

## Prevalence and Associated Factors of Cervico vaginal HPV Infection Among 35 Year Age Cohort Ever-Married Women in a District of Sri Lanka: A Cross- Sectional Study

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### Abstract

**Introduction:** All cervical cancers are virtually associated with sexually transmitted cervicovaginal Human papillomavirus (HPV) infection. The objective of the study was to determine the prevalence and associated factors of cervicovaginal HPV infection among ever-married women.

**Materials and methods:** A community based descriptive cross-sectional study was conducted from 1st of July 2018 to 30th November 2018. The study population comprised of ever-married women 35 years of age in Kalutara district. Three women from each cluster (n = 413) were selected by consecutive sampling. A total of 918 women were recruited. HPV/DNA cervical specimen collection (n = 822) was carried out. Cervical specimens were tested by well-trained cyto-screener with the cobas 4800 HPV/DNA automated Polymerase Chain Reaction (PCR) machine. Interviewer administered questionnaire was used to gather information regarding socio-demographic, reproductive health, contraceptive methods, and sexual behaviors. Multivariate logistic regression was performed and expressed as odds ratio (OR) and 95% confidence interval (CI).

**Results:** The prevalence of the HPV infection was 6.2% (95% CI: 6.18%-6.22%), while the prevalence of high-risk genotypes 16 and 18 was 1.94% (95% CI: 1.93%-1.95%). The prevalence of 12 pooled high-risk HPV infection was 4.14% (95% CI: 4.13%-4.15%).

Age at marriage  $\leq 24$  years (OR = 4.04, 95% CI: 1.75-9.34), history of any abortion (OR = 10.1, 95% CI: 3.07-33.7), use of hormonal contraceptives for  $\geq 3$  months (OR = 45.5, 95% CI: 18.7-110.5) and number of vaginal deliveries  $> 2$  (OR = 9.7, 95% CI: 3.7-25.2) were significantly associated with HPV infection, while average monthly income  $> Rs. 15,000$  (OR = 0.12, 95% CI: 0.04-0.32) and ever use of condom by spouse (OR = 0.04, 95% CI: 0.01-0.16) were found to have a significant protective association with HPV infection in the logistic regression model.

**Conclusions:** Prevalence of carcinogenic HPV infection among ever-married women of 35 years old was high. The generalizability of the research findings to the whole country can be done as population characteristics and public health infrastructure of the district are more or less similar to other districts in Sri Lanka. HPV/DNA screening as a primary cervical cancer screening method should be considered in Sri Lanka after careful assessment of its feasibility.

**Keywords:** Cervical cancer, Human papillomavirus infection, Prevalence, HPV/DNA screening

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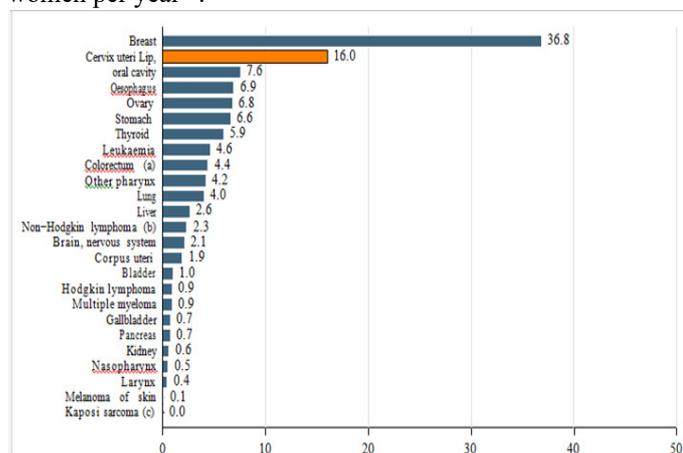
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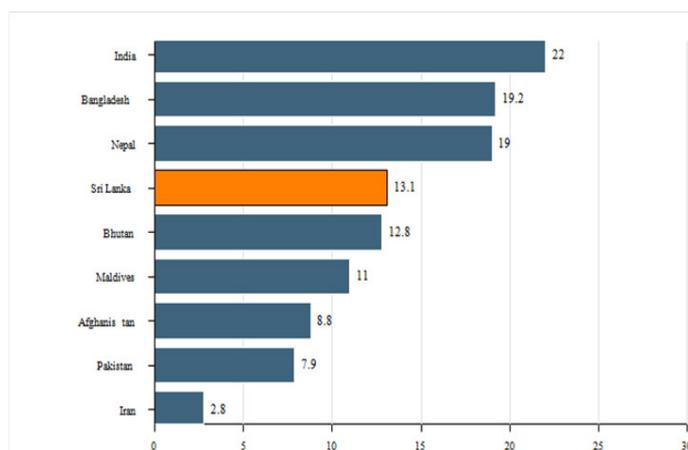
## Introduction

