Comparison of an optoelectronic scan of the cervix, cervical cytology and HPV genotyping for CIN screening

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Disclosures

- Onko Solutions Ltd: Financed the protocol expenses and provided the equipment for the clinical trial in México. This company distributes the optoelectronic scan device (made in U.K. by Turscreen Ltd.) in Latin America. None of the author or co-authors are employees or investors of the company.

- Regional Hopsital Dr. Valentín Gómez Farías provided clinical infraestructure and patients for the trial.

- GineMed Guadalajara S.C. provided clinical infrastructure and patients for the trial.

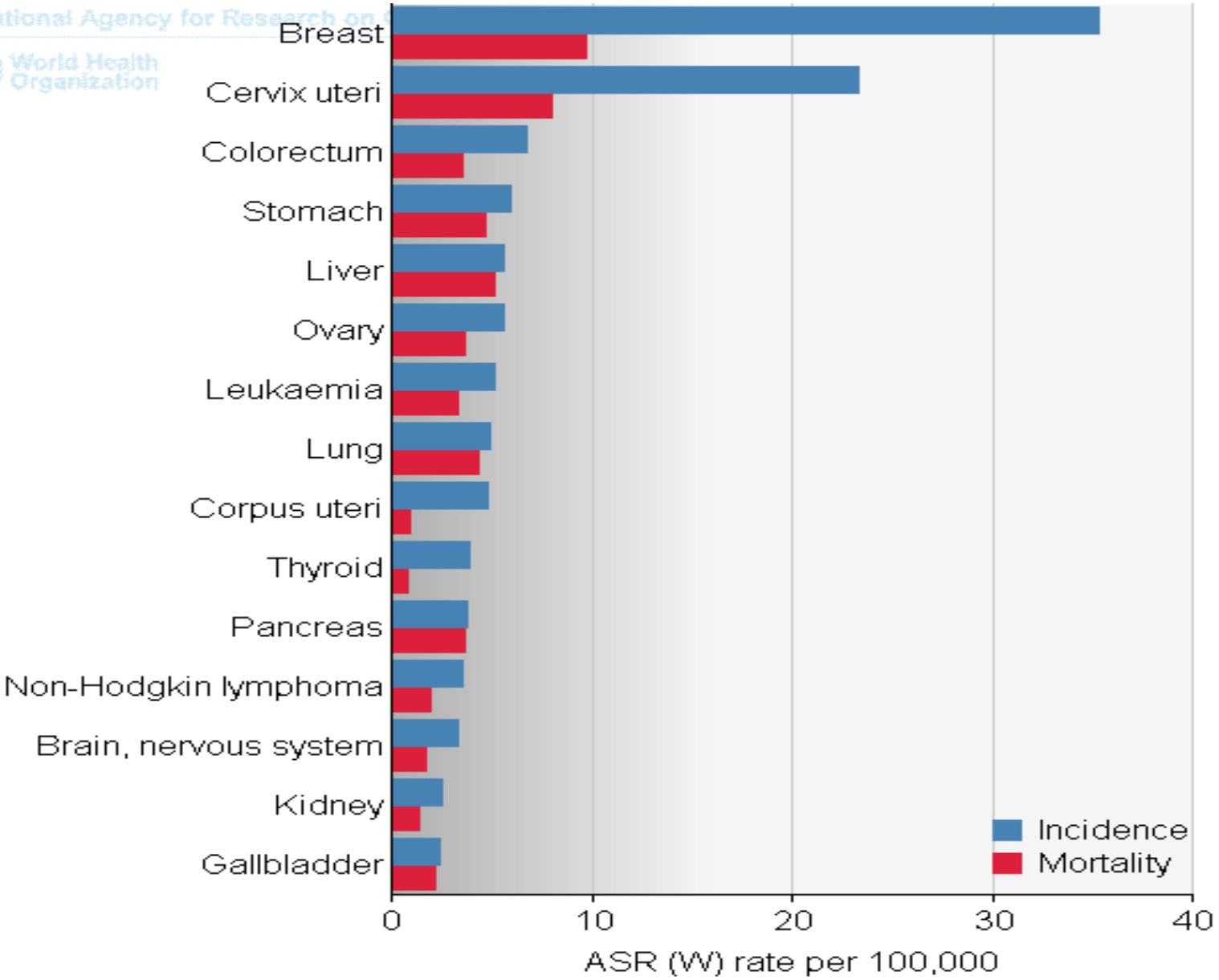
Introduction

CERVICAL CANCER IN MEXICO:

- 2nd cause of death in mexican women[1]. (mortality: 5,600)
- 10 women diagnosed every 2 hours[2]. (incidence 47,000)
- 1 woman dies every 2 hours as a result of cervical cancer[2].

