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Published in:
European Journal of Obstetrics, Gynecology, and Reproductive Biology

DOI:
10.1016/j.ejogrb.2020.11.012

Publication date:
2021

European Journal of Obstetrics & Gynecology and Reproductive Biology 256 (2021) 263–269

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Electronic Continuous Pain Measurement vs Verbal Rating Scale in gynaecology: A prospective cohort study

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ARTICLE INFO

Article history:
Received 5 February 2020
Received in revised form 27 October 2020
Accepted 6 November 2020

Keywords:
Pain
Continuous Pain Score Meter
Continuous real-time pain measurement
Electronic pain measurement
Verbal Rating Scale
Visual Analogue Scale
Outpatient hysteroscopy
Colposcopy
Ovum pick-up

ABSTRACT

Objective: To compare pain measured with a new electronic device – the Continuous Pain Score Meter (CPSM) – and the Verbal Rating Scale (VRS) during gynaecological procedures in an outpatient setting, and to correlate these outcomes with baseline anxiety and patient (in)tolerance to the procedure.
Study design: This prospective cohort study was undertaken in two centres: a university hospital and a large teaching hospital in The Netherlands. Patients undergoing an outpatient hysteroscopy, colposcopy or ovum pick-up procedure for in-vitro fertilization in one of the two participating hospitals with availability of the CPSM were included. Pain was measured by both the CPSM and the VRS. Patient tolerance to the procedure was reported. Various outcomes of the CPSM were compared with those of the VRS and related to baseline anxiety scores.
Results: Ninety-one of 108 included patients (84 %) used the CPSM correctly during the procedure, and it was possible to analyse the CPSM scores for 87 women (81 %). The CPSM scores were all linearly related to the VRS. The peak pain score on the CPSM (CPSM-PPS) had the strongest correlation with the VRS score for all three procedures. Higher CPSM-PPS was related to patient (in)tolerance to the procedure ($p = 0.03$–0.002). Anxiety at baseline was not correlated with pain perception, except for VRS during colposcopy ($r = 0.39$, $p = 0.016$).
Conclusion: The majority of patients were able to use the CPSM correctly, resulting in detailed information on pain perception for each individual pain stimulus during three outpatient gynaecological procedures. The CPSM-PPS had the strongest correlation with the VRS score and patient (in)tolerance to the procedure.

Introduction

Minimally invasive surgery has evolved in all surgical disciplines. More and more gynaecological procedures are performed in an outpatient setting given the health and economic benefits of these minimally invasive procedures [1–3]. For example, diagnostic and therapeutic hysteroscopies are performed increasingly in outpatient settings [4–7]. Patient perceptions of pain experienced during a procedure play a key role in their perceived tolerance and their satisfaction concerning the treatment [8–12]. However, pain perception can differ widely between patients and could be aggravated by anxiety [13–15], underlining the need for pain measurement and assessment of patient tolerability [16,17]. Obtaining detailed information on pain perception during different parts of a procedure enables adjustments that aim to reduce pain and improve perceived tolerance and the success rate of specific interventions.

In general, pain intensity is measured after a procedure using the Visual Analogue Scale (VAS) or the Verbal Rating Scale (VRS) [18]. These scores are obtained with the use of an 11-point scale indicating 'no pain' to 'worst imaginable pain'. Although quick and easy to perform, these methods have their limitations: inability to measure pain of different pain stimuli during a procedure, inaccuracy of memory to recall the sensation of pain, and lack of information on the possible relationship between pain tolerance and length of procedure. To overcome these limitations, a new instrument has been developed – the validated Continuous Pain Score Meter (CPSM). This measures pain continuously, generating an 'experienced pain curve' obtained during all steps of an

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https://doi.org/10.1016/j.ejogrb.2020.11.012
0301-2115/

intervention [19]. Previous studies have demonstrated the feasibility of electronic pain measurement and patients preferred this to pain evaluation on paper [20–23]. To the authors' knowledge, use of the CPSM during gynaecological procedures has not been evaluated previously.

The aim of this study was to determine the feasibility of the CPSM during three different gynaecological outpatient procedures, and to compare the outcomes with reported VRS scores, patient perceived tolerance and baseline anxiety scores.

Materials and methods

Study design and participants

This prospective cohort study was conducted between August and November 2011 at the outpatient clinics of the Department of Gynaecology of the Onze Lieve Vrouwe Gasthuis (OLVG) and the VU medical centre (VUmc) in Amsterdam, The Netherlands.

Eligible patients were asked for informed consent. Inclusion criteria were: age 18–80 years; and scheduled to undergo colposcopy, ovum pick-up or hysteroscopy in an outpatient setting. Exclusion criteria were: inability to comprehend Dutch or English properly; and (for hysteroscopy) pregnancy or being in the luteal phase without the use of contraception; known cervical stenosis or malignancy; current sexually transmitted disease or pelvic inflammatory disease; or contra-indications for the use of non-steroidal anti-inflammatory drugs (NSAIDs).

