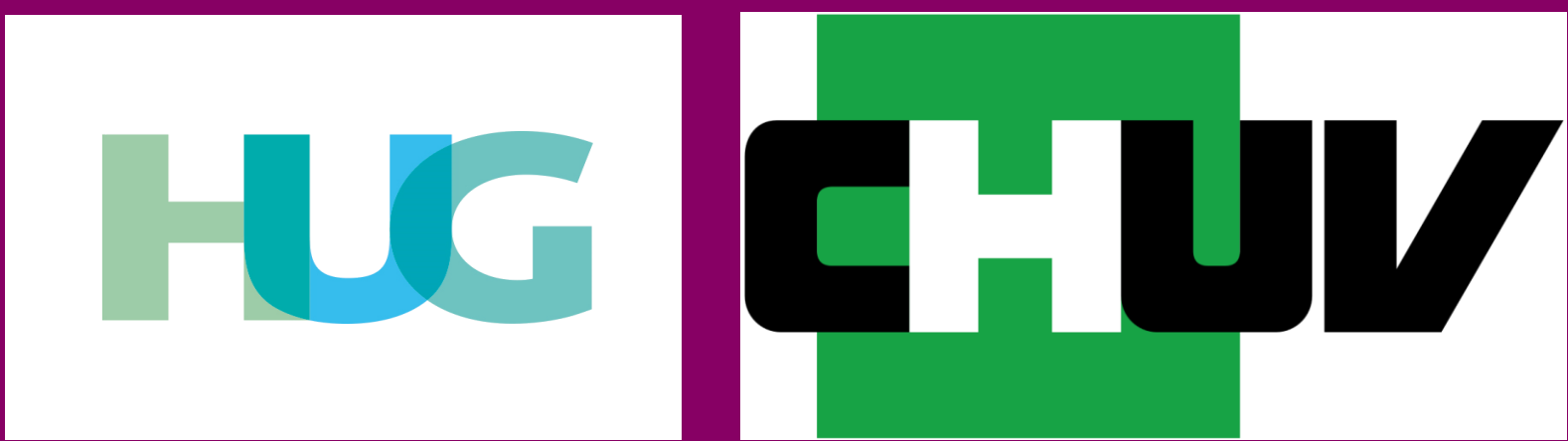




An Innovative Atraumatic Uterine Cervical Traction Device: A Randomized Trial

Yaron M¹, Legardeur H², Barcellini B¹, Akhoundova F¹, Jacot-Guillermot M², Mathevet P²

1. Department of Woman, Child & Adolescent, Geneva University Hospitals, Geneva, Switzerland 2. Department Woman, Mother & Child, Lausanne University Hospital, Lausanne, Switzerland



INTRODUCTION & AIM

- There is a significant unmet need for intrauterine contraceptive device (IUD) insertion procedures associated with less pain and discomfort, particularly for nulliparous women¹⁻³
- We have recently reported very low pain and high overall satisfaction rates in an open-label pilot study with an investigational soft-suction device (Carevix®) for atraumatic stabilisation of the cervix during IUD insertion⁴
- We here present the results from a randomised, controlled trial with the Carevix device

MATERIALS & METHODS

Objective:

- To compare patient-reported pain and bleeding, and safety during IUD insertion, between procedures employing the suction-based atraumatic tenaculum device or a commonly used single-tooth tenaculum (Pozzi forceps)

Design:

- Single-blinded randomised interventional study
- 100 women** >18 years were enrolled
- Exclusion criteria were contraindication for IUD insertion, oral anticoagulant use, history of cervical operations or severe vaginal bleeding of unknown origin, or use of analgesics within 12 hours of the procedure
- Eligible subjects were randomised to the Carevix device or control, with randomisation stratified within each study arm to balance the distribution of nulliparous and parous participants

Endpoints:

- The primary end point was patient-reported pain at 7 specific steps during IUD insertion, measured on a 0-100 mm Visual Analogue Scale (VAS)
- Safety was assessed by amount of bleeding (measured by weight of buffers used for haemostasis), adverse events and serious adverse events
- Overall provider satisfaction and overall patient satisfaction were recorded using standardised questionnaires

