Journal of Communicable Diseases
Volume 58, Issue 2 - 2026, Pg. No. 152-170
Peer Reviewed & Open Access Journal

Review Article

Importance of High-Risk HPV in India: Unravelling Genotypic Prevalence, Advanced Diagnostics, and Vaccination Strategies

Mashila A[1], Jothimani Pradeep[2], Sunil Indernath S[3], Prabha P[4], Lavanya L[5], Balasubramanian M[6], Sowmya S[7]

[1]PhD Scholar, MGM Advanced Research Institute (MGMARI), Sri Balaji Vidyapeeth, Puducherry, India
[2]Associate Professor, Microbiology, Mahatma Gandhi Medical Advanced Research Institute, Sri Balaji Vidyapeeth (Deemed-to-be-University), Puducherry, India
[3]Vels Institute of Science Technology & Advanced Studies (VISTAS), Tiruvallur, India
[4]Sri Lalithambigai Medical College & Hospital, Dr M G R Educational and Research Institute, Chennai, India
[5]Swamy Vivekananda Medical College Hospital & Research Institute, Tamil Nadu, India
[6]Mahatma Gandhi Medical Advanced Research Institute, Puducherry, India
[7]Mahatma Gandhi Medical College & Research Institute, Sri Balaji Vidyapeeth (Deemed-to-be-University), Puducherry, India
DOI: https://doi.org/10.24321/0019.5138.202641

I N F O

Corresponding Author:
Jothimani Pradeep, Mahatma Gandhi Medical Advanced Research Institute, Sri Balaji Vidyapeeth (Deemed-to-be-University), Puducherry, India
E-mail Id:
drpradeepmicro@gmail.com
Orcid Id:
https://orcid.org/0000-0001-7368-5846
How to cite this article:
Mashila A, Pradeep J, Indernath S S, Prabha P, Lavanya L, Balasubramanian M, Sowmya S. Importance of High-Risk HPV in India: Unravelling Genotypic Prevalence, Advanced Diagnostics, and Vaccination Strategies. J Commun Dis. 2026;58(2):152-170.

Date of Submission: 2025-09-13
Date of Acceptance: 2026-05-09

A B S T R A C T

Background: Human papillomavirus (HPV) is a significant contributor to cervical cancer, with high-risk genotypes HPV 16 and 18 accounting for 70% of cases. Despite the availability of screening and vaccination, the burden of HPV-related malignancies remains high in India.

Objectives: This review aims to assess the prevalence and distribution of high- and low-risk HPV genotypes across Indian states. It also evaluates current screening techniques, diagnostic advancements, and vaccination strategies to improve HPV-related cancer prevention.

Materials and Methods: A systematic literature search was conducted using databases such as PubMed, Scopus, ScienceDirect, and Google Scholar. Keywords included "HPV," "Cervical Cancer," and "HPV Genotypes." Studies from 2000 to 2024 were reviewed following PRISMA guidelines. Inclusion criteria encompassed research on HPV prevalence, diagnostic methods, and vaccination programs in India, while non-Indian and animal studies were excluded.

Results: HPV screening methods in India include Pap smears, HPV DNA testing, and molecular diagnostics like PCR and Hybrid Capture 2. High-risk genotypes, particularly HPV 16 and 18, dominate cervical cancer cases. Southern India exhibits a higher burden, while states like Kerala report lower prevalence. Advanced techniques like CRISPR-Cas9 and Next-Generation Sequencing (NGS) show promise for improving diagnosis. Vaccines such as Cervarix and Gardasil provide protection, but awareness and coverage remain limited.

Conclusion: Enhanced HPV screening, early detection using molecular diagnostics, and widespread vaccination are crucial to reducing HPV- associated cancers in India. Increased public awareness and policy-driven vaccination programs can significantly impact disease burden and prevention strategies.

Keywords: HPV, Cervical Cancer, Screening, Molecular Diagnostics, Vaccination, India

