

Feedback from a service evaluation of a modified intrauterine device insertor: A first step to a change of the IUD standard insertion procedure

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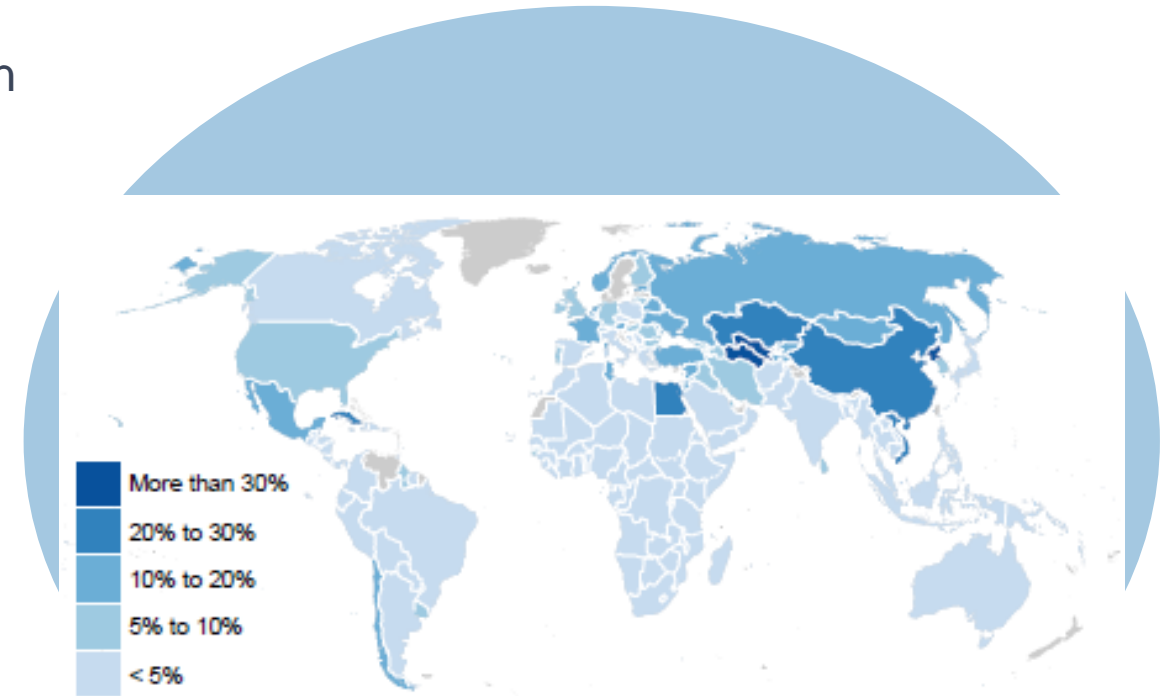
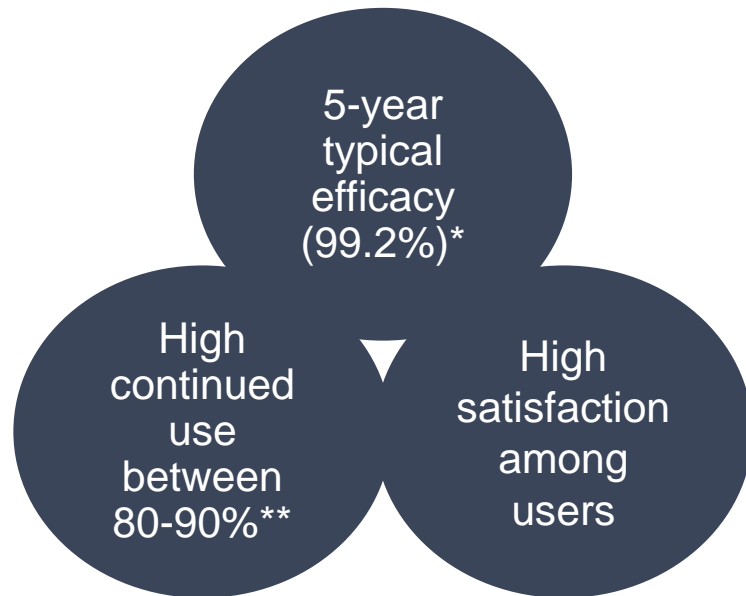
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Background: Copper Intrauterine Device (IUD)

