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Breakthrough bleeding with combined hormonal contraception

Most women find that combined hormonal contraception (CHC) provides reliable cycle control.

Indeed the combined oral contraceptive (COC) pill is often prescribed for the management of menstrual disorders such as menorrhagia and dysfunctional uterine bleeding [1] [2] .

However, although new formulations with low doses of oestrogen offer health benefits, they may provide less satisfactory cycle control [3] . The risk of bleeding may also be related to the dose and type of progestogen. It may be that third-generation COC pills are associated with less menstrual irregularity. Unfortunately, methodological differences between studies have also made it difficult to compare rates of breakthrough bleeding between different preparations [4] .

Epidemiology

Irregular bleeding whilst taking CHC is a common problem. Up to 20% of women experience breakthrough bleeding or spotting [5] . Bleeding usually settles with time, and it is therefore recommended that women persevere for three months before considering changing their contraceptive pill [6] .

Mechanism of action

Normal endometrial maturation depends on complex interactions between oestrogen and progesterone. CHC provides a continuous supply of oestrogen and progestogen to the endometrium. The low dose of oestrogen in modern CHCs is insufficient to maintain endometrial integrity and the opposing effect of progestogen promotes atrophy of glands and stroma. The resulting endometrium is thin, fragile and prone to bleeding. The exact mechanisms of bleeding associated with CHC are not well understood, but the frailty of blood vessels within the endometrium appears to be a factor, along with changes in local endometrial concentrations of, and response to, hormones [7] .

Contraceptive efficacy

No relationship has been identified between serum steroid levels, unscheduled bleeding and loss of efficacy. In the absence of missed or late pills, vomiting or drug interactions, lack of contraceptive efficacy has not been proven [6] .

Factors which influence bleeding

Patient factors

- Adherence. Missed pills are the most likely cause of irregular bleeding.
- Cigarette smoking has anti-oestrogenic properties and may affect cycle control.
- Medication interaction. Certain prescribed medications, as well as over-the-counter preparations such as St John's wort can interfere with hormonal levels.
- Non-CHC-related causes of bleeding, which must be considered. See 'Other considerations', below.

CHC formulation factors

- COC pills containing only 20 micrograms of ethinylestradiol (EE) cause more disrupted bleeding patterns than those containing higher doses [3] .

- There is no evidence yet that biphasic, triphasic or quadriphasic preparations confer better control than standard monophasic preparations [8] [9] [10] .
- First-generation progestogens (eg, norethisterone) may provide poorer cycle control than second-generation (levonorgestrel) and third-generation progestogens. However, a Cochrane review determined that trial methodology is flawed and this has not yet been proven [4] .
- There is no significant difference between CHC pills and CHC patches in terms of irregular bleeding [7] .
- Incidence of breakthrough bleeding with the vaginal ring is lower than with the COC pill [5] .
- Women using extended cycle regimes to control timing of menses may experience more breakthrough bleeding but this can be improved by tailoring their pill use. Advise them to continue taking the pill until breakthrough bleeding occurs, then to have a break, and thereafter to use this as a guide for when to have a break [5] .

Pattern of pill taking [6]

2019 guidance from the Faculty of Sexual and Reproductive Healthcare (FSRH) recommends that there are no health benefits from the seven-day hormone-free interval for combined oral contraception. It therefore recommends that women should be offerred information about both standard and tailored CHC regimens to broaden their contraceptive choice. Options include:

- **Standard use** - 21 days (21 active pills or 1 ring, or 3 patches), 7-day hormone-free interval (HFI).
- **Shortened HFI** - 21 days (21 active pills or 1 ring, or 3 patches), 4-day HFI.
- **Extended use (tricycling)** - 9 weeks (3 x 21 active pills or 3 rings, or 9 patches used consecutively), 4- or 7-day HFI.
- **Flexible extended use** - continuous use (≥21 days) of active pills, patches or rings until breakthrough bleeding occurs for 3-4 days, 4-day HFI.