Cervical cancer is the fourth commonest cancer among females worldwide and it contributes to 15.1% of all female cancers<sup>[1]</sup>. According to 2012 estimates indicate, that annually 527,624 women are diagnosed as having cervical cancer. Out of total female cervical cancers, 284,823 cases were diagnosed in Asia with an age-standardized incidence rate (ASR) of 12.7 per 100,000 women per year, while the highest number was recorded in Southern Asia (145,946 cases) with an ASR of 22 per 100,000 women per year<sup>[1]</sup>.

Cervical cancer is the second commonest female cancer in Sri Lanka (Figure 1) and it contributes to 10% of all female cancers. According to the 2012 estimates, the ASR of the cervix uteri among Sri Lankan women was 13.1 per 100,000 (Figure 2) women per year<sup>[1]</sup>.



**Figure 1:** Comparison of cervical cancer incidence to other cancers in women of all ages in Sri Lanka. Adapted from “Human papillomavirus and related disease report, Sri Lanka” by WHO, 2017, p 7.



**Figure 2:** Comparison of age-standardized incidence rates of cervical cancer of Sri Lanka across Southern Asia. Adapted from “Human papillomavirus and related disease report, Sri Lanka” by WHO, 2017, p 12

In 1998, Sri Lanka took an initiative to include screening for cervical cancer with conventional papanicolaou (pap) smear in the Well Woman Clinics (WWCs). However, even after 20 years of cervical cancer screening (with pap smears), there is no marked reduction in incidence, morbidity, and mortality of cervical cancer in Sri Lanka. One major drawback of the present cervical cancer screening programme is suboptimal sensitivity (53%)<sup>[2]</sup> of the pap smear to detect cervical lesions. Therefore

the National Cervical Cancer screening programme needs to review with special attention.

All cervical cancers are virtually associated with exclusively sexually transmitted human papillomavirus (HPV) infection. Most women even infected with high-risk HPV types never develop cervical cancer, as most of these infection regardless of HPV type are short-lived and the body eliminates them spontaneously in  $\leq 2$  years. A small percentage of women with high-risk HPV infection can have persistent infection and progress into pre-cancer and even fewer women will progress to have invasive cancer<sup>[3]</sup>.

More than a hundred and fifty HPV genotypes have been identified to date and nearly 60 different types of them are known to infect the human genital tract including cervix uteri. There are carcinogenic and non-carcinogenic genotypes and 10-15 carcinogenic genotypes are mainly associated with cervical cancer<sup>[4]</sup>. Some carcinogenic genotypes are classified as “high risk” (16,18,31,33,35,39,45, 51,52, 56,58, and 59) as there is evidence of increased risk association between high-risk HPV infection and cervical cancer<sup>[5]</sup>. Compared to other carcinogenic genotypes of HPV infection, genotypes 16 and 18 have 190 times increased risk of developing cervical cancer<sup>[6]</sup>. Besides, HPV genotypes 26, 53, 66, 68, and 72 are considered as possible carcinogens but their role related to cervical carcinogenesis is unclear<sup>[7]</sup>.

Factors favoring HPV infection are not well defined and the following risk factors probably play a role; genotype of the HPV and its oncogenicity, commencement of sexual activity at an early age, multiple sexual partners, a partner who participate in high-risk sexual activities, immune suppression acquired or primary, poor socio-economic status- poor hygiene and connection with other sexually transmitted agents<sup>[3]</sup>.