Long term efficacy, safety, hormone free contraception



Total worldwide use of IUDs is estimated to 17%*** of women of reproductive age (15-49 years)

* World Health Organization Tiered approach to contraceptive effectiveness - Family Planning - A global handbook for providers, 2022 edition

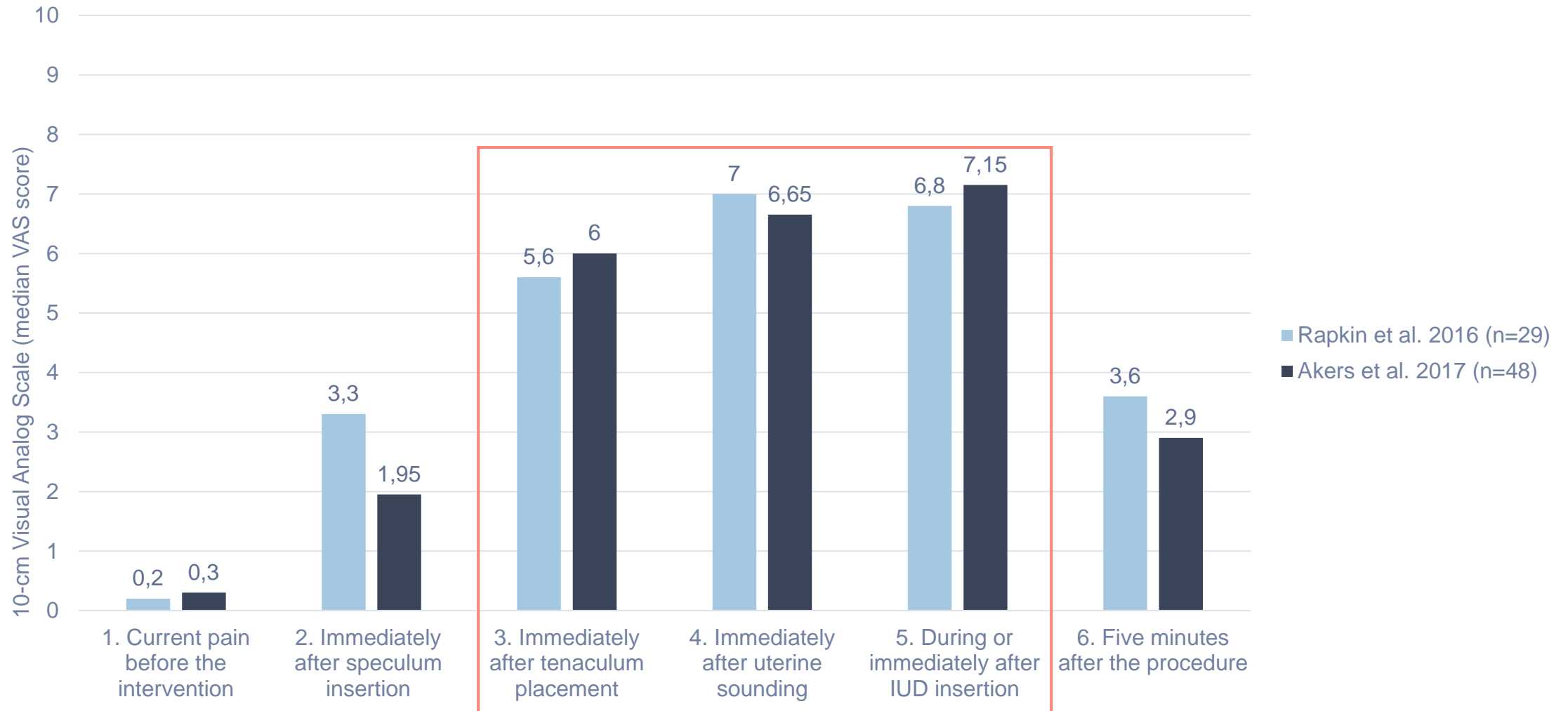
** Peipert, et al. *Obstet Gynecol.* 2011 May;117(5):1105-1113.; Hubacher et al. *Am. J. Obstet. Gynecol.* 2017;216(2):101-109.; H Akintomide et al. *BMJ Open.* 2022 Oct 3;12(10):e060606.,