Introduction

Human papilloma virus (HPV) is a DNA virus with more than 200 known genotypes, which belonging to the Papillomaviridae family.[1] Of the 200 genotypes, high-risk HPV 16 and HPV 18 account for 70% of cervical cancer occurrences globally.[2] Sexual contact with risk factors for chronic infection, such as early sexual debut, multiple sexual partners, smoking, hormonal contraceptive usage, and immunosuppression (e.g., HIV-positive individuals), is the main way that HPV is transmitted.[3] Approximately 20% of all human malignancies worldwide are linked to HPV. HPV and its genotypes are classified based on their severity: Low-Risk includes HPV 6 and 11, which are associated with genital warts appeared in the external genitalia, perianal area, and mucosal surfaces. High-risk (HR) HPV genotypes. particularly HPV 16 & HPV 18 are oncogenic which contains viral proteins E6 and E7 responsible for the progression of cervical and other HPV associated cancers worldwide and other high-risk types are HPV 31, 33, 35, 45, 52, and 58.. Persistent infection with high-risk HPV genotypes may lead to precancerous lesions such as cervical intraepithelial neoplasia (CIN), which can progress to invasive cervical carcinoma if left untreated. Nowadays, there are many difficulties for diagnosis and treatment of HPV which was linked to non-cervical malignancies.[4] Although the Pap smear was introduced in the 1940s, greatly decreased the mortality rate from cervical cancer, traditional cytology techniques have limitations in terms of sensitivity and specificity.[5] Diagnosis of HPV is solely relied on cytological abnormalities that might not show up in the early stages of infections, but Liquid-Based Cytology (LBC) has increased diagnostic accuracy.[6] Despite its great accuracy, histopathology is intrusive and unsuitable for widespread screening. Conventional molecular diagnostic methods like mRNA for viral oncogenic expression, HPV DNA testing and Hybrid Capture 2 (HC2) have high sensitivity and specificity.[7] These technologies have efficient screening and advancements in diagnostics will allow an early identification of active oncogenic infections and high-risk HPV genotypes. New technologies like CRISPR-Cas9 and Next-Generation Sequencing (NGS) have the potential to develop HPV diagnostics.[8] Furthermore, the addition of whole-genome sequencing for positive samples seeks to offer a more thorough comprehension of the genetic traits and diversity of different HPV strains. Self-sampling is a comfortable method to improve screening accessibility, especially in underserved areas.[9] Conducting vaccination program for men as well as women will reduce infections and precancerous lesions linked to HPV 16 and HPV 18, such as Cervarix and Gardasil, also provide cross-protection against additional high-risk genotypes.[10] Further, the administration of appropriate vaccine doses will help to reduce the frequency of HPV 16 and HPV 18, and also the additional high-risk forms like HPV 31, 33, 45, 52, 56, and 58 for progression of oncogenesis. It is still difficult to detect high-risk HPV genotypes, accurately even with advancements in screening and vaccination.[6] This review has the potential to find out the prevalence and distribution of high and low – risk HPV genotypes in Indian states. The main objective of this review is to update the knowledge on screening as well as diagnostic methods available for the detection of high-risk HPV related cancers in India.

Materials & Methods

This systematic review has been initiated with a search of the published research articles in the category of Human Papilloma Virus (HPV) infection in India. This work flows with detection of diagnostic methods like PCR, Nested PCR, Real Time PCR and various HPV genotypes, available in India. The literature was searched using various search engines viz., Scopus, PubMed, Science Direct, Medline, Google Scholar using the appropriate keywords: “HPV”, “Cervical Cancer” and “HPV Genotypes”. This review has incorporated both criteria inclusion and exclusion for detection, collection and investigation of the research articles. This review strictly adheres to the PRISMA guidelines and their checklist.[11]

Inclusion & Exclusion Criteria

All review articles, research articles, short communications and case reports were included for this work based on the prevalence, diagnostic methods, in-silico informatics of HPV genotypes as well as vaccination data from our Indian population. Published literature from other continents as well as animal related studies excluded from this review. This review has identified 255 HPV related articles from the year 2000 to 2024 from above mentioned database. Figure 1 shows the strategies used for the selection of HPV related studies for this systematic review. Finally, we have retrieved 117 articles from the data after a thorough screening of published literature from the above database.

ISSN: 0019-5138
DOI: https://doi.org/10.24321/0019.5138.202641

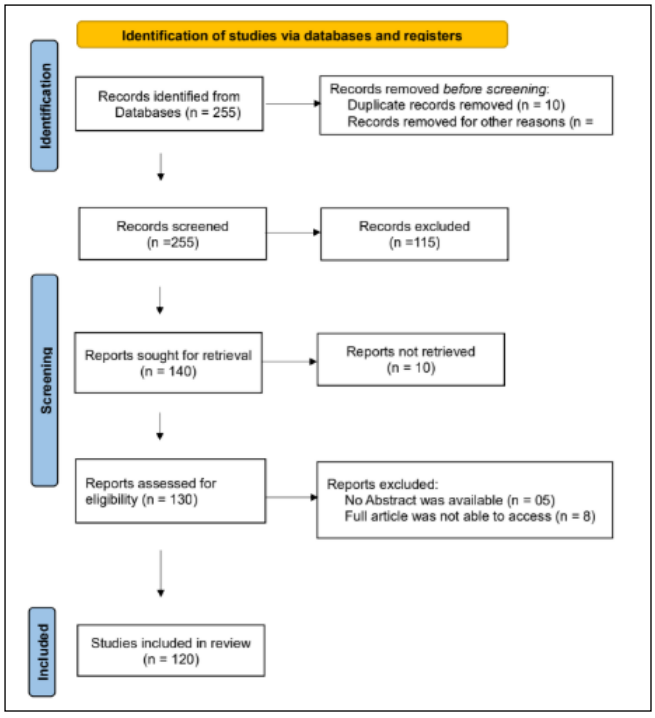

Figure 1.PRISMA 2020 flow diagram for new systematic reviews which included searches of databases