The risk of HPV infection was higher in women aged 25 to 34 years, in married women below 20 years of age, and women with parity > 4. Prevalence of HPV genotype 18 (1.4%) was greater than that of HPV genotype 16 (0.6%)<sup>[8]</sup>. The prevalence of HPV infection among the general populations varies from 7%-14.5% and the age-specific prevalence across age groups is constant with no clear peak in young women in India, Bangladesh, Nepal, and Sri Lanka<sup>[9]</sup>. Overall cervicovaginal HPV prevalence in 2009 among 20-59 years old ever-married women in Gampaha district was 3.3% in Sri Lanka<sup>[10]</sup>.

The sensitivity of the HPV/DNA screening test is high<sup>[11]</sup>. The HPV/DNA test is used to detect cervicovaginal HPV infection of women in some developed countries<sup>[3]</sup>.

The objective of the study was to determine the prevalence and associated factors of cervicovaginal HPV infection among 35 year age cohort of ever-married women in a district in Sri Lanka, which would enable to find the primary preventive measures for human papillomavirus infection and to assess the suitability of HPV/DNA screening test as a cervical cancer screening method.

## Materials and Methods

### Study setting and population

A community-based cross-sectional study was conducted from 1<sup>st</sup> of July 2018 to 30<sup>th</sup> November 2018. The study population comprised of ever-married women in 35 year age cohort in Kal-

utara district.

### Exclusion criteria

Women with diagnosed invasive cervical cancer, per vaginal bleeding, active infection at the time of examination evidenced by medical records or by visual inspection, who were currently on treatment for HPV infection, pregnancy,  $\leq$  three months in the postpartum period, and who had undergone hysterectomy were excluded from the study.

### Sample size calculation

For the calculation of the sample size, we assumed that the expected prevalence of HPV was 3.3%<sup>[10]</sup> and the degree of accuracy desired specified as 0.016 ( $3.3/100 \times 2$ ). Therefore we needed 479 women. To account for the cluster effect, it was necessary to adjust the required sample size having it multiplied by the design effect, which was taken as 1.1. Further adjustment to the sample size was made by considering the previous year Well Woman Clinic (WWC) non-response rate (42.4%) in the Kalutara district<sup>[12]</sup> and the final required sample size was 915.

### Sampling technique

A Public Health Midwife (PHM) area was taken as a cluster. In the district, there are 413 PHM areas. Eligible couple registers were the sampling frame. Three women were selected from each cluster from the list of 35 year age cohort ever-married women population prepared from relevant area eligible family register/s according to the ascending order of register numbers. We selected the first subject from the list by using a lot method<sup>[13]</sup> and then two more subjects were selected forward and consecutively. A total number of 918 women were recruited to the study after applying exclusion criteria in the field setting.

### Data collection procedure

Information regarding socio-demographic characteristics, reproductive health history, contraceptive history, gynecological history, behavior information of participants, and information on the marital and sexual partners were gathered by using an interviewer- administered questionnaire. Face and content validity were assessed by the panel of experts during the process of questionnaire development. The questionnaire was pre-tested with 15 women at a WWC to identify deficiencies and for necessary modifications.

HPV/DNA cervical specimen collection was carried out by well-trained health care workers at WWCs. Cusco's speculum was inserted to visualize the cervix before obtaining the HPV/DNA cervical specimen. HPV/DNA specimens obtained from the cervix using special broom-like devices were separately placed into HPV/DNA specimen collection containers with cell collection media/thinprep-20 ml (Figure 3). Cervical specimens were packed and transported to the laboratory District General Hospital, Kalutara. Prepared guidelines (supplementary file) strictly adhered to during data collection, barcoding, and preparation for transport. Cervical specimens were screened at the laboratory by well-trained cyto-screener with cobas4800 HPV/DNA automated PCR machine, which consists of cobas 4800x instrument and cob as analyzer. Cobas 4800 HPV/DNA screening machine was included several quality control mechanisms such as internal quality control, external quality control,

and contamination control. Sensitivity and specificity to detect  $\geq$  Cervical Intraepithelial Neoplasia (CIN) II viral load by cobas 4800 HPV/DNA test are 92.9% and 71% respectively<sup>[11]</sup>. It detects 14 high risk carcinogenic HPV genotypes, such as; 16, 18 and 12 pooled high risk (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).



