A Randomized Single-Blinded Trial of VeraCept, a Novel Nitinol Low-Dose Copper Intrauterine Contraceptive Compared With a Copper T380S Intrauterine Contraceptive [16]

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INTRODUCTION: We aimed to compare VeraCept, a novel low-profile nitinol intrauterine contraceptive with 175 mm² of copper surface area, with a commercially available copper T380S.

METHODS: We performed a randomized subject-blinded comparison of VeraCept and a copper T380S in a two-to-one fashion. The primary outcome was total continuation. We also examined pain on insertion, ease of placement, expulsion, satisfaction, tolerability, and pregnancy. Satisfaction ratings were on a 5-point Likert scale. We report data from insertion through 9-month follow-up.

RESULTS: We enrolled women in a single clinic with 199 allocated to VeraCept and 101 to the T380S. Insertion was successful in 198 women for VeraCept and 100 for the T380S (P = .2). Mean age was 25 years, and median parity was two (range 1–4) with 39% having only had cesarean deliveries. No women developed clinical infection or reported serious adverse events. In the VeraCept and T380S groups, mean pain at insertion was 1.4 and 2.4, respectively (P = .01). At the 9-month visit for VeraCept and T380S, respectively, continuation was 86% and 70% (P < .004) with partial and complete expulsions in 5.0% and 12.0% (P < .05) and removal for pain or bleeding in 3.5% and 13.0% (P < .05). No pregnancies were diagnosed after insertion with 1,562 and 643 women-months for VeraCept and T380S, respectively. One “luteal phase” pregnancy was identified at the first follow-up with conception estimated at 1–1.5 weeks before VeraCept insertion.

CONCLUSION: VeraCept resulted in less pain at insertion, fewer expulsions, and higher total continuation than the T380S with equal contraceptive efficacy to date.

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