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Evaluation of the utilization of primary healthcare staff for control of oral cancer: A Sri Lankan experience

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Abstract

Background: Population-based screening programmes utilizing primary healthcare (PHC) staff have been undertaken in several countries with high incidence of oral cancer and oral potentially malignant disorders (OPMDs).

Objective: The main objective of this study is to re-evaluate the utilization of PHC staff for the detection of OPMD and the early detection of oral cancer.

Methods: A cross-sectional community-based study was done in the Sabaragamuwa province in Sri Lanka by conducting interview and oral examination on 1029 subjects aged 30 years or more, over a 1 year period from November 2006. The study protocol included an interviewer-administered questionnaire to gather sociodemographic factors and lifestyle habits. A 2-day training programme involving didactic sessions followed by practical field training was held for all local PHC staff ($n = 67$). Subjects screened by PHC staff were re-examined by the principal investigator (PI) to assess the validity of the screening.

Results: A total of 685 subjects were screened by both PHC staff and the PI. In terms of the detection of any abnormality, sensitivity of the screening by PHC workers was 63%, with a specificity of 82.6%, a positive predictive value (PPV) of 24.8% and negative predictive value of 96.1%. Of the various OPMDs, poor agreement was noted in the detection of early oral submucous fibrosis. Among intra-oral sites missed by PHC staff, surprisingly high numbers were in the buccal mucosa and commissures.

Conclusion: Low sensitivity and PPV in the present study indicate the necessity for improved training and facilities for better visualization of all intra-oral sites and/or an entirely different approach. An alternative strategy based on determining risk factors in the lives of individuals, with referral to local government dental clinics, could be a better option for screening for early detection of oral cancer in the South Asian scenario.

Keywords

Oral cancer, oral potentially malignant disorders, screening, early detection, risk factors

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Introduction

Oral (ICD-10, C00-C08) and oropharyngeal cancers (C09-10, C12-14) taken together represent the ninth most common cancer in the world: there were some 442,760 new cases worldwide in 2012. In men, this represents the 8th most common cancer in the world with 314,106 cases and in women, this is 14th with 128,654 cases in 2012.[1] According to GLOBOCAN 2012, it was estimated that 241,418 deaths were due to oral and

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other pharynx cancer, constituting the 11th most common reason for global cancer deaths.[1] It also estimated that 56% of the world's oral and other pharynx cancer burden is from Asia. In Sri Lanka, the incidence of oral and other pharynx cancer was 15.5 per 100,000 population; 3981 cases were estimated in 2012.[1]

According to the National Cancer Registry, 2009, the incidence of cancer of the oral cavity and oropharynx in Sri Lanka, excluding salivary neoplasms, standardized to the world population, was 19.4 and 5.2 per 100,000 population in males and females, respectively. About 13.6% of all reported cancers were oral cancers, carrying the highest number of deaths among all types of cancers.[2]

Oral and pharyngeal cancer is often preceded by oral potentially malignant disorders (OPMD). The global prevalence of OPMD has been reported at 1–5%,[3] but higher prevalences are described from south and south–east Asia, with male preponderance, for example, Taiwan (12.7%),[4] and in some Western Pacific countries, for example, Papua New Guinea (11.7%).[5] In Sri Lanka, the prevalences of oral leukoplakia and of oral submucous fibrosis (OSF) were reported as 26.2 and 4.0 per 1000, respectively.[6] Such wide geographical variations are due to lifestyles specific to the country or region. Betel quid chewing, comprising principally areca nut (and often other condiments), with or without tobacco, is a major risk factor for the causation of oral cancer and OPMD in the South Asian region.[7]