Results

HPV screening tests available in India

The Pap smear detects abnormal cervical cells, caused by HPV infection, but it does not directly detect the virus or its genotypes. The Pap smear has moderate sensitivity with a higher rate of false negatives, whereas HPV DNA testing has its higher sensitivity and can detect the virus in early stage.[12] Geethalakshmi et al., have recorded the low prevalence of oncogenic HPV 16/18 genotypes and its progression to cervical cancer in Puducherry state.[13] Commercial rapid kits such as the OncoE6TM Cervical Test, M-Strip HPV Screening Kit etc., demonstrate moderate to high sensitivity and specificity for detecting multiple HPV genotypes. On the other hand, directly detect HPV DNA and identify specific HR types, particularly HPV16 and 18[14,15] While more specific and faster, rapid kits are generally more expensive than the Pap smear and focus solely on identifying the virus rather than cellular changes.[16] HPV antigen rapid kits detect viral proteins in cervical cells, offering faster results and higher sensitivity compared to the Pap smear. However, these kits are limited to detecting antigens rather than providing comprehensive screening for cellular abnormalities or specific genotypes.[17] It is useful for immediate results as they are not recognized as a standard screening tool and are typically used in tandem with Pap smears for better accuracy.

Prevalence of Cervical carcinoma in India

Cervical carcinoma is the major threat for public health among middle aged women. A research report was projected in India, will be approximately 225,000 and the new cases will be increased by 2025. It stated that 17% of cervical cancer deaths were occurred in women aged from 30 to 69 years.[18] Especially, in southern parts of India, the prevalence of cervical cancer patients caused by HPV is consistently high, ranging from 80–90%. Kerala demonstrates the lowest age-standardized rate of cervical cancer in India, with 115.2 Disability Adjusted Life Years (DALYs) per 100,000 women, reflecting effective healthcare interventions. Karnataka has reported a high burden of HPV associated cervical cancer, with approximately 85 - 90% of cervical cancer cases involving high - risk HPV genotypes, especially HPV16 and HPV18.[19] Tamil Nadu exhibits a moderate level of cervical cancer burden (5.73%), with higher incidences reported in urban and rural mix areas like Chennai (60.7%) [20].Andhra Pradesh and Telangana have reported a high prevalence of high - risk HPV infection, ranging from 80 - 90% among cervical cancer cases, particularly involving HPV16 and HPV18, highlighting the continued need for public health interventions and HPV vaccination programs.[21]

In Northern India, HPV prevalence in cervical cancer cases ranges between 80–85%, consistent with national trends. Uttar Pradesh bears the highest burden, with an estimated 45,682 new cases annually, followed by Rajasthan with approximately 17,000 and Punjab exceeding 10,000 cases.[22] Urban regions such as Delhi demonstrate a higher burden of HPV - associated cervical cancer cases (72%), likely due to increased population density and limited screening coverage among marginalized populations. Table – 1 summarizes the prevalence of cervical cancer caused by HPV and The corresponding diagnostic assays used in different studies. Higher prevalence of Penile HPV (53%) was observed in Gurgaon region [23] and the details were recorded in Table – 2.

Molecular Diagnosis of HPV genotypes

Molecular diagnostic techniques such as Polymerase Chain Reaction (PCR), real-time PCR,Hybrid Capture 2 (HC2), and HPV DNA assays provide sensitive and early detection of high - risk HPV genotypes, offering a significant advantage over cytology alone.[24] Molecular diagnostic assays facilitate early detection of high - risk HPV infection before progression to precancerous lesions and invasive cervical carcinoma, thereby reducing disease burden through timely clinical intervention. Table – 3 shows Prevalence of HPV genotypes reported in different states of India using different molecular assay. In various states like Kerala, Odisha, Lucknow, Tamil Nadu, South Andaman,

ISSN: 0019-5138
DOI: https://doi.org/10.24321/0019.5138.202641

Western part of India, Bihar, and Andhra Pradesh have recorded the most significant HR-HPV genotypes like HPV 16 & 18.[25] Some researchers have recorded other genotypes like HPV 33, HPV 35 HPV 45 HPV 52 HPV 58, HPV 59 and HPV 73.[26] Several studies have conducted in India have evaluated HPV DNA detection using E6/E7 nested PCR, COBAS 4800 qPCR- based HPV (5.73%), HELINI HPV 16/18 PCR, TRUPCR@HPV-HR HPV 16 & HPV 18 and in-house TaqMan Real – Time PCR methods primarly targeting HPV16 & HPV18.[27] Other assays like Multiplex Nested PCR, Care HPV System, Digene Hybrid Capture 2 (hc2) assay, Roche PCR-based line blot are helpful in detecting other HR-HPV types during the community screening.[28]