1- INEGI 2011. 2- Gobocan 2012

Introduction



Introduction

Sensitivity 39 – 62%

Specificity 70 – 96%

- Overview of the European and North American studies on HPV testing in primary cervical cancer screening. AU, Cuzick J, et al. Int J Cancer. 2006;119(5):1095.
- Diagnostic accuracy of human papillomavirus testing in primary cervical screening: a systematic review and meta-analysis of non-randomized studies. Koliopoulos G, et al. Gynecol Oncol. 2007;104(1):232.
- Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. Mayrand MH, et al, N Engl J Med. 2007;357(16):1579.

Introduction

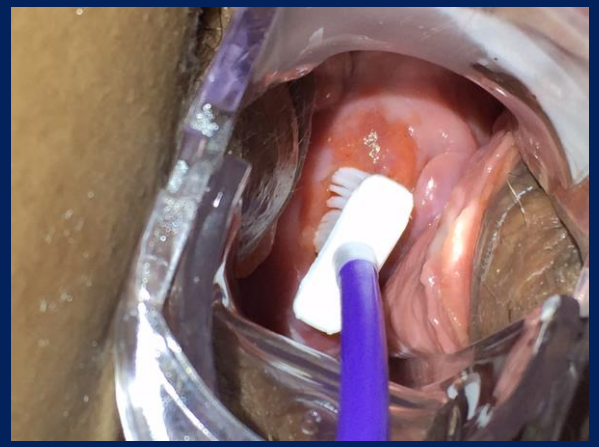
High risk HPV PCR 16, 18 & Other 12 .COBAS 4800 ROCHE.

Sensitivity 80 – 96%

Specificity 94 – 96%

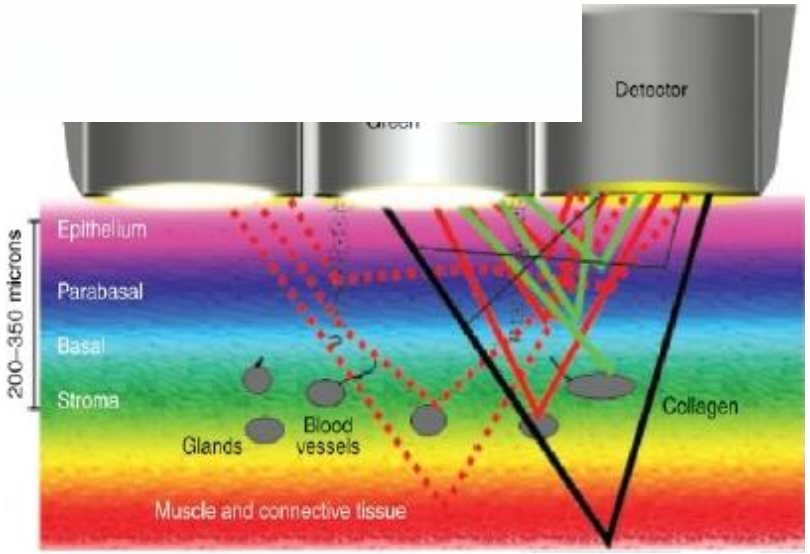
- Overview of the European and North American studies on HPV testing in primary cervical cancer screening. AU, Cuzick J, et al. Int J Cancer. 2006;119(5):1095.
- Diagnostic accuracy of human papillomavirus testing in primary cervical screening: a systematic review and meta-analysis of non-randomized studies. Koliopoulos G, et al. Gynecol Oncol. 2007;104(1):232.
- Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. Mayrand MH, et al, N Engl J Med. 2007;357(16):1579.

