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Effect on quality of life of switching to combined oral contraception based on natural estrogen: an observational, multicentre, prospective phase IV study (ZOCAL Study)

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ABSTRACT

Objectives: This observational, multicentre, prospective phase IV study examined change in health related quality of life (QOL) from baseline to 6 months in women initiating combined oral contraception (COC) based on natural estrogen.

Methods: Eligible women attending a baseline and 6-month gynaecology appointment belonged to one of three groups: group 1 used barrier contraception (condoms) and elected to continue this method; group 2 used condoms and elected to switch to COC based on natural estrogen; group 3 used COC based on ethinylestradiol and elected to switch to COC based on natural estrogen. The Spanish Society of Contraception (SEC)-QOL scale assessed health-related QOL. Secondary outcomes included symptoms of premenstrual syndrome, intermenstrual bleeding, duration and intensity of menstrual bleeding, contraception continuation rate, and tolerability.

Results: A total of 857 women were enrolled and 785 completed the study. Group 2 (n=224 completed) had significantly lower SEC-QOL global and dimension scores at baseline and
significantly greater increases in SEC-QOL from baseline to 6 months compared with groups 1 (n=72) and 3 (n=489). Group 3 reported a similar SEC-QOL score to that of group 1 at baseline but showed significantly greater improvement in SEC-QOL global and psychological scores from baseline to 6 months. Among women receiving COC based on natural estrogen, the contraception continuation rate was 713/780 (91.4%); treatment-related adverse events were reported by 13/780 (1.7%).

Conclusions: Improved SEC-QOL after 6 months was found in women who were dissatisfied with their current contraception at baseline and chose to switch to COC based on natural estrogen.

KEYWORDS
Combined oral contraception; E2V/DNG; natural estrogen; NOMAC/E2; quality of life

改变避孕方式为以天然雌激素为主的复方口服避孕药对生活质量的影响：一项观察性、多中心、前瞻性 IV 期研究（ZOCAL 研究）

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摘要
目的：这是一项观察性、多中心、前瞻性 IV 期的试验，观察服用6个月复方口服避孕药（COC）的女性在健康相关生活质量（QOL）上的变化，这种口服避孕药以天然雌激素为主要成分。方法：入选合格的女性在基线水平于妇科门诊就诊并分为3组，治疗6个月后随访：组1采用屏障避孕法（避孕套）并持续这种方法；组2采用避孕套，随后改为以天然雌激素为主要成分的COC；组3采用炔雌醇为主要成分的COC，随后改为以天然雌激素为主的COC。健康相关QOL的变化由西班牙避孕学会(SEC)——QOL量表评估。次要结局包括经前期综合征症状，经间期出血，月经持续时间和程度，避孕持续率和耐受性。结果：本研究共有857名女性参与，其中785名全部完成。与组1（n=72）和组3（n=489）相比，组2（n=224名完成）在基线水平SEC-QOL得分较低，6个月后显著增加。组3在基线水平的SEC-QOL得分与组1相似，但治疗后在SEC-QOL得分和心理得分上显著改善。在所有服用天然雌激素COC的女性中，避孕持续率为713/780（91.4%）；治疗相关的不良事件报道为13/780（1.7%）。结论：研究发现，对目前避孕方式不满意并改为基于天然雌激素的COC的女性在治疗6个月后可改善其SEC-QOL得分。
关键词： 复方口服避孕药；戊酸雌二醇/地诺孕素；天然雌激素；醋酸诺美孕酮/E2；生活质量