**Figure 3:** HPV/DNA specimen collection instrument: Container with “thinprep cell collection media-20ml” and broom-like device”.

Public Health Midwives (PHMM) were uniformly trained to locate households. A two-day training session was conducted for research assistants (RA) (five pre-intern medical graduates) to familiarize them with proceedings. Research assistant's guide on observation of service provision related to cervical cancer screening programme at the community WWC and the reference laboratory for cytology was distributed. They were uniformly trained to administer an interviewer-administered questionnaire. The questionnaire was administered at a separate and neutral place within the house to maintain the privacy and confidentiality of data collection. Once a questionnaire was completed, the participant was given a clinic appointment card with a reference number and invited to attend the clinic. During the study, 10 participants from each RA were randomly selected and re-interviewed by the first author to assess the reliability. Kappa statistics for each item was a range between 0.96 to 1.00.

Staff training was done to collect cervical HPV/DNA specimens. Videos and guidelines were used for staff training. Instruction regarding accurate numbering of specimens, completion of specimen request forms, and preparation for transport were also included in the training sessions. Two cyto screeners were uniformly trained for specimen barcoding to handle the machine and report writing to ensure the quality of performance. Colposcopists too were uniformly trained to ensure the quality of performance.

### Data entry and statistical analysis

Data were entered by using SPSS version 20. The overall prevalence of the cervicovaginal HPV infection and subgroup analysis (HPV genotype 16, 18, and 12 pooled risk) were estimated.

Bivariate analysis was performed to assess the association of selected factors with cervicovaginal HPV infection. Multivariate logistic regression analysis was carried out to assess the confounding effect of multiple factors associated with the cervico-vaginal HPV infection. The dependent variable was HPV/DNA positive (1) or HPV/DNA negative (0). Independent variables were all variables with  $p < 0.25$  at bivariate analysis. The backward stepwise selection was applied. Results were expressed by p values, OR and 95% CI  $\{(\sqrt{pq/n})^2\}$ . If the p-value  $> 0.1$  in the Hosmer-Lemeshow goodness of fit test, then the model is a good fit<sup>[14]</sup>.

## Results

Eight hundred and thirty-six women attended community clinics. Therefore, the response rate was 91.1%. Fourteen were excluded at the clinic setting due to pregnant status (n = 3), vaginal discharge (n = 4), cervicitis (n = 3), fungal infection (n = 2), and cervical erosion (n = 2). Altogether 822 women were subjected to HPV/DNA cervical specimen collection. Out of 822 participants 9% (n = 74) had not completed years of school education beyond the 5<sup>th</sup> grade and another 12.2% (n = 100) remained at 6-11th grade. The majority (n = 553, 76.2%) were educated up to an advanced level.

Of the 822 participants, 51 had tested positive for HPV infection. Therefore, the prevalence of cervico-vaginal HPV infection among ever-married women of the 35-year old age cohort was 6.2%. The prevalence of high-risk carcinogenic HPV genotypes 16 and 18 was 1.94%, while the other 12 pooled high-risk HPV genotypes were 4.14% (Table 1).

**Table 1:** Prevalence of cervico-vaginal HPV infection in the District

Cervical HPV/DNA specimen results for HR-HPV genotypes	Number of women	Prevalence %	95% CI for the prevalence %
Negative	771	93.8	
12 pooled positive	34	4.14	4.13-4.15
16 positive	14	1.7	1.69-1.71
18 positive	2	0.24	0.23-0.25
16 & 12 pooled positive	1	0.12	0.1-0.13
Total	822	100	

There was a statistically significant protective association between the prevalence of cervicovaginal HPV infection and Sinhala ethnicity (OR = 0.28), Buddhist religion (OR = 0.22), the higher level of education (OR=0.43), and high average monthly income (OR = 0.2). The risk association between the prevalence of cervicovaginal infection and age at married  $\leq 24$  years (OR = 4.1), with  $\geq$  three pregnancies (OR = 3.62) and with  $>$  two vaginal deliveries (OR = 6.91) were statistically significant. There was a statistically significant risk association between the prevalence of cervico-vaginal HPV infection and history of abortions (OR = 5.48), ever use of contraceptives (4.36) and use of hormonal contraceptives for  $\geq$  three months (OR = 9.5), while the association with condom ever used by a spouse was significantly protective (OR = 0.25)(Table 2).

