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Yanae®: Painless Alternative for Successful IUD Insertion - Interim Results from Study

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INTRODUCTION/BACKGROUND

Copper IUD is the most efficient method of non-hormonal contraception. However, the current insertion procedure might be challenging for healthcare providers and painful for the women. This procedure usually involves measuring the uterine cavity, using a tenaculum or vulsellum to facilitate insertion and employing a rigid IUD insertor. These factors can create apprehension about IUD use among both women and healthcare providers[1,2].

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, painless and dependable cervical crossing without using vulsellum or hysterometer/uterine sound (Fig.1)**.

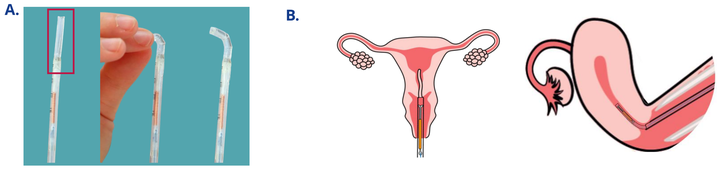

Figure 1: A. Zoom on flexible inflatable membrane in the red box . B. Cervical access with the inflatable membrane carry on the IUD.

OBJECTIVES

Primary objective: Evaluate the **efficacy of intrauterine device (IUD) insertion with Yanae®.**

Secondary objective:

1. Assess participant **pain score** after IUD insertion.
2. Measure the level of satisfaction of participants and providers.

Additional objective:

1. Perform **subgroups analyses according the use of tenaculum / vulsellum** for IUD insertion
2. Evaluate **safety profile** during and after insertion procedure.

METHODS

Women desiring long-term contraception were invited to participate from four distinct clinical sites or medical Institutes in India.

The efficacy of IUD insertion with Yanae® was assessed based on successful insertion and correct fundal placement, confirmed by ultrasound immediately post-insertion. The necessity for additional instruments such as hysterometer or tenaculum / vulsellum was also recorded.

Pain levels experienced by participants were evaluated using a Visual Analog Scale (VAS-10cm).

Participant and provider satisfaction was self-rated using a qualitative scale from Dissatisfied to Very satisfied.

Follow-up safety data were collected to monitor adverse events for up to 12 months post-insertion.

CONCLUSIONS

Interim findings demonstrate the benefit of Yanae® for both women and health care providers in **making IUD insertion easier and less painful**. Yanae® enables successful IUD insertion in nearly all cases (98.9%), with minimal need for prior use of a vulsellum (89.2%). Furthermore, the procedure is associated with minimal or no pain for all participants.

RESULTS

For this interim analysis, 94 women were included out of a planned sample size of 164, with participant ages ranging from 21 to 50 years and a median age of 32 years. The majority (92.5%) had prior experience with contraceptive methods, with 42.5% having previously opted for an IUD. All participants were multiparous.

1 Primary objective: Yanae® was successfully inserted in 93 women (98.8%)

The study's primary objective is to validate the efficacy of IUD insertion using Yanae® insertion procedure. The endpoint to evaluate this primary objective is the success rate of the insertion procedure measured by three parameters – device preparation, insertion procedure and device placement.

Out of 94 participants, the study device, Yanae®, allowed **successful IUD insertion and correct placement in 93 women (98.8%)** (Fig.2). In one case (1.1%), insertion failed after two attempts despite vulsellum use due to an impassable cervix. Since the protocol does not permit a third attempt with Yanae®, an alternative IUD device, Cu 375, was inserted after cervical dilatation. Hysterometer use prior to insertion was never required.

The procedure time (placement of device at ext os to cutting of thread) was 58 ± 49 seconds.

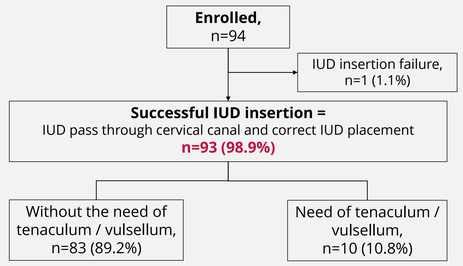

Figure 2: Participant disposition

2 Secondary objective: Low pain level and high satisfaction reported after IUD insertion with Yanae®

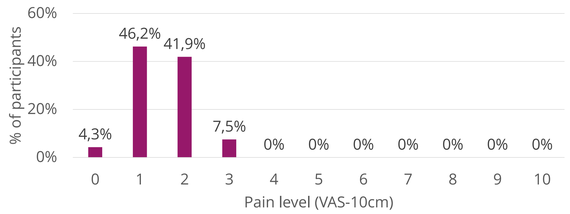

Figure 3: Distribution of pain level as cm in a 10-cm VAS (0: no pain, 10: maximum possible pain) (n=93)

Out of 93 participants who had IUD insertion, participant pain level was evaluated using a 10 cm VAS scale. Participant and provider satisfaction was self-rated using a qualitative scale from *Dissatisfied* to *Very satisfied*.

1. **Very low pain levels were reported: median pain score was 1 (range from 0 to 3) and average pain score was 1.5 ± 0.1**.

As indicated in Figure 3, 4,3% (n=4) of women reported no pain (0 cm) and 95.7% (n=89) of women reported minimal pain (1, 2 and 3 cm) during insertion. No participant had a VAS of 4 cm and above.

2. **High level of satisfaction was obtained in 88 cases (94.6%) according to healthcare providers and in 93 cases (100%) according to participants**. Most of participants (93.5%) would recommend Yanae® to others.

3 Exploratory analysis according the use of tenaculum / vulsellum

Out of 93 IUD insertion with Yanae®, all insertion were done without prior uterine sound and **83 were done without the use of tenaculum / vulsellum (89.2%)**. The primary reasons for tenaculum / vulsellum use were to enhance visualization of the external os or stabilize the cervix.

Mean pain score of participants was 1.5 ± 0.7 when insertion was done without tenaculum, versus 1.7 ± 0.9 when it was done with tenaculum / vulsellum (Table 1).

Successful IUD insertion	n	%	Median	Mean (SD)
Only with Yanae®	83	89.2	1.0	1.5 ± 0.7
WithYanae® and tenaculum / vulsellum	10	10.8	2.0	1.7 ± 0.9

Table 1: Participant pain level according to the use of tenaculum / vulsellum

4 Safety information: Yanae® was well-tolerated,

No adverse event was reported during insertion procedure.

According to available follow-up data, one pregnancy was reported two months post-insertion, and one case of heavy bleeding/menorrhagia occurred two weeks after insertion, resolving upon IUD removal.

CONTACT INFORMATION

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