RESULTS

Figure 1: Study flow

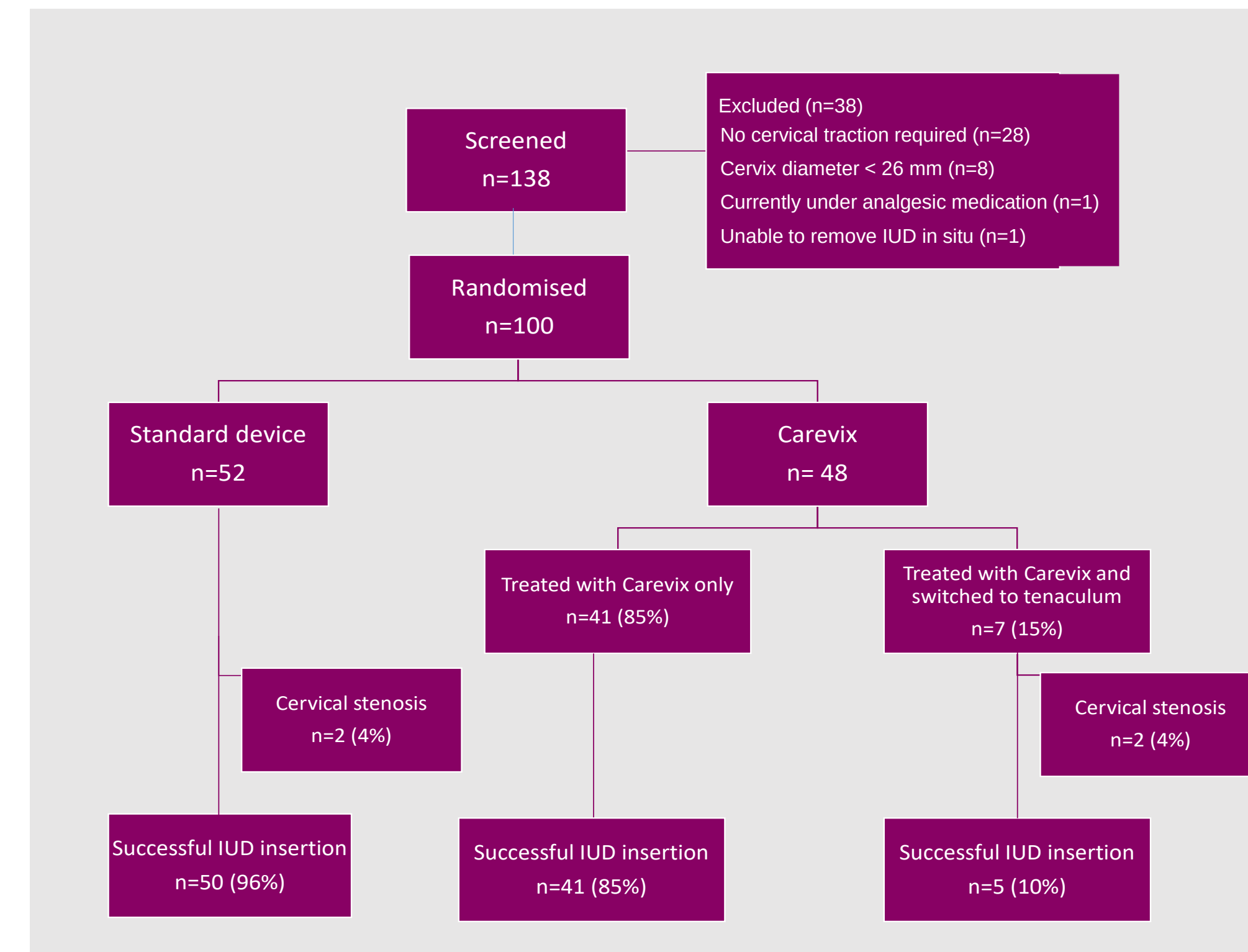


Table 1. Safety assessments

Safety			
	Carevix	Tenaculum	p value
Bleeding overall	13%	60%	<0.001
Light	13%	52%	
Medium	0%	8%	
Ecchymosis	20%	0%	

