

DOES YANAE® FACILITATE IUD INSERTION IN NULLIPAROUS WOMEN? REAL-WORLD SURVEY IN FRANCE

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BACKGROUND

Intrauterine devices (IUDs) are highly effective, long acting, reversible and safe method of contraception [1].

A significant barrier to IUD adoption is the pain and discomfort associated with insertion. Conventional insertion techniques, involving cervical traction with a tenaculum and uterine sounding, can cause pain, anxiety, and bleeding [2]. Additionally, rigid IUD insertors often fail to adapt to the cervical canal's shape, increasing discomfort. Studies evaluating women's pain during these stages of IUD insertion report moderate pain levels (4 to 6 over 10-point scale) during tenaculum placement, sounding and IUD insertion [3,4]. Furthermore, anatomical, cultural, or psychological factors can contribute to a more painful experience [5], leading to apprehension about IUD use among both women and health care providers [6].

In collaboration with CrossBay (US), CEMAG Care (France) has developed an innovative insertor combined with a copper IUD, called Yanae®. This specific insertor has a flexible inflatable membrane allowing self-guided, atraumatic, and dependable cervical crossing reducing the use of a cervical forceps (Fig. 1).

AIMS AND OBJECTIVES

The main objectives were to evaluate :

1. Effectiveness of IUD insertion using Yanae® measured by IUD insertion success rate and correct placement
2. Patient pain during Yanae® insertion procedure
3. Healthcare providers' and participants' satisfaction

DESIGN AND METHODS

An observational, prospective, multicentre study conducted across various clinical sites in France.

Following dedicated training, operators were instructed that uterine sound and tenaculum use may not be necessary with Yanae®. Data were collected from June 2022 to December 2024 through structured questionnaires completed both by health care providers (including gynaecologists, general practitioner, and midwives) and patients in France. Main data collected were:

- Success of IUD insertions,
- Patient-reported pain levels during insertion using a visual analogic scale (VAS-10 cm), and
- Satisfaction from both patients and operators.

This was an open label evaluation and statistical analysis conducted was purely descriptive.

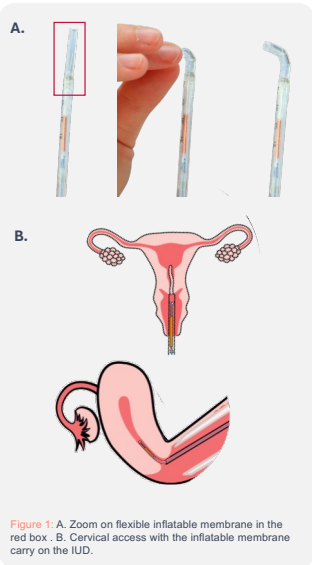


Figure 1: A. Zoom on flexible inflatable membrane in the red box. B. Cervical access with the inflatable membrane carry on the IUD.

RESULTS

Out of 98 total feedback responses, this analysis focused on 55 nulliparous patients (57%) who received the intervention with Yanae®. Among them, 40% were aged ≤24 years.

1 95% success IUD insertion and correct IUD placement in nulliparous

Insertion was successful with a correct IUD placement in 52 women (95%) (Fig. 2).

There were 3 insertion failures for the reasons described hereafter:

- Difficult visualization and crossing the external os despite the use of tenaculum
- Incorrect use of the device leading to incorrect deployment of the membrane.
- Anteverted, anteflexed uterus with a very pronounced cervical angle.

IUD insertion practices in the 52 successful insertions observed that:

- Uterine sounding was performed in 2% of cases (n=1)
- Tenaculum was used in 8% of cases (n=4)

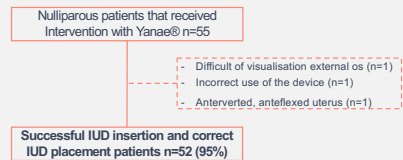


Figure 2: Yanae® insertion outcome in nulliparous women (n=55)

2 Patient-reported pain average score of 2.6 on a 10 cm Visual Analogue Scale (VAS)

Patient pain level was evaluating using a 10 cm VAS on 52 patients.

Mean patient level pain was 2.6 (range 0 to 6) and median pain level was 2.

Highest reported frequency was at VAS 2 (25% of patients), and interesting 13% women reported no pain level (n=7).

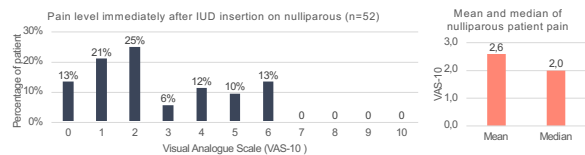


Figure 3: Distribution, mean and median of patient pain as cm in a 10-cm VAS (0: no pain, 10: maximum possible pain)

3 High practitioner and patients' satisfaction

Satisfaction was assessed in 53 patients and practitioners. High level of satisfaction was reported by 96% or more in both practitioners and patients. According to health care providers, Yanae® helped to improve comfort during insertion for 89% (n=49) of patients.

Most of patients, 98% (n=52), recommend Yanae® to a friend or a family member.

CONCLUSION

The findings of this French real-world evaluation highlight the successful and acceptable use of the Yanae® IUD in nulliparous women, a demographic increasingly choosing IUDs for contraception.

The high success rate, alongside manageable pain levels and strong satisfaction reported by both users and providers, suggests that **Yanae is particularly beneficial as more young, nulliparous women are choosing IUDs for contraception, a population for whom IUD insertion can be more challenging and painful.**

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