

Comparison of bleeding patterns in women using a contraceptive pill or vaginal ring continuously for 12 months

Edith Weisberg, Gabriele Merki, Kevin McGeechan Ian S. Fraser
Sydney Centre for Reproductive Health Research, FPNSW
University of Sydney
Clinic for Reproductive Medicine University of Zürich

Aims

- To compare continuous use for 12 months on a menstrually-signaled regimen of:
 - combined contraceptive vaginal ring
15µg ethinyl oestradiol and 150 µg etonogestrel
 - combined oral contraceptive pill
20µg ethinyl oestradiol and 100µg levonorgestrel
- Assessing
 - acceptability,
 - satisfaction
 - breakthrough bleeding rates
- To determine whether 4 days cessation of treatment is sufficient to stop an episode of bleeding.

Methods

- Eligible women were randomized to:
 - daily COC ingestion
 - continuous CVR use with a new ring every 28 days.
 - start the pill or insert the ring on the first day of their next period
- Daily menstrual diary.**
 - taken their pill or had the ring in situ,
 - record bleeding or spotting
- Menstrually signalled regimen**
 - if an episode of bleeding lasted > 4days
 - stop their pill or remove the CVR on the 5th day
 - to restart after a four day interval.
- Follow up**
 - Face to face 2, 4, 6 and 12 months after starting their medication.
 - By telephone 1, 3 and 5 months to ensure they were completing the daily diary and following the menstrually signaled regimen correctly.

Enrolments

	Pill	Ring	Total
Screened			144
Randomised	66	66	132
Withdrawn	19	18	37
Completed	46	47	93

Summary of demographics

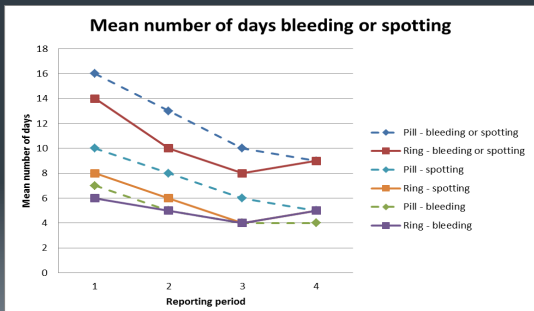
No significant differences between COC and CVR users

- Aged 20-29 70%
- Tertiary educated >80%
- Never pregnant >70%
- Majority Caucasian

Comparison of mean number of bleeding/spotting days and episodes between continuous COC and CVR use over 12 months

- There was no difference in the mean number of days bleeding and spotting between the two groups in any 90 day reference period (P=0.33).
- The mean number of days bleeding and spotting decreased over the four reference periods for both methods (P<0.001).
- No difference in mean number of bleeding/spotting episodes between the two groups - decreased over the four reference periods (P<0.001).

Comparison of mean bleeding/spotting days between CVR and COC users



Definitions for determining "convenience of bleeding pattern per reference period (Merki)

Very convenient

- Amenorrhoea
- 2 bleeding/spotting episodes lasting < 7 days
- 1 prolonged episode lasting ≤ 8

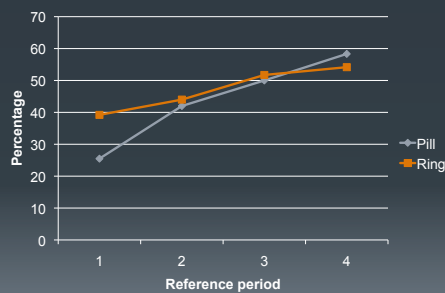
Acceptable

- ≤ 2 episodes of prolonged bleeding (≤ 8 days)
- 3 episodes of bleeding/spotting lasting ≤ 7 days
- 4 episodes of bleeding/spotting lasting ≤ 2 days

Very inconvenient

- > 3 episodes of bleeding/spotting lasting > 7 days
- > 4 episodes of bleeding/spotting lasting > 4 days
- ≥ 1 episode prolonged bleeding >10 days

Percentage who reported a convenient bleeding pattern



Compliance with regimen

- Adherence to the menstrually signaled regimen was **haphazard**
- Compliance per bleeding episode (total episodes 685)
 - In 42% of bleeding episodes medication was stopped after 4 days of bleeding
 - In 52% of episodes medication was stopped for 4 days
- In compliant episodes (stopped medication for 4 days)
 - Bleeding/spotting stopped in 64% of episodes within 5 days of stopping medication
- In episodes of bleeding/spotting which stopped spontaneously (73)
 - 63% lasted 4 days or less.
 - 26 (35%) stopped between 5-8 days

Conclusions

- Majority of women **happy with continuous combined hormonal contraception**
- **Bleeding patterns** for individual women are **impossible to predict**
- The majority of **episodes will stop spontaneously within 8 days**
- Women can be reassured that if an episode of **bleeding is troublesome stopping the hormones for 4 days will stop the bleeding in most episodes within 5 days**
- **Impression**
 - Continuous use of the CVR is more likely to provide a bleed every 2-3 months but it is likely to last for up to 8 days of combined bleeding and spotting.
 - Continuous low dose COC use is more likely to produce more frequent but shorter spotting episodes.
 - Numbers insufficient to provide a statistical confirmation