**Table 2:** Association between cervico-vaginal HPV infection and socio-demographic factors, maternal factors, abortion status, contraceptive methods, and sexual relationship

Variable	B	SE	OR, (95%CI)	p-value
Average monthly income				
>15,000				
$\leq 15,000^*$	-2.15	0.51	0.12(0.04-0.32)	<0.001
Age at Marriage				
$\leq 24$ years				
$>24$ years*	1.4	0.43	4.04(1.75-9.34)	0.001
Condom ever user at coitus				
Yes				
No*	-3.15	0.69	0.04(0.01-0.16)	<0.001
Any abortions				
Yes				
No*	2.32	0.61	10.1(3.07-33.7)	<0.001
Contraceptive ever user				
Yes				
No*	1.3	0.73	3.66(0.87-15.3)	0.08
Hormonal contraceptives $\geq 3$ months				
Yes				
No*	3.82	0.45	45.5(18.71-110.5)	<0.001
Number of vaginal delivery				
$>2$				
$\leq 2^*$	2.27	0.49	9.70(3.71-25.2)	<0.001

Maternal factors	HPV+	%	HPV-	%	Total	OR	95% CI	p value
<b>Age at marriage</b>								
≤ 24 years	39	10.3	341	89.7	380	4.1	2.11-7.95	<0.001
>24 years*	12	2.7	430	97.3	442			
<b>Ever pregnant</b>								
No	1	1.9	52	98.1	53	3.62	0.49-26.7	0.18
Yes*	50	6.5	719	93.5	769			
<b>Duration of time between marriage &amp; first pregnancy</b>								
> 5years	11	10.6	93	89.4	104	2	0.99-4.04	0.07
≤ 5years*	40	5.6	678	94.4	718			
<b>Number of pregnancies</b>								
≥ 3	3	20	12	80	15	3.95	1.08-14.48	0.04
< 3*	48	5.9	759	94.1	807			
<b>Mode of delivery</b>								
Vaginal	47	6.5	676	93.5	723	1.65	0.58-4.69	0.34
Non-vaginal*	4	4	95	96	99			
<b>Number of vaginal delivery</b>								
> 2	14	25.9	40	74.1	54	6.91	3.42-13.8	<0.001
≤ 2*	37	4.8	731	95.2	768			

\*Reference category

In the multivariate logistic regression model, age at marriage ≤ 24 years (OR = 4.04), history of any abortions (OR = 10.1), use of hormonal contraceptives ≥ three months (OR = 45.5), and number of vaginal delivery > two (OR = 9.7) were found to have a statistically significant risk association. Average monthly income > Rs. 15,000 (OR = 0.12) and condom ever user at coitus (OR = 0.04) were found to have a statistically significant protective association (Table 3).

**Table 3:** Multivariate logistic regression model of factors determining cervicovaginal HPV infection

Variable	B	SE	OR, (95%CI)	p-value
<b>Average monthly income</b>				
>15,000	-2.15	0.51	0.12(0.04-0.32)	<0.001
≤ 15,000*				
<b>Age at Marriage</b>				
≤ 24 years	1.4	0.43	4.04(1.75-9.34)	0.001
>24 years*				
<b>Condom ever user at coitus</b>				
Yes	-3.15	0.69	0.04(0.01-0.16)	<0.001
No*				
<b>Any abortions</b>				
Yes	2.32	0.61	10.1(3.07-33.7)	<0.001
No*				
<b>Contraceptive ever user</b>				
Yes	1.3	0.73	3.66(0.87-15.3)	0.08
No*				
<b>Hormonal contraceptives ≥ 3months</b>				

Yes	3.82	0.45	45.5(18.71-110.5)	<0.001
No*				
<b>Number of vaginal delivery</b>				
>2	2.27	0.49	9.70(3.71-25.2)	<0.001
≤ 2*				

\*Reference category

Lemeshow goodness of fit test p value = 0.34, p > 0.10

## Discussion

In 1998, conventional papanicolaou smear screening was included in the WWC programme as a cervical cancer screening method. After 20 years of existence of the programme, in contrast to the vigorous preventive measures, there is no marked reduction of incidence, morbidity, and mortality of cervical cancer in Sri Lanka.

