



Prescribing Combined Oral Contraceptives-Are we taking risks?

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Background



- Pills first used in the UK- 1961
- 1995-Pill scare-CSM letter
- Increase in unplanned pregnancies and abortions the next year
- Independent risk of 3rd generation COC pills- increase of 2 deaths per million per year! --same as driving a car for just 1 hour per year(2)



Risks linked to the COC Pill

- COC pills known to increase arterial and venous thrombosis risk but this risk varies with other factors like smoking, age, obesity, HT and DM

Why do we need to think twice??-

VTE

- Current users of COC's –low absolute risk of VTE but 3-6 times that of non- users and highest in 1st yr of use(1)
- But this risk is smaller as compared to the risk of VTE associated with pregnancy.
- This risk rises with increasing age, obesity, recent surgery etc.

Why do we need to think twice??- VTE

- Smoking & raised BP which are important risk factors for arterial disease do not affect risk of VTE that much.(1)
- If any WHO2 or 3 risk factor for VTE then 3rd gen COC –like Mercilon (which has DSG) & Femodette (which has GSD) are contraindicated.

Why do we need to think twice??-

Acute MI

- Women who do not smoke and have their BP checked, do not have HT or DM are at no increased risk of Acute MI if using COC's as compared to never users of the same age.(1)
- However RR of Ac MI in current users with HT is 3 times that of users without HT.
- RR in users who are heavy smokers is 10 times that of non smokers/non users.

Why do we need to think twice??- Stroke

- Any incidence of or mortality from CVD attributable to use of COC is very small if users do not smoke and do not have other risk factors for CVD like HT/DM
- Risk of mortality from CVD attributable to COC much greater(upto 10 fold) among women aged 40-44 than aged 20-24

Guidelines/Recommendations

- 1999-WHO-Scientific group meeting – Cardiovascular disease and hormonal contraception-conclusions as above
- Our responsibility as prescriber's is to be aware of guidelines(amongst hundreds of other guidelines!!) and help our patients make informed choices.

WHO Criteria



WHO classification devised in 1994-Medical eligibility Criteria (UK-MEC)(2) and recommended by FRSH(3)

- WHO -1 (A)- Always usable
- WHO-2 (B)- Broadly usable
- WHO-3 (C)- Caution/Counselling
- WHO-4 (D)- Do not use
- Any category 3 + either one Category 2 or 3 becomes Category 4-Do not use

WHO-4 - VTE

A decorative graphic at the top of the slide consists of a row of six circles. The first circle is solid light purple and contains the text 'WHO-4'. The second circle is hollow with a light purple outline and contains the text '- VTE'. The third circle is solid light purple. The fourth circle is hollow with a light purple outline. The fifth circle is solid light purple. The sixth circle is solid light purple.

- BMI > 40
- Bed bound
- Age > 51
- Clotting abnormalities
- Current sclerotherapy
- Current Superficial Venous thrombosis

WHO-4-Arterial disease



- Smoking >40cpd
- BMI >40
- Age >51
- HT > 160/100 on repeat testing
- Severe diabetes/with complications
- Migraine with aura

WHO-3-Arterial disease



- Smoking 15-39 cpd
- DM-not severe
- BP 140-159/ 90-99 or on anti HT treatment
- BMI> 30-39
- Migraine without aura
- Gall stones symptomatic or being medically treated.

Any 2 of these would be WHO-4 →Absolute c/i

Who decides??



- ?Patient wishes to continue COC even if they fit WHO-4 criteria
- ?Informed choice-will you prescribe?
- ?Justifiable in case an adverse event occurs → Personal decision



Audit

- GMS Practice –list size 10,500 patients
- Usual practice is initiation of COC pill by GP's and follow up at 3 months by nurses or GP's
- Template for COC- alerted to ask for smoking status, headache and check BP, BMI.
- ?Template used by all?



Audit Criteria

- Audit criteria based on WHO-4-Absolute C.I to prescribing the COC pill (CVD Criteria)

We only picked these 3 which could be checked from our records

- BMI>40
- Age>51
- Age >35 + Smoking >15cpd

Method



- Emis LV search tool-each of these search criteria applied independently to all women prescribed the COC pill in the previous 12 months.
- The identified women's records checked for accuracy of information gathered.



Results

- Number of women on the pill-436
- 3 Women identified with current prescription of COC pill and BMI>40
- 9 Women identified Age >35+ smoking>15cpd and on the COC pill(2 of these women also had DM)
- No woman aged>51 on the pill
- Overall small numbers 12/436 but we only looked at 3 criteria

Changes as a result



- These 12 women invited for routine consultation with the GP's and offered alternative choices-after explaining the risks/benefits.
- All 12 women chose to try an alternative method mostly the POP pill or Mirena coil.

Changes as a result



22 women were also identified with two WHO2 or 3 criteria eg.

- women with BMI>30
- On anti HT drugs
- smoking>15cpd
- DM

but these were not part of the initial audit question so these patients were not recalled and screen messages were left to discuss this with the patient on their next pill check appointment or other consultation



Discussion

- Audit served as a reminder to all prescriber's in our practice of some important risk factors and C/I to the COC pill.
- The templates were modified to alert if BMI/BP /Age were above the WHO3 limit or the patient was diagnosed with DM to check for other risk factors.
- Easy reference guide with these criteria uploaded to our centralised system that could be accessed by prescriber's during a consultation.



Summary

- COC's safe for the vast majority of women if caution taken in those with pre existing risk factors

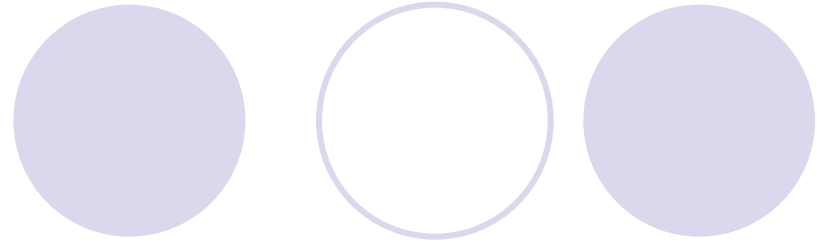
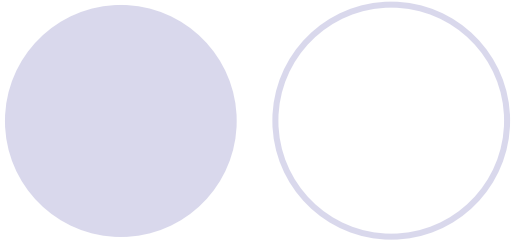
Main factors to remember-

- Age
- Smoking status
- BP
- BMI
- DM



References

1. 1999-WHO-Scientific group meeting – Cardiovascular disease and hormonal contraception-conclusions
2. Contraception: Your Questions Answered
John Guillebaud 2003
3. WHO criteria www.who.int/reproductive-health
4. Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. FFPRHC Guidance (Jan 2007). First prescription of combined oral contraception.



● Any Questions!!