All gynaecological procedures were performed under standardized conditions. In all hysteroscopy cases, a 5.5-mm rigid scope with a 30° optical angle was used (Olympus Europe, Hamburg, Germany at OLVG; Storz, Tüttlingen, Germany at VUmc). Operating sheaths were 5 Fr and 7 Fr, respectively. Patients were instructed to take NSAIDs (500 mg Naprosyne) the evening before and 2–3 h before hysteroscopy. Local anaesthesia in the cervix (cervical block), a combination of Articain and adrenaline (3.4 ml Ultracain D-S forte, 40 mg – 5 μg/mL, Sanofi-Aventis, Paris, France), was given only if cervical dilatation was performed. During this procedure, small intracavitary abnormalities were removed if detected. Cusco specula and an Olympus OCS 500 colposcope were used in all colposcopy patients; none of them received anaesthetic. Ovum pick-up procedures were achieved using a 1.4-mm (~17GA, Repromed) needle with a length of 35 cm. In advance of the pick-up, all women received opioids (2 ml pethidine, 50 mg/mL, Martindale Pharmaceuticals, London, UK) and benzodiazepines (7.5 mg Dormicum in women weighing <70 kg or 15 mg Dormicum in women weighing >70 kg, Alliance Healthcare, Chessington, UK). Applied medication and eventual co-interventions were registered.

Continuous Pain Score Meter and pain software

The CPSM was developed in 2008 and validation followed in 2009 measuring reproducible pain stimuli in healthy volunteers [19]. An adjustable slider which is a voltage divider (Studiofader 100 KB, Alps Electric Co., Ltd, Tokyo, Japan) is attached to the meter, a 30-cm box, to mark pain intensity on a continuous scale based on the VAS from 0 to 10 (Fig. 1). When a patient releases this slider, it will return to its original position, thereby preventing erroneous high measurement. The CPSM is connected to a computer that contains special developed pain software (PainScope). It measures and documents, through the (changing) position of the slider, 10 pain stimuli per second and transforms the imported information in a graph (Fig. 2). Obtained data are translated into three outcomes: the area under the curve (CPSM-AUC), the peak pain score (CPSM-PPS, the highest registered score) and the average pain per second (CPSM-APS, the total CPSM-AUC divided by the total operation time). During pain measurement, the examiner is able to mark the beginning and end of specific parts of a procedure (e.g. placement of a speculum, start and end of cervical dilatation, scope passage through the endocervix, or start and end of a polyp resection). These markers will be depicted in the pain graph, which makes it possible to evaluate the pain outcomes of these specific parts of the intervention. All these data are processed for data management and statistical analyses using Excel (Microsoft Corp., Redmond, WA, USA) and SPSS (IBM Corp., Armonk, NY, USA) software.

Data collection

First, baseline characteristics and patients' anxiety scores (Likert scale: 0 = no anxiety to 10=extremely anxious) were registered. When the patient was positioned, she received instructions on the use of the CPSM; as a part of this instruction, the CPSM was tested once before the start of the procedure by giving the patient a mild pressure stimulus on her hand. Women were asked to express their pain by controlling the CPSM during the entire procedure. When the examiner suspected incorrect use or no usage at all, patients were reminded of the presence of the CPSM and gently asked to use it. The degree of (in)correct usage according to the investigator and patient, using an 11-point scale

Fig. 1. The Continuous Pain Score Meter: laptop with the software (PainScope) and the pain slider.

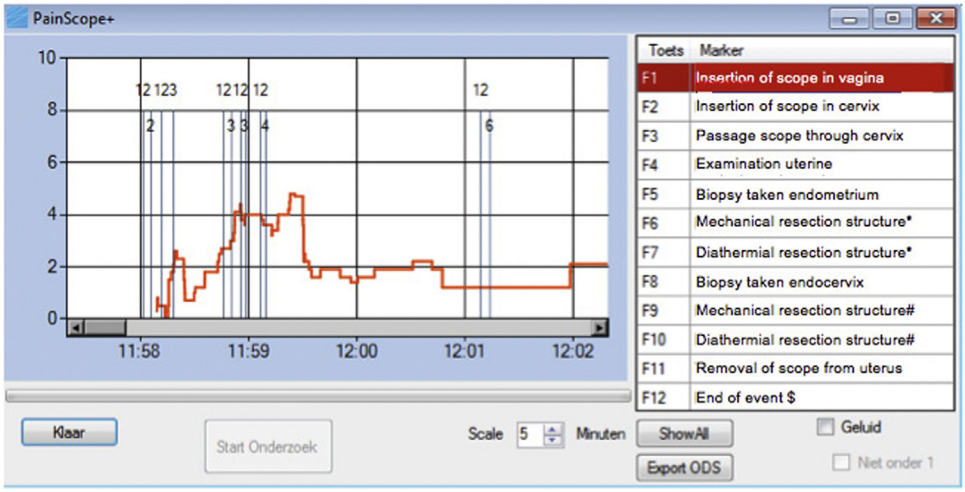

Fig. 2. Example of a pain score graph during hysteroscopy. Different standardized markers (i.e. start and/or end of specific procedures) are depicted in the graph while the procedure took place.

