Real world performance of an atraumatic cervical stabiliser for intrauterine device insertion: single centre observational study

Intrauterine devices (IUDs) are among the most effective forms of reversible contraception, but their uptake remains low, particularly among nulliparous and younger women.[1] A major barrier is the anticipated and experienced pain, bleeding, and vasovagal responses during IUD insertion, most commonly associated with the use of a single-tooth tenaculum for cervical stabilisation.[2]

A novel device, Carevix (figure 1), has been developed as a single use, suction based cervical stabiliser, intended to reduce procedural discomfort and trauma by atraumatic stabilisation of the cervix during transcervical procedures. Clinical trials have demonstrated lower pain scores and bleeding rates compared with traditional tenacula.[3 4]

To better understand how the use of Carevix can support atraumatic care, clinical trial findings shall be complemented with real world evidence. Our prospective observational study evaluated the real world performance of Carevix during IUD insertions at a midwifery centre in Malmö, Sweden. Over 20 weeks, four midwives and one nurse manager performed routine IUD insertions using Carevix in 72 women, most of whom were parous (71%) and menstruating (94%) at the time of insertion. Outcomes were procedural completion rates, patient reported pain, bleeding, safety and satisfaction in both patients and healthcare providers.

The procedure was successfully completed using Carevix alone in 93% of cases. In five cases (7%), a tenaculum was required: twice due to inadequate grasping and three times due to spontaneous release of the device. Procedural completion rates using Carevix alone were slightly lower but still high in nulliparous compared with parous women (86% vs 96%, respectively). Neither uterine position nor menstrual cycle status appeared to influence procedural completion rates. Use of modern single handed inserters was associated with higher procedural completion rates (98%) than two handed inserters (85%).

The overall mean patient reported pain was 3.8 on a 0–10 numeric rating scale, with nulliparous women reporting significantly higher scores than parous women (mean 5.2 (SD 2.32) vs 3.2 (SD 2.21); p=0.0016). Bleeding requiring management was rare (10%, n=7) and resolved within 2 min using a compress. No vasovagal episodes (fainting, syncope or spasms), adverse events or device malfunctions were reported. Additionally, pain scores were not significantly influenced by the IUD inserter type (p=0.870), and pre-procedure analgesia (64%) did not appear to be associated with lower pain scores.

Women's satisfaction was high, with 99% reporting satisfaction and 74% finding the procedure more comfortable or less painful than expected. Among healthcare providers, 86% reported overall satisfaction with Carevix during IUD procedures. The most positively rated features included adequate cervical visibility (81%), adequate pulling strength (76%) and a perception of reduced patient discomfort compared with conventional instruments (75%). Healthcare providers particularly valued the low risk of vasovagal episodes. The learning curve was short, with familiarity achieved after five procedures.

The clinical implications of these findings are noteworthy. Across 72 procedures, no signs of vasovagal responses were observed. Bleeding rates (10%) were substantially lower than those reported in previous studies where the use of a tenaculum during IUD insertion resulted in bleeding rates approximately four times higher.[5] Additionally, in nulliparous women, weaker pelvic muscles may cause slippage of the speculum, often necessitating removal and repositioning of the tenaculum, which can be traumatic and painful. With Carevix, healthcare providers noted that repositioning was achievable with substantially less pain, making the procedure less traumatic.

While this was a single centre, non-randomised study with a modest sample size, the findings align with previous controlled trials[3 4] and provide valuable real world evidence supporting the potential clinical utility of integrating Carevix into routine clinical practice. Larger, multicentre comparative studies would help further define its role in everyday gynaecological care.

Figure 1 Carevix suction device used for atraumatic cervical stabilisation during insertion of an intrauterine device at a midwifery centre in Malmö, Sweden.

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Competing interests Carevix devices were provided by Aspivix SA.

Patient consent for publication Not applicable.

Ethics approval This study was conducted at Capio Barnmorskemottagning Malmö Centrum, Sweden, between October 2023 and February 2024, under routine clinical conditions. No experimental interventions were performed, and in accordance with Swedish national regulations, formal approval from an external ethics review board was not required for this observational study, carried out within routine clinical practice. Informed consent was obtained from all participating patients for the use of anonymised clinical data for

research and publication purposes. All data were handled in compliance with applicable data protection laws, and patient confidentiality was maintained throughout the study.

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