Yanae : a painless alternative for successful IUD insertion – Final clinical trial results

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BACKGROUND

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 [1]. Additionally, rigid IUD insertors often fail to adapt to the cervical canal's shape, exacerbating discomfort. Studies evaluating women's pain during these stages of IUD insertion report moderate pain levels during tenaculum placement, sounding and IUD insertion [2,3].

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, to facilitate the cervical crossing (Fig. 1).

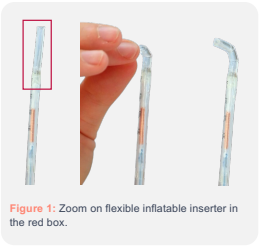

Figure 1: Zoom on flexible inflatable inserter in the red box.

OBJECTIVES AND DESIGN

A prospective, multicentre, open-label, single-arm study conducted across four distinct clinical sites or medical Institutes in India.

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

Secondary objective:

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

Additional objective:

- Perform subgroups analyses according to the use of tenaculum for IUD insertion
- Evaluate safety profile during and after insertion procedure.

METHODS

Women desiring long-term contraception were invited to participate from participating sites. IUD insertion was performed according to Yanae® instructions for use (Fig. 2).

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 uterine sound 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.

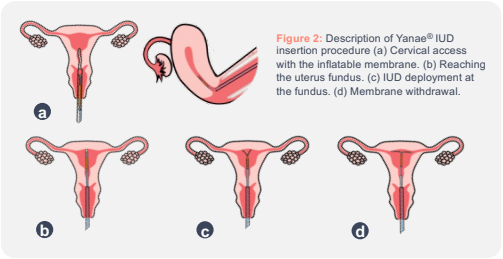

Figure 2: Description of Yanae® IUD insertion procedure (a) Cervical access with the inflatable membrane. (b) Reaching the uterus fundus. (c) IUD deployment at the fundus. (d) Membrane withdrawal.

RESULTS

This study enrolled 167 women (median age 31 years), with 99.4% being multiparous and 34.1% had previously used IUD as contraception method.

❶ Successful insertion was achieved in 99,4% of cases

The success rate of the insertion procedure was measured by three parameters –device preparation, insertion procedure and device placement.

Out of 167 participants, the study device, Yanae® enabled **successful IUD insertion and correct placement in 166 women (99.4%)** (Fig.3).

In one case (0.4%), insertion failed after two attempts despite vulsellum use due to an impassable cervix.

Ultrasound measurements showed a median fundal distance of 3 mm from the superior edge of the IUD (vertical arm) to the internal endometrial verge.

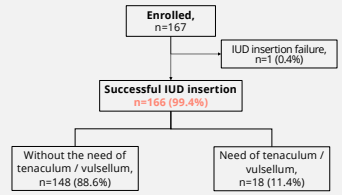

Figure 3: Yanae® insertion outcome (n=167)

❷ Ease of IUD insertion using Yanae®

- The vast majority (88.6%, n=148) of insertions were done without the use of a tenaculum/vulsellum,
- Uterine sound to insertion was never required,
- Cervical dilation was necessary in only two cases (1.2%) due to non-negotiable internal os,
- The insertion procedure time (placement of device at ext os to cutting of thread) was short (58 ± 49 seconds).

❸ Pain reported by patients is minimal : mean score of 1.5 on a 10 cm Visual Analogue Scale (VAS)

Among the 166 participants who successfully received IUD insertion, the Yanae® device was well-tolerated, with very low pain levels reported.

- **Patient pain mean score was 1.48 ± 0.7.**
- No participants reported a pain score higher than 3.
- The mean pain score was 1.4 ± 0.7 in patients without tenaculum/vulsellum use, compared to 1.8 ± 0.8 in those where it was required..

❹ Both HCPs and patients express very high level of satisfaction

156 participants (93.9%) reported high satisfaction, and healthcare providers reported high satisfaction in 161 cases (96.9%).

Furthermore, 92.2% of participants indicated that they would recommend Yanae® to others.

"Yanae is a novel and convenient copper IUD. Insertion process being less painful made it more woman compliant and acceptable".
Prof. Richa Singh, S. N. Medical College, Agra

CONCLUSION

This multicenter study confirms that **Yanae® device offers a safe, effective, and well-tolerated approach to IUD insertion, significantly reducing procedural pain and enhancing both user and provider satisfaction**. This innovative technique has the potential to promote wider adoption of IUDs for long-term contraception.

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