Awareness among HPV Vaccination in India

As per the literature from India, Gardasil-9C, Bivalent, Quadrivalent HPV, 9-Valent HPV and Attenuated combination vaccines (Tdap) vaccines are available.[29] Mostly as per the Indian guidelines, the vaccine can be incorporated at the age of 9 to 14 years old. Only one study has conducted clinical trial on girls and women (9-45 years) with Quadrivalent & 9-Valent HPV Vaccines.[30] Two more studies have been conducted on two dose vaccination method viz., one for modelling and another community based to know the feasibility, acceptability and Safety of HPV vaccination.[31] Table – 4 shows the details of HPV vaccine study conducted in India. Long-term follow-up cohort study was conducted in Delhi including unmarried girls at age of 10-18 years to detect antibody response of Quadrivalent HPV vaccine.[32]

Table 1.Studies on Prevalence of Cervical Cancer in India

S. NO	Diagnostic Assay	Type of Population	Type of Sample	Prevalence (%)	HPV genotypes	Year of the study	City	Reference
1	Hybrid Capture 2 qPCR	Rural	Cervical Urine	17.50% 25.50%	HPV multiple genotypes	2024	Sikkim	Gupta et al
2	Histopathology Immunohisto-chemistry	Urban	Cervical tissues	68%	HPV – genomic integration observed	2024	Hyderabad	Sujatha et al.
3	HPV self-sampling	Rural Urban non-slum Urban Slum	Cervical Swab	8.5%, 7% 7.80%	HPV multiple genotypes	2024	Mumbai	Mishra et al
4	TaqMan-based real-time PCR	Urban/City with rural women	with and without invasive cervical cancer	37.3%;	HPV multiple genotypes	2024	Patna	Pankaj et al.,
5	HPV DNA PCR assay	Rural Married women	Cervical Swab	5.90%	HPV 16 & 18	2023	Port Blair,	Rehnuma Parvez et al
6	p16 Immunohisto chemistry, mRNA ISH, qPCR	Urban/City	Eyelid SCC patients	9%	HPV 16	2024	New Delhi,	Aanchal Kakkar et al.

ISSN: 0019-5138
DOI: https://doi.org/10.24321/0019.5138.202641

7	PCR assay, sequencing analysis	Rural Women	Cervical scrapes	3.20%	HPV 16	2023	South Andaman Island	Rehnuma Parvez et al.,
8	PCR, tissue biopsy analysis	Urban/City	Cervical and endometrial biopsy samples	72%	HPV 16, HPV 18	2023	New Delhi	Heena et al.,
9	Cobas 4800 (qPCR-based HPV molecular testing)	Urban/City	Cervical swab	5.73%	HPV 16 & 18	2023	Chennai,	Vijayalakshmi et al.
10	Epidemiological data from NCRP using cancer registries	Urban/City	Cervical swab	87.6%,	HPV multiple genotypes	2023	Bengaluru	Thilagavathi et al.
11	PCR, Pap smear cytology, and real-time PCR	Urban/City	HIV-positive women,	66.60%	HPV multiple genotypes	2022	Pune	Mahima et al.
12	Immunohistochemistry for p16INK4A, semi-quantitative PCR	Urban/City	Cervical cancer cases	90.67%	HPV multiple genotypes	2021	Hyderabad	Thathapudi Sujatha et al.
13	Nested multiplex PCR assay detecting 38 mucosal HPV types	Semi – Urban / Rural women	Cervical Swab	86.70%	HPV 16 & 18	2022	Tirupati,	Mudhigeti Nagaraja et al.,
14	On-site cervical cytology smear with toluidine blue	Semi – Urban / Rural	ROSE technique	97.60%	-	2023	Kalyani,	Santosh et al.
15	Next-generation sequencing, Sanger sequencing	Urban / Rural mix	Cervical cancer tissues	60.70%	High-risk HPV16/18	2022	Chennai,	Mathew et al.
16	nested multiplex PCR assay	Urban	Cervical cancer cases	Histologically confirmed case	15 HPV types	2022	Tirupati	Nagaraja et al.
17	HPV testing	Urban/ Rural women	menstrual pads	58.9% of 945 women participated	15 HPV types	2022	Mumbai,	Atul et al

