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Analysis of the effectiveness of visual inspection with acetic acid/Lugol's iodine in one-time and annual follow-up screening in rural China

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Abstract

Purpose—Via a large population-based survey conducted in rural, southwestern China, we aim to evaluate the effect of visual inspection with acetic acid/Lugol's iodine (VIA/VILI) on diagnosing cases of cervical cancer and of precancerous lesions while exploring the mode of cervical prevention and control in low-resource settings in China.

Methods—Women aged 30–59 years from Chongqing, China were recruited from 2006 to 2009. Participants underwent VIA/VILI, and, if positive, received colposcopy-directed or random biopsies. Women with negative VIA/VILI or biopsy-confirmed cervical intraepithelial neoplasia (CIN) I lesions diagnosed in the first round of screening were re-screened in the following year with the same procedure.

Results—In total, 10,269 women received VIA/VILI. The average age of participants was 40.9 ± 7.6 years. Overall, 0.85% (87/10,269) of women were diagnosed via pathology-confirmed biopsy with CIN1, 0.25% (26/10,269) with CIN2, 0.27% (28/10,269) with CIN3, and 0.02% (2/10,269) with cervical cancer. Over half (57.7%) of CIN2 lesions, the majority of CIN3 lesions (89.3%), and all cancer cases (100%) were detected in the first round of screening.

Conclusion—In a rural, low-resource setting in China, onetime VIA/VILI screening detected more than a half of CIN2 cases, most CIN3 cases and all the cervical cancer cases. Detection rates of CIN2 lesions significantly increased with a 1-year follow-up VIA/VILI screen. Therefore, if multiple cervical cancer screenings are not feasible logistically or financially, a one-time VIA/VILI may be the most efficient strategy to detect cervical cancer and most CIN3 lesions in women in low-resource settings.

Keywords

Cervical cancer screening; Visual inspection with acetic acid/Logol's iodine; Low-resource; China

Introduction

Cervical cancer, one of the most common malignancies in women, disproportionately affects women in less-developed countries [1] due to the logistic difficulties of establishing or maintaining comprehensive, cytology-based screening campaigns in low-resource settings [2]. China, the world's most populous country, currently lacks a national secondary cervical cancer prevention program. Cervical cancer screening in China remains opportunistic and urban-based [3], resulting in inadequate population coverage, particularly in rural areas where up to 90% of China's cervical cancer cases are estimated to occur [3]. To close this gap, in 2004, the Chinese Ministries of Health and Finance funded a Program for Cervical Cancer Prevention and Control [3, 4]. This program aims to evaluate the effect of visual inspection with acetic acid/Lugol's iodine (VIA/VILI) on diagnosing cases of cervical cancer and of pre-cancerous lesions while exploring the mode of cervical prevention and control in low-resource settings in China.

Fuling County, in Chongqing, China, was selected as one of the first sites in this program. From 2006 to 2009, medical centers in Fuling County screened 63,596 women for cervical cancer with visual inspection with acetic acid/Lugol's iodine (VIA/VILI) or liquid-based cytology (LBC). Currently the method recommended by the World Health Organization (WHO) for cervical cancer screening in low-resource settings [3, 5, 6], VIA/VILI has been shown to cheaply and effectively detect high-grade cervical lesions with one screen-and-treat intervention [5]. By analyzing the screening results from Fuling County, this paper aims to evaluate whether the implementation and effectiveness of VIA/VILI is acceptable in China, and a second round of VIA/VILI is necessary.

Materials and methods

Study subjects

From 2006 to 2009, 30- to 59-year-old women were recruited for cervical cancer screening from Jiangdong, Linshi, Mawu and Lidu districts in Fuling County, Chongqing City. Eligible women had an intact uterus, no history of cervical surgery or pelvic radiation therapy, were not pregnant at the time of screening, and had not engaged in sexual intercourse for 24 h prior to the consultation. All enrolled women provided written informed consent.

Screening methods and diagnostic standards

Practitioner training—Senior pathologists and senior gynecologists from China's premier cancer hospital, the Cancer Institute of the Chinese Academy of Medical Sciences (CICAMS), traveled to Chongqing to provide local providers and senior physicians from Chongqing Cancer Institute and Hospital with an intense day-long workshop in VIA/VILI screening practices and results classification. Then senior physicians from Chongqing Cancer Institute and Hospital traveled every 3 months to each hospital to conduct on-site retraining while supervising local providers conducting VIA/VILI.

