Pain, anxiety and patient satisfaction in office hysteroscopy, is there a link? Are patient satisfaction questionnaires reliable?

# Santos- Paulo, Antonio 1,2

1Department of Obstetrics and Gynecology, Hospital Centre Tondela, Viseu, Portugal 2 Center for Interdisciplinar Investigação in Health (CIIS), Portuguese Catholic University Viseu, Portugal

Email: antoniosantospaulo@sapo.pt

Keywords: Office hysteroscopy, Anxiety, Satisfaction questionnaires

EXTENDED ABSTRACT

# Introduction

Hysteroscopy is considered gold standard in uterine abnormal bleeding (1-4). Office hysteroscopy (OH) is becoming increasingly popular (5-7).

Anxiety is always present before an aversive medical intervention (8-10) and may play a role in pain perception (11, 12) affecting Visual Analog Scale (VAS) pain reporting (12).

State Anxiety-Trait Inventory for Adults (STAI) Form Y1 (13) and Form Y2 have been validated for evaluation and scoring of anxiety (14). OH patients may have higher VAS scores with longer waiting time (16, 17) and women with higher STAI scores may experience more pain (16, 18). Distractions such as music may be associated with lower pain and anxiety (19).

There are two questions we will try to answer: Is pain perception linked to anxiety? And how well do patient satisfaction questionnaires correlate with pain score?

# Materials and methods

From March to June 2015 patients scheduled for OH at Centro Hospitalar Tondela-Viseu, Portugal were enrolled in this study.

# Inclusion criteria

Before examination, a STAI Y1 and a STAI Y2 (<u>www.mindgarden.com</u>) questionnaire was offered to participants.

Hysteroscopy was performed using the vaginal no touch approach with a 3.5mm outer sheet device fore oblique 30° mini-hysteroscopy.

At the end of procedure the woman was shown a ruler having on the side facing the patient a straight 10cm line with markings "no pain" (left end) and "maximal pain" (on the right end). A sliding courser was freely placed by the patient matching to her pain experience. Authors valued centimeters and only whole numbers were taken into account (e.g. 0 to 9mm score zero, 1 to 1.9mm scored one and so forth).

After scoring patient's VAS, each women was asked to answer three satisfaction questions: *Procedure was easy?* (With three possibilities "easy", "some discomfort" or "hard to endure"); second question *Pain medication* (with three possibilities "very important to have medication", "important to have medication" or "not important to have medication") and a third question *would you take medication next time?* (With three possibilities "no", "don't know" or "would take").

Statistical analysis was performed with SPSS 22.0 IBM for windows and in a statistical hypothesis test with a p value < 0.05 the effect was considered significant. The confidence intervals are consequently reported with a 95% assurance level. The normal goodness of fit testing was applied for all quantitative variables. Kolmogorov-

Smirnov test revealed that for almost all quantitative variables the normal distribution fit is rejected. In accordance we performed non parametric statistical tests. Kruskal Wallis test was used to evaluate the association between the pain score and the satisfaction variables, Spearman's correlation was used to correlate anxiety and pain, and finally Receiver Operating Characteristic (ROC) were constructed with answers from satisfaction questionnaires in order to establish cutoff points.

# Results

The association between variables was evaluate by Spearman's correlation. There seems to be a weak correlation between anxiety and pain score which is not significant (p value>0.05): 8% correlation between pain score and STAI Y1 and 15% for STAI Y2. Scatter plots visually express this lack of correlation and so probably anxiety is not a significant factor in pain perception. The Kruskal Wallis test was used to evaluate the association between the pain score and the satisfaction. Once again, anxiety scores do not show significant results (p value>0.05). In contrast, this same Kruskal Wallis test shows significant association between pain score and replies from satisfaction questionnaires (p<001).

We further explored the satisfaction questionnaires. Replies were broken down to binary responses for analysis. First we considered "easy versus not easy" (this latter group aggregating *some discomfort* and *hard to endure* responses) giving a total of twenty two for "easy" versus seventy eight for "not easy". A second set of binary responses was considered involving "tolerable" (joining up easy and some discomfort groups) versus "hard to endure" giving a total of twenty nine for "tolerable" and seventy one for "hard to endure".

These responses allowed a ROC curve to be constructed from theses binary responses to identify procedures as *easy* and *hard to endure*. From the ROC curve we calculated a Yoden index and for each plot a cutoff point was attained. The cutoffs matching to the maximum Yoden index values are highlighted in yellow. Testing of the area under a ROC curve was conducted and the statistical results were significant (p value <0.001).

The best cutoff points matched VAS 2.5 and VAS 6.5 for answer shifts, and we split results into categories "Easy" (zero to two) "Some discomfort" (three to six) and "Hard to endure" (seven to ten).

#### Discussion

Our data do not support a correlation between STAI form Y1 (trait anxiety) and an increased pain score. We did however, find a significant correlation between satisfaction questionnaires and women's discomfort (p<001) and all three questions are consistent in responses.

# Conclusions

We did not find an association between anxiety and pain scores in women undergoing OH.

VAS evaluation scores of 2.5 to 3 cm are the lower boundary of moderate pain and scores above the upper limit of VAS 6.5 cm should define pain as severe.

Questionnaires on patient satisfaction reflect closely patient experience

## Acknowledgements

No funding was received or sought by authors

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ACCEPTED ENTENDED ABSTRAC



Figure 1 - Scatter plot pain score vs anxiety score

Figure 2 - Yoden Index constructed from ROC curve							
Coordinates of the Curve				Coordinates of the Curve			
Test Result Variable(s):	Pain Score			Test Result Variable(s):	Pain Score		
Positive if Greater	Sensitivity	1 -	Yoden	Positive if Greater	Sensitivity		Yoden index
Than or Equal To"		Specificity	index	Than or Equal To"	Ċ	Specificity	
-1,00	1,000	1,000	0,000	-1,00	1,000	1,000	0,000
,50	1,000	,864	0,136	,50	1,000	,958	0,042
1,50	,974	,455	0,520	1,50	1,000	,803	0,197
2,50	,910	,182	0,728	2,50	,966	,662	0,304
3,50	,756	,091	0,666	3,50	,862	,507	0,355
4,50	,615	,091	0,524	4,50	,828	,366	0,461
5,50	,513	,045	0,467	5,50	,793	,254	0,540
6,50	,372	,045	0,326	6,50	,690	,141	0,549
7,50	,192	,045	0,147	7,50	,414	,056	0,357
8,50	,077	0,000	0,077	8,50	,172	,014	0,158
9,50	,051	0,000	0,051	9,50	,103	,014	0,089
11,00	0,000	0,000	0,000	11,00	0,000	0,000	0,000
The test result variable(s): Pain Score has at least one tie between the				The test result variable(s): Pain Score has at least one tie between the			
positive actual state group and the negative actual state group.				positive actual state group and the negative actual state group.			
a. The smallest cutoff value is the minimum observed test value minus 1, and the largest outoff value is the maximum observed test				a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test			
value plus 1 All the other cutoff values are the averages of two				value plus 1. All the other cutoff values are the averages of two			
consecutive ordered observed test values.				consecutive ordered observed test values.			

# Figure 2 - Yoden Index constructed from ROC curve

Test variable is "pain score" and State variable is question "procedure was easy" dichotomized as: easy vs not easy