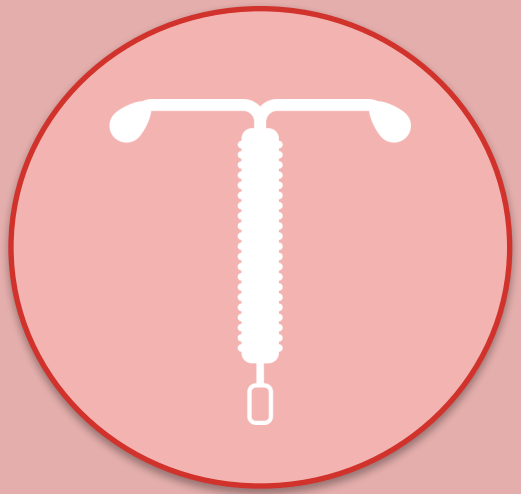
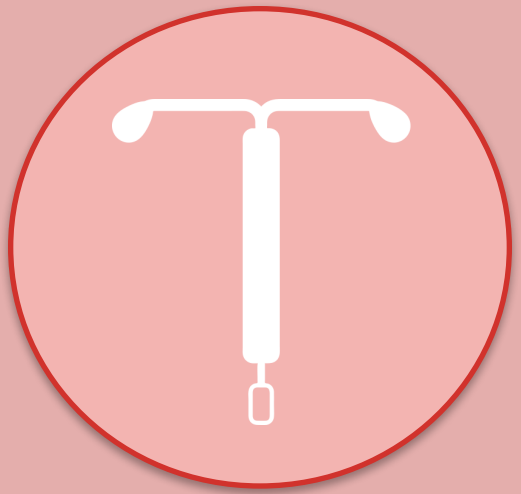
Intrauterine instillation of Mepivacaine for pain relief at IUD insertion: A double-blind randomized controlled trial





WHO I AM

WHY ANOTHER TRIAL

WHAT WE DID

RESULTS

CONCLUSIONS

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WHO I AM

Registered nurse midwife - RNM
RFSU Clinic in Stockholm Sweden
STI and Contraceptive counseling

PhD Student
Dept. of Women's and Children's Health
Div. of Obst. and gyn.

Conflicts of interest
NONE

WHY ANOTHER TRIAL?

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IUDs - the "Golden" contraception

- Highly effective with a PI below 1
- High satisfaction among users
- High continued use between 80-90%
- Very few contraindications

HOWEVER IUDs are underutilized

- Worldwide use of IUDs is estimated to be 14%*
- IUDs are still not considered as a first option by some service providers
- Fear of pain during insertion - a often stated barrier**

*United Nations, 2015
**Bharadwaj P et al. 2011 & 2012

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WHAT WE DID

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Intrauterine Instillation IUI

A Double-blind randomized controlled trial
Two study sites in Stockholm

Inclusion criteria:
At least 18-year-old, opting for an IUD, nulliparous.

Exclusion criteria: previous conization, known cervical stenosis, signs of ongoing genital infection, known uterine abnormality, bleeding disorder or contraindications to any local anesthetic