Screening procedures—After receiving education on cervical cancer prevention and providing informed consent, participants received VIA/VILI conducted by trained local

gynecologists. Colposcopy was performed in test-positive women, and colposcopy-directed or random biopsies were taken for pathology-confirmed final diagnosis.

Visual inspection with acetic acid—Five percent acetic acid was applied to the cervix through embedded cotton swab and then observed after 1 min. Normal cervical cells do not change; however, the increased number of proteins and cytokeratins in cervical intraepithelial neoplasia (CIN) causes these cells to become white and opaque. Initial diagnoses were classified into negative, positive, and suspected disease according to the presence, thickness, extension, and surface morphology of the opaque acetowhite lesions.

Visual inspection with Lugol's iodine—The cervix was swabbed with 5% iodine solution. Normal cervical epithelium absorbs iodine and turns brown in color. But proliferative lesions like CIN or cancer have less glycogen compared to surrounding epithelium, resulting in a mustard-yellow color of CIN or cancer. The initial diagnosis was classified into negative, positive, and suspected disease according to the presence, extension, surface morphology, appearance of boundary, and the distance to squamo-column boundary of the yellow-mustard lesion.

Colposcopy—Women with positive VIA or VILI were referred to colposcopy and biopsy with a 2 mm bronchoscopy biopsy instrument. Directed biopsy was used in cases of visible lesions, when the Reid colposcopic index (RCI) [6] was greater than or equal to 3, corresponding to CIN 1 or CIN 2 (RCI 3–5) or CIN 2, CIN 3, or invasive cervical cancer (RCI 6–8). When the modified RCI was less than 3, suggesting the cervix was either normal or inflamed, the VIA/random (four-quadrant) punch biopsy method was indicated, and biopsies were taken at positions of two, four, eight, and ten o'clock. Of note, the diagnostic gold standard in this study was pathology-confirmed biopsy, which classified biopsy results into normal, CIN1, CIN2, CIN3 and cervical cancer. Senior pathologists at Chongqing Cancer Hospital confirmed all diagnoses. Women with unsatisfactory colposcopy were contacted to return for colposcopy 1 month after initial colposcopy. Data were not recorded on the number of women who had unsatisfactory initial colposcopy.

Treatment principle and follow-up

Screen-negative women and women diagnosed with CIN1 underwent the same screening procedure with VIA/VILI 1 year after the preliminary screen. Women diagnosed with CIN2+ lesions at either initial or follow-up VIA/VILI were treated according to the National Comprehensive Cancer Network's guidelines. Specifically, women with CIN 2 and CIN 3 lesions were treated with the loop electrosurgical excision procedure (LEEP) whereas women diagnosed with invasive cancer were treated with hysterectomy, with radiotherapy or chemotherapy when needed to treat more advanced disease states.

Statistical analysis

Among the 10,285 women who enrolled in this study, 99.8% elected to undergo VIA/VILI. Thereafter, a total of 10,269 women with VIA/VILI results were included in subsequent data analysis for the initial screen. Of the 10,227 women who were requested to return for follow-up VIA/VILI 1 year after initial screen, 8,263 (80.8%) returned for secondary

screening (Fig. 1). The prevalence of CIN1, CIN2, and CIN3+ were examined for trends in both primary and secondary VIA/VILI screening, and proportions of disease status between the primary and secondary VIA/VILI screenings were tested with the nonparametric Wilcoxon test. Data were entered twice in a FoxPro database to confirm the absence of duplications or omissions and were analyzed on SPSS11.5 software.

Results

Demographic information

A flow-chart of methodology (Fig. 1) shows how we obtained our final study population of 10,269 women for initial VIA/VILI and 8,263 women for follow-up VIA/VILI. The mean age of the 10,269 Chinese women in our study population was 40.9 ± 7.6 years, with average age of sexual debut at 20.3 ± 2.1 years. In addition, 6,224 women received demographic questionnaires. Of these women the median number of pregnancies was 3.0 and median parity was 1.0. In terms of educational attainment, only 8.5% had graduated from senior middle school, with 44.7% reporting they had completed junior middle school. Nearly half of the women (46.7%) had not graduated from primary school. The majority of study participants (88.5%) reported an annual familial income of less than 10,000 RMB (1,180 Euros), with 8.9 and 2.8% of participants reporting an annual income of 10,000–20,000 RMB (1,180–2,360 Euros) or greater than 20,000 RMB (2,360 Euros), respectively.