Screening is offered as a method of early detection for diseases with a long latency period. In Sri Lanka and some other low- and middle-income countries, an extensive network of primary healthcare workers (PHCWs) exists: a cadre drawn from local residents with training mainly in midwifery, mother and childcare, nutrition and immunization. A population-based screening programme utilizing PHC staff was trialled in Sri Lanka in 1984: this showed a sensitivity of 95% for the detection of oral cancer and what was then termed precancer, using professional oral medicine specialists as gold standard.[8] The utility of oral visual screening was later established in the Trivandrum oral cancer screening (TOCS) studies conducted in Kerala, India in the 1990s. The TOCS protocol included three rounds of oral visual screening a year apart by trained clinicians. This randomized controlled trial subsequently revealed a significant 34% reduction in oral cancer mortality among the high-risk group of tobacco and/or heavy alcohol users in the general population, because of the opportunities for early intervention, including habit cessation and treatment where necessary.[9] Historically, oral visual screening has been implemented in national cancer screening programmes in Cuba, Malaysia and Taiwan. The Cuban investigators observed downstaging – a size shift – in oral cancers detected by screening, with a significant reduction in the prevalence of advanced oral cancer over time.[10] Mouth self-examination using a mirror has also been evaluated as a screening tool in a few studies,[11,12] but whether this could reduce mortality from oral cancer is not known.

In Sri Lanka, in spite of the encouraging results mentioned earlier, there have been obstacles to widespread adoption of the approach utilizing PHC staff. There are no clear, nationally accepted, guidelines as to the responsibilities of PHC staff for screening the mouth, and there have been no comprehensive, continuing training programmes. Importantly, it has never been defined as to which individuals in communities, be they rural or urban, should be examined. A heavy workload, devolution of all vertical preventive programmes to the provincial level, and inadequate availability of standardized education and assessment systems for health workers have contributed to the demise of oral screening across the nation.[13] Doubts exist as to the ability of PHC staff to detect significant OPMD and/or malignant lesions, especially at the early stages.

Therefore, the aim of the present community-based study is to reassess the validity and reliability of screening through PHC staff for the detection of OPMD and the early detection of oral cancer.

Subjects and methods

A cross-sectional community survey, employing a house-to-house method, to screen for OPMD and oral cancer was conducted in the Sabaragamuwa province throughout 2006. Ethical approval was obtained from the Faculty of Medicine, University of Colombo, and subjects signed their informed consent before data collection. The population is described in detail elsewhere: approximately 87% lived in small villages and were employed in farming; around 9% lived and worked on tea and rubber estates.[14]

A 2-day training program was conducted according to a lesson plan for all local primary healthcare (PHC) staff, consisting of 35 public health midwives (PHM), 7 public health inspectors (PHI) and 25 health volunteers (HV) in each of the selected Medical Officer of Health (MOH) areas. At a local MOH facility, they were instructed on the nature, range and classification of oral mucosal lesions and on the risk factors involved. At the end of training, participants' knowledge was tested by requesting them to identify both normal and abnormal oral mucosa in photographs and name any lesions seen. At the end of the programme, PHC staff were given a manual containing instructions on how to complete the questionnaire dealing with demographics, lifestyle and any areca nut/betel quid, tobacco, alcohol and other habits of participants. Within a month of the course, a field training program was conducted to familiarize staff with the interview processes and the method for screening the mouth.

Using a multistage, stratified, clustered sampling technique, the screeners approached people aged 30 or more residing permanently in the cluster. Subjects who declined to participate or were unable to provide accurate data because of sickness or infirmity were excluded. The study was conducted over a year starting from November 2006. During this period, we approached 1118 subjects and an interviewer-administered questionnaire was applied to collect sociodemographic and lifestyle variables. Of these, 8% declined to participate in the screening, leaving a study sample of 1029. Of these, 685 subjects complied with the double examination

Table 1. Staging of OPMD and oral cancer by PHC staff and the corresponding clinical diagnosis.[a]

Staging by PHC staff	Clinical diagnosis	Subjects detected number (%)
Normal	Normal mucosa	540 (78.8%)
Stage 1	Low-risk cases: homogenious leukoplakia and lichen planus	86 (12.5)
Stage 2	High-risk cases: Non-homogenious leukoplakia, erosive lichenplanus and submucous fibrosis	58 (8.5)
Stage 3	Oral cancer already treated	1 (0.1)
Total		685

OPMD: oral potentially malignant disorders; PHC: primary healthcare.
[a]Stages 1–3 is an adaptation the first PHC study in Sri Lanka (Warnakulasuriya et al.[8]).

of the mouth by both PHC staff and, some days later, by the principal author (PI).