Women randomized using SNOSE,
Allocation ratio 1:1

Method for IUI

Data collection

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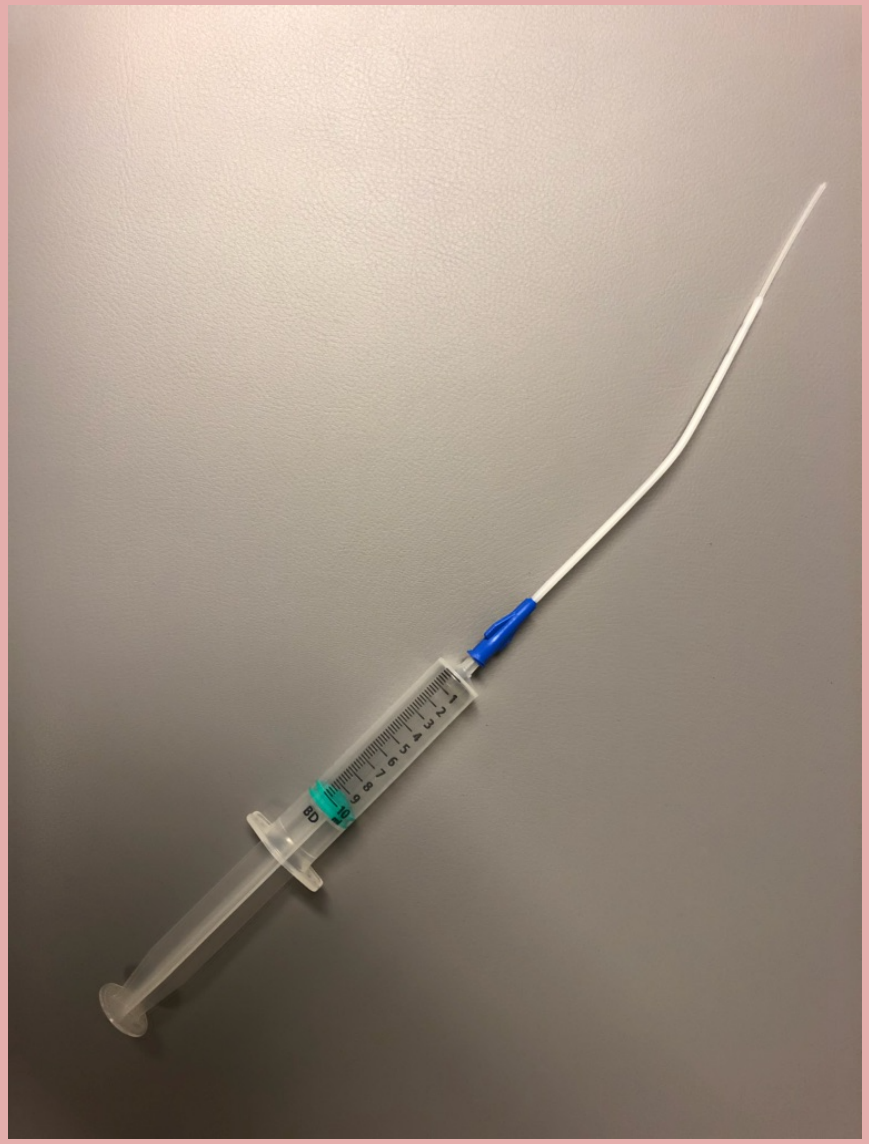
METHOD FOR IUI



- This catheter is thin
- It has no balloon tip
  -> less pain during instillation

Intervention: 10 ml of Mepivacaine, 10 mg/ml (1%), administered through IUI 5 minutes prior to IUD insertion

- Mepivacaine is widely used in clinics
- Mepivacaine is less toxic than Lidocaine*
- Hyphotesized to numd the uterine and cervical lining

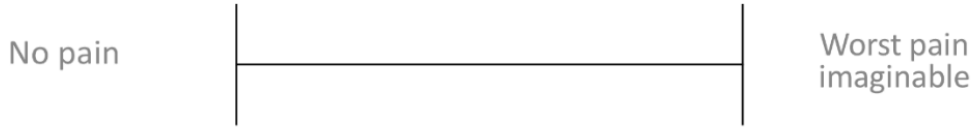
Placebo: 10 ml of NaCl, 0,9 mg/ml, same administration.

*Kazaba et al, 2003

Data collection

Primary outcome: Difference in VAS at IUD insertion

Pain experience during procedure (mark with a vertical line on this line)



Secondary outcomes:

- Pain in VAS at IUI
- Tenaculum placement
- Uterine sounding
- Before leaving the clinic.
- Method acceptability - could recommend or not recommend?
- Entire insertion procedure experienced as easier than expected, as expected or worse than expected

Follow up:
Telephone interviews after 10 days, 3 months and 6 months measuring

- Continued use of IUD
- Reasons for discontinuation
- Acceptability of IUD as willingness to use again and recommending IUD use to a friend

RESULTS

Study population:

- 105 women assessed for eligibility
- 86 accepted and were randomized
- 2 failed insertions, 2 failed instillations, 1 excluded from analysis (not nulliparous)
- 81 in the analysis

Characteristics

Primary and secondary outcome

Primary and secondary outcome

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Characteristics

Table 1. Characteristics of Study Participants by randomized study arm.			
	Intervention	Placebo	
	n=41	n=40	P*
Age (years)	22.6±4.2	22.8±4.0	.73
Normal menstrual cramping (VAS)	4.3±2.4	4.1±2.6	.41
Previous Medical abortion	6 (14.6)	5 (12.5)	1
Previous Surgical abortion	1 (2.4)	3 (7.5)	0.36
Previous IUD insertion	7 (17.1)	6 (15)	1
Type of inserted IUD			
LNG-IUS 52	20 (48.8)	18 (45)	.82
Copper-IUD 380	7 (17.1)	11 (27.5)	.29
LNG-IUS 13,5	13 (31.7)	11 (27.5)	.62
LNG-IUS 19,5	1 (2.4)	0 (0)	1