VIA/VILI detection results, by initial or follow-up screen

Within this study population of 10,269 Chinese women, the overall detection rate of CIN lesions and cervical cancer was 1.39% (143/10,269). More specifically, the detection rate of CIN1 was 0.85% (87/10,269); CIN2 was 0.25% (26/10,269); CIN3 was 0.27% (28/10,269), and cervical cancer was 0.02% (2/10,269). All CIN lesions and cervical cancer cases were confirmed via pathological diagnosis. Overall, the colposcopy referral rate was 10.0% in initial screening (data not shown). The follow-up rate for secondary screening among screen-negative women or those diagnosed with biopsy-confirmed CIN1 lesions was 80.8%, meaning that 8,263 women returned to repeat VIA/VILI screening a year later (Table 2).

In the first screen, nearly all women (99.0%; 10,166/10,269) were screen-negative, while 0.59% (61/10,269) were diagnosed with CIN1; 0.15% (15/10,269) with CIN2; 0.24% (25/10,269) with CIN3, and 0.02% (2/10,269) with cervical cancer (Table 1). Comparatively in the 1-year follow-up screen, a similar number of women had negative VIA/VILI (99.5%; 8,223/8,263), though the rate of women diagnosed with CIN1 (0.31%; 26/8,263); CIN2 (0.13%; 11/8,263); CIN3 (0.04%; 3/8,263), and cancer (0.0%; 0/8,263) were lower compared to those from initial screen (Table 1; Fig. 1). Thus, one round of VIA/VILI detected over half (57.7%) of CIN2 lesions, most CIN3 lesions (89.3%), and all cancer cases (100%) (Table 2), and the distributions of diagnoses were significantly different between initial and follow-up screening ($T = 76348677$, $P < 0.0001$) (Table 1).

Age-stratified CIN1+ results

Women diagnosed with CIN lesions were similar in age. The mean age of women diagnosed with CIN1 was 37.1 years [standard deviation (SD): 4.7 years]; CIN 2 was 37.4 years (SD:

5.7 years) and CIN3 was 37.0 years (SD: 4.5 years). Thus, the mean age of women diagnosed with CIN2+ lesions was 36.8 years (range 30–55 years) (data not shown).

Discussion

Well-organized, comprehensive cytology-based screening programs have been shown to reduce the cervical cancer incidence by up to 80% [1]. However, in many low-resource settings, including rural China, these programs are infeasible as they require extensive infrastructure to collect, store, and transport samples in addition to highly trained cytotechnologists to read the samples [3]. VIA/VILI is a cheap, simple, and rapid screen-and-treat method that does not require equipment or extensive training [8]. Moreover, recent studies show the sensitivity and specificity of VIA varies from 55.55 to 96% and 44 to 94.6%, respectively, and the sensitivity and specificity of VILI varies from 36.3 to 87.2% and 48.93 to 96.2%, respectively [9–13], indicating that VIA/VILI is a relatively effective screening tool for CIN and cervical cancer.

This large population-based screening study evaluated the effectiveness of VIA/VILI in a region in China without an existing cervical cancer screening program. In a study population of over 10,000 rural Chinese women aged 35 to 59 years, 56 participants were diagnosed with CIN2+ and provided with appropriate follow-up treatment, demonstrating that VIA/VILI is a feasible, effective intervention that decreases the cervical cancer burden in China. Thus, data from this study population support the results from a recent worldwide meta-analysis [5] and cluster randomized controlled trial in India [14], which both found VIA/VILI to be a technically undemanding, inexpensive, screen-and-treat intervention for cervical cancer in low-income communities without access to medical care.

This study also explored the effectiveness of one-time VIA/VILI screening compared to multiple rounds of VIA/VILI. Our data indicate that one-time VIA/VILI detects more than half of CIN2 lesions (57.7%), most CIN3 lesions (89.3%), and all cervical cancers, generally supporting results from a similar study in rural China [4], which diagnosed the same proportion of CIN2 lesions (53.45%) but fewer CIN3 lesions (68.81%) and cervical cancer cases (91.67%) in one-time VIA/VILI screening. The differing detection rates of CIN3 lesions and cervical cancer cases in our follow-up screen compared to those from the prior study could be secondary to population-based differences in cervical cancer prevalence in the two populations. Indeed, the prior study was conducted in Shanxi Province [4], where rates of cervical cancer are among the highest worldwide [15], so it is likely that their population is at higher risk for cervical cancer compared to ours. Another explanation for the discordance between this study and prior research in China is that recent data from Tanzania indicate VIA positivity increases immediately after training and retraining of practitioners [16]. Health providers in our study were newly trained to conduct VIA/VILI and were retrained every 3 months during the program; comparatively, practitioners in the Shanxi Province studies had been trained and retrained for VIA/VILI since 1999 [15]. Differences in VIA/VILI training could correlate to the varying rates of CIN and cancer detection between populations as well as explain the low detection rate of CIN lesions in our study. Only 1.39% of all women were diagnosed with CIN-lesions or cervical cancer on colposcopy, but 10% of all women had positive VIA/VILI and were referred for colposcopy.