***UN Contraceptive Use by Method 2019 - Data from women married or in free union

Standard IUD insertion procedure

- 1** Tenaculum placement at the cervix
Uterus sounding to measure the uterine cavity length
- 2** Cervix traction with the tenaculum
Passing the cervix and Crossing the uterus canal
- 3** IUD placement at the fundus
Removal of the insertor device

Patient pain during IUD insertion procedure



Yanae[®]: a disruptive innovation in the IUD world

Y shape Copper 380
IUD (or mini)



Crossglide[™]
insertor



Fully device
patented



CE Mark

Class III Medical
device



Device characteristics

- A frictionless and atraumatic technology to access the uterine cavity*



Clinical benefits**

- Easy access procedure to the cervix
- Fit to every uterus shape
- Less risk of complications



Benefits for the patient**

- Significant improvement of comfort
- Reduction of complications
- Less adverse effects and risks

*www.crossbaymedical.com

**<https://crossbaymedicalinc.com/crossglide-technology/>

Yanae[®]: Insertor membrane

Yanae[®] IUD insertion procedure


- 1** Membrane placement at the cervix
The inflated membrane passes through the cervix
- 2** The membrane with the IUD reach the uterine cavity
- 3** IUD placement at the fundus
Removal of the insertor device

IUD insertion using Yanae[®]

Service Evaluation Investigation performed in France
(June 2022-January 2023)












YANAE-S22002-REX

Objectives

- **Primary outcome:** Effectiveness of IUD insertion using Yanae®
 - IUD insertion success rate
 - IUD correct placement
 - **Secondary outcome:** Patient pain during Yanae® insertion procedure
 - **Additional:** Practitioners' and patients' satisfaction
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Materials and Methods

- Using Yanae[®] IUD insertion
- Operator questionnaire including information of IUD insertion (success, IUD placement, satisfaction)
- Patient questionnaires including (fear before IUD insertion, Pain (VAS score (10-cm)) and satisfaction)

										
0 Pain Free	1 Minimal	2 Mild	3 Uncomfortable	4 Tolerable	5 Distracting	6 Distressing	7 Unmanageable	8 Intense	9 Unbearable	10 Unable to move
No Pain	Minor Pain			Moderate Pain			Severe Pain			

Result: Characteristics

Operators

Number of Site (Paris, Tarbes)	2
Number of operator forms completed	31
Number of operators	4
Type of healthcare operators	n=4
Gynecologists	2 (50%)
Midwives	2 (50%)
History of use of hysteroscopy prior to insertion	n=4
Always	3 (75%)
Never	1 (25%)
History of use of cervical tenaculum during insertion	n=4
Always	1 (25%)
Depending on case	2 (50%)
Never	1 (25%)