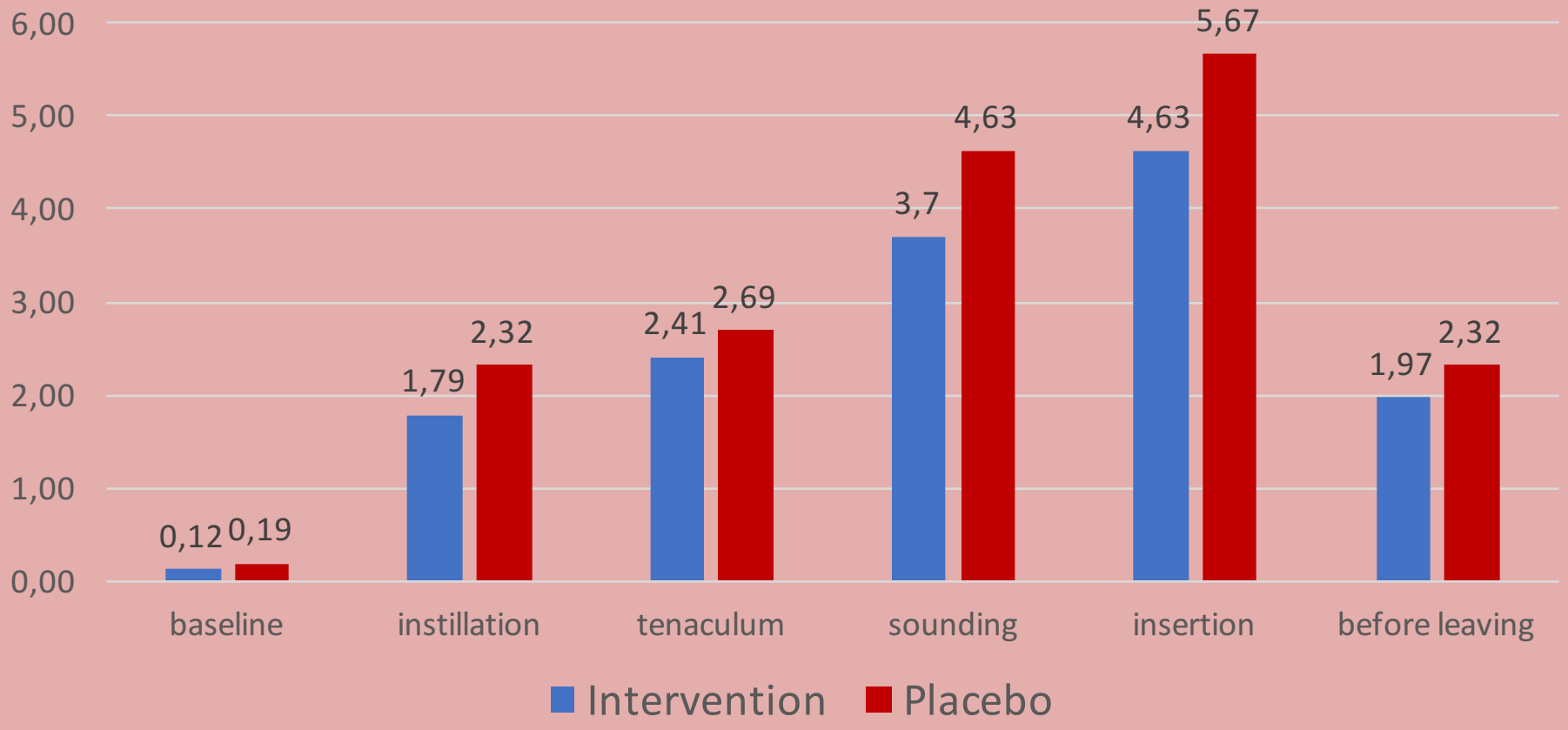
Randomization successful – no significant differences between groups.

Primary and secondary outcome

Table A2. Primary and secondary outcomes, VAS at all procedures and overall experience by randomized study arm			
	Intervention	Placebo	
	n=41	n=40	P*
VAS			
Baseline	0,12±0.21	0,19±0.51	.402
Instillation of study drug or placebo	1,79±1.39	2,32±2.02	.178
Tenaculum	2,41±2.17	2,69±2.29	.583
Sounding	3,7±2.46	4,63±2.23	.079
IUD insertion	4,63±2.21	5,67±2.62	.058
Before leaving the clinic	1,97±2.08	2,32±2.42	.479
Experience of IUD insertion procedure			
Easier than expected	26 (63.4)	15 (37.5)	
As expected	12 (29.3)	11 (27.5)	
Worse than expected	3 (7.3)	14 (35)	.003**

- Pain reduction at insertion didn't reach statistical significance
- Only 3 in the intervention group compared to 14 in the placebo group experienced the insertion procedure as worse than expected

Mean VAS at all procedures



Conclusion

- Pain reduction in VAS for the intervention didn't reach statistical significance compared to placebo *(p=0.058).* Future studies with larger sample size needed
- Significantly fewer women in the intervention group stated that the procedure was worse than expected *(p=0.003)*

Implications

- Mepivacaine and the catheter is easy to access - easy to use
- Experiencing the IUD insertion as easier or as expected is **clinically important** since it might affect future use and immediate recommendation of IUDs.

Thank you!

Your queries – my plesure

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