Medical professionals who conducted VIA/VILI in our study may have over-diagnosed disease prevalence, resulting in a markedly decreased specificity of VIA/VILI compared to other studies [15, 16].

In this study, age was found to be independent of the grade of cervical lesion. Historically, the morphologic progression from low-grade CIN1 to high-grade CIN2 and CIN3 to cervical cancer correlates with increasing age [17]. However, the average age of CIN1 (37.1 years), CIN2 (37.4 years) and CIN3 (37.0 years) was similar in our study population, directly contradicting the historic data [17] as well as the previous study in China [4]. A possible explanation is due to the low sensitivity of VIA/VILI among older women, especially post-menopausal women [14]. More research is needed to determine whether our finding is reflective of population-based CIN prevalence in Chongqing. Nevertheless, the age range of women diagnosed with CIN and cervical cancer in our study was within the age range established in prior studies as the target range for effective cervical cancer screening programs [14].

There were several strengths to this study. First, the healthcare professionals who conducted VIA/VILI were trained by national experts and retrained every 3 months by provincial senior physicians, likely resulting in a relatively consistent level of disease detection throughout initial and secondary VIA/VILI [16]. Second, our large study population included women living in rural, suburban, and urban districts of Chongqing, providing a sample size that is more representative of this area compared to prior conducted solely in rural areas [4, 15]. Potential limitations to this study include a loss of follow-up of nearly 20% of women who were either screen-negative or diagnosed with CIN1 in initial screen. We believe, however, that our large sample size of women who returned for secondary screening still allows us to report on the capacity for VIA/VILI to detect CIN and cervical cancer on secondary screening.

VIA/VILI is a primary cervical cancer screening method that does not require advanced technology or specially trained experts. As other more sensitive and specific screening methods, like cytology screening and HPV DNA testing, are not economically or logistically feasible in underdeveloped rural regions worldwide, reducing the cervical cancer burden in these areas can only be achieved by widespread population coverage with VIA/VILI. This study supports prior research [4, 14, 18] concluding that one-time screening of VIA is a cost-effective technique appropriate in developing countries. As this VIA/VILI screening campaign was designed and implemented in an economically underprivileged geographic region in China, we believe this study could serve as a model for implementing similar cervical cancer screening interventions in other low-resource settings in China and worldwide.

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FHZ and YLQ had full access to all the data in the study and take responsibility for the accuracy of the data analysis. RL, QZ, FHZ, and AKL organized the study's concept and design. ML acquired the raw data, RL and AKL analyzed and interpreted the data. AKL, RL, and FHZ drafted the manuscript. FHZ and QZ revised the manuscript. RL and SYH did statistical analyses. The authors wish to thank the local doctors and women who participated in our study. This work was supported by the Fogarty International Clinical Research Scholars Program

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Fig. 1.
Flow-chart of screening procedures and prevalence of cervical intraepithelial neoplasia (CIN) and cancer in 10,269 Chinese women

Table 1

Detection rate of cervical lesions in the two consecutive screenings among the population of 10,269 women during 2006–2010

Screening type	Disease status					
	Number of women	Normal* % (n)	CIN1 % (n)	CIN2 % (n)	CIN3 % (n)	Cancer % (n)
Initial	10,269	99.0 (10,166)	0.59 (61)	0.15 (15)	0.24 (25)	0.02 (2)
Follow-up	8,263	99.52 (8,223)	0.31 (26)	0.13 (11)	0.04 (3)	0.00 (0)

Wilcoxon test

$T = 76348677, P < 0.0001$

Includes VIA/VILI negative women and VIA/VILI positive but histopathology normal women

Table 2

Proportion of cervical lesions detected in the two rounds of screening among a population of 10,269 women

Screening type	CIN1 % (n)	CIN2 % (n)	CIN3 % (n)	Cancer % (n)
Initial	70.1 (61)	57.7 (15)	89.3 (25)	100.0 (2)
Follow-up	29.9 (26)	42.3 (11)	10.7 (3)	0.0 (0)
Total	100.0 (87)	100.0 (26)	100.0 (28)	100.0 (2)

Diagnosis based on histopathology