First, PHC staff examined subjects under natural light without using any instruments and categorized abnormalities according to the stages shown in Table 1, this being an adaptation of the first PHC study in Sri Lanka by Warnakulasuriya et al.[8] Stage 1 refers to low-risk cases, stage 2 to high-risk cases of OPMD and stage 3 is overt oral cancer cases. Immediately after, the PI examined the same subjects under natural light using a mouth mirror, tweezers and gauze when needed. The diagnostic criteria for the detection of OPMD, such as leukoplakia, erythroplakia, OSF and lichen planus, were based on the recommendations of World Health Organization.[15–17] Definitions of these conditions and descriptions of sampling and data collection methods are described elsewhere.[14]

All cases identified were referred to the nearest government hospital for confirmation of diagnosis and further management by oral maxillofacial (OMF) surgeons, where biopsies were performed for histopathological diagnosis. Moreover, 40% of the cases were re-examined by OMF surgeons to evaluate the accuracy of detection of OPMD by the PI: this revealed near-perfect agreement ($\kappa = 0.9$).

Statistical analysis

Data were recorded manually, using the pretested questionnaire, and entered into the SPSS 17 software package, which was used for all statistical analyses. The relationships between two categorical variables and validity of the screening test were calculated in terms of sensitivity and specificity.

Results

A total of 685 subjects were screened by both PHC staff and the PI as shown in Table 1. Of these, 540 (78.8%) were labelled as healthy, leaving 145 subjects (21%) detected as abnormal by the PHC staff. Of the latter, 12.5% were regarded as stage 1 and 8.5% as stage 2. Of those regarded as abnormal, 39 subjects (5.7%) were diagnosed as leukoplakia, 12 (1.7%) as having OSF and four subjects (0.6%) as suffering from oral lichen planus.

According to the clinical diagnosis by the PI, 109 (17%) of the initial 540 subjects regarded as normal by the PHCWs were identified as abnormal by the PHC staff. Moreover, 3.8% (21 subjects) of the abnormalities were classified as normal by PHC staff. One case of oral cancer was identified as stage 2 and 36.6% (15cases) of the homogenous leukoplakia and lichen planus were identified incorrectly by the PHC staff. Moreover, 50% (six cases) of OSF were classified as normal by PHC staff and other six cases of OSF were classified as stages 1 and 2 (Table 2).

Validity of the detection by PHC staff

Sensitivity of screening by PHCW, compared to the PI as gold standard, was 63%, with a specificity of 82.6%, a positive predictive value (PPV) of 24.8%, a negative predictive value (NPV) of 96.1%, a false positive rate (FPR) of 17.3% and a false negative rate (FNR) of 36.2% (Table 3).

Mucosal sites of the diagnosis by PI and missed in screening by PHC staff

Abnormalities in different sites in the oral cavity were recorded by both PHC staff and the PI. Table 4 shows the sites of lesions identified by the PI, when considering two disorders: leukoplakia and lichen planus. Owing to the extent of the lesions, multiple sites were recorded in the same subjects. The majority of the lesions were on buccal mucosa (34.5%) and the commissures (32.7%; Table 4). Ten lesions (9.1%) were identified on the gingiva and eight lesions (7.2%) were identified on the tongue.

However, a total of 28 intra-oral sites having lesions were missed by the PHC staff: 11 (39%) buccal mucosal lesions, 5 (18%) lesions on the gingiva, 5 (18%) lesions on the alveolar mucosa, 4 (14%) commissural lesions, 2 (7%) lesions on the floor of the mouth and 1 (3.6%) lesion on the ventral surface of the tongue.

Discussion

In Sri Lanka, curative and preventive healthcare services are provided mainly through government health services free of charge to the public. The PHC staff attached to the medical officer health areas are responsible for providing preventive care services to the public in villages and the agricultural estates. In the estate sector, some non-governmental organizations are also helping to provide free health services to the inhabitants. PHM, PHI and these HV represent the grass-root level of health workers and are collectively referred to as PHC staff. This team is responsible for the all the preventive health programmes that are conducted in their areas, but in the recent past, these teams are overburdened by additional work with the devolution of vertical programmes from the Ministry of Health to the provincial level. The main focus of these cadres is on

Table 2. Comparison between clinical diagnoses of the subjects screened by the PHC staff and PI.