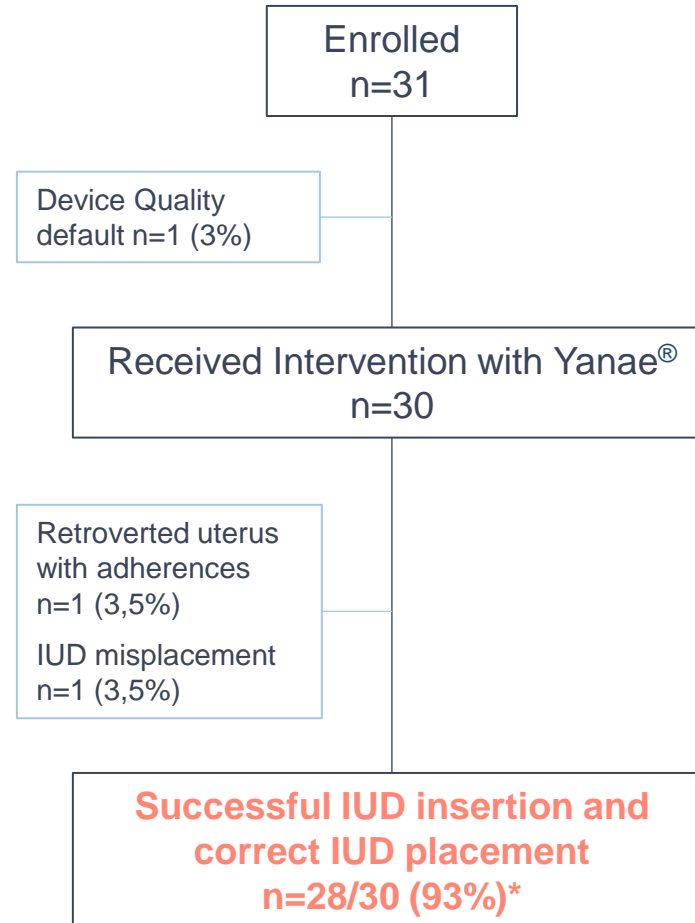
Participants

Number of patient forms completed		n=29*	
Age	n=29	Pain killer before insertion ?	n=29
Mean	28	Yes	18 (62%)
Median	27	No	11 (38%)
Min.	18	Emergency contraception ?	n=29
Max.	47	Yes	1 (3%)
Vaginal delivery?	n=29	No	28 (97%)
Yes	14 (48%)	Previous IUD ?	n=29
No	15 (52%)	Yes	10 (34%)
Number of births	n=14**	No	19 (66%)
Mean	2		
Median	2		
Min.	1		
Max.	3		

*n=29, only 29 women completed the form (one case, device could not be used; another case, insertion failed, in both cases patients' form were not completed)

**n=14, only parous women were considered

Primary outcome: Yanae[®] IUD insertion procedure



*Successful rate and correct IUD placement were assessed only on patients receiving intervention with Yanae (n=30)

Primary outcome: Changes from usual practice

Practitioners (Type)	History of hysteroscopy	Use of hysteroscope with Yanae® (nb of cases using hysteroscopy / total patient cases)	History of use of tenaculum	Use of tenaculum with Yanae® (nb of cases using tenaculum / total patient cases)
AB paris (Gynecologist)	Always	No use (0/4)	Never	1/4 use
TB (Gynecologist)	Never	No use (0/13)	Always	1/13 use
TL (Midwife)	Always	No use (0/1)	Depending on cases	No use (0/1)
TR (Midwife)	Always	No use (0/13)	Depending on cases	No use (0/13)