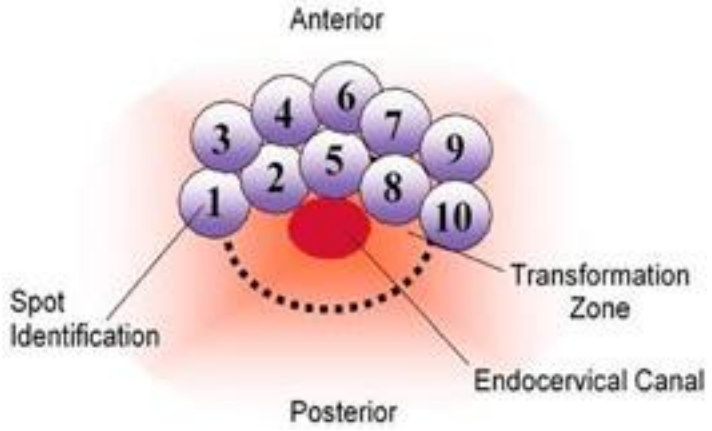
Objetive



To compare the utility of a cervix optoelectronic scan with cervical cytology and HPV genotyping for cervical intraepithelial neoplasia screening.


TruScreen


Detector
Epithelium
Parabasal
Basal
Stroma
200–350 microns
Glands
Blood vessels
Collagen
Muscle and connective tissue


Anterior
1
2
3
4
5
6
7
8
9
10
Spot Identification
Transformation Zone
Endocervical Canal
Posterior

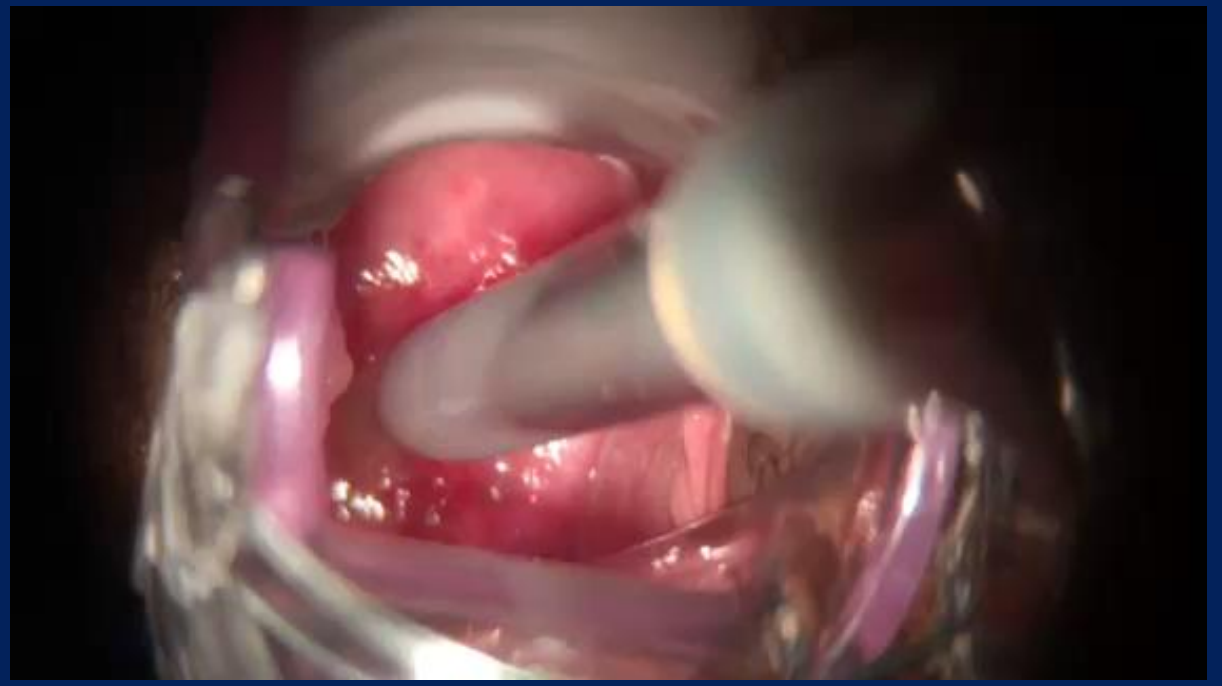
Methods

- Analytical cross-sectional study diagnostic test type in a screening population at 3 gynecologic centers in Guadalajara México.
- 521 women who were included had an optoelectronic scan of the cervix with real time result (blinded for the colposcopist), a cervical cytology, a sample of cervical cells for HPV genotyping and a colposcopy all at the same physical evaluation.
- Biopsy was taken in all subjects with colpocopic changes.

