Accuracy of cytology and visual screening in the early detection of cervical neoplasia in Solapur District, India

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BACKGROUND

- Women aged 30-49 years were recruited in two phases in Solapur district, India for a study to facilitate the development of affordable, safe, accurate, rapid and acceptable biochemical tests (START project) for cervical screening in low-resource settings
- In the 1st Phase, 2980 women were recruited and 2931 were eligible for analysis
- In the 2nd Phase, 7083 women were recruited and 6935 were eligible for analysis
- All women had Pap smear, visual screening with 5% acetic acid (VIA) and visual screening with Lugol's iodine (VILI) provided by nurses
- We present the results of accuracy of the above tests in detecting CIN 2 and 3 lesions and invasive cervical cancer in this communication

Health education program

Counselling for attending women

Colposcopy examination

Laboratory reporting

METHODS

- Positive Cytology: ASCUS or worse results
- Positive VIA: Definite AW lesions on the cervix
- Positive VILI: Definite yellow lesions on the cervix
- True positive disease: CIN 2 or CIN 3 or AIS or invasive cervical cancer on histology
- Reference investigations for establishing true positive disease: colposcopy and directed biopsies or ECC or diagnostic loop excision based on colposcopy findings
- Internal and external quality assurance for tests and reference standard, particularly histology
- In Phase 1, women positive on any one or more of the screening tests had reference investigations
- In Phase 2, all women had reference investigations, irrespective of screening results
- Accuracy parameters directly calculated using 2 X 2 tables

RESULTS: Phase 1 (2931 women)

- 237 (8.1%) positive on Pap smear
- 436 (14.9%) positive on VIA
- 498 (17.0%) positive on VILI
- 540 (18.4%) had colposcopy
- 411 (14.0%) had histology
- 43 (1.3%) diagnosed with true positive disease based on reporting by Indian pathologists
- *36 (1.2%) diagnosed with true positive disease when EQC histopathology results are incorporated*

Accuracy of screening tests

Screening Test	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
VIA	86.0	86.2	8.5
VILI	88.4	84.1	7.6
VIA and VILI *	100.0	82.8	7.9
VIA and VILI **	74.4	87.5	8.1
Cytology	67.4	92.8	12.2

** If one of these is positive taken as positive*
*** If one of these is negative taken as negative*

RESULTS: Phase 2 (6935 women)

- 416 (6.0%) positive on Pap smear
- 1161 (16.7%) positive on VIA
- 1070 (15.4%) positive on VILI
- 6935 (100%) had colposcopy
- 964 (13.9%) had histology
- 133 (1.9%) diagnosed with true positive disease based on reporting by Indian pathologists
- *88 (1.2%) diagnosed with true positive disease when EQC histopathology results are incorporated*

Accuracy of screening tests

Screening Test	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
VIA	65.4	84.2	7.5
VILI	68.4	85.6	8.5
VIA and VILI *	68.4	82.3	7.0
VIA and VILI **	65.4	87.5	9.3
Cytology	43.6	94.7	13.9

** If one of these is positive taken as positive*
*** If one of these is negative taken as negative*

Results incorporating EQC histopathology

- When external quality control results of histopathology were considered for defining true positive disease. 36 women had true positive disease in Phase 1 and 88 in Phase 2

Accuracy of screening tests in Phase 1 incorporating histopathology external quality control results

Screening Test	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
VIA	86.1	86.0	7.1
VILI	88.9	83.9	6.4
VIA and VILI *	100.0	82.6	6.7
VIA and VILI **	75.0	87.4	6.9
Cytology	80.6	92.8	12.2

** If one of these is positive taken as positive*
*** If one of these is negative taken as negative*

Accuracy of screening tests in Phase 2 incorporating histopathology external quality control results

Screening Test	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
VIA	73.9	84.0	5.6
VILI	77.3	85.3	6.4
VIA and VILI *	77.3	82.0	5.3
VIA and VILI **	73.9	87.3	7.0
Cytology	61.4	94.7	13.0

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*** If one of these is negative taken as negative*

CONCLUSIONS

- Higher estimates of sensitivity in Phase 1 due to verification bias (reference standard only for screen positives)
- Lower estimates of sensitivity for all tests when all women had reference standard investigations (minimal verification bias)
- Overcalling of CIN by Indian pathologists as compared to Western quality control (EQC) pathologists
- Estimates for sensitivity increased for all tests when EQC results were incorporated for true positive disease
- Visual tests had a higher sensitivity but lower specificity as compared to Pap smear
- Results are consistent with previous reports from India (Jaipur, Kolkata, Mumbai, New Delhi, Trivandrum)
- Visual tests are useful cervical screening tests

ACKNOWLEDGEMENTS

Our thanks to

- The participants and their families
- Solapur district Administrative and Health Services Authorities
- Bill & Melinda Gates Foundation for their kind support through PATH

Supported by the Bill & Melinda Gates Foundation, Seattle, USA through PATH, Seattle

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