- **Continuous use** - continuous use of active pills, patches or rings, no HFI.

Continuous and extended COC pill regimes are associated with an increase in breakthrough bleeding, but frequency and intensity subsequently decrease over time. There is limited evidence that a similar reduction in bleeding or spotting days over time is seen with continuous use of the contraceptive transdermal patch and the contraceptive vaginal ring as with the COC pill.

Assessment of breakthrough bleeding

History

Take a clinical history to assess:

- The woman's concerns.
- Correct use of the method (eg, pill taking, patch use).
- Use of interacting medication - including over-the-counter remedies.
- Illness altering absorption of orally administered hormones.
- Other symptoms (eg, pain, dyspareunia, abnormal vaginal discharge, heavy bleeding, postcoital bleeding).
- History of, risks for, sexually transmitted infections.
- Cervical screening history.
- The need to consider a pregnancy test.

Examination

If the patient started using this method of contraception less than three months previously, examination and further investigations are not indicated if all the above have been checked and confirmed/excluded as appropriate. The patient should be reassured and follow-up arranged - if requested, medical management can be considered as for women who have had persistent bleeding for more than three cycles [7] .

Speculum examination is indicated where there is consistent correct use of the CHC method for more than three months with persistent irregular bleeding and/or [7] [11] :

- Pain.
- Dyspareunia.
- Vaginal discharge.
- Postcoital bleeding.
- No history of regular cervical smears.
- Ongoing symptoms despite change to a different CHC or other contraceptive method after 6-8 weeks.
- New onset of bleeding after three months.
- A changed bleeding pattern.
- Request for examination by the woman.

If there are symptoms suggestive of sexually transmitted infections, swabs should be taken or a referral made to the local genitourinary medicine (GUM) clinic. Risk factors include age under 25 years, a new sexual partner and having had more than one sexual partner in the preceding year.

If bleeding is heavy or if there is associated pain, dyspareunia or heavy bleeding, referral for further assessment should be considered.

Other considerations [7]

Although CHC is a common cause of irregular bleeding, other unrelated causes must also be considered such as:

- Chlamydia or other sexually transmitted infections.
- Intrauterine or ectopic pregnancy.
- Endometrial or cervical polyp. The role of uterine polyps, fibroids or ovarian cysts as a cause of unscheduled bleeding is limited. Nevertheless, for all women using hormonal contraception with unscheduled bleeding, if such a structural abnormality is suspected, a transvaginal ultrasound scan and/or hysteroscopy may be indicated.
- Cervical cancer.

- Endometrial cancer. Consideration should be given to referral for further assessment (endometrial assessment such as with ultrasound scan, biopsy, hysteroscopy) for women aged 45 or over, or for under-45s with risk factors for endometrial cancer.

Management

Evidence is not yet of sufficient quality for there to be evidence-based guidelines or recommendations. Having excluded other causes:

- Reassure patients that breakthrough bleeding is a common side-effect of CHC and usually resolves after three cycles of use.
- Advise women who smoke that stopping smoking may improve cycle control.
- If bleeding persists after three cycles, consider changing formulation:
    - Increase dose of oestrogen, particularly if on a 20-microgram ethinylestradiol (EE) preparation, to a maximum of 35 micrograms of EE. (There is no evidence that increasing the dose from 30 micrograms to 35 micrograms is effective, but it may work for some women.)
    - Try a preparation with a different progestogen or a higher dose.
    - There is currently no evidence of any particular preparations being better than any others with regard to breakthrough bleeding.
    - Consider the vaginal ring, which has lower rates of breakthrough bleeding.
    - Advise women that there are no data on managing bleeding associated with the combined patch. They should be advised to continue for at least three months as bleeding may settle during this time.
    - Consider tailored pill use, as above, for women on extended cycle regimes.

- If bleeding persists despite a different formulation, consider an alternative form of contraception.

Further reading

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