WHO/RHR/10.15

World Health Organization

Statement

Combined hormonal contraceptive use during the postpartum period

Department of Reproductive Health and Research

Combined hormonal contraceptive use during the postpartum period

26 January 2010, Geneva, Switzerland

Background

Contraception after childbirth is an important issue, and evidence supports increasing birth intervals to improve both a woman's and her child's health. When used during lactation, combined hormonal methods of contraception may adversely affect milk production; for this reason, these methods are generally not recommended for use during lactation until six months postpartum. However, combined hormonal methods (CHCs) are an important contraceptive option during the postpartum period for non-breastfeeding women.

Numerous haematologic changes occur during normal pregnancy, such as increasing concentrations of coagulation factors and fibrinogen, and decreasing concentrations of or development of resistance to natural anticoagulants protein S and protein C. These changes shift a pregnant woman's coagulation and fibrinolytic systems towards hypercoagulability. While this adaption has likely developed to prevent fatal haemorrhage at delivery, it predisposes women to venous thromboembolism (VTE) during pregnancy and into the postpartum period.

CHCs are associated with an increased risk of developing VTE among healthy, reproductive age women. Although most women may use CHCs without restriction, for some women with other risk factors for VTE, these methods may be a less desirable contraceptive choice.

The Department of Reproductive Health and Research (RHR) of the World Health Organization (WHO) produces evidence-based guidelines on contraceptive use, which include the *Medical eligibility criteria for contraceptive use, 4th Edition 2009* and *Selected practice recommendations for contraceptive use, 2nd Edition 2005*. The *Medical eligibility criteria for contraceptive use* (MEC) provides recommendations on the use of various contraceptive methods by women and men with specific characteristics or with known pre-existing medical conditions. The *Selected practice recommendations for contraceptive use* provides guidance on how to use contraceptive methods safely and effectively once they are deemed medically appropriate.

The MEC provides guidance regarding the use of combined hormonal contraceptives during the postpartum period. The current recommendation states that, in women who are not breastfeeding, the risks of CHC use prior to 21 days postpartum usually outweigh the contraceptive benefits of use (Category 3), and that there is no restriction for the use of CHCs at or after 21 days postpartum (Category 1). This guidance had been based on expert opinion, with some supporting data that blood coagulation and fibrinolysis variables affected during pregnancy return to normal in women by 21 days postpartum, and the assumption that elevated postpartum risk of venous thromboembolism (VTE) returns to prepregnancy levels by that time.

The identification of new evidence regarding the risk of VTE in postpartum women (not associated with CHC use) indicated the need to evaluate this recommendation. A technical consultation was convened by WHO via teleconference on 26 January 2010. The consultation brought together international family planning experts, including clinicians, epidemiologists, haematologists, and perinatologists.

The consultation focused on the risk of developing VTE during the postpartum period, and the theoretical additional risk that use of CHCs could pose. Discussions of safety addressed the declining risk of postpartum VTE as time passes after delivery, weighed against the increasing risk of pregnancy during that time.

The data considered in the consultation included two systematic reviews addressing the risk of VTE during the postpartum period and the timeframe of returning fertility in nonlactating postpartum women, along with expert presentations of the mechanism of VTE development during the postpartum and the theoretical additional risk posed by CHC use during this time.

Summary of the evidence

No studies were found evaluating the risk of VTE in postpartum women currently using CHCs. Studies assessing the risk of VTE development in postpartum women indicate that during the first six weeks postpartum, risk is substantially increased – 22 to 84-fold when compared to nonpregnant, nonpostpartum reproductive age women. However, this risk is most pronounced immediately after delivery, declining rapidly in the first 21 days after delivery and returning to near baseline levels by 42 days postpartum. Only one study reviewed indicated an elevated risk of VTE beyond 42 days postpartum.

These epidemiological data were complemented by human laboratory data indicating that coagulation parameters and venous blood flow, both of which are significantly perturbed by pregnancy, return to nonpregnant levels at various times during the postpartum. Some return to baseline within several days of delivery, while others may not completely normalize until six to eight weeks postpartum, underscoring the observed gradual decline in VTE events following parturition.

The mechanism of VTE development is best described as a process in which, in general, women with multiple risk factors for VTE are at a substantially greater risk than those with a single risk factor, and those with one risk factor are at greater risk than those without risk factors. In nonpregnant, nonpostpartum women, the absolute risk of developing VTE is very low (3–5/10 000 woman-years), CHC use increases this risk 3 to 7-fold. When combined with other risk factors (such as thrombophilia, obesity, smoking, age greater than 35, or being postpartum) these risks may become unacceptably high. Data specifically delineating any additional risk posed by CHC use during the postpartum are lacking.

Data regarding nonlactating postpartum women's return to fertility indicate that, although most women will likely not experience a fertile ovulation until after the first 42 days postpartum, some will ovulate earlier – in some cases as early as 25 days postpartum. This body of evidence is small, however, and techniques used to determine the potential fertility of ovulation are imprecise.