Methods

- All colposcopy were done by 5 experimented and certified colposcopists at the different centers.
- All cytology were read by cytotechnologists and pathologist from the pathology department of the Regional Hospital.
- All biopsies were read by 2 pathologists at the same hospital.

"Authorization of patients signed for using pictures of them with academic purposes".



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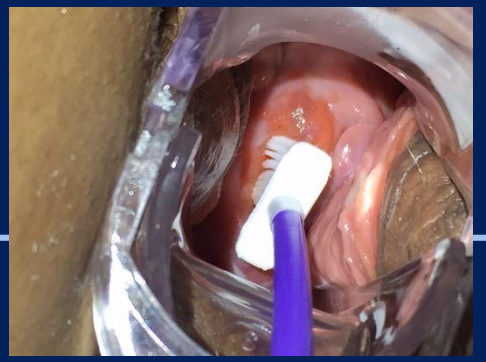
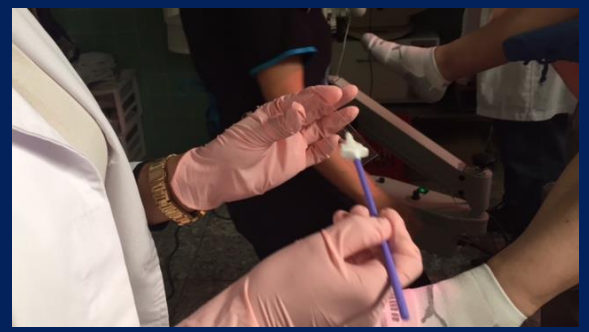




Results

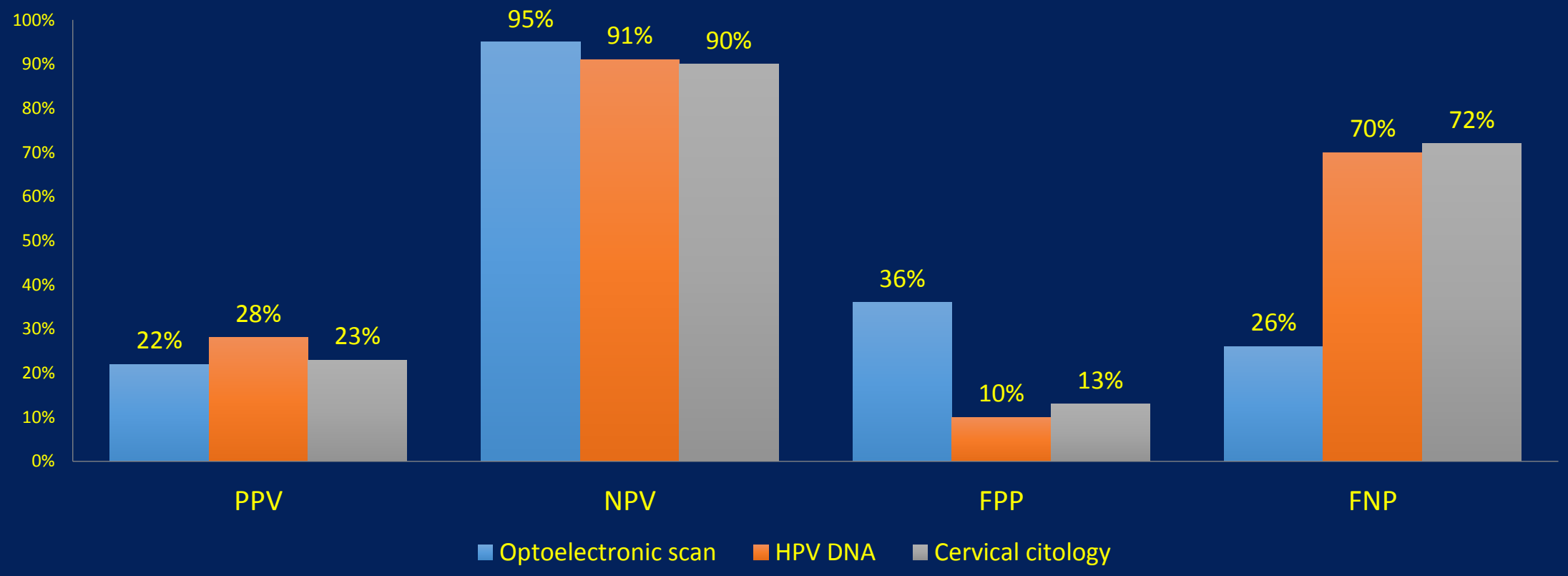
- Of 517 women we found 61 (11.8%) CIN of all grades, of which 52 (85.3%) were CIN 1 and 9 (14.7%) were CIN 2 or worse.

