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LETTER TO THE EDITOR—CORRESPONDENCE

Side effects of intrauterine devices are often related to disproportion with the endometrial cavity—is there a role for pre-insertion ultrasound?

Dear Editors,

We would like to comment with reference to an earlier article by Van Schoubroeck et al. entitled "Pain and bleeding pattern related to levonorgestrel intrauterine system (LNG-IUS) insertion". The authors address a serious and underappreciated aspect of intrauterine contraceptive use, i.e. *pain during and post insertion* and provide the scientific community with interesting ad hoc *data*. They conclude that pain or bleeding at LNG-IUS insertion and in the 6 weeks following insertion do *not* predict the position of the LNG-IUS; and also that the mere absence of pain does *not* assure proper placement. They propose – quite convincingly – that adequate *sonographic assessment should be performed if it is required to confirm the positioning of the intrauterine device/system* [1].

The study was conducted in a heterogeneous (parity 0–5) population with follow-up of 6 weeks. The short duration of follow-up seems a significant limitation for clinical purposes since conclusions on *proper IUD placement* at a later date cannot be ruled out. Recommending sonographic evaluation to confirm 'proper' position of the IUD/IUS at follow-up is undoubtedly a very good practice, but given the factual duration of use for LNG-IUS systems – i.e. about 3–5 years, and up to 10 years for copper releasing systems – the assessment of the factual position of the IUD/IUS should, in our opinion – be made periodically on clinical grounds, over the full life span of the device/system.

In many ways IUDs/IUSs are the near ideal form of long-acting reversible contraception (LARC) and are strategically important for family planning in general and for preventing unintended pregnancies in particular. Their ability to reduce unintended pregnancy is governed by women *continuing* to use them, whereby the *tolerability of the device* has shown to be paramount to achieving this aim. Long-term use of the same device is promoted if health care providers give attention to the size and shape of the uterine cavity prior to insertion of a 'standard size IUD/IUS' [2]. This can be accomplished by using ultrasonography, either 2-D or 3-D. Maximum comfort during prolonged IUD/IUS use and a high continuation rate is achieved by using an IUD/IUS of which the greatest transverse dimension of the IUD/IUS is equal or slightly in excess of the fundal transverse dimension, as was established using mechanical methods decades ago [2,3]. These geometric relationships promote IUD retention and stability while minimizing endometrial/myometrial trauma.

Most current copper T-shaped IUDs and the Mirena LNG-IUS have a transverse arm length of 32 mm. The new smaller version of Mirena LNG-IUS, Jaydess, has a transverse arm length of 28 mm. The impact of uterine forces can be significant if the transverse arm of the IUD/IUS is significantly greater or smaller than the fundal transverse diameter [4]. If these contractions are severe, they can compress, distort, displace, and expel the IUD/IUS, particularly if the IUD/IUS is not capable of adaptive changes [5,6]. It is not surprising that an expulsion rate of 18% was found in a recent study of LNG-IUS and TCu380A in young women less than 20 years of age [7]. Displacement and embedment could not be analyzed as this was a telephone survey. It is ironic that whilst this group of women is most vulnerable to unintended pregnancy [8], suitable IUDs are not yet made available to them. In a Finnish study conducted in 165 nulliparous women the mean width of the uterine cavity, measured by ultrasonography was 24.4 mm, ranging from 13.8 to 35.0 mm. In 2/3 of these young women the transverse width was less than this distance [9]. In parous women the uterine cavity width in the fundus is hardly more [2].

In our experience uterine cavity widths can be exceptionally small or very large, even in nulliparous women. We have seen uterine widths – based on routinely performed 3-D ultrasonic measurements – much smaller than 24 mm or wider than 40 mm. The smallest uterine cavity observed had an internal diameter at the fundus of only 6 mm [10]. Without the aid of ultrasonic measurements physicians may be routinely, unknowingly inserting devices of sizes approaching 32 mm in uteri much too small to accommodate them. Given the muscular nature of the uterus forcible placement and eventual uterine accommodation may be achievable but at what clinical expense? Assessment of uterine cavity widths and IUD compatibility is therefore optimally desirable (Fig. 1).

Embedment of the transverse arms into uterine walls has been repeatedly demonstrated. Even the referenced study by Van Schoubroeck noted that in more than 50% of women apparent embedment was noted on 3-D ultrasonic measurements only 6 weeks after insertion of the IUD. It is unknown if the embedment represents the presence of a penetrating transverse arm or a true secondary perforation. Their observation that the presence of 'embedding' did not *influence* the pain score, does not rule out its factual or potential clinical importance. Clinical judgment is necessary for management and follow up of possible perforation. It rather illustrates the simple visualization that the device itself was not of a size to fit 'properly' within the uterus to guarantee a long-term patient tolerability and functionality as LARC.