(0=always correct to 10=always incorrect), was registered in the case report form. Pain measurements were excluded from analysis when the investigator, patient or both scored ≥5 (i.e. incorrect use) on this scale. Various standardized markers (e.g. for hysteroscopy, two of the 12 registered markers are passing external os and passing internal os) were placed in the pain score graph electronically by the examiner during the procedure in order to enable later differentiation between various parts of the procedure, as they may serve as different pain stimuli (Fig. 2).

Immediately after the procedure, participants were asked to express the average pain experienced during the entire procedure using the VRS. Also, the patient's perception on how they tolerated the procedure was registered (tolerated yes/no, willingness to undergo the procedure again if needed and their recommendation to a friend).

Statistical analysis

SPSS Version 25 for Windows was used after importing the data from an Excel data sheet. To correlate the new pain units and baseline anxiety with the VRS score, Pearson's correlation was calculated with 95 % confidence intervals [24]. Two-sided *p*-values were reported. A probability level of <0.05 was used for statistical significance.

The Mann–Whitney *U*-test was used to compare medians of non-normally-distributed pain scores and to differentiate between tolerability and intolerability of a procedure. When results were normally distributed, calculations were executed using the independent samples *t*-test. Boxplots visualized patient tolerance of hysteroscopic procedures compared with pain scores. Stata/IC Version 11.2 was used to create receiver operating characteristic (ROC) curves to report patient tolerance for non-normal distributions in order to compare CPSM scores with VRS scores.

A post-hoc power analysis was performed to confirm adequate power and thereby ensure the significance of the results. The primary objective of this study was to determine the correlation between results of two different measurement instruments: the VAS and the CPSM (CPSM-AUC, CPSM-PPS, CPSM-APS). The analysis was based on correlations of 0.80, 0.82 and 0.39 (Table 3).

Results

Of the women who met the selection criteria, 108 women agreed to participate in this study. Baseline characteristics are described in Table 1.

Table 1
Baseline characteristics of the participants.

Patient variables	Procedure		
	Colposcopy (*n* = 51)	Ovum pick-up (*n* = 27)	Hysteroscopy (*n* = 30)
Age (years), mean ± SD	34.6 ± 9.3	36.0 ± 4.3	45.8 ± 13.9
BMI (kg/m^2), mean ± SD	21.5 ± 2.5	23.5 ± 3.2	25.2 ± 4.5
Smoking, *n* (%)			
Yes	19 (37.2)	2 (7.4)	4 (13.3)
No	29 (56.9)	25 (92.6)	24 (80.0)
Unknown	3 (5.9)	0 (0.0)	2 (6.7)
Contraceptive use, *n* (%)			
None	18 (35.3)	27 (100.0)	22 (73.3)
Hormonal	23 (45.2)	0 (0.0)	3 (10.0)
Condom	2 (3.9)	0 (0.0)	5 (16.7)
Other	8 (15.6)	0 (0.0)	0 (0.0)
Parity, median (IQR)	0.0 (2.0)	0.0 (1.0)	1.0 (2.0)
Caesarean delivery	0	0.0 (0.0)	0.0 (0.0)
Nulliparous, *n* (%)	33 (64.7)	19 (70.0)	9 (30.0)
Menopausal state, *n* (%)			
Premenopausal	50 (98.0)	27 (100.0)	21 (70.0)
Postmenopausal	1 (2.0)	0 (0.0)	9 (30.0)
Surgical procedure in history, *n* (%)			
Cervix	4 (7.8)	1 (3.7)	0 (0.0)
Uterus	3 (5.9)	2 (7.4)	5 (16.6)
Tubes	0 (0.0)	4 (0.15)	2 (6.6)
Indication for the procedure, *n* (%)			
AUB	0 (0.0)	0 (0.0)	24 (80.0)
Infertility	0 (0.0)	27 (100.0)	2 (6.7)
Abnormal cervix cytology	42 (82.4)	0 (0.0)	0 (0.0)
Postcoital bleeding	9 (17.6)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	4 (13.3)

BMI, body mass index; SD, standard deviation; IQR, interquartile range; AUB, abnormal uterine bleeding.

Colposcopy

All pain measurements were completed for the 51 patients in this group. In 12 cases, the investigator (*n* = 3), the patient (*n* = 5) or both (*n* = 4) judged the usage of the CPSM to be incorrect. In this subgroup, mean experienced pain (VRS) was equal to and anxiety was higher compared with the group who used the CPSM correctly (*p* = 0.088 and *p* = 0.005, respectively) (Table 2). The results for the remaining 39 women (76 %) were analysed.

Table 2 shows the results of the pain measurements and tolerability during colposcopy. All CPMS outcomes (CPSM-AUC, CPSM-PPS and CPSM-APS) were linearly related to the VRS

Table 2
Outcome measures concerning pain during and after the procedure; anxiety score at baseline; total procedure time; and overall patient tolerance of colposcopy, ovum pick-up and hysteroscopy.