- The sensitivity of the optoelectronic scan, cervical cytology and HPV genotyping was 74% (CI 62-83%), 28% (CI 18-40%) and 31% (CI 21- 44%) respectively for all CIN.

Results

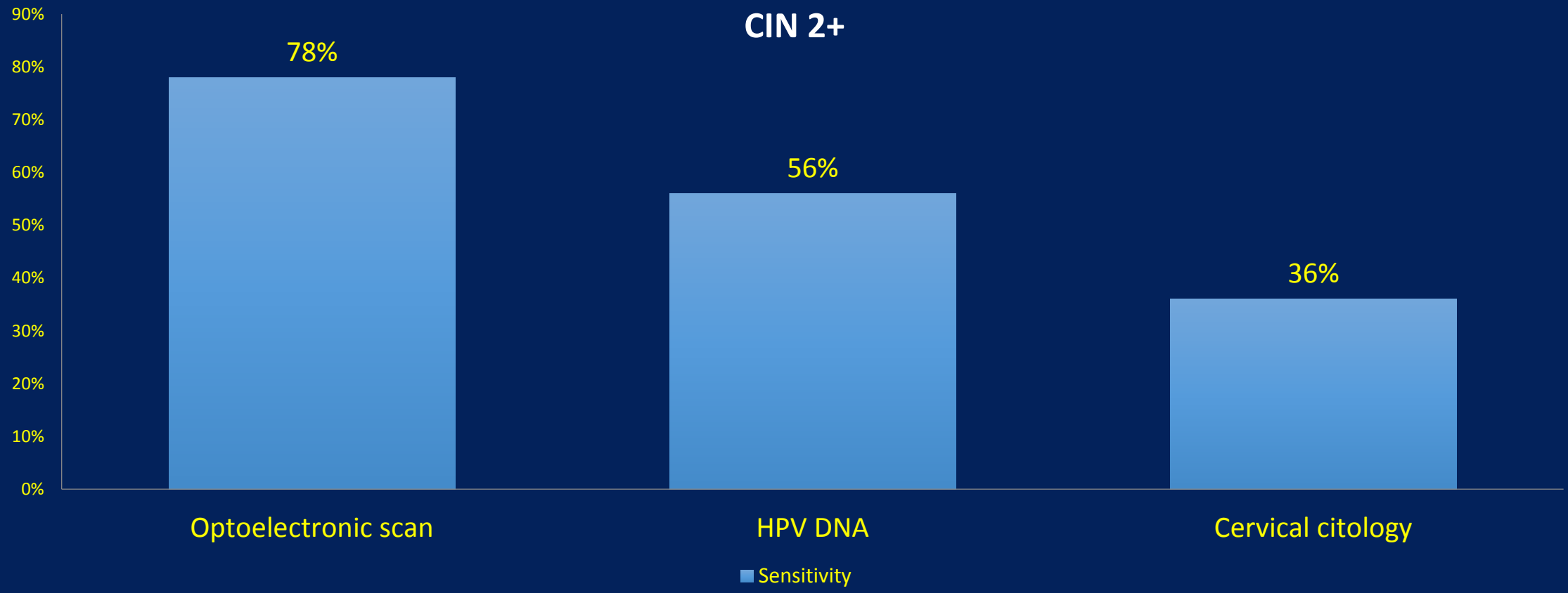
- The sensitivity of the optoelectronic scan, cervical cytology and HPV genotyping was 78% (CI 45-94%), 36% (CI 19-76%) and 56% (CI 27-81%) respectively for CIN2 or worse.
- The sensitivity of the co-test (cervical cytology and HPV genotyping) was 78% (IC 45-94%) for CIN2 or worse.
- The negative predictive value for all CIN of the optoelectronic scan, cervical cytology and HPV genotyping was 95% (CI 92-97%), 90% (CI 87-93%) and 92% (CI 88-93%) respectively.