Staging as given by the PHC staff	Clinical diagnosis of the PI – number (%) according to the PHC staff staging					
	Normal	Stage 1 (HL and lichen planus)	Stage 2 (NHL and erosive lichen planus)	Stage 2 (OSF)	Stage 3 (Oral cancer)	Total (%)
Normal	519 (82.6)	15 (36.6)	0	6 (50)	0	540 (78.8)
Stage 1	65 (10.3)	18 (43.9)	0	3 (25)	0	86 (12.6)
Stage 2	44 (7)	8 (19.5)	2	3 (25)	1 (50)	58 (8.5)
Stage 3	0	0	0	0	1 (50)	1 (0.1)
Total	628	41	2	12	2	685

PHC: primary healthcare; PI: principal investigator; HL: homogenious leukoplakia; NHL: nonhomogenious leukoplakia; OSF: oral submucous fibrosis.

Table 3. Relationship between the identification of abnormalities by PHC staff and results of the examination by PI.[a]

Identification of abnormalities by PHC staff	Identification of abnormalities by PI-number		
	Positive	Negative	Total
Positive	36	109	145
Negative	21	519	540
Total	57	628	685

PHC: primary healthcare; PI: principal investigator.
[a]Sensitivity = 63%; specificity = 82.6%.

Table 4. Distribution of the intra-oral sites diagnosed by PI and sites missed in screening by PHC staff.

Site of the lesions	Number of sites correctly diagnosed by PI	Number of sites missed in screening by PHC staff
Lip	0	0
Commissure	36 (32.7)	4 (14.3)
Tongue dorsal and lateral	6 (5.4)	0
Tongue ventral	2 (1.8)	1 (3.6)
Buccal mucosa	38 (34.5)	11 (39.3)
Palate	2 (1.8)	0
Retro molar area	6 (5.4)	0
Gingiva	10 (9.1)	5 (17.8)
Alveolar mucosa	5 (4.5)	5 (17.8)
Floor of the mouth	5 (4.5)	2 (7.1)
Total	110	28

PHC: primary healthcare; PI: principal investigator.

maternal and child health. The time available for cancer screening is consequently very limited.

The Alma-Ata declaration highlighted the PHC approach as the most efficient and cost-effective way to organize a health system.[18] Utilization of PHC staff for early detection of oral cancer is justifiable in countries where the professional dental manpower is insufficient and is consonant with the Alma-Ata declaration.

Although this study was performed a decade ago, it remains relevant, because the range of duties of these PHC staff has been expanded further: they would have less time, and inclination, now to engage in the deeper training and subsequent field work, which is clearly necessary.

Utilization of the PHC staff for 'oral visual examination' for the early detection of oral cancer and 'precancer' was shown to be effective in our pioneer study in Sri Lanka in 1984.[8] Such programmes have not been sustained over the intervening decades mainly for lack of staff time and poor diagnostic accuracy for some lesions. Therefore, it is timely to suggest an alternative approach. Screening of people based on risk factors and risk markers could be such an alternative strategy. PHC staff can be used to detect high-risk people according to the risk and referral could be made to the nearest dental professional (dental clinic) to confirm PHC findings. This approach would overcome the problem of poor diagnostic accuracy and lack of staff time. We have devised, and evaluated, a risk factor model suitable for this purpose.[19] Its application should now be tested in respect of its cost-benefit and cost-utility in the Sri Lankan and, with modification, in other populations.

In this study, PHC staff performed oral screening without using any instruments (i.e. mouth mirrors) and under natural light, and this service was provided without any additional service delivery payment. These factors may have contributed to the low sensitivity and high level of FNR of the PHCW diagnoses in the present study, compared to previously published studies from Sri Lanka and India (See Table 5).[8,13,20,21]

Identification of early submucous fibrosis is made according to the consensus criteria from a Workshop held in Kuala Lumpur, Malaysia, in 1996.[16] That Committee recommended that OSF could be diagnosed on the basis of one or more of the following characteristics: palpable fibrous bands, the mucosal texture feels tough and leathery and blanching of the mucosa together with histopathological features. In our experience, some early stages appear as blanching of the lip with tiny circumoral fibrous bands, with or without depapillation of the tongue, and hypo- and/or hyper-pigmentated patches on the buccal mucosa. Although we have trained PHC staff to recognize the early signs of OSF, it is very difficult to visualize those changes with minimal training: Six cases of OSF were missed by PHC staff. These were mostly early cases: nevertheless, their detection in a screening programme is important to prevent future suffering. On the other hand, all symptomatic cases of OSF were diagnosed by PHC staff.