Measurement variables[a]	Procedure		
	Colposcopy (n = 39)	Ovum pick-up (n = 21)	Hysteroscopy (n = 27)
VRS + CPSM[b]	2.8 ± 2.3	4.5 ± 2.8	4.1 ± 2.9
VRS – CPSM[c]	4.2 ± 2.6	4.7 ± 0.6	7.0
CPSM-AUC	496.0 (1971.4)	2610.9 (6414.7)	1175.8 (4263.3)
CPSM-PPS (VASmax)	1.8 (5.5)	3.6 (5.5)	2.9 (4.7)
CPSM-APS (Tauc/Ttime)	1.5 (4.4)	8.0 (12.4)	4.3 (5.9)
Anxiety + CPSM[d]	4.4 ± 2.5	4.2 ± 2.5	4.5 ± 2.6
Anxiety – CPSM[e]	6.7 ± 1.8	1.7 ± 1.5	1.0
Total procedure time (min)	7.5 ± 3.0	7.6 ± 2.4	8.1 ± 6.9
Tolerability (%)	37 (94.9)	14 (66.7)	22 (81.5)

VRS, Verbal Rating Scale; CPSM, Continuous Pain Score Meter; VAS, Visual Analogue Scale; AUC, area under the curve; PPS, peak pain score; APS, average pain per second; IQR, interquartile range.
[a] Median (IQR) unless otherwise stated.
[b] Mean VRS ± SD of the women who used the CPSM correctly.
[c] Mean VRS ± SD of the women who did not use the CPSM correctly.
[d] Mean baseline anxiety ± SD of the women who used the CPSM correctly.
[e] Mean baseline anxiety ± SD of the women who did not use the CPSM correctly.

Table 3
Correlation between Verbal Rating Scale (VRS) and Continuous Pain Score Meter (CPSM) outcomes.

Procedure		r-value	p-value
Colposcopy			
	CPSM-AUC	0.82	0.001
	CPSM-PPS	0.86	0.001
	CPSM-APS	0.82	0.001
Ovum pick-up			
	CPSM-AUC	–	0.053
	CPSM-PPS	0.80	0.001
	CPSM-APS	0.55	0.009
Hysteroscopy			
	CPSM-AUC	0.39	0.042
	CPSM-PPS	0.77	0.0001
	CPSM-APS	0.43	0.025

VRS, Verbal Rating Scale; CPSM, Continuous Pain Score Meter; AUC, area under the curve; PPS, peak pain score; APS, average pain per second.

(p = 0.001) (Table 3). The CPSM-PPS showed the strongest 'almost perfect' correlation (r = 0.86); for both the CPMS-AUC and the CPSM-APS, the correlation coefficient was 0.82.

All women except two reported that colposcopy was tolerable without additional anaesthesia. The mean VRS score in the 'tolerable' group was 2.8 [standard deviation (SD)±2.4] compared with 5.0 (SD ± 2.8) in the 'intolerable' group. The median CPSM scores for the 'tolerable' vs 'intolerable' groups were: CPSM-AUC 311.8 [interquartile range (IQR) 1907.6] vs 3749.0 (IQR -); CPSM-PPS 1.9 (IQR 5.3) vs 10.0 (IQR -); and CPSM-AP: 1.5 (IQR 4.2) vs 7.3 (IQR -)]. The difference was significant for CPSM-PPS (p = 0.03).

Anxiety at baseline showed significant 'fair' correlation (r = 0.39) with the VRS score (p = 0.016), but not with any of the CPSM scores.

Ovum pick-up procedure

Of the 27 women in the ovum pick-up group, CPSM measurements could be included for 21 (78 %) women for statistical pain analysis. There was software failure in two cases, and four patients scored ≥5 indicating incorrect use of the CPSM. Mean experienced pain score (4.7) and mean baseline anxiety score (1.7) were equal compared with women who used the CPSM correctly (p = 0.87 and p = 0.088, respectively) (Table 2).

Pain scores during ovum pick-up are reported in Table 2. VRS scores were 'substantially' correlated with CPSM-PPS (r = 0.80, p = 0.001) and 'moderately' correlated with CPSM-APS (r = 0.55, p = 0.009), but were not correlated with CPSM-AUC (see Table 3).

One-third of the women reported that they experienced ovum pick-up under the current conditions as intolerable due to the perceived pain (n = 7). Pain scores were significantly higher compared with women who reported that the procedure was tolerable (n = 14); mean VRS score 7.0 (SD ± 2.2) vs 3.3 (SD ± 2.3) (p = 0.007); median CPSM-AUC 4681.5 (IQR 12204.3) vs 591.3 (IQR 3620.8) (p = 0.009); median CPSM-PPS 9.2 (IQR 3.3) vs 2.9 (IQR 3.1) (p = 0.002); and median CPSM-APS 12.8 (IQR 23.7) vs 1.5 (IQR 8.7) (p = 0.007), respectively.

Anxiety score at baseline was not correlated with the VRS score or any of the CPSM scores ($p \geq 0.49$).

Outpatient hysteroscopy

In total, 30 patients were included in the hysteroscopy group; the CPSM outcomes could be analysed for 27 of these patients (90 %). In one case, the CPSM failed because of software problems; in another case, hysteroscopy failed due to cervical stenosis; and in the third case, the patient forgot to adjust the CPSM slider during the procedure. The reported mean VRS score (7.0) and baseline anxiety score (1.0) were similar in the group with evaluable CPSM outcomes and the group with non-evaluable outcomes (p = 0.34 and p = 0.21, respectively) (Table 2).