Results


100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
22%
28%
23%
95%
91%
90%
36%
10%
13%
26%
70%
72%
PPV
NPV
FPP
FNP
Optoelectronic scan
HPV DNA
Cervical citology

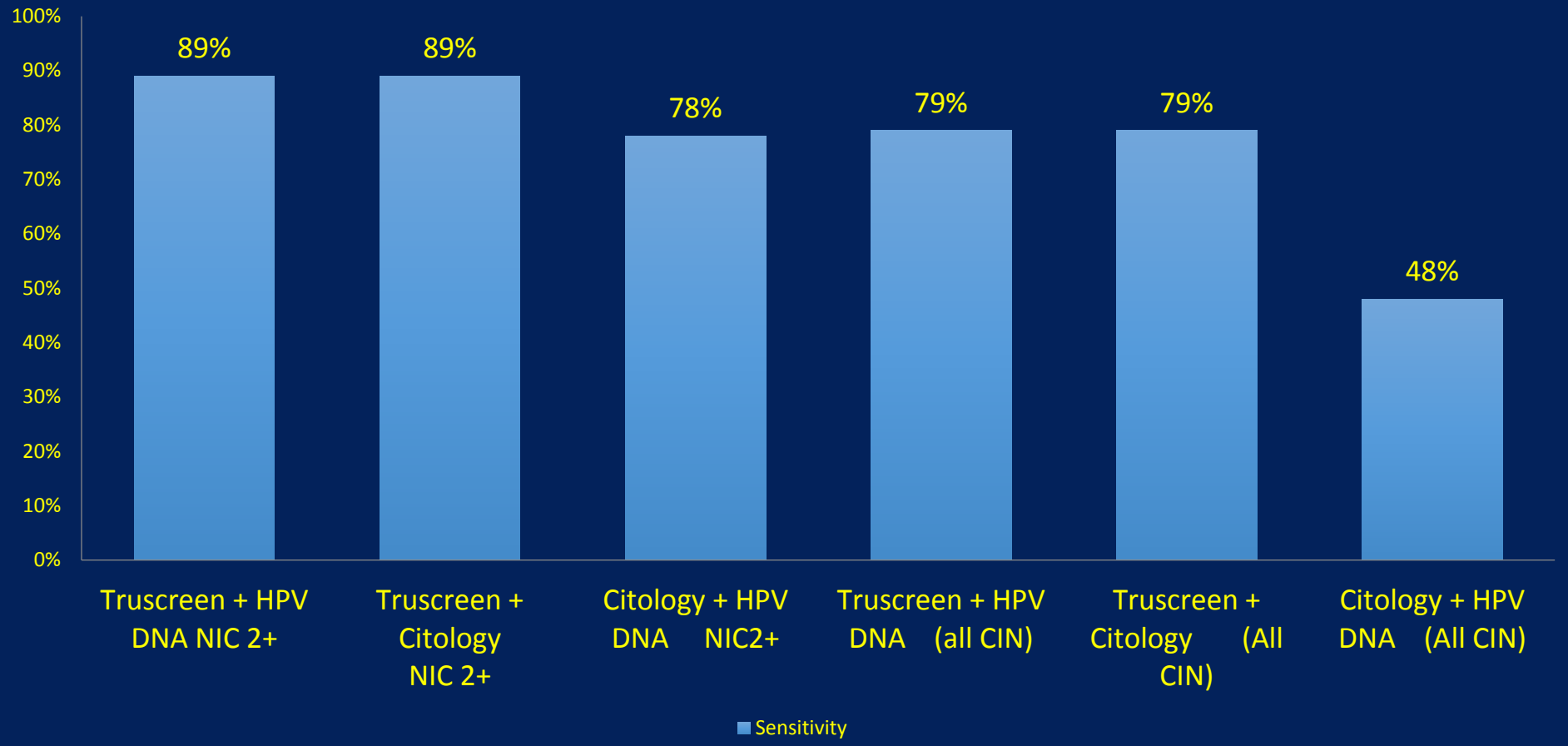
Dato estadístico	Prueba	Parámetro (IC 95%)
Para las lesiones intraepiteliales NIC2+		
Sensibilidad	Lectura optoelectrónica	78% (45-94%)
	Tipificación de VPH	56% (27-81%)
	Citología cervical	36% (19-73%)
Especificidad	Lectura optoelectrónica	64% (56-64%)
	Tipificación de VPH	88% (85-91%)
	Citología cervical	86% (83-89%)
Valor predictivo positivo	Lectura optoelectrónica	3.4% (1.6-7%)
	Tipificación de VPH	8% (3-17%)
	Citología cervical	5,3% (2-13%)
Valor predictivo negativo	Lectura optoelectrónica	99% (97-99%)
	Tipificación de VPH	99% (97-99%)
	Citología cervical	99% (97-99%)
Proporción de falsos positivos	Lectura optoelectrónica	37% (35-44%)
	Tipificación de VPH	12% (9-15%)
	Citología cervical	14% (11-17%)
Proporción de falsos negativos	Lectura optoelectrónica	22% (6-55%)
	Tipificación de VPH	44% (19-73%)
	Citología cervical	56% (27-81%)
Valor global de la prueba	Lectura optoelectrónica	61% (57-65%)
	Tipificación de VPH	87% (84-90%)
	Citología cervical	85% (82-88%)
Razón de verosimilitud positiva	Lectura optoelectrónica	1.9 (1.3-2,8)
	Tipificación de VPH	4.6 (2.4-8.7)
	Citología cervical	3.1 (1,1-5,9)
Razón de verosimilitud negativa	Lectura optoelectrónica	0.37 (0.11-1.2)
	Tipificación de VPH	0.50 (0,26-1)
	Citología cervical	0,65 (0,36-1.1)
Razón de momios de la prueba (OR)	Lectura optoelectrónica	5.3 (1-25)
	Tipificación de VPH	9 (2.4-31)
	Citología cervical	4.9 (1,02-12,5)