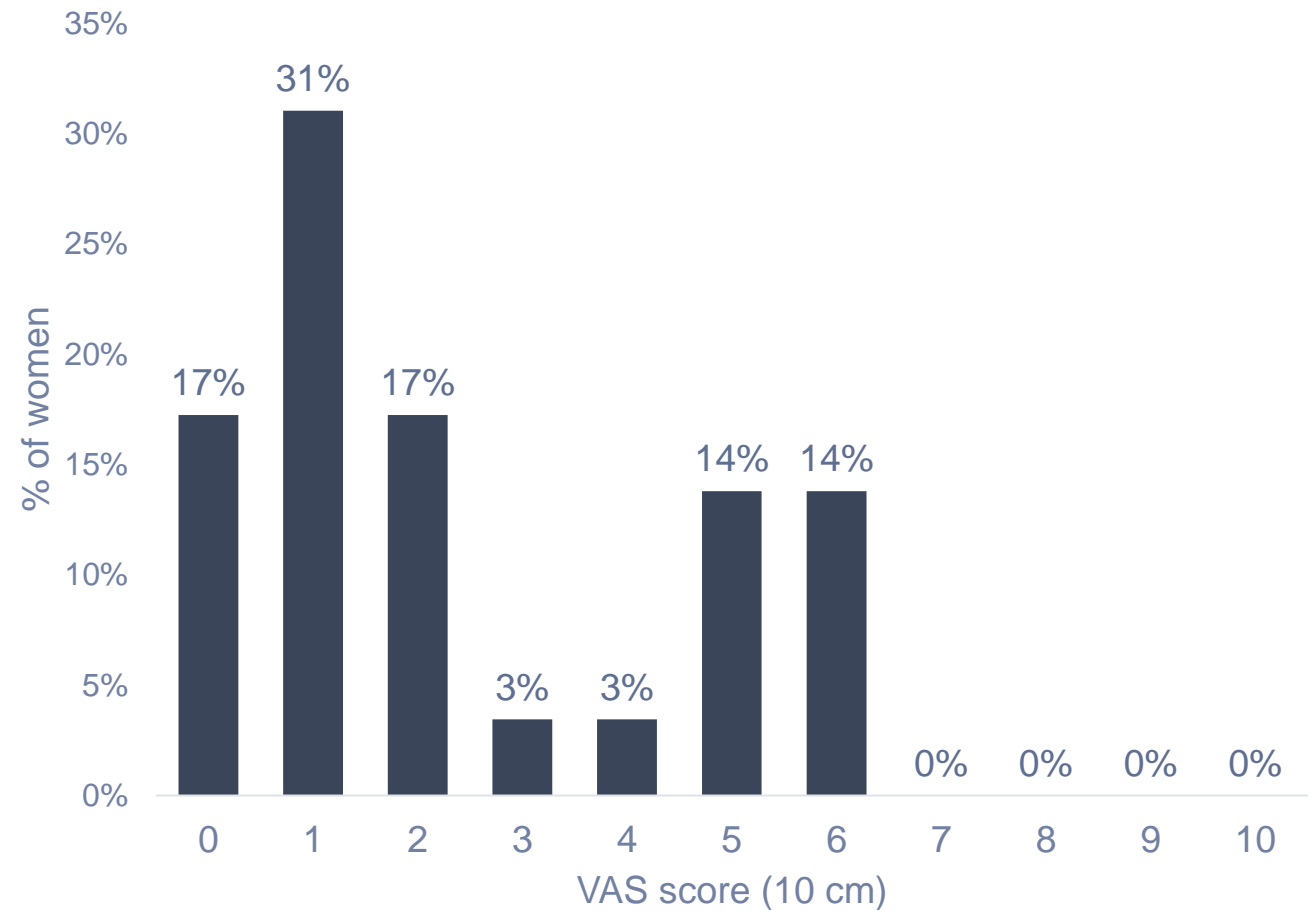
During the Yanae® insertion procedures:

- **Hysteroscopy was not longer used** by all practitioners even among those who previously relied always on it.
- **The three practitioners**, who initially declared to use the tenaculum “Always” or “Depending on cases”, **decreased their utilization**. There was only one observed case where one of these practitioner employed the tenaculum.