Pain scores, anxiety scores, tolerability and total operation time are reported in Table 2. VRS scores were linearly related to all of the CPSM outcomes (Table 3). CPSM-PPS was 'substantially' (r = 0.77) related (p = 0.0001), CPSM-AUC was 'moderately' (r = 0.43) related (p = 0.025) and CPSM-APS was 'fairly' (r = 0.39) related (p = 0.042).

Reported VRS scores were significantly lower in the group of patients who reported that the procedures were tolerable (n = 22) under the current conditions compared with those who reported that the procedures were intolerable (n = 5) (Fig. 3). The mean VRS score was 3.1 (SD ± 2.3) vs 7.2 (SD ± 2.6), respectively (p = 0.007). Median CPSM-PPS was 2.5 (IQR 3.0) and 10.0 (IQR 6.0), respectively (p = 0.014). Differences in median CPSM-AUC and CPSM-APS were not significant: CPSM-AUC 1173.5 (IQR 2903.4) vs 2470.0 (IQR 5094.8) (p = 0.26) and CPSM-APS 3.5 (IQR 6.89) vs 5.5 (IQR 4.56) (p = 0.26). The degree of anxiety at baseline was not related to any of the reported pain outcomes during hysteroscopy ($p \geq 0.59$).

The pain scores of the different parts of the hysteroscopic procedures are reported in Table 4. The four events that were

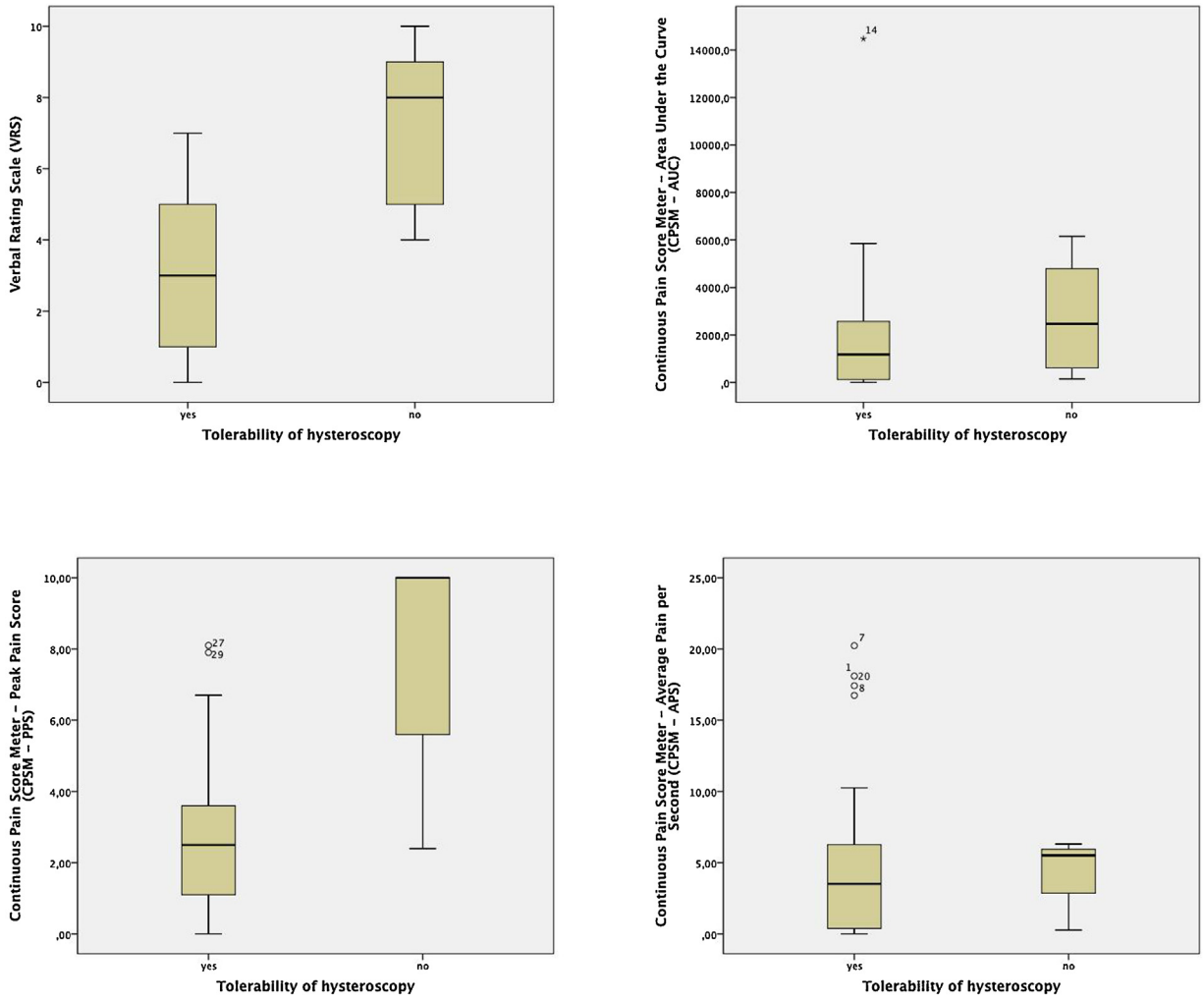

Fig. 3. Box and Whisker plots of Verbal Rating Scale (VRS) and Continuous Pain Score Meter (CPSM) scores in patients who reported the outpatient hysteroscopy to be tolerable (yes) vs intolerable (no).