Results


CIN 2+
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
78%
56%
36%
Optoelectronic scan
HPV DNA
Cervical citology
Sensitivity

Dato estadístico	Prueba	Parámetro (IC 95%)
Combinaciones de las pruebas para las lesiones NIC 2+		
Sensibilidad	Lectura optoelectrónica + VPH	89% (57-98%)
	Lectura optoelectrónica + Citología	89% (57-98%)
	Citología + VPH	78% (45-94%)
Especificidad	Lectura optoelectrónica + VPH	56% (51-60%)
	Lectura optoelectrónica + Citología	53% (49-57%)
	Citología + VPH	77% (73-81%)
Valor predictivo positivo	Lectura optoelectrónica + VPH	3.4% (2-7%)
	Lectura optoelectrónica + Citología	3.2% (1.7-6.3%)
	Citología + VPH	5.7% (3-11%)
Valor predictivo negativo	Lectura optoelectrónica + VPH	99.6% (98-99.9%)
	Lectura optoelectrónica + Citología	99.6% (97.9-99.9%)
	Citología + VPH	99.5% (98-99.9%)
Proporción de falsos positivos	Lectura optoelectrónica + VPH	45% (40-49%)
	Lectura optoelectrónica + Citología	47% (43-51%)
	Citología + VPH	23% (19-27%)
Proporción de falsos negativos	Lectura optoelectrónica + VPH	11% (2-43%)
	Lectura optoelectrónica + Citología	11% (2.43%)
	Citología + VPH	22% (6-55%)
Valor global de la prueba	Lectura optoelectrónica + VPH	56% (51-60%)
	Lectura optoelectrónica + Citología	54% (49-58%)
	Citología + VPH	77% (72-80%)
Razón de verosimilitud positiva	Lectura optoelectrónica + VPH	2 (1,6-2,7)
	Lectura optoelectrónica + Citología	1,8 (1.5-2.1)
	Citología + VPH	3.4 (2.3-5)
Razón de verosimilitud negativa	Lectura optoelectrónica + VPH	0.20 (0,03-1.3)
	Lectura optoelectrónica + Citología	0.21 (0,03-1.3)
	Citología + VPH	0,2 (0,08-0.85)
Razón de momios de la prueba (OR)	Lectura optoelectrónica + VPH	10 (2.7-9.2)
	Lectura optoelectrónica + Citología	9 (1.1-72)
	Citología + VPH	12 (2.4-58)

Results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89%
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79%
48%
Truscreen + HPV DNA NIC 2+
Truscreen + Citology NIC 2+
Citology + HPV DNA NIC2+
Truscreen + HPV DNA (all CIN)
Truscreen + Citology (All CIN)
Citology + HPV DNA (All CIN)
Sensitivity

Limitations

- A endocervical curetage was not done in all patients , that gives the chance to have an endocervical lession not seen in colposcopy.

