

Visual screening with acetic acid application reduces cervical cancer mortality in a cluster randomized trial in rural India

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Background:

The impact of a single round of screening with visual inspection with acetic acid (VIA) on cervical cancer incidence and mortality is being investigated in a cluster randomized controlled trial in South India. Women aged 30-59 years in 113 clusters in Dindigul District were randomized to VIA screening (57 clusters, 48,225 women) by nurses and to a control group (56 clusters, 30,167 women). 30,577 eligible women were screened between May 2000 and April 2003. Screen-positive women were investigated with colposcopy/ biopsy. Women with CIN were treated with cryotherapy or loop electrosurgical excision procedure (LEEP) and the invasive cancer cases were treated at the base hospital (CFCHC). Data on participation, test positivity, cervical intraepithelial neoplasia (CIN) detection and treatment rates were analyzed. The preliminary findings after the screening phase are reported here.

Study location-Dindigul District, India:



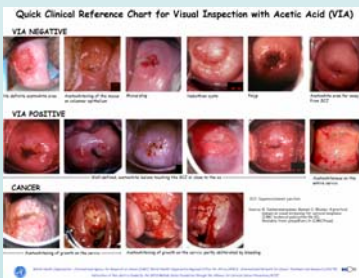
Notional Map Showing Dindigul District, Tamil Nadu State, India

Objectives:

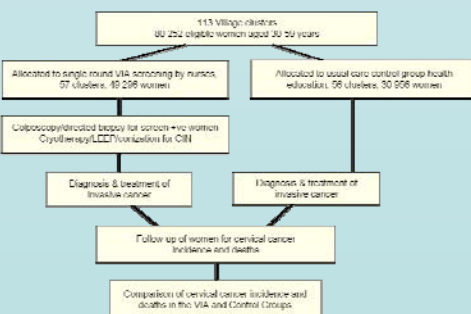
To evaluate :

- the reduction in cervical cancer incidence and mortality associated with a single round of screening with VIA as compared to a control group with no screening;
- the cost-effectiveness (CE) of VIA screening.

Definition of screen positivity:



Study design:



Evaluation:

Process measures

- Coverage by screening, investigations and treatment; test positivity rates

Intermediate outcome measures

- Detection rates of CIN and cancer;
- Stage distribution of cervical cancer;
- Case fatality and survival from cervical cancer.

Final endpoint:

- Reduction in incidence of and mortality from cervical cancer.

Follow-up – active and passive methods:

- Linkage with population-based cancer registry and death registers;
- Active enumeration of participants by house visits for information on changes in family circumstances/health.

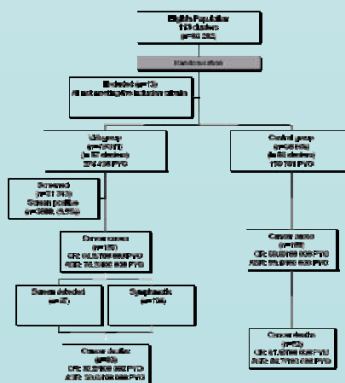
Baseline characteristics of eligible individuals:

	Control group	Intervention group
Eligible women	30 508	48 225
Household		
Household (< 100-45 persons)	78%	73%
Individual		
Mean age	41	39
Married	93%	92%
No education	73%	63%
Housewife	77%	47%
Married	91%	86%
Mean parity	3	3
Last menstruation (< 12 months ago)	69%	70%

Screening findings by age in the intervention group:

Age group	Number	Screened	Screened (%)	Screened positive	Screened positive (%)	Screened positive per 1000	Screened positive per 1000 (95% CI)
20-29	207	164	79	16	10	20	20 (10-30)
30-39	1340	1020	76	102	10	102	102 (90-114)
40-49	1140	720	63	102	14	102	102 (90-114)
50-59	1140	420	37	102	24	102	102 (90-114)
Total	4707	3324	71	320	14	320	320 (300-340)

Flow chart of study results:



Stage of cervical cancer by study group (2002-2006):

Stage	Control	Intervention (VIA)
IA	18(3)	18(18.3)
IB	12(3.3)	12(9.6)
2+	50(12.8)	10(6.2)
Unknown	44(27.8)	20(17.4)
Total	124(200.9)	48(270.0)

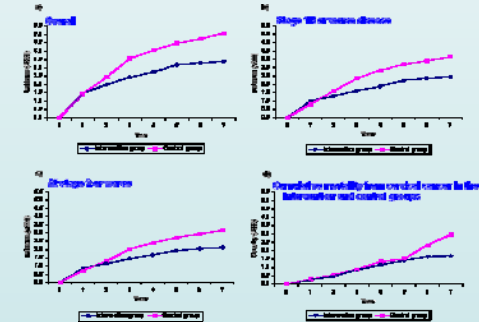
Data on number of individuals (%)

Overall and age-specific hazard ratio for incidence for all cervical cancers and for cervical cancer deaths:

	Hazard ratio (95% CI)
Control group	1.0
Intervention group (VIA)	
Overall	
Cervical cancer incidence	0.76 (0.65-0.89)
Cervical cancer death	0.59 (0.47-0.76)
30-39 years	
Cervical cancer incidence	0.82 (0.45-1.50)
Cervical cancer death	0.34 (0.16-0.69)
40-49 years	
Cervical cancer incidence	0.62 (0.35-1.06)
Cervical cancer death	0.55 (0.21-1.00)
50-59 years	
Cervical cancer incidence	0.76 (0.30-1.16)
Cervical cancer death	0.59 (0.26-1.00)

CI: Confidence Interval

Cumulative incidence and mortality from cervical cancer (2000-2006):



Conclusions:

- Women accept VIA screening
- Appropriate service delivery strategies result in satisfactory participation in screening / diagnosis / treatment / follow-up
- Successful VIA screening leads to reduction in cervical cancer incidence through accurate detection and effective treatment of precancerous lesions
- Immediate availability of VIA results facilitated the adaptation of 'see and treat' principles to achieve maximum compliance of screen positive women for diagnosis and cryotherapy
- Nurses, after adequate and sustained in-service training, can effectively perform screening, colposcopy, biopsies, cryotherapy and follow-up evaluation
- With an average of 4.95 and 5.22 years of follow-up in the VIA and control groups, respectively cervical cancer incidence and mortality rates were lower in the VIA compared to the control group
- limitations of VIA in women older than 40 years in terms of reduction in incidence and mortality of cervical cancer



Sankaranarayanan R, Esmy PO, Rajkumar R, Muwonge R, Swaminathan R, Shanthakumari S, Fayette JM, Cherian J. Effect of visual screening on cervical cancer incidence and mortality in Tamil Nadu, India: a cluster-randomised trial. *Lancet* 2007; 370: 398-406.

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