Table 4
Pain scores related to various parts of a hysteroscopy procedure.

Specific part of the hysteroscopy	Hysteroscopy			
	n	CPSM-AUC [median (IQR)]	CPSM-PPS [median (IQR)]	CPSM-APS [median (IQR)]
Cervical passage hysteroscope	27	359.0 (1381.4)	2.3 (4.9)	5.6 (8.0)
Dilatating cervix	5	343.1 (565.3)	1.9 (6.4)	6.2 (24.3)
Inserting speculum	9	23.8 (82.6)	0.1 (1.6)	0.9 (3.4)
Tenaculum placement	7	0.4 (33.6)	0.0 (0.2)	0.0 (9.2)
Cervical block	6	6.3 (30.7)	0.1 (0.6)	0.2 (1.0)
Resection of polyp	10	106.8 (3608.5)	1.7 (5.5)	0.9 (14.2)
Synechiolysis	2	121.5 (-)	2.4 (-)	0.1 (-)
Endometrial biopsy	3	88.7 (-)	0.9 (-)	1.4 (-)
Inserting IUD after hysteroscopy	2	37.5 (-)	0.1 (-)	1.3 (-)

CPSM, Continuous Pain Score Meter; AUC, area under the curve; PPS, peak pain score; APS, average pain per second; IQR, interquartile range; IUD, intrauterine device.

registered as most painful were passage of the scope through the cervical canal (defined as the period between the start of the passage of the external os until the end of the passage of the internal os, and thus when the scope reached the uterine cavity), cervical dilatation, synechiolysis and polyp resection.

To illustrate the accuracy of the various pain scores using patient tolerance to a procedure as a reference test, various ROC curves were plotted (see Fig. 4). The area under the ROC curve was largest for VRS score (0.89) and CPSM-PPS (0.86). The AUCs of the ROC curves for CPSM-AUC and CPSM-APS were both 0.66.

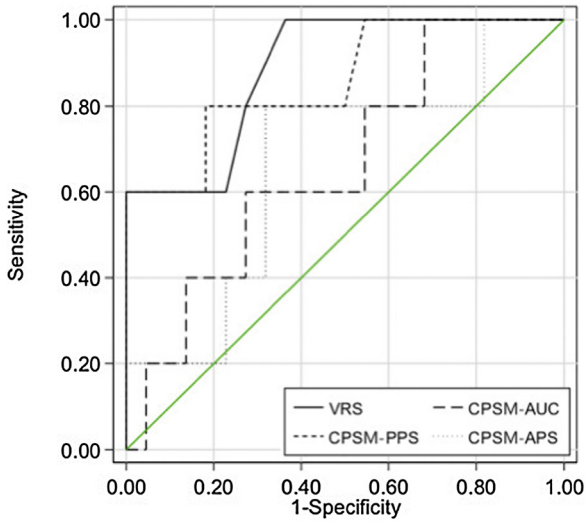

Fig. 4. Receiver operating characteristic curve of pain outcomes using tolerability of the hysteroscopy as the reference test. Largest areas under the curve were found for the Verbal Rating Scale score (VRS; 0.89) and the Continuous Pain Score Meter peak pain score (CPSM-PPS; 0.86). For the CPSM area under the curve (CPSM-AUC) and CPSM average pain per second (CPSM-APS), the areas under the curve were both 0.66.

Discussion

Main findings

This study confirmed the feasibility of the use of the CPSM for three different gynaecological outpatient procedures. After proper instruction, 91 of 108 patients (84 %) managed to operate the device adequately. However, during pain measurements, some patients had difficulties handling the CPSM correctly. Subgroup analysis was performed afterwards, and the results between the group who operated the CPSM correctly and the group who did not operate the CPSM correctly were not significantly different; however, this may have been influenced by the relatively small sample size. In general, higher VRS scores were registered in women who failed to use the CPSM correctly; 65 % of the 17 patients who did not use the CPSM correctly scored above the median score for the patients who used the CPSM correctly. It appears to be more difficult to execute this task while experiencing severe pain; however, by controlling the CPSM slider, patients may feel a greater degree of control, which could be even more relevant for anxious patients. These items may be the topic of future studies.

The VRS score was linearly correlated with all the CPSM scores (CPSM-AUC, CPSM-PPS and CPSM-APS) during all assessed procedures. CPSM-PPS showed the strongest correlation with the VRS score. Both the VRS score and CPSM-PPS showed the strongest correlation with patient judgement concerning whether the procedure was tolerable or intolerable under the given circumstances.