Patient continuation rates, corrected for removal for planned pregnancy, for conventional T-shape devices with a transverse width of approximately 32 mm, are reduced by up to 10% each year yielding 5 year continuation rates of only 40–50% [10]. In contrast,

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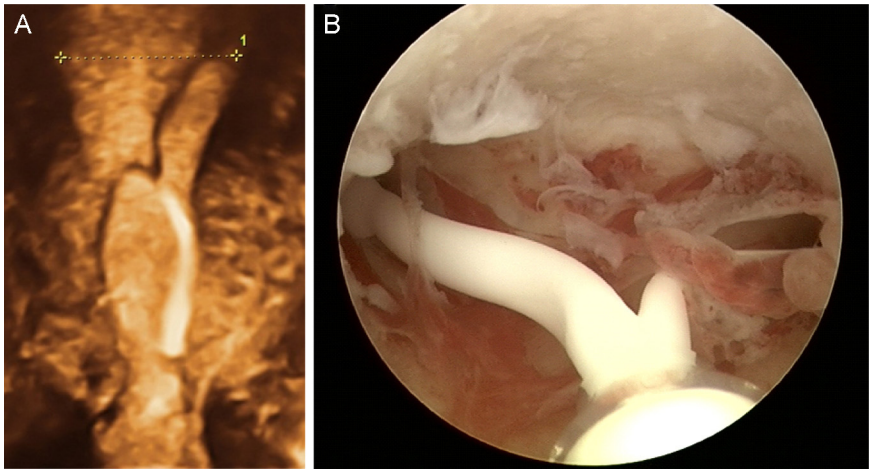

Fig. 1. (A) 3-D ultrasonography of an intrauterine system in a uterine cavity which is too small for the IUS. The uterine cavity is 19.56 mm wide at the fundus whilst the length of the transverse arms is 32 mm. (B) Hysteroscopic view of an IUS with embedded transverse arms due to spatial discrepancy with the uterine cavity leading to early removal of the IUS.

the 5 year adjusted continuation for frameless copper IUD and a frameless LNG-IUS exceeds 90%. Frameless devices lack a transverse arm entirely and are retained within the uterine cavity by means of a non-biodegradable uterine anchor. Patients have retained the frameless systems for over 12 years. Given the lack of transverse arms of any kind inadvertent embedment is eliminated. Furthermore the external total diameter width of frameless devices is below 3 mm making them suitable for use in all women irrespective of uterine cavity size. Lack of a transverse arm and ability of the frameless system to provide optimal relationship even within the smallest uterine cavities of young and adolescent women may account for their improved continuation rates and the resultant low rates of removal for bleeding and pain (Fig. 2) [11]. The length of the IUD does not seem to be important clinically, unless there is a great difference between cavity length and the length of the stem of the IUD.

Of interest is the relatively high degree of pain these patients experienced at insertion and with some continuing for 6 weeks. The study reports pain scores of 4.5 ± 2.6 immediately post insertion, 2.6 ± 2.6 in the first 3 days post insertion and 0.7 ± 1.6 at 4–6 week follow-up. Statistical analysis assuming normal distribution would suggest that approximately 15% of the women had exhibited a pain score of greater than 7.1 post insertion, 5.2 up to 3 days post insertion and even 2.3 at 6 weeks. Thus for a substantial portion of the population pain is quite significant and explains the high removal rate at 6 months to one year in many studies [11]. For comparison, a score of 10 was defined as "the most severe pain ever experienced". Even at 6 weeks a low to moderate level of pain is still unacceptable, given that the indication of use is for (long-term reversible) contraception.

When evaluating the size and shape of the uterine cavity, 3-D ultrasonography is by far the easiest and cheapest method to also diagnose uterine anomalies or other gynecological conditions which may affect IUD–IUS/uterus compatibility. Unfortunately, sonographic cavimetry and screening for congenital or gynecological uterine anomalies is not yet able to be carried out routinely in most clinical practices.

In our opinion the knowledge assessment of a patient's probable uterine cavity size is very important in the selection of an appropriate IUD/IUS. IUD systems such as frameless intrauterine devices hold significant clinical advantages in that they are the only devices currently available which will fit any size uterine cavity. While ultrasound affords invaluable information it must be remembered that prior to its use many women tolerated what we now know were ill-fitting IUDs. Ultrasound remains complimentary to good clinical evaluation and vigilance.

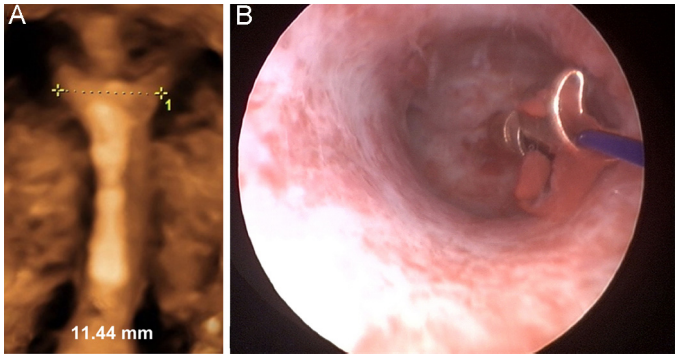

Fig. 2. (A) 3-D ultrasonography of a uterine cavity with largest transverse diameter of 11.44 mm. A frameless copper intrauterine device fits into very narrow uterine cavities like this one. (B) Hysteroscopic view of a frameless copper IUD inserted in a very narrow uterine cavity.

Conflict of interest

Dr. Wildemeersch, MD, PhD is a developer of frameless and framed intrauterine devices and systems for contraception and treatment. Dr. Thomas Hasskamp, MD was invited to participate in this paper because of his many years of experience as a referral doctor in solving IUD/IUS problem. Dr. Norman Goldstuck, MD has longstanding experience with intra-uterine contraception.

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