Recommendations

Consultation participants determined that current WHO guidance regarding the use of CHCs in nonlactating postpartum women was discordant with the above evidence. The guidance inadequately reflected the gradually declining risk of VTE during the postpartum, and the potential impact of multiple risk factors on VTE formation during this period. In order to more closely fit the available data, WHO has revised their recommendations, stratifying guidance by time since delivery, and presence or absence of additional risk factors for VTE. In addition, WHO developed clarifying statements discussing the impact of additional risk factors for VTE on overall VTE risk, as well as return to fertility in nonlactating postpartum women. These revised recommendations are summarized below and in the following table.

Prior to 21 days postpartum, risks of CHC use generally outweigh the advantages and CHCs should generally not be used (Category 3); for some women with additional risk factors for VTE other than being postpartum, CHCs should not be used (Category 3/4). Women who are breastfeeding during the first 21 days postpartum should not use CHCs (Category 4).

Between 21 and 42 days postpartum, advantages of CHC use generally outweigh the risks and CHCs generally can be used (Category 2), although for some women with additional risk factors for VTE, these methods should not be used unless other more appropriate methods are not available or acceptable (Category 2/3).

For women up to 42 days postpartum with other risk factors for VTE, such as previous VTE, thrombophilia, immobility, transfusion at delivery, BMI >30 kg/m^2, postpartum haemorrhage, immediately postcaesarean delivery, pre-eclampsia or smoking, use of combined hormonal contraceptives may pose an additional increased risk of VTE. Women's risk should be assessed according to the number, severity and combination of VTE risk factors present. Because each women is unique with respect to her personal risk profile, clinical judgment will be necessary to determine if she may safely use CHCs. Women who are breastfeeding between 21 and 42 days postpartum should not use CHCs (Category 4).

Finally, in nonlactating women beyond 42 days postpartum, CHCs may be used without restriction. Although the risk of VTE is the same in breastfeeding as non-breastfeeding women, use of CHCs is generally not recommended prior to six months postpartum in women who are breastfeeding.

It is expected that these recommendations will remain valid until 2012, at which time RHR will be responsible for initiating a review of the document that contains these recommendations, the *Medical eligibility criteria for contraceptive use* located at (http://www.who.int/reproductivehealth/publications/family_planning/9789241563888/en/index.html).

The body of evidence that was reviewed during the consultation will be published in a complete meeting report and will be accessible on the WHO website at http://www.who.int/reproductivehealth.

Revised recommendations for the use of CHCs (combined oral contraceptive pill, patch, ring, and combined injectable contraceptives) in non-breastfeeding women during the postpartum period.

Condition	Recommendation	Clarification/evidence
POSTPARTUM (in non-breastfeeding women) **a) <21 days** i) Without other risk factors for VTE ii) With other risk factors for VTE	3 3/4	**Clarification:** Although the risk of VTE is the same in breastfeeding as non-breastfeeding women, use of CHCs is generally not recommended prior to 6 months postpartum in women who are breastfeeding. For non-breastfeeding women <21 days postpartum with other risk factors for VTE, such as previous VTE, thrombophilia, immobility, transfusion at delivery, BMI >30 kg/m^2, postpartum haemorrhage, immediately postcaesarean delivery, pre-eclampsia or smoking, use of combined hormonal contraceptives may pose an additional increased risk of VTE. The category should be assessed according to the number, severity and combination of VTE risk factors present. Because each woman is unique with respect to her personal risk profile, clinical judgment will be necessary to determine if she may safely use CHCs. **Evidence:** There is no direct evidence examining the risk of VTE among postpartum women using CHCs. VTE risk is elevated during pregnancy and the postpartum; this risk is most pronounced in the first weeks after delivery, declining to near baseline levels by 42 days postpartum. Use of CHCs, which increases the risk of VTE in healthy reproductive age women, may pose an additional risk if used during this time. Risk of pregnancy during the first 21 days postpartum is very low, but increases after that point; ovulation before first menses is common.
b) ≥21 days to 42 days i) Without other risk factors for VTE ii) With other risk factors for VTE	 2 2/3*	***Clarification:** Although the risk of VTE is the same in breastfeeding as non-breastfeeding women, use of CHCs is generally not recommended prior to 6 months postpartum in women who are breastfeeding. For non-breastfeeding women ≥21 days to 42 days postpartum with other risk factors for VTE, such as previous VTE, thrombophilia, immobility, transfusion at delivery, BMI >30 kg/m^2, postpartum haemorrhage, immediately postcaesarean delivery, pre-eclampsia or smoking, use of combined hormonal contraceptives may pose an additional increased risk of VTE. The category should be assessed according to the number, severity and combination of VTE risk factors present. Because each woman is unique with respect to her personal risk profile, clinical judgment will be necessary to determine if she may safely use CHCs. **Evidence:** There is no direct evidence examining the risk of VTE among postpartum women using CHCs. VTE risk is elevated during pregnancy and the postpartum; this risk is most pronounced in the first weeks after delivery, declining to near baseline levels by 42 days postpartum. Use of CHCs, which increases the risk of VTE in healthy reproductive age women, may pose an additional risk if used during this time.
c) >42 days	1	

Explanation of categories

1. No restriction for the use of the contraceptive method.
2. Advantages of using the method generally outweigh the theoretical or proven risks.
3. Theoretical or proven risks usually outweigh the advantages of using the method.
4. There is an unacceptable health risk if the contraceptive method is used.

Abbreviations

CHC – Combined hormonal contraceptive
BMI – Body mass index
VTE – Venous thromboembolism

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