Interpretation of the results, clinical implications and future perspectives

Accuracy of the new pain scores obtained by electronic pain measurement with the CPSM was high and comparable with the commonly used VRS. Given the high correlation between CPSM-PPS and patient judgement of the (in)tolerability of the procedure, and its strong correlation with the VRS score, it can be concluded that people appear to have the best recall of the worst experienced pain. It is possible that this moment represents the pain perception of the entire procedure. The greatest advantage of the CPSM over the VRS is its ability to measure continuously during the entire procedure, providing information on all individual steps. This allows the detection of specific steps that are most painful, measured more objectively. The potential applications of the CPSM are numerous. It can reveal, for example, specific patient characteristics in relation to pain perception, with the result that strategies to reduce pain can be developed at an individual level and improve patient tolerance to all types of procedures. It could also be used to study the effect of oral painkillers, to compare local anaesthetics with placebo during various office procedures, and to determine the consequences of using different intrauterine agents during sonohysterography or hysterosalpingography. In addition, non-pharmacological effects on pain can be studied in detail, such as the presence of a nurse guiding the patient, or the use of music or images. Work has already commenced on this by the authors' study group, comparing two types of gels used during gel infusion sonography, and a comparative study was performed using misoprostol vs placebo before hysteroscopy to determine the effect on pain [25]. For years, efforts have been made, in vain, to discover the best method for pain reduction in outpatient procedures, especially during hysteroscopy. However, there is still no unambiguous advice, either pharmacological or non-pharmacological [26–28]. The CPSM may be the solution to provide more clarity and insight to reduce pain during these procedures.

The CPSM results are depicted graphically, but another possible feature is that feedback could be given by a sound. Higher tones reflect more pain. This sound can be switched on or off, and the intensity can be changed. Therefore, the CPSM could theoretically be used for immediate feedback to the surgeon, potentially resulting in less pain due to the surgeon's ability to adjust the treatment directly in order to reduce pain. In addition, this could reduce pain due to changes in the patient's perception of pain, with the knowledge that there is immediate feedback and therefore more control. Future studies should be undertaken to determine if the use of the CPSM does alter the perception of pain.

Various studies have reported that fear and anxiety may aggravate pain [13–15]. Apart from the VRS scores in colposcopy, the present results did not support this finding. Remarkably, women reported higher anxiety scores before colposcopy than before ovum pick-up, while lower pain scores were reported during colposcopy. It is hypothesized that apart from the fear of pain, other factors may play a role, such as the fear of the histological result (i.e. cervical carcinoma) in these patients.

Strengths and limitations

All procedures were performed under standardized conditions, and intervariability only existed between patients. All examinations were undertaken by well-trained and experienced practitioners, so the factor time or disability that comes with inexperience did not play a role in this study. Continuous real-time pain measurement was performed during three different gynaecological procedures, allowing comparison between the patient groups, and also allowing evaluation of its feasibility during different procedures.

The newly obtained CPSM pain scores were compared with a validated pain score (VRS), and the CPSM itself is a validated instrument. Therefore, measurement accuracy is likely.

A limitation of this study is that the three study groups were relatively small. Additionally, some selection bias cannot be excluded because study registration was only executed when the CPSM and the researcher were available. In three of 108 cases, software failure occurred. Software upgrades will prevent this in future studies. Another limitation of this study is that the data were acquired in 2011 and analysed in 2019. However, it is believed that the current data are still highly innovative and relevant for daily

practice. No studies on continuous pain measurement have been published in the last 8 years.

Conclusion

In general, patients undergoing a gynaecological procedure in an outpatient setting are able to operate the CPSM whilst undergoing the procedure, and the measured CPSM outcomes correlate well with the commonly used VRS. One of the main advantages of pain evaluation using the CPSM over the VRS is that the CPSM reports the pain outcomes of various stimuli during one procedure, separately. Both the CPSM-PPS and the VRS score correlate well with the judgement of women concerning their tolerance or intolerance of the procedure in the current setting, and this can be used during future studies to optimize various outpatient procedures in gynaecology in order to reduce pain.

Contribution to authorship

Contributors MLO, HBR and JHU designed the study. PKE and WHE were involved in the study design. MLO included patients. MLO and BLI analysed the data. MLO wrote the manuscript. All authors critically reviewed and approved the final manuscript. JHU is the guarantor.

Details of ethics approval

Approval, date 01-06-2011, was obtained from The Medical Ethics Review Committee of VU University Medical Center that is registered with the US Office for Human Research Protections (OHRP) as IRB00002991. The FWA number assigned to VU University Medical Center is FWA00017598. The study is registrated at the ISRCTN registry and the clinical trial number is: ISRCTN15427669.

Funding

None.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

The authors wish to thank all of the patients who consented to participate in this study; Ewout Bosch who helped with development of PainScope; their co-workers F. Poelsma, M. Vreeburg, S. Graumans, E. van de Oudeweetering and A. Zikmund for their supportive activities; and all the other participants involved in this study.