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18	PCR	Urban	Patients with Condylo-mata acuminate	63.60%	HPV 6 or 11	2021	Chandigar h	Mini P et al.,
19	PCR and Southern Blotting	Rural	Women with serous epithelial ovarian cancer	No HPV DNA detected	(HPV 16, 18, 6, 11)	2022	Mumbai	Pavan Kumar et al.
20	PCR	Urban	HeLa cervical cancer cell line (HPV 18)	Reduction in HPV 18 viral load	HPV 18 L1 gene	2021	Coimbator e,	V M Berlin
21	Pap smear	Urban	Women from rural and urban areas (HPV not specified)	1.00%	0.63% prevalence of SIL, 0.37% HSIL	2022	Trivandru m,	M C Kalavathy et al.
22	TruNAT HPV-HR, PCR, Hybrid Capture 2 (HC2)	Urban	Women with cervical cancer risk, HPV 16, 18, 31, 45 (HR-HPV)	10.70%	HPV 16, 18, 31, 45 (HR-HPV)	2020	Noida	Roopa et al.,
23	PCR, Southern hybridization, HPV GenoArray	City	cervical cancer cases and healthy women (Control)	92.8% in cases, 7.3% in controls	HPV-16, 18, 51 & 33	2019	Mumbai	Priyanka W et al.
24	PCR	Urban	50 cases of chronic prostatitis/ CPPS, 50 controls (sexually active men, primary infertility) -	52% in cases, 12% in controls	HPV-16	2020	Kolkata, West Bengal	Pritesh Jain et al.,

ISSN: 0019-5138
DOI: https://doi.org/10.24321/0019.5138.202641

25	Any plex qPCR	Urban	Premalignant and malignant cervical pathology	76.3% in CIN, 100% in SCC, 100% in adenocar-cinoma	(HPV 16, 18, 39, 33)	2019	Raipur, Chhattisgarh, India	Negi et al.,
26	LAMP assay	Urban / Rural mix	Cervical cancer patients	92% sensitivity	HPV 16 and 18	2019	Tirupati	Nagaraja et al,
27	PCR and Cytology	Urban	Cervical abnormalities	21.1%,	Chlamydia, co-infection	2019	New Delhi	Nisha Madaan,
28	Conventional Pap Smear (CPS), Liquid-Based Cytology (LBC), PCR	Urban	Cervical swab	6.45%	(HPV 16, & 18)	2018	Patna Patna	Sangeeta Pankaj et al
29	PCR, ELISA, Immunohisto-chemistry, Real-Time PCR	Urban	CaCx cases, controls	Predominant HPV-16	(HPV-16)	2020	Guwahati, Assam	Chandana Ray Das et al.
30	HC2/PCR	Rural	Menstrual pads	Population A: 3.2%, Population B: 4.9%	HPV positive	2018	Pune and Jamkhed	Atul Budukh et al.
31	Immunohisto-chemistry, Methylation Specific PCR	Urban / City	HR-HPV-infected squamous cell carcinoma	83.80%	HPV16/18:	2017	New Delhi	Arif Ahmad et al.,
32	Multiplex PCR	Urban / City	Cervical cancer and cervical intraepithelial neoplasia	52.90%	(HPV16 and HPV18)	2017	Chandigar h	Singh et al.,
33	Hybrid Capture 2, Pap smear, biopsy	Urban / City	HPV DNA (18%), CT DNA (4.8%); HPV/CT co-infection (0.7%)	18%	HPV DNA	2013	New Delhi	Neerja Bhatla et al.

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34	Western blot and Immunohisto-chemistry Western blot and Immunohisto-chemistry	Urban / City	cervical cancer and precancer lesions	96.0 % (cancer), 83.00% (precancer)	HPV16 & 18	2013	Chandigar h	 Neha Singh al.
35	Hybrid Capture 2 DNA assay	Urban / City	HPV (+11.7%, - 84.4%, borderline 3.9%), strong positivity (17.3% of positives)	11.7	HPV genotypes	2013	Lucknow	Saumya Pandey et al.
36	HPV genotyping, Pap smear	Urban	HIV-infected women	20.0 % (HIV- infected), 18.7% (controls)	HPV16 HPV45, 52, 31 & 58	2012	Chandigar h	Ritu Aggarwal et al.
37	HPV genotyping, Viral integration assay (chromosomal loci 1p, 3q, 6q, 11q, 13q, 20q)	Urban	Cervical biopsies	63%	HPV16 HPV18	2012	Navi Mumbai	Poulami Das et al.
38	Methylation-specific PCR (MSP), Sequencing, RT-PCR	City	North Indian population	36% (p16), 8.8% (p14), 11.2% (p15)	HPV unspecified	2012	Chandigar h	Abhimanyu et al.
39	Methylation-specific PCR	Urban	North Indian population,	12%(p53), 25.6% (p73), others < 12	HPV unspecified	2012	Chandigar h	Abhimanyu et al.
40	Reverse Line Blot Assay	Urban	Young women in Slum area	5/1000 women	HPV 16, 18, 59, 52	2012	Delhi	Palika et al.
41	Review of Vaccination and Screening Methods	Urban	Indian population,	60.7 % (HPV16), 16 % (HPV18)	HPV 16, 18	2012	India (General)	Habib et al.

