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

Matthew F. Reeves, MD, MPH
ContraMed, Washington, DC
Mark J. Hathaway, MD, MPH, Juan M. Canela Oleaga, MD, Bob H. Katz, MSBE, MBA, and Michael G. Tal, MD, MBA

INTRODUCTION: We aimed to compare VeraCept, a novel low-profile nitinol intrauterine contraceptive with 175 mm^2 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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