Secondary outcome: Patient pain during Yanacae[®] insertion procedure

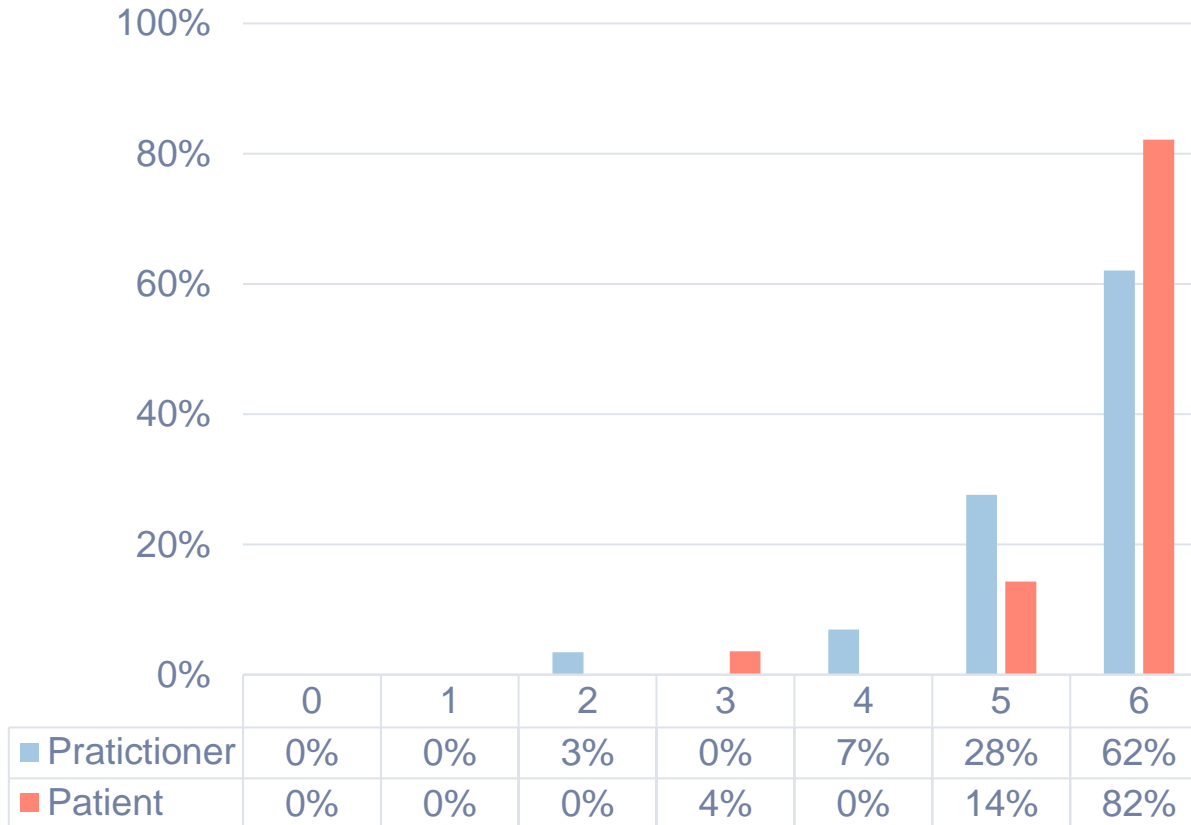
Patient Pain*	VAS score (10 cm)
Mean	2,4
Median	2,0
Min.	0
Max.	6

- 17% (n=5) of women reported **no pain** during insertion
- 51% (n=15) of the women experienced a **minor pain** (VAS 1, 2 and 3 cm) including 31% (n=9) women reporting minimal pain.
- Patient pain was always <7 (Severe pain)



Additional outcome: Practitioners' and patients' satisfaction

Practitioners' and Patients' satisfaction on a 0 (bad) to 6 (excellent) scale



High level of satisfaction in 29 insertions is 90% or more in both practitioners and patients.

Yanae® helped to improve comfort during insertion for 86% (n=18*) of patients according to practitioners.

92% (n=23) of patients recommend Yanae®** to a friend or family member.

*Satisfaction level was recorded in only 28 operators' forms (n=28)

**Satisfaction level was completed in only 28 patients' forms (n=28)

Conclusions

Yanae[®] constitutes a significant step forward in the use of copper IUDs for any woman:

- **Simplifying the insertion procedure:** the need of hysteroscopy or tenaculum is dramatically reduced / is limited.
- **Improvement of patient comfort** during insertion should enable the procedure to be used more widely for nulliparous women and for emergency contraception
- **Insertion success rate** is high and consistent with other IUD insertion procedure.