ISSN: 0019-5138
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42	PCR	City	Ovarian cancer patients,	40 (HPV), 80 (Chlamydia), 50 (CMV)	HPV 6	2012	Tiruchirappalli	Shanmughapriya et al.
43	Nested PCR, Southern hybridization	Urban	Women worldwide	9.90%	HPV 16, HPV 18	2012	Eastern India (Kolkata)	Sankhadeep Dutta et al.
44	PCR, TUNEL assay	Urban	Cervical carcinoma cases in Indian population	97% HPV positivity	(HPV 16, HPV 18)	2012	New Delhi	M Shabbir Alam et al.
45	Systematic literature survey, Meta-analysis	Semi - Urban	Women worldwide	32.10%	(HPV 16, HPV 18)	2012	Tiruchirappalli,	Vinodhini et al.
46	Systematic Review of Screening Techniques	Urban / City	General population, cytology, and visual inspection	Cervical cancer incidence varies widely (highest: 23.07/ 100,000 in Mizoram)	HPV DNA prevalence in visual and cytology – based screenings	2016	Mumbai, Maharashtra	Saurabh Bobdey et al., Indian J Med Paediatr Oncol (2016)

Table 2.Studies on Penile carcinoma patients in India

S. No	Diagnostic Method Used	Target Used	Type of Sample	Types of patients	Prevalence (%)	State/Union Territory	Reference
1.	HPV Subtyping and Telomerase Activity	E6/E7 mRNA expression	Tissue samples	uncircumcised controls	42.5%	New Delhi	Sharma et al.,
2.	Immunohisto chemistry	p16ink4a & p53	Tissue samples	SCC	Tumours - 53%, p16ink4a - 47%	Gurgaon	Sambit et al.,
3.	Premalignant conditions	-	-	Male genital premalignant dermatosis	Case Report	Karamsad, Gujarat, India	Rochit RS et.al,
4.	Treatment of BLT	-	-	Penile Buschke-Löwenstein tumour patients (HPV-related wart	Case Report	Gurugram, India	Sidharth S et.al,

ISSN: 0019-5138
DOI: https://doi.org/10.24321/0019.5138.202641

Table 3.Prevalence of HPV genotypes reported in different states of India

S No	Type of Study	Material & Methodology	HPV Genotypes	Prevalence (%)	Year	Place	Author name
1.	Cross Sectional Study	Care HPV System, nested PCR, sequencing	HPV 16 & HPV 33	60.7%	2021	Kerala	Alka Suresh et.al
2.	Cross Sectional Study	L1 – PCR, Sequencing, E6/E7, nested PCR	HPV 16 & HPV 18	17%	2017	Odisha	Rashmirani Senapati et.al
3.	Cervical Screening	HPV – DNA testing, rural camp samples	HPV 18 & HPV 33	11.7%	2021	Lucknow	Anand et.al
4.	Case – control study	PCR protocols (MY09/11, GP5+/6+) type – specific PCR	HPV 16 & HPV 18	52.9%	2012	Tamil Nadu	Vinodhini et.al
5.	Cross Sectional Study	Blood and swab sample from FSWs - HELINI HPV 16/18 PCR kit	HPV 16 & HPV 18	20%	2015	Chennai	DoraiRaj Kalpanaraj et.al
6.	Cross Sectional Study	PCR	HPV 16 & HPV 18	5.9%	2018	South Andaman	Rehnuma Parvez et.al
7.	Observational Study	TRUPCR@HPV- HR	HPV 16 & HPV 18	16%	2023	Western India	Varun Kothari et.al
8.	Hospital – Based Study	TaqMan Real – Time PCR Statistical methods	HPV 16 & HPV 18	37.3%	2024	Bihar	Sangeeta Pankaj et.al
9.	Biopsy – Based	Multiplex Nested PCR	HPV 16 & HPV 18	86.7%	2023	Andhra Pradesh	Mudhigeti Ngaraja et.al
10.	Epidemiological Systematic Review	National Registry Program data analysis	HPV 16 & HPV 18	87.6%	2024	National - India	Thilagavathi Ramamoorthy et.al
11.	Cross Sectional Study	cervical swab for HPV DNA testing - Digene Hybrid Capture 2 (hc2) assay, Roche PCR-based line blot – in a community screening	HPV 16, 18, 33, 35, 45, 52, 58, 59 and HPV 73	10.7%	2005	Andhra Pradesh	A Pavani Sowjanya et.al

