

# Evaluation of an innovative IUD insertor (Yanae®) : Results of real-world survey in France

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## BACKGROUND

Copper IUD is one of the most efficient and cost-effective contraception. Standard IUD insertion procedure usually involves measurement of uterine cavity with a hystrometer and the use of a tenaculum to facilitate device insertion. Both procedures may be painful for patients which is often a barrier to IUD use for both women and health care providers<sup>1,2</sup>.

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).

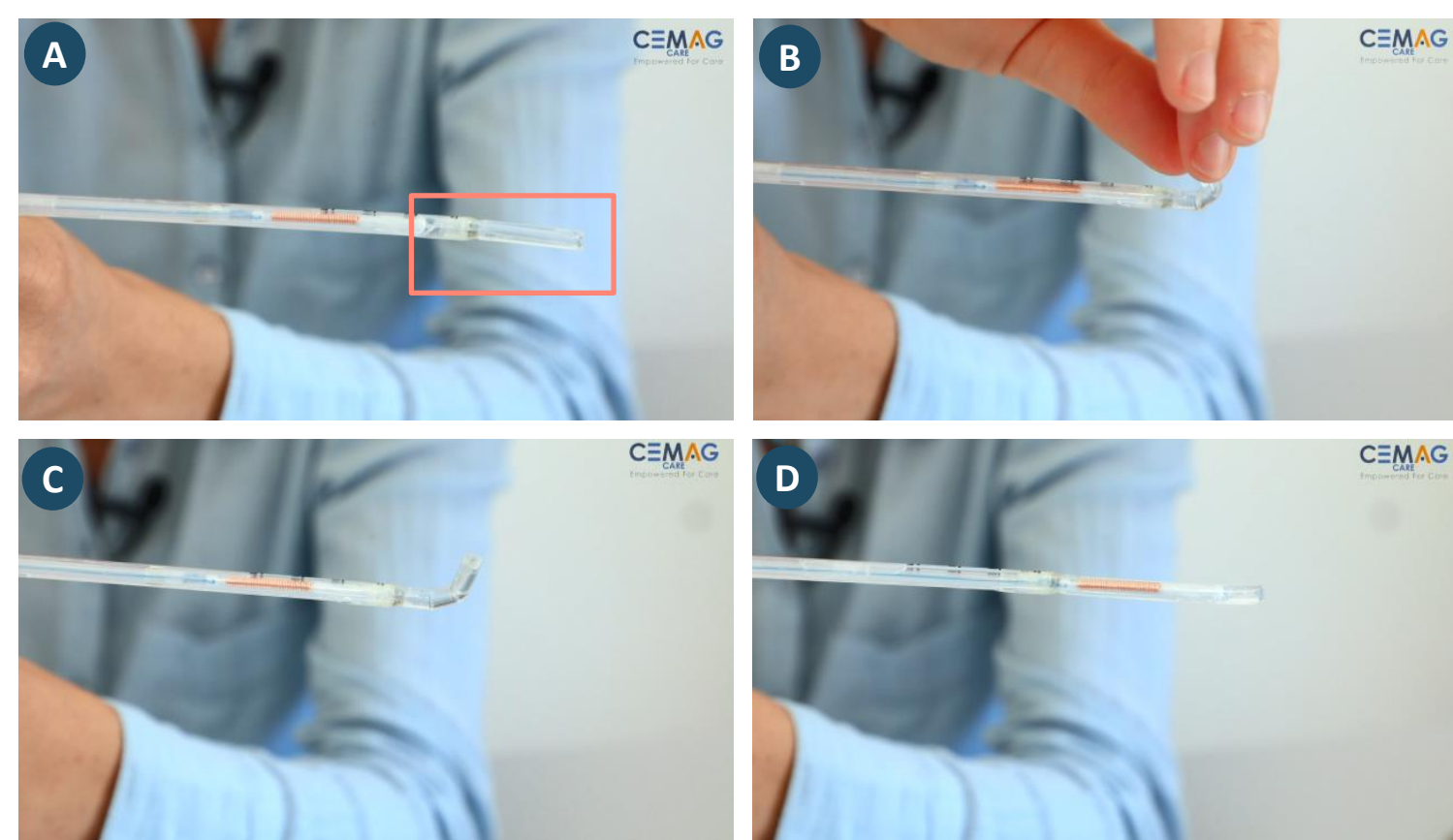


Figure 1: Inflatable membrane in the red box (A) is flexible (B), it keeps the shape (C) and can carry a copper IUD (D).

## AIMS AND OBJECTIVES

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

Following dedicated training, operators were instructed that hystrometry and tenaculum use may not be necessary with Yanae®. The data collected through a specific questionnaire included:

- Provider reported effectiveness and ease of the insertion procedure.
- Patient reported satisfaction and pain perception during insertion using a visual analogic scale (VAS-10 cm).

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

## RESULTS

In this real-data study, IUD insertion using Yanae® was performed on 5 sites (Paris, Tarbes, Pluvigner, Saint André de Cubzac and Issoudun) in 39 women by 7 operators (2 Gynecologists and 5 Midwives) from June 2022 to October 2023.

In 37 women with available post-insertion assessment, median age was 26 years, 54% were multiparous, most of them had no previous IUD insertion (62%) and had taken a pain killer (65%).

### 1 Primary objective: Success IUD insertion and correct IUD placement

Successful rate and correct IUD placement were assessed only on patients receiving intervention with Yanae® (n=38).

**Insertion was successful with a correct IUD placement in 36 women (95%)**

(Fig. 2). There were 2 insertion failures for the reasons described hereafter:

- the IUD could not be inserted in a strongly retroverted uterus: the practitioner attempted to insert another type of copper IUD using a tenaculum: this attempt was again a failure.
- the IUD deployed into the isthmus and had to be removed.

Over 37 insertions, IUD insertion was done without prior use of hystrometer (81%) or tenaculum (86%).