Ongoing evaluation with a larger sample size will corroborate these results.



Thank you for your attention!

Any additional questions, please contact:
contact@cemagcare.com

Yanae® Cu 380 with Crossslide inserter (Yanae®) is a hormone free intrauterine contraceptive device manufactured by Pregna International LTD (India) / EC Authorized Representative: MT Promedt Consulting GmbH (Germany). CE 2460

Yanae® is a hormone free contraceptive providing women of childbearing age with an almost complete protection against pregnancy during 5 years.

This medical device (Class III) is a regulated healthcare product, which, pursuant to this regulation, bears the CE marking.

Read the leaflet carefully before use.

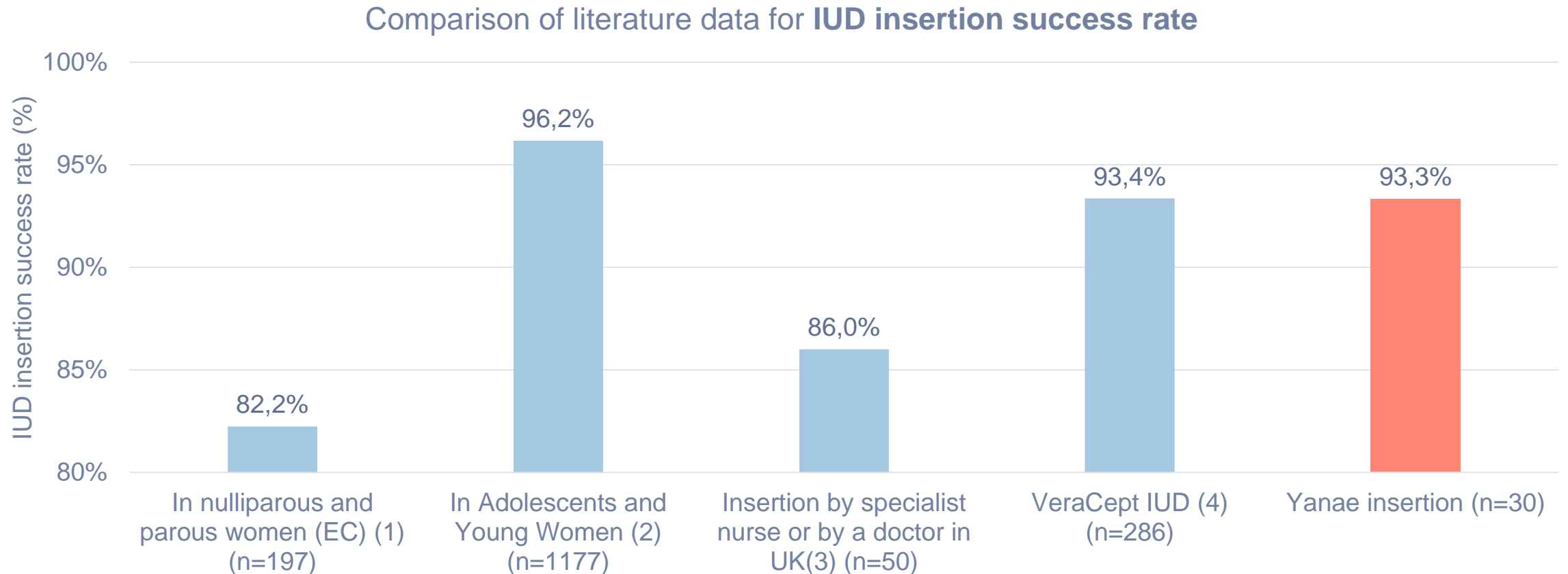
Yanae® does not protect against sexually transmitted diseases.

Yanae® is a product reimbursed in France. Code LPP 6111479.