ISSN: 0019-5138
DOI: https://doi.org/10.24321/0019.5138.202641

Table 4.Studies on HPV Vaccines in India

S. NO	Name of the Vaccine	Methods employed	Year of the study	Type of Study	Target Population	Study place	Key Findings	Reference
1.	Quadrivalent HPV	Single – dose efficacy study	2024	Randomized Controlled Trial	Unmarried girls aged 10-18 years	Barshi, Solapur, India.	The single - dose Quadrivalent HPV vaccine demonstrated high protective efficacy against persistent HPV 16 and HPV 18 infections among adolescent girls ages 10 - 18 years	Sylla G. et al.,
2.	GARDASIL-9	Comprehensive analysis	2024	Literature Review	General population	New Delhi	GARDASIL - 9 provided broad protection against multiple high - risk HPV genotypes and showed potential for reducing HPV - associated cervical cancer burden	Karuna et al.,
3.	Quadrivalent HPV Vaccine (Antibody Response Study)	Long-term follow-up cohort study	2024	Observational (Multicentre Study)	Unmarried girls (10-18 years)	New Delhi	Long - term follow-up demonstrated sustained antibody response and prolonged immunogenicity of the Quadrivalent HPV vaccine among unmarried adolescent girls	Neerja et al.
4.	Single-dose and two – dose HPV Vaccine	Modelling Study of vaccination impact	2022	Modelling Study	Nationwide (India)	Nationwide (India)	Modelling studies predicted that both single - dose and two - dose HPV vaccination strategies could significantly reduce HPV infection rates and future cervical cancer burden in India	Irene Man et al.,
5.	Quadrivalent HPV vaccine	Multi-site infection surveillance	2023	Prevalence Study	Marginalized urban women (30-45 years)	Gandhinagar, India	Multi - site surveillance studies highlighted the importance of increasing HPV vaccination coverage and cervical cancer screening programs among marginalized urban women	Kranti et al.,
6.	Quadrivalent & 9-Valent HPV Vaccines	Clinical trial analysis and safety study	2022	Clinical Trial	Indian girls & women (9-45 years)	India (multiple cities)	Clinical trials demonstrated strong immunogenicity, favourable safety profile and effective protection against high - risk HPV infections among Indian girls and women aged 9 - 14 years	Suzanne M et al.,

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7.	HPV Vaccination (2-Dose Method)	Community – based HPV vaccine project	2021	Feasibility, Acceptability and Safety of HPV vaccination	Adolescent girls (9-14 years)	Kolkata, West Bengal	Community - based studies reported that the two - dose HPV vaccination program was feasible, safe, acceptable and effective among adolescent girls aged 9 - 14 years	Ranajit et al.
8.	HPV Vaccination (Multicentric Study)	Multi-centric cohort study (community based)	2020	Cohort study	Young sexually active women	Multiple States in India	Multicentric cohort studies showed reduced HPV infection prevalence and improved vaccine effectiveness among vaccinated sexually active women across different Indian states	Richard et al.
9.	HPV Vaccination (Bivalent and Quadrivalent Vaccines)	Independent Comparison	2020	Immunogenicity study comparing bivalent and quadrivalent HPV vaccines	Adolescent girls (Finland and India)	New Delhi	Comparative immunogenicity studies demonstrated that both Bivalent and Quadrivalent vaccines produced strong immune responses against HPV 16 and HPV 18 infections	Filipe et al.
10.	Human Papillomavirus (HPV) Vaccine	Randomized Controlled Trial	2019	Follow – up cohort study for 2 – dose vs 3 – dose HPV vaccine efficacy	Adolescents (15-18 years)	Multicentric	Follow - up cohort studies indicated that two - dose HPV vaccination schedules provided immunogenicity and protection comparable to three - dose schedules in adolescents	Partha et al.
11.	Human Papillomavirus (HPV) Vaccine - Two-Dose Cohort Study	Immuno genicity comparison	2023	Experimental (Randomized Controlled Trail)	Girls aged 15-18 years	New Delhi	Experimental cohort studies demonstrated strong immunogenicity and sustained antibody response following two - dose HPV vaccination in adolescent girls	Neerja Bhatla et al.
12.	Human Papillomavirus (HPV) Vaccine - Gardasil - Single Dose Trial	Clusrer randomized trial	2018	Clinical trial	Unmarried girls aged 10-18	Pune	Cluster randomized clinical trials showed that a single dose of Gardasil provided significant protection against persistent HPV infection among unmarried girls	Rengaswamy et al.