Table 5. Comparisons between studies conducted in Sri Lanka and India for utilization of PHC staff for early detection of oral cancer.

	Present study in 2007, Sabaragamuwa Province, Sri lanka	Warnakulasuriya et al.,[8] in Central province Sri Lanka	Warnakulasuriya and Nanayakkara,[20] in Galle district Sri Lanka	Mehta et al.,[21] in India	Amarasinghe et al., 1995[13] in Kalutara, Sri Lanka	
					3 MOH areas	33 estates
Duration of the screening	1 year	1 year	1 year	9 months	1 year	1 year
Target population	Rural and estate adults	Rural adults	Rural adults	High-risk adults	Rural adults	Rural adults
Population screened	1029	29,295	57,124	39,331	6338	9624
Screening setting	Homes	Homes	Homes	Homes	Homes	Homes
Seen by both PHC staff and dental professionals (%)	66.5	50	62	72	29	69
Sensitivity (%)	63.1	95	97	59	–	–
Specificity (%)	82.6	81	75	98	–	–
Positive predictive value (%)	24.6	58	80	31	34	27

PHC: primary healthcare; MOH: Medical Officer of Health.

Coincidentally, it is important to note that most patients with OSF who complained of a burning sensation of the mouth had been diagnosed as having iron deficiency anaemia by medical officers in these geographical areas prior to our screening program and had been treated for this before our study. In this scenario, it is reasonable to question all individuals diagnosed with anaemia regarding their consumption of areca nut, because habit cessation is essential to prevent further progression of this incurable disease. This observation also highlights the necessity of training Medical officers on this, and other aspects of oral diseases, as argued by ourselves earlier.[22] An increasing trend of OSF is reported in Sri Lanka;[7] therefore in the present context all medical, dental professionals and all health staff should be trained specially to diagnose OSF in its early or mild stages.

In this analysis, we looked into whether any particular intra oral sites were missed by PHCWs during their screening examination. This was made possible because the same subjects were examined by PHC and PI without any time lapse. Differences observed in the diagnosis of the site of the abnormalities were mainly due to the examination methods: Mouth mirror and gloves used by the PI, whereas PHC staff examined the oral cavity by asking subjects to show the different site by retracting their soft tissues with their own fingers. PHC staff missed a substantial number of buccal and commissural lesions, accessible sites which should be easy to visualize. During retraction of the soft tissues by patients' fingers, these sites may be inadvertently covered and this needs emphasis in training.

Two day programmes have been shown to be feasible to train PHC staff in case detection.[8,20] However, additional training regarding the early signs and symptoms of OSF seems to be desirable. We highlight oral sites often missed by PHC staff which should receive emphasis during training.

Study limitations

Although we have included 1029 subjects for this study only 685 subjects were screened by both PI and PHC staff. We could have generated an improved data set if all subjects had been so screened.

Conclusions

The present study shows that implementation of oral screening through existing primary health staff needs strengthening. We propose that a strategy based on determining the risk factors present in the individual subject would be a logical solution for the early detection and prevention of oral cancer in these high-risk populations.[14]

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Declaration of Conflicting Interests

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Translational value of the study

Although the early detection of oral cancer is entirely feasible, more than 70% of the cases currently reported to the cancer treatment centres in Sri Lanka are in stages III or IV of the Tumor, Nodes and Metastasis (TNM) classification.[2] In low- and middle-income countries, a fully qualified dental workforce is insufficient to undertake population screening. To fill this gap, PHC staff may be suitable, provided they received adequate training. Several studies have shown the feasibility of utilizing primary healthcare (PHC) staff, but detailed analyses of shortcomings are missing. The present evaluation demonstrates substantial gaps in detection of oral potentially malignant disorders by PHC staff. This is particularly true for the early stages of OSF, a disease that is increasing in South and South East Asia. Moreover, in oral visual screening, some areas are frequently obscured due to improper tissue retraction. The translational value of this study finding is to highlight the difficulties in utilizing PHC staff for oral visual screening and to propose alternative methods for better utilization of such staff for early detection of oral cancer.