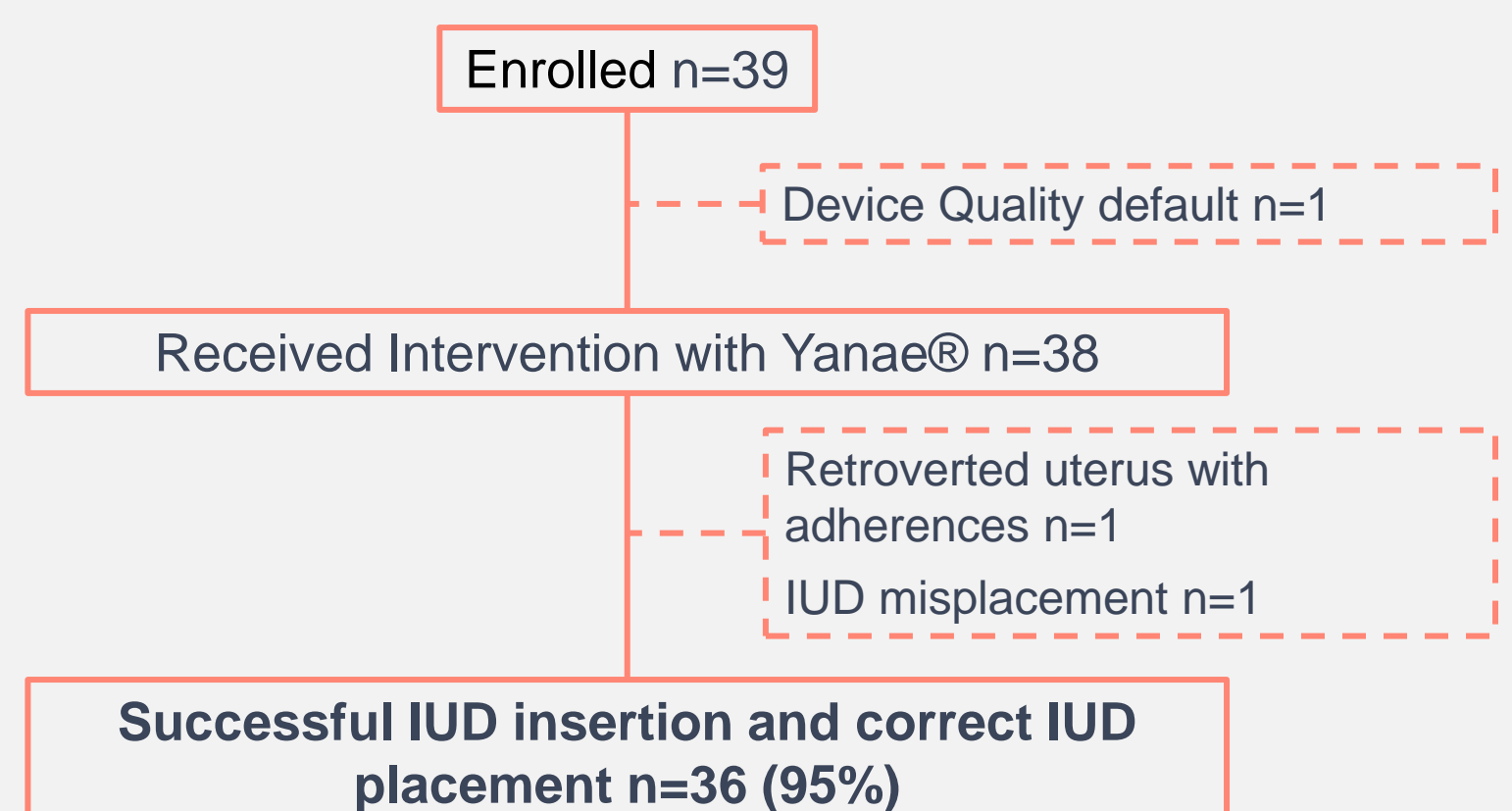


Figure 2: Yanae® insertion outcome in the Intention To Treat population.

### 2 Secondary objective: Analysis of patient pain during insertion

Patient pain level was evaluating using a 10 cm VAS on 37 patients.

**Mean patient level pain was 2.4 (range 0 to 6) and median pain level was 2.**

As indicated in Fig. 3, 22% (n=8) of women reported no pain (0 cm) and 49% (n=18) of women reported minimal pain (1, 2 and 3 cm) during insertion. No patient had a VAS of 7 cm and above.