ISSN: 0019-5138
DOI: https://doi.org/10.24321/0019.5138.202641

13.	Human Papillomavirus (HPV) Vaccine - Intramuscular (bivalent, quadrivalent, non-valent)	Systematic review & observational	2018	Observational study	Girls aged 9-13 years	Chennai	Systematic reviews demonstrated that bivalent, quadrivalent and non - valent HPV vaccines were safe, immunogenic and effective in preventing HPV - associated infections.	Prabhdeep et al.
14.	Attenuated combination vaccines (Tdap) vaccines	Review & discussion of vaccination schedules	2013	Observational study	Adolescents	Cochin	Observational studies suggested that combination vaccination schedules improved vaccine compliance and supported broader immunization strategies among adolescents	Jeeson et al.
15.	Gardasil and Cervarix	Expression of HPV L1 protein in Pichia pastoris, VLPs	2011	Experimental	Mice	Hyderabad	Experimental studies successfully demonstrated HPV L1 protein expression in Pichia pastoris, supporting future vaccine development and virus-like particle (VLP) based vaccine research in India.	Hanumantha et.al.,

Discussion

HPV plays a crucial role in the pathogenesis of several cancers, most notably cervical cancer. High-risk HPV genotypes, particularly HPV16 and HPV18, account for nearly 70% of cervical cancer cases worldwide.HPV contains an approximately 8kb double - stranded DNA genome and primarily infects basal epithelial cells of the epidermis, upper respiratory tract and ano-genital mucosa.[33] More than 100 genotypes are responsible for infecting genital tract. It contains three functional parts: they are early promoter (E) which encodes E1-E7 proteins for viral replication followed by capsid which recognizes two structural proteins, Late promoter (L1 & L2) for assembly and last non- coding region refers long control region (LCR) for replication and transcription of viral DNA. Two early proteins (E1 & E2) recognize replication as well as viral gene transcriptor. E4 and E5 may act both in early and late stages. E6 and E7 are major viral oncoproteins involved in disruption of the host cell cycle and also maintain the stability of viral episomes and enhance to differentiate the cells for re-entering into the S-phase. The L1 and L2 proteins assemble in capsomers, which form icosahedral capsids around the viral genome during the generation of progeny virions.[33] Viral oncoproteins E6 and E7, which interferes with tumour suppressor pathways and contribute to oncogenesis when high-risk HPV genotypes persist within host tissues. The viral oncoproteins E6 and E7 inactivate tumour suppressor protein p53 and retinoblastoma protein (pRb), resulting in uncontrolled cell proliferation and carcinogenesis.[34] Persistent HPV infections significantly increases likelihood of developing precancerous lesions and malignancies involving the cervical, anal, vulvar, vaginal, penile and oropharyngeal regions. Although, most of the HPV strains are asymptomatic and self-limited.[33]

Ramamoorthy et al., from Karnataka have recorded the HPV related cancers particularly in 87.6% cases in cervical region and 63.2% cases in oropharyngeal regions from NCRP cancer registries.[35] Different research studies have evaluated the prevalence rate of HPV ranges from 0.63% to 97.6% using an on-site cervical cytology under ROSE technique.[36] Till date, a low prevalence of HPV 16/18 was found in Puducherry based on the Pap smear.[37] Among women who tested negative on Pap smears, about 9.60% still test positive for HPV DNA, highlighting the potential for missed diagnoses using cytology alone. Other methods of assessment and awareness studies have carried out to acquire the knowledge on cervical cancer among Puducherry population.[38] In Chennai, Vijayalakshmi et al., detected 1.2%

ISSN: 0019-5138
DOI: https://doi.org/10.24321/0019.5138.202641

positivity using screening of population in the community for HPV related cancers.[39] HPV 16 and 18 are responsible for the majority of cervical precancerous lesions and invasive cervical cancers in India.[40] This aligns with global patterns where these two genotypes contribute to about 70% of cervical cancers. Different molecular diagnostic methods, including Hybrid Capture 2 (HC2), COBAS PCR assay, TRUENAT PCR and real - time PCR assays have been effectively employed for detecting high - risk HPV DNA among women at increased risk of cervical carcinoma in the Noida region.[41] About 9% of HPV DNA was detected in eyelid Squamous Cell Carcinoma among Delhi patients using p16 Immunohistochemistry and qPCR.[42] In Pune, the prevalence of HPV in HIV positive women was 66.6% by using PCR and cytology.[43] A recent multicentric Indian study evaluating HPV vaccination demonstrated significant reduction in persistent HPV 16 and HPV18 infections following vaccination programs.[44] Several Indian studies involving clinical trials, observational studies and community - based vaccination programs have consistently demonstrated favourable safety, immunogenicity and long - term efficacy of HPV vaccines among adolescent girls and young women.[45]

Although only limited Indian studies have explored experimental HPV vaccine protein expression systems, Hanumantha et al. successfully demonstrated expression of HPV L1 protein in Pichia pastoris using Gardasil and Cervarix vaccine constructs.[46] These findings highlights the potential for future HPV vaccine development and optimization within the Indian research context. Overall , the available evidence strongly supports the importance of molecular screening and HPV vaccination strategies for reducing HPV - associated cancer burden in India.

Conflict of Interest: None

Acknowledgement

Authors have grateful to the Chancellor, Vice-Chancellor, Dean Research, Sri Balaji Vidyapeeth (Deemed-to-be-University) for providing the Sri MVK Iyer Fellowship.

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