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Experimental Nitinol IUD May Cause Less Pain

Laird Harrison | May 12, 2015

SAN FRANCISCO — Women experience less pain during insertion with an experimental nitinol intrauterine device (IUD) than with a copper-T IUD, and are more likely to continue using it, new research shows.

Overall, the nitinol IUD (*VeraCept*, ContraMed) compared "very favorably" to the copper IUD (*Cu T380*, Injeflex), reported Matthew Reeves, MD, from the National Abortion Federation in Washington, DC.

Dr Reeves presented the study results here at the American Congress of Obstetricians and Gynecologists Annual Clinical Meeting 2015.

Although IUDs are a safe and effective method of contraception, many women feel pain during insertion or experience cramps, bleeding, or expulsion, sometimes leading to discontinuation.

The nitinol IUD is designed to minimize these problems. Insertion is less painful because the device has a smaller profile and can be put in place with a smaller inserter, Dr Reeves explained.

Nitinol is a combination of nickel and titanium that is prized for its biocompatibility and is used in many small medical devices, such as valves and stents.

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"One of its great properties is shape memory," said Dr Reeves. "It can be folded and pressed — whatever you want to do with it as long as you want — and it will pop back to the exact same shape."

In their study, Dr Reeves and his colleagues randomly assigned 199 women to the nitinol IUD and 101 to the copper IUD. The women were unaware of which device they received.

The nitinol IUD is 30 mm × 32 mm, has 175 mm² of copper at the cervix and cornua, and has precut strings. And the inserter for the nitinol IUD is smaller than for the copper IUD (3.7 vs 4.4 mm in diameter).

All the women were 18 years or older, menstruating, fertile, and in good health. All had given birth to at least one child.

There were no significant differences between the nitinol and copper groups in terms of age, parity, or the number of women who underwent caesarean delivery. There was one insertion failure in each group.

Women in the nitinol group reported less pain during insertion on a 5-point Likert pain scale than women in the copper group, and were more likely to continue using the IUD after 12 months.

Table. Outcomes With the Two IUDs

Outcome	Nitinol IUD	Copper IUD	*P* Value
Mean pain score during insertion	1.4	2.4	.01
Reason for discontinuation			
Expulsion, %	5	12	.03

Intolerability, %	4	17	.0001
Other, %	7	3	.19

There was one ectopic pregnancy in the nitinol group during the study period, but no other pregnancies in either group.

On the basis of these results, the researchers are planning to conduct trials that will support approval of the device by the US Food and Drug Administration. ContraMed hopes to bring the nitinol IUD to market "in a few years," said Dr Reeves.

After the presentation, Dr Reeves was asked by an audience member about infections. There were none in either group, he reported, even though antibiotics were not used at insertion.

Another person asked whether there has been any research on nulliparous women. Dr Reeves said that the research team has been evaluating the device in some nulliparous women, "and they're doing great."

The potential of the nitinol device is interesting, but further studies are needed, said session moderator J.K. Williams, MD, from the University of South Florida in Tampa.

Efforts to design new IUDs have always had to balance conflicting criteria, Dr Williams told *Medscape Medical News*. "Since the 1930s, the whole goal has been to make it smaller with less bleeding and cramping," he explained. "But the smaller it is, the greater the failure."

As for the pain on insertion, it is short-lived, he said. "If something doesn't hurt much and something else hurts less, is that significant?"

This study was funded by ContraMed. Dr Reeves was hired as a consultant by ContraMed. Dr Williams has disclosed no relevant financial relationships.

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