Cervical cancer is almost always associated with HPV infection<sup>[3]</sup>. The overall HPV prevalence rate was 3.3% among 20-59 years age ever-married women in Sri Lanka in 2009<sup>[10]</sup>. Therefore, reassessment of the prevalence of cervicovaginal HPV infection among target age cohort women (35years) in Sri Lanka is very important to review the National Cervical Cancer Screening programme with special attention.

There was a marked elevation of the prevalence of the cervicovaginal HPV infection from 2009 (3.3%) in the Gampaha district<sup>[10]</sup> to 2019 (6.2%) in the Kalutara district among the ever-married women population (p = 0.16). Usually, the transient HPV infection rate was high among sexually active women ≤ 30 years of age<sup>[3]</sup>, so the absolute prevalence rates of HPV infection at 35 year age cohort in 2009 may be even smaller than the mentioned data<sup>[15]</sup>. Moreover, high-risk genotypes 16 and 18

prevalence was elevated from 1.2% to 1.94% within the same duration. The prevalence of other high risk HPV genotypes (except genotype 16 and 18) were too markedly increase from 2.1% in 2009<sup>[10]</sup> to 4.14% in 2019.

A prospective cohort study carried in 2004 has revealed the prevalence of cervicovaginal HPV infection is 9.6% among Muslim women and 7.5% among Hindu women in India<sup>[8]</sup>. A study carried out in 2008 regarding the human papillomavirus infection and cervical cancer prevention in India, Bangladesh, Sri Lanka, and Nepal has revealed the prevalence of HPV infection among the general population varies from 7-14%<sup>[9]</sup>. Therefore, the prevalence of cervicovaginal HPV infection among Sri-Lankan females gives a much similar pattern to some countries in South-East Asia.

When the proportion of women tested positive for high-risk HPV/DNA in a country are at least 1%, it indicates a good quality standard for the HPV/DNA screening test as a cervical cancer screening method<sup>[16]</sup>, therefore HPV/DNA screening test can be considered to be incorporated in to the National Cervical Cancer Screening programme in Sri Lanka as the prevalence of high-risk HPV genotypes were  $\geq 1\%$ .

To prevent the cervicovaginal HPV infection, HPV vaccination was initiated into the National Immunization Schedule in Sri Lanka, in July/2017. Two doses of vaccine are given to 10-11- year-old girls (in grade 6) with a minimum interval time of 6 months through a school based vaccination programme to prevent cervical cancer. Even though the sero conversion was 100%, it will take another 25-30 years for the effect of the vaccine benefits to appear. The quadrivalent HPV vaccine was developed to avert risks attributed by genotypes 16 and 18 for cervical cancer prevention (70%), which included protection for non-oncogenic components of genotypes 6 and 11 for the prevention of genital warts and recurrent respiratory papillomatosis. So the rest of the 30% of high-risk carcinogenic HPV viruses are not covered by the present quadrivalent HPV vaccine in Sri Lanka. Vaccine cost remains high for two doses, therefore even if the vaccination against cervicovaginal HPV infection is sustainable screening remains the feasible option to prevent cervical cancer in Sri Lanka<sup>[10]</sup>.

The HPV/DNA screening for cervical cancer is presently available only in some developed countries. Several HPV/DNA screening strategies are used in the world for cervical cancer screening such as; cytology followed by HPV/DNA testing for equivocal cytological results (cytology with HPV/DNA test triage), HPV/DNA testing followed by cytology for positive HPV/DNA screening results (HPV/DNA test with cytological triage-primary screening method), combined HPV/DNA testing with cytology as a co-test.