Discussion

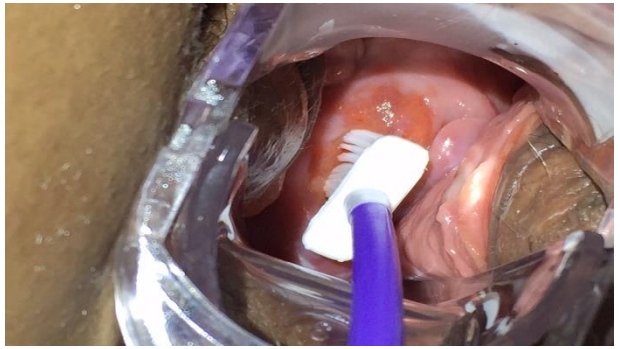
- 1st sudy in México & Latin America. No precedents.

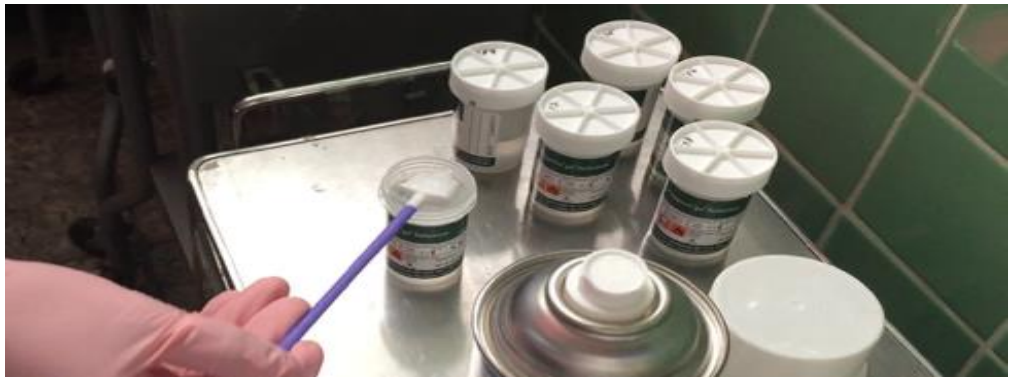
- A better clinical utility of a new screening test was demostrated.

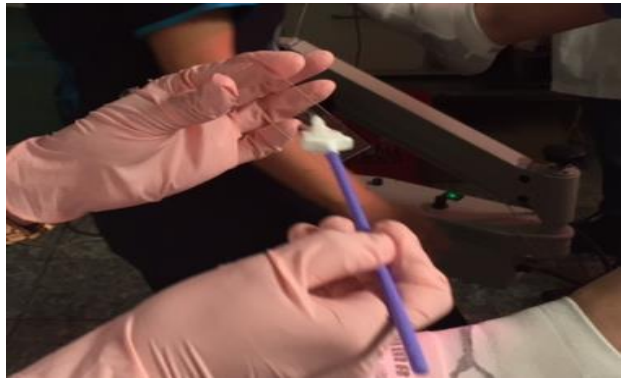
    - The optoelectronic scan of the cervix had a higher sensitivity compared with the other 2 test fo CIN 2+:

    - 46% more than citolgy.
    - 43% more than HPV DNA genotyping.

VS







Discusion

- The optoelectronic scan alone had the same performance in sensitivity than the co-test for CIN2+.

- Any combination with the optoelectronic scan had better performance in sensitivity than co-test for CIN2+.

Conclusions

- The optoelectronic scan demonstrated superiority to the other tests for screening scenarios.
- The combination of tests showed better results when performed with optoelectronic scan; The latter was just as sensitive as the combination of cytology and HPV for high-grade lesions.
- All tests increased their effectiveness in detecting high-grade lesions.

Conclusions

- A high add value from the optoelectronic technology is the inmediate result.

- With more controlled studies, optoelectronic technology could be taken into account as an effective screening method for cevical cancer precursor lesions.

Thank You all…

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