Figure 2: Primary outcome: Average VAS Pain Score

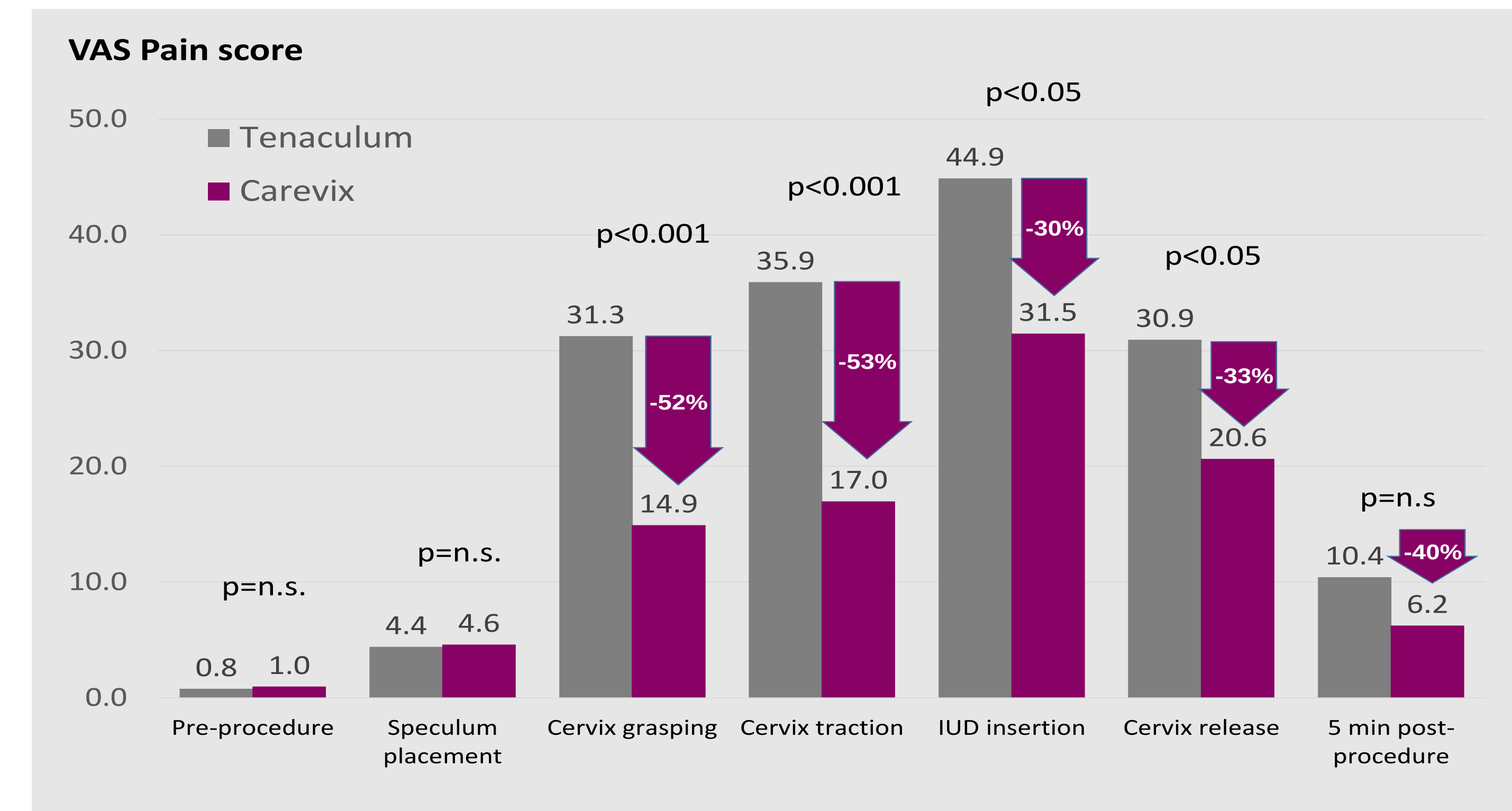
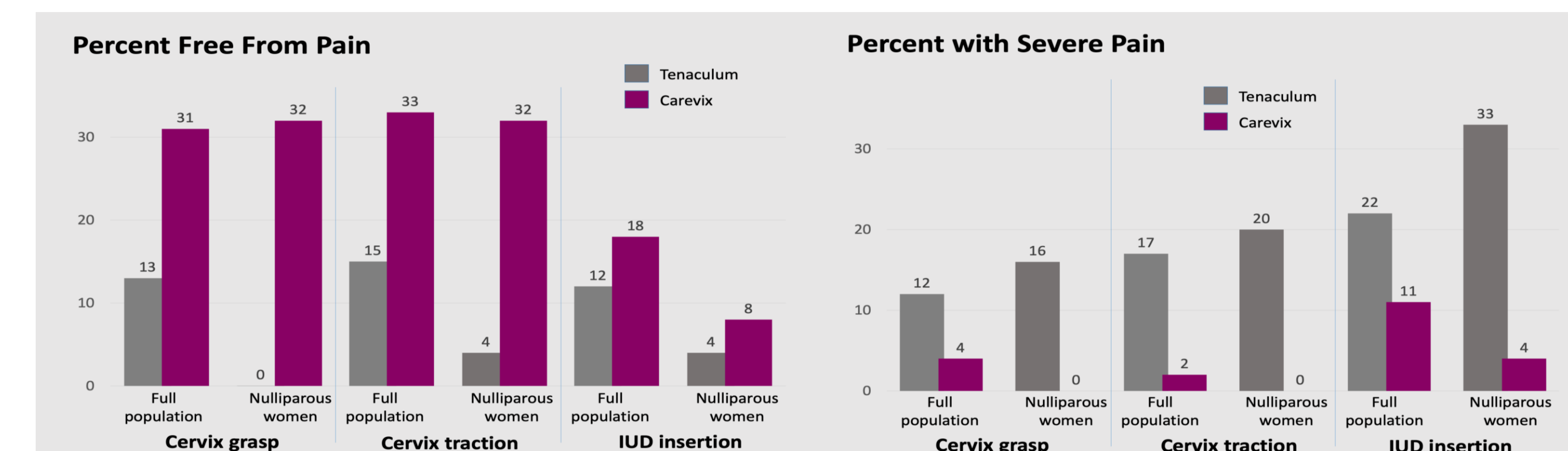