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Discussion: IUD insertion success rate in literature data



1) Dermish, et al. (2013) Contraception, 87(2), pp. 182–186.

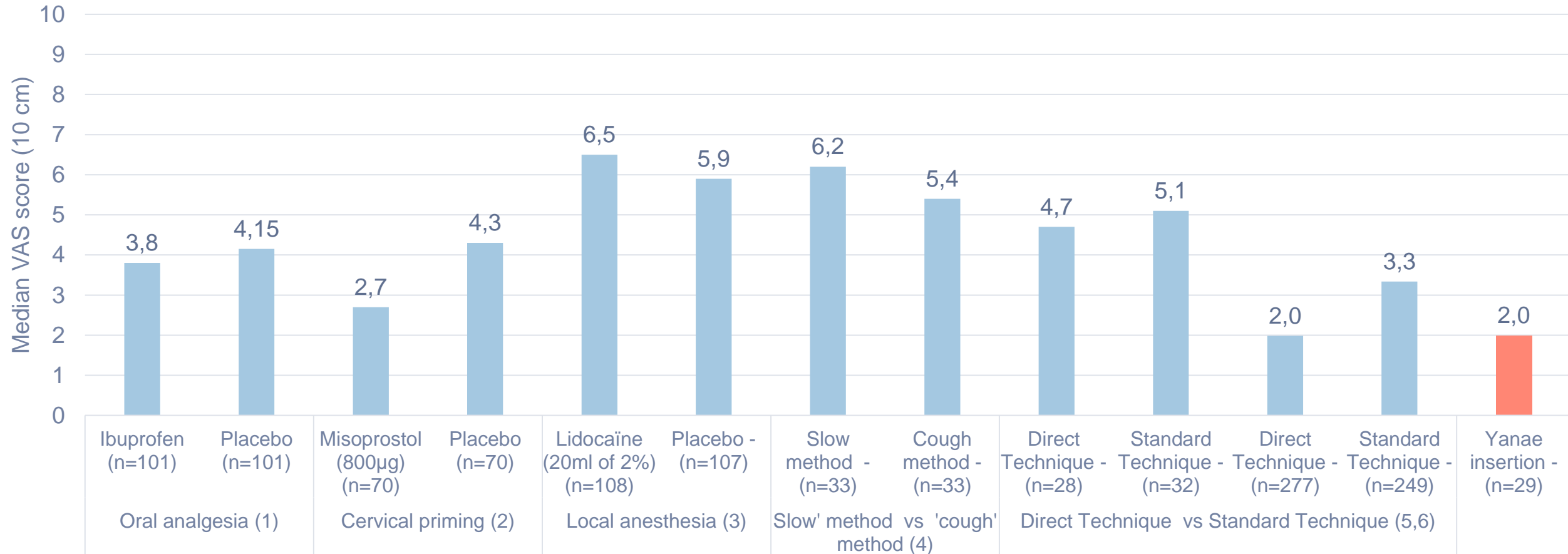
2) Teal, et al. (2015). American Journal of Obstetrics and Gynecology,

3) Andrews, et al. (1999). The European Journal of Contraception & Reproductive Health Care, 4(1), 41–44.

4) Turok, D.K. et al. (2020) Obstetrics and Gynecology, 135(4), pp. 840–847.

Discussion: IUD insertion patient pain

Comparison of literature data for IUD insertion pain



1) Bednarek et al. 2015 Contraception. 91:193-197.

2) Abdellah et al. 2017. Contraception. 95:538-543.

3) Conti JA, et al. 2019. Am J Obset Gynecol. 220:177.e1-177.e7.

4) Lambert et al. 2020 BMJ Sex Reprod Health. 46(2):126-131.

5) Rahou Aissat et al. 2019 J Gynecol Obstet Hum Reprod, 48 719-725

6) Bastin et al. 2019 Eur J Contracept Reprod Health Care., 24(5):399-406.