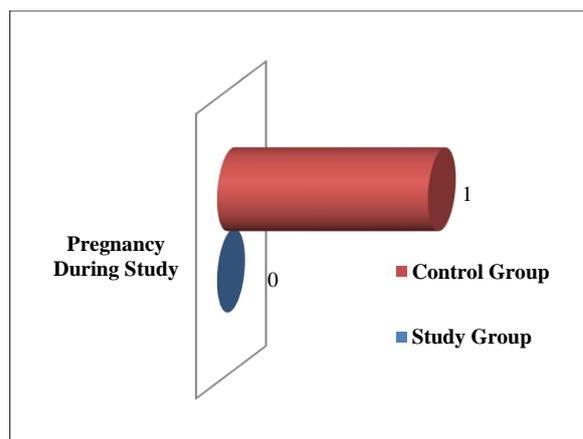


Figure 2: Pregnancy during study in both groups.

In the study group there was no pregnancy reported during study Figure 2. In the control group 1 pregnancy report during study. The p value was more than 0.05 which was statistical insignificant).

DISCUSSION

Total of 100 women of 20 to 40 years were subjected to detailed history, examination and relevant investigation, divided into two groups of 50 cases each. Present study conducted with aim to compare the efficacy, acceptability and side effects of vaginal ring and combined oral contraceptives.

Table 8: Comparison of incidence of adverse events in both groups with studies done by other authors.

Study	Pregnancy during study	Incidence of side effects
Ahrendt et al <sup>7</sup>	Combined contraceptive vaginal ring	65.3%
	Combined oral contraceptive pills	63.3%
Ragnheidun et al <sup>6</sup>	Combined contraceptive vaginal ring	33.9%
	Combined oral contraceptive pills	24.6%
In present study	Combined contraceptive vaginal ring	31.6%
	Combined oral contraceptive pills	27.4%

Table 9: Comparison of acceptability in both groups with studies done by other authors.

Study	Pregnancy during study	Satisfaction	Recommendation
Diben et al <sup>9</sup>	Combined contraceptive vaginal ring	86%	90%
Novak et al <sup>8</sup>	Combined contraceptive vaginal ring	96%	97%
Ahrendt et al <sup>7</sup>	Combined contraceptive vaginal ring	84%	87%
	Combined oral contraceptive pills	87%	92%
In present study	Combined contraceptive vaginal ring	82%	94%
	Combined oral contraceptive pills	80%	90%

Cases in both groups matched well regarding to age, parity, and social-economic status. Gain in mean weight was more with combined oral contraceptives.

No pregnancy occurred with vaginal ring and 1 pregnancy with combined oral contraceptives during study period. The difference is statistical insignificant.

**Table 10: Comparison of contraceptive efficacy in both groups with studies done by other authors.**

Study	Pregnancy during study	Pearl index
Diben et al <sup>9</sup>	Combined contraceptive vaginal ring	1.75
Oddsson et al <sup>10</sup>	Combined contraceptive vaginal ring	1.23
	Combined oral contraceptive pills	1.19
Ahrendt et al <sup>7</sup>	Combined contraceptive vaginal ring	0.25
	Combined oral contraceptive pills	0.99
Soni A et al <sup>11</sup>	Combined contraceptive vaginal ring	0.0
In present study	Combined contraceptive vaginal ring	0
	Combined oral contraceptive pills	2

Incidence of intended withdrawal bleeding was 70% in the study group and 60% in control group. Incidence of early and late withdrawal bleeding in study group 12% and 16% and in control group was 10% and 22%. Cycle control is better in study group and difference is statistically significant.

During study period 31.6% of cases in study group and 27.4% of cases in control group developed adverse event and the differences statistically insignificant.

In study group 84% of cases satisfied with vaginal ring, 72 % willing to continue, 94% recommended to others. In control group 80% of cases satisfied with combined oral contraceptives, 64% want to continue, 90% recommended it to others and difference is statistically insignificant.

## CONCLUSION

This study demonstrates, on comparing vaginal ring and combined oral contraceptives, it was found that both the methods are effective as a contraceptive as studied by efficacy and acceptability.

No major side effects reported in any of the group. Combined contraceptive vaginal ring is an effective and reliable contraceptive.

No need of daily dosing further increase compliance, long term continuous release via vaginal route confer unique benefit.

Once the Government of India supplies the device free of cost as the case with combined oral contraceptive, it will have wide acceptability and may become contraceptive of choice in Indian women. However, studies with large number of cases, comparing these two methods are suggested to reach more confirmatory results.

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