References

[1] Mettler L, Clevin L, Ternamian A, Puntambekar S, Schollmeyer I, Alkatout I. The past, present and future of minimally invasive endoscopy in gynaecology: a review and speculative outlook. Minim Invasive Ther Allied Technol 2013;22:210–26.
[2] Hartel W. The historical impact of minimally invasive surgery. Nihon Geka Gakkai Zasshi 2000;101:274–5.
[3] Moawad NS, Santamaria E, Johnson M, Shuster J. Cost-effectiveness of office hysteroscopy for abnormal uterine bleeding. JSLS 2014;18: e.2014.00393.
[4] Centini G, Troia L, Lazzeri L, Petraglia F, Luisi S. Modern operative hysteroscopy. Minerva Ginecol 2016;68:126–32.
[5] Readman E, Mahler PJ. Pain relief and outpatient hysteroscopy: a literature review. J Am Assoc Gynecol Laprosc 2004;11:315–9.
[6] Salazar AC, Isaacson KB. Office operative hysteroscopy: an update. J Minim Invasive Gynecol 2018;25:199–208.
[7] Bennett A, Lepage C, Tavorn K, et al. Effectiveness of outpatient versus operating room hysteroscopy for the diagnosis and treatment of uterine conditions: a systematic review and meta-analysis. J Obstet Gynaecol Can 2019;41:930–41.
[8] Del Valle C, Solano JA, Rodríguez A, Alonso M. Pain management in outpatient hysteroscopy. Gynecol Minim Invasive Ther 2016;5:141–7.
[9] Royal College of Obstetricans and Gynaecologists. Best practice in outpatient hysteroscopy. RCOG Green-top guideline No. 59. London: RCOG; 2011.
[10] McIlwaine K, Readman E, Cameron M, Maher P. Outpatient hysteroscopy: factors influencing post-procedure acceptability in patients attending a tertiary referral center. Aust N Z J Obstet Gynaecol 2009;49:650–2.
[11] Campo R, Molinas CR, Rombauts L, et al. Prospective multicentre randomized controlled trial to evaluate factors influencing the success rate of office diagnostic hysteroscopy. Hum Reprod 2005;20:258–63.
[12] Ireland LD, Allen RH. Pain management for gynecologic procedures in the office. Obstet Gynecol Surv 2016;71:89–98.
[13] Kokanali MK, Cavkaytar S, Guzel AI, et al. Impact of preprocedural anxiety levels on pain perception in patients undergoing office hysteroscopy. J Chin Med Assoc 2014;77:477–81.
[14] Cicinelli E, Rossi AC, Marinaccio M, Matteo M, Saliani N, Tinelli R. Predictive factors for pain experienced at office fluid minihysteroscopy. J Minim Invasive Gynecol 2007;14:485–8.
[15] Gupta Jk, Clark Tj, More S, Pattison H. Patient anxiety and experiences associated with an outpatient 'one-stop' 'see and treat' hysteroscopy clinic. Surg Endosc 2004;18:1099–104.
[16] de Freitas Fonseca M, Sessa FV, Resende Jr. JA, Guerra CG, Andrade Jr. CH, Crispi CP. Identifying predictors of unacceptable pain at office hysteroscopy. J Minim Invasive Gynecol 2014;21:586–91.
[17] Ma T, Readman E, Hicks L, et al. Is outpatient hysteroscopy the new gold standard? Results from an 11-year prospective observational study. Aust N Z J Obstet Gynaecol 2017;57:74–80.
[18] Huskisson EC. Measurement of pain. Lancet 1975;304:1127–31.
[19] Boormans EM, van Kesteren PJ, Roberto SP, Brölmann HA, Zuurmond WW. Reliability of a continuous pain score meter: real time pain measurement. Pain Pract 2009;9:100–4.
[20] Aaron L, Turner J, Mancl J, Brister H, Sawchuk C. Electronic diary assessment of pain-related variables: is reactivity a problem? Pain 2005;6:107–15.
[21] Cook A, Roberts D, Henderson M, Van Winkle L, Chastain D, Hamill-Ruth R. Electronic pain questionnaires: a randomized, crossover comparison with paper questionnaires for chronic pain assessment. Pain 2004;110:310–7.
[22] Jamison RN, Gracely RH, Raymond SA, et al. Comparative study of electronic vs. Paper VAS ratings: a randomized, crossover trial using healthy volunteers. Pain 2002;99:341–7.
[23] Stinson J, Petroz G, Feldman B, Streiner D, McGrath P, Stevens B. e-Ouch: usability testing of an electronic chronic pain diary for adolescents with arthritis. Clin J Pain 2006;22:295–305.
[24] Landis JT, Koch GG. The measurement of observer agreement for categorical data. Biometrics 1977;33:159–74.
[25] Tasma ML, Louwerse MD, Hehenkamp WJ, et al. Misoprostol for cervical priming prior to hysteroscopy in postmenopausal and premenopausal nulliparous women; a multicentre randomised placebo controlled trial. BJOG 2018;125:81–9.
[26] Riemma G, Schiattarella A, Colacurci N, et al. Pharmacological and non-pharmacological pain relief for office hysteroscopy: an up-to-date review. Climacteric 2020;23:376–83.
[27] Amer-Cuenca JJ, Marín-Buck A, Vitale SG, et al. Non-pharmacological pain control in outpatient hysteroscopies. Minim Invasive Ther Allied Technol 2020;29:10–9.
[28] O'Flynn H, Murphy LL, Ahmad G, Watson AJS. Pain relief in outpatient hysteroscopy: a survey of current UK clinical practice. Eur J Obstet Gynaecol Reprod Biol 2011;154:9–15.