International Agency for Research on Cancer
Centre International de Recherche sur le Cancer

Cluster randomized controlled trial of cervical visual screening in rural south India

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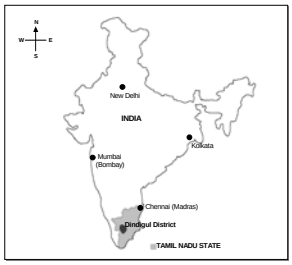
Background

The impact of a single round of visual screening 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 49,311 women) by nurses and to a control group (56 clusters, 30,958 women). 31,343 eligible women were screened between May 2000 and April 2003. Screen-positive women were investigated with colposcopy/biopsy. Women with cervical intraepithelial neoplasia (CIN) were treated with cryotherapy or loop electrosurgical excision procedure (LEEP) and the invasive cancer cases were treated at the Christian Fellowship Community Health Centre (CFCHC). Data on participation, test positivity, 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

Primary: to evaluate

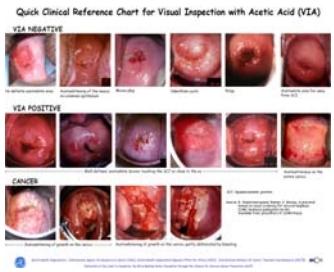
- the reduction in cervical cancer incidence and mortality associated with a single round of VIA as compared to a control group with no screening;
- the cost-effectiveness (CE) of VIA screening.

Secondary: to evaluate

- determinants of participation for screening/diagnosis/treatment;
- over-treatment associated with treatment decisions based on colposcopy;
- safety and effectiveness of cryotherapy by nurses in field conditions;
- safety and effectiveness of LEEP by mid-level clinicians.

Definition of screen positivity

- VIA: Well-defined acetowhite lesions close to the squamocolumnar junction, to the external os or on a cervical growth



Field procedures


Enumeration


Interview

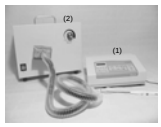
Health education by drama and puppet show

Field procedures (continued)

- Enumeration of all women and listing of eligible women (30-59 years);
- Interview and informed consent of eligible women;
- Educational programmes and preparation for screening clinics;
- Screening in village clinics;
- Colposcopy and biopsy for screen-positive women, under the medical officer's supervision;
- Treatment with cryotherapy by nurses after obtaining a biopsy under the medical officer's supervision;
- Clinical follow-up of treated women.


Colposcopy


Cryotherapy



Electrosurgical generator (1) and smoke evacuator (2)

Procedure at the CHCHC


Data entry


Review of project activities

- Data management
- Treatment of CIN with LEEP and invasive cancer by surgery/ radiotherapy

Control Arm

Eligible women were:

- enumerated and interviewed;
- informed about cervical cancer symptoms, signs and treatment options;
- informed of how to avail of diagnosis and treatment of cervical neoplasia at CFHCHC and other hospitals;
- offered free screening and treatment at CFCHC.

Evaluation

Process measures

- Coverage per screening, investigations and treatment.

Intermediate outcome measures

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

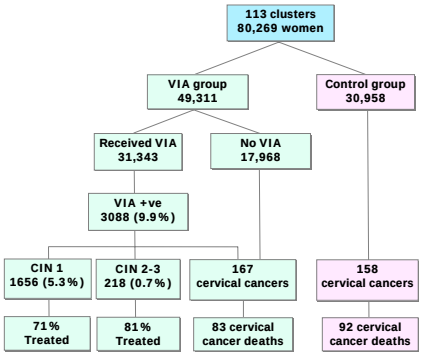
Final endpoint

- Reduction in incidence of and mortality from cervical cancer.

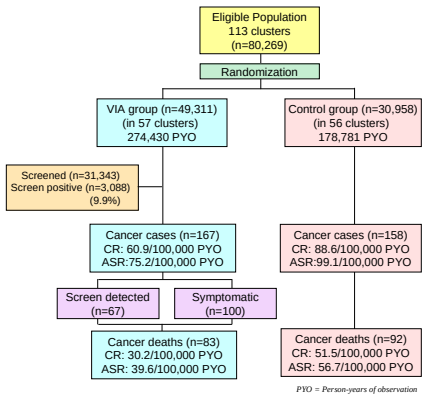
Follow-up – active and passive methods

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

Preliminary results after the screening phase



Follow-up results after the screening phase



PYO = Person-years of observation

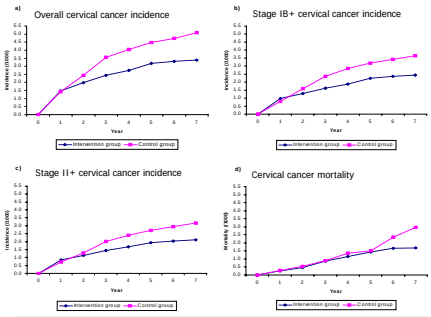
Relative hazard adjusted for age, parity, cluster design

Group	End point	Relative hazard (95% CI)
Control		1.00 (reference)
VIA	Cervical cancer incidence	0.75 (0.59-0.95)
	Stage 2+	0.76 (0.57-1.02)
	Cervical cancer death	0.65 (0.47-0.89)

Age-specific relative hazard adjusted for parity, cluster design

Group	End point	Age Group 30-39	40-49	50-59
		Relative hazard (95%CI)	Relative hazard (95%CI)	Relative hazard (95%CI)
Control		1.00 (reference)	1.00 (reference)	1.00 (reference)
VIA	Incidence	0.62 (0.40-0.96)	0.82 (0.55-1.24)	0.76 (0.50-1.16)
	Stage 2+	0.51 (0.29-0.92)	0.85 (0.52-1.40)	0.86 (0.52-1.41)
	Death	0.34 (0.18-0.66)	0.55 (0.31-1.00)	0.99 (0.58-1.66)

Cumulative incidence and mortality



Conclusions

- With age, prevalence of cancers at screening increased and that of CIN 1 decreased;
- VIA detected large numbers of prevalent cancers, with rates 3 times higher than the expected incidence in the absence of screening;
- 20% of the cancers detected at early stage were in the VIA group and 10% in the control group;
- 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;
- A significant reduction of 25% in incidence and 35% in mortality has been observed in the intervention group.

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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(9585):398-406.