Figure 3: Pain scores for nulliparous women vs full population



- The study flow is shown in Figure 1. A total of 100 subjects were randomised, 48 to the Carevix group and 52 to standard tenaculum. Average age was 29.1 years and 55 (**55%**) were **nulliparous**
- Subjects undergoing IUD insertion with the **Carevix** device reported significantly **lower pain scores at all relevant points of the procedure** compared with tenaculum use (Figure 2)
- Nulliparous** women experienced the **greatest benefits** from the Carevix device (Figure 3). In this group, 32% of subjects were free from pain during cervix grasping and cervix traction while 8% were completely free of pain during IUD insertion
- No nulliparous subjects experienced severe pain during cervix grasping or cervix traction and <5% experienced severe pain during IUD insertion
- Rates of **bleeding** were **reduced by 78%** when using the Carevix device compared with tenaculum (Table 1)
- Procedural failure rates were low (4%) with both devices. There were 4 adverse events in the Carevix arm, one relating to the device and 3 relating to the IUD insertion. There were **no serious adverse events**

SUMMARY / CONCLUSION

- ✓ IUD insertion with the Carevix device is associated **with significantly lower rates of pain** than standard Pozzi tenaculum **at all relevant procedural stages**
- ✓ **Nulliparous women benefited most** from the Carevix device. This population has the greatest unmet need for less painful IUD insertion procedures¹⁻³
- ✓ Rates of **severe pain were extremely low in the Carevix group** and no nulliparous women experienced severe pain during cervix grasping or cervix traction
- ✓ **Bleeding rates were significantly lower** in the Carevix group
- ✓ **Procedural success rates were >95%** in both groups

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The study is registered on Clinicaltrials.gov: NCT04441281

REFERENCES / COI

- Hubacher D, et al. Pain from copper intrauterine device insertion: randomized trial of prophylactic ibuprofen. Am J Obstet Gynecol 2006; 195: 1272–1277. doi:10.1016/j.ajog.2006.08.022
- Zimmermann Y et al. Swiss gynecologists' opinions and perceptions concerning the use of intrauterine devices by nulliparous and multiparous women: an online survey study. IJWH 2019; Volume 11: 153–159. doi:10.2147/IJWH.S189051
- Black KI et al. Global survey of healthcare practitioners' beliefs and practices around intrauterine contraceptive method use in nulliparous women. Contraception 2013; 88: 650–656. doi:10.1016/j.contraception.2013.06.000
- Legardeur H, et al. Safety and Efficacy of an Atraumatic Uterine Cervical Traction Device: A Pilot Study. Frontiers in Medicine 2021;8:6.

The authors report no conflicts of interests in relation to the present work