The prevalence of cervicovaginal infection varies with the ethnicity of the study population in the present study. Similar ethnic differences had been reported in some other countries i.e. Brazil<sup>[17]</sup>. In the present study, the prevalence of cervicovaginal infection was higher among participants with education level  $\leq$  fifth grade and average monthly income of  $\leq$  Rs.15000. It indicates lower awareness of health, ignorance, risky sexual behavior, poor nutrition, and low immunity. In 2011, a study involved in Hong Kong and a region of China has revealed low education and a higher number of sexual partners were significantly associated with the HPV infection<sup>[6]</sup>. A study carried out in Nigeria in 2018 too has revealed the significant association of

the higher prevalence of HPV infection with a lack of formal education and low income<sup>[18]</sup>. Some other studies also had revealed the higher prevalence rates of cervico-vaginal HPV infection among low average monthly income women<sup>[3,10,19]</sup>.

The prevalence of cervicovaginal HPV infection was higher among women, who were married before  $\leq 24$  years of age and frequency of coitus  $\geq$  two times per month, which showed the higher ability of vaginal mucosa to acquire the infection at a younger age and persistence of the infection. Polygamy and younger age at sexual debut are significant risk factors according to a study carried out in Nigeria in 2018<sup>[18]</sup>. Several studies have revealed the higher association of cervicovaginal HPV infection among women who married  $\leq 24$  years of age<sup>[3,8,20]</sup>. The prevalence of cervicovaginal infection was lower among females with ever use of a condom by a spouse, which showed a similar pattern with some other countries i.e. China, India<sup>[18,21]</sup>. The prevalence of cervico-vaginal HPV infection was higher among participants with number of pregnancy  $\geq$  three. A similar association of prevalence with the number of pregnancies was observed in some other countries i.e. Eastern China, India, Nepal, Turkey<sup>[22]</sup>. The prevalence of cervico-vaginal infection was higher among women with vaginal deliveries  $>$  two and a similar pattern of prevalence was observed in a study carried out in Sri Lanka in 2009<sup>[10]</sup>. The prevalence of cervico-vaginal HPV infection was higher among participants with the number of abortions  $>$  two, which gives a similar type of association to a study carried out in Sri Lanka in 2012<sup>[15]</sup>. The prevalence of cervico-vaginal HPV infection was higher among participants, who were on hormonal contraceptives for  $\geq 3$  months. Long term contraceptive use was given as an established co-factor for HPV infection by another report in Sri Lanka<sup>[1]</sup>.

The prevalence of cervico-vaginal HPV infection was increased in Sri Lanka due to poor primordial and primary preventive strategies to address risk behaviors. Further, the present prevalence trend will ultimately increase the risk of cervical cancer more as the present cervical cancer screening programme has two major drawbacks; low sensitivity of the pap test and poor coverage of the programme. Therefore the National Cervical Cancer screening programme in Sri Lanka needs to review carefully.

This study was restricted to one district out of 25 districts in Sri Lanka due to logistic constraints. The population characteristics and the public health infrastructure of the district favored the generalizability of the research findings to the whole country.

## Conclusions and Recommendations

The present study has revealed that the prevalence of cervicovaginal HPV infection among 35 year age cohort of ever-married women was high. Therefore, incorporating HPV/DNA screening test as a primary cervical cancer screening method into the National Cervical Cancer Screening programme in Sri Lanka among 35 year age cohort of ever-married women is highly recommended after careful assessment of its feasibility.

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**Availability of data and materials:** The datasets used to analyze in this study are available at the corresponding author on reasonable request.

**Author's contribution:** KCMP has participated in the design of the study; coordinated data collection performed the statistical analysis, and drafted the version of the manuscript. HTCSA and NM have participated in the design of the study. HTCSA has performed the statistical analysis and interpreted data. Both HTCSA and NM were helped to draft the manuscript. All three authors were read and approved the final manuscript.

**Ethical approval and consent to participate:** Ethical clearance was obtained from the Ethics Review Committee (ERC), National Institute of Health Science (NIHS), Kalutara, Sri Lanka (ref number NIHS/ERC/18/06R). Informed written consent was obtained from each of the selected participants in the field during the study. Confidentiality was highly maintained, while handing over individual HPV/DNA result reports. Administrative clearance to conduct the study was obtained from Provincial Director of Health Services/Western Province, Regional Director of Health Services/Kalutara district, Director/ District General Hospital Kalutara, and Director /National Institute of Health Science Kalutara.

**Consent for publication:** Not applicable

**Competing interests:** The Authors were declared that they have no competing interests

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