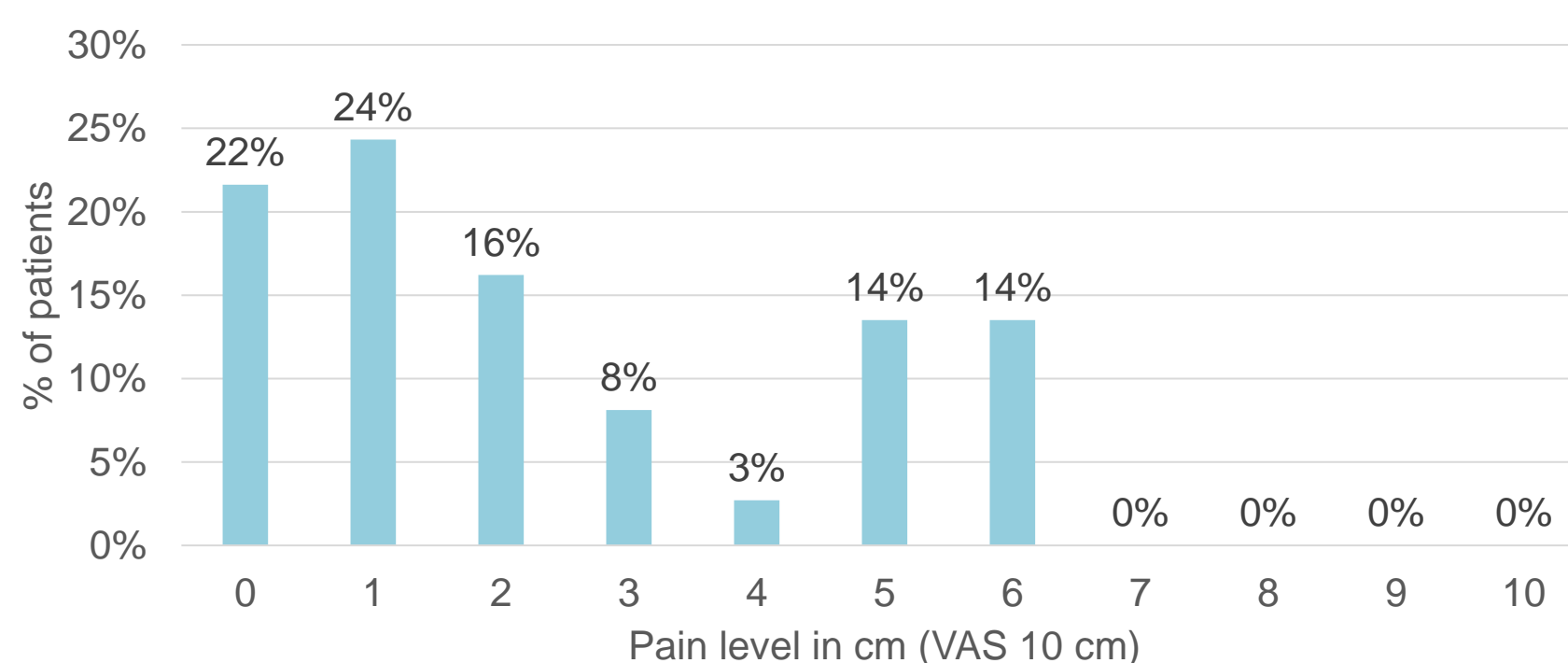


Figure 3: Distribution of pain as cm in a 10-cm VAS (0: no pain, 10: maximum possible pain) (n=37)

### 3 Additional outcome: Practitioner and patients' satisfaction

Satisfaction was assessed in 36 patients and practitioners. High level of satisfaction was reported by 92% or more in both practitioners and patients.

According to healthcare, Yanae® helped to improve comfort during insertion for 83% (n=30) of patients.

Most of patients, 97% (n=35), recommend Yanae® to a friend or a family member.

## CONCLUSION

This real-world evaluation confirms the benefit of Yanae® for both women and health care providers in making IUD insertion easier and less painful. IUD insertion success rate was high (95%) whereas for other IUD insertion methods, this observed rate is between 82%-96%<sup>3,4</sup>.

This new technology paves the way for a larger use of non-hormonal IUD for patients with complex uterus anatomy but also for all women for whom, fear of pain or getting hurt could be a barrier to IUD insertion.

## REFERENCES

- 1) Rapkin et al. Self-Administered Lidocaine Gel for Intrauterine Device Insertion in Nulliparous Women: A Randomized Controlled Trial. *Obstet Gynecol.* 2016 Sep;128(3):621-8
- 2) Akers et al. Reducing Pain During Intrauterine Device Insertion: A Randomized Controlled Trial in Adolescents and Young Women. *Obstet Gynecol.* 2017 Oct;130(4):795-802.
- 3) Dermish, et al. Failed IUD insertions in community practice: an under-recognized problem? *Contraception* 2013, 87(2), pp. 182–186.
- 4) Teal, et al. Insertion characteristics of intrauterine devices in adolescents and young women: success, ancillary measures, and complications. *American Journal of Obstetrics and Gynecology*, 2015 Oct;213(4):515.e1-5.

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