



Prevalence and type distribution of human papillomavirus among women older than 18 years in Egypt: a multicenter, observational study[☆]



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SUMMARY

Objectives: Persistent infection with high-risk (HR) human papillomavirus (HPV) is associated with premalignant lesions and cervical cancer, the third most common cancer amongst women globally and the second most frequent in Egypt. We studied the prevalence and type distribution of HPV and documented HPV infection awareness and health-related behaviours for HPV infection.

Methods: This was a multicenter, hospital-based observational study of women ≥ 18 years of age who attended for a gynaecological examination during October 2010–August 2011. Cervical samples were tested using Linear Array HPV genotyping. Two questionnaires on awareness and health-related behaviour were completed.

Results: Four hundred and forty-three women with a mean age of 39.3 ± 14.0 years were included in the analysis. HPV DNA was detected in 10.4% of women; a single HPV-type infection was found in 6.5% and multiple infections in 3.8%. The most prevalent HR types among HPV-positive women were HPV-16 (19.6%) and HPV-31 and HPV-51 (15.2% each); low-risk types included HPV-62 (17.4%) and HPV-84 (10.9%). The prevalence of HPV-18 was low (6.5%). The prevalence of any HR HPV-type was highest in women aged 45–54 years (9.2%).

Conclusions: The overall prevalence of HPV in Egypt was 10.4% and was highest (9.2%) amongst women aged 45–54 years. These data provide important reference information for public health authorities considering HPV prevention in Egypt.

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1. Introduction

Persistent infection with high-risk human papillomavirus (HPV), a sexually transmitted disease,¹ is a necessary and established cause of cervical cancer.² This is the third most frequent cancer in women worldwide; in 2008, an estimated 530 000 new cases were recorded and 275 000 deaths were caused by this cancer.³ The majority of cervical cancer-related deaths occur in developing countries,¹ such as Egypt where a population

of 25.76 million women over 15 years of age are at risk of developing cervical cancer.⁴ Indeed, it has been estimated that around 514 women are diagnosed with cervical cancer and 299 die from the disease in Egypt each year; thus cervical cancer ranks as the second most frequent cancer among Egyptian women.⁴

The epidemiological classification of cervical cancer-associated HPV types describes 15 as carcinogenic or high-risk (HR) (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73 and 82) and 12 as low-risk (LR) (6, 11, 40, 42, 43, 44, 54, 61, 70, 72, 81, and CP6108).⁵ Of these, HPV-16 and HPV-18 are the two most common HR HPV types. They are responsible for 61% and 10%, respectively, of cervical cancer cases worldwide, and 48% and 23%, respectively, of cervical cancer cases in Africa.⁶

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Two vaccines are currently licensed in many countries around the world, including Egypt, to protect against HR HPV types 16 and 18: Cervarix (bivalent; GlaxoSmithKline, Belgium) and Gardasil (quadrivalent; Merck and Co., Inc., Whitehouse Station, NJ, USA). Both vaccines have good safety and efficacy profiles^{7–11} and are reported to provide cross-protection against non-vaccine HPV types.¹² Although both of these vaccines are already licensed in Egypt,⁴ they are currently not included in the national immunization program.¹³ In order to measure the impact of implementing a nationwide policy for HPV prevention, baseline epidemiological data are required. However, current epidemiological data for HPV in Egyptian women are limited, and only a few publications on HPV prevalence and attitudes towards and awareness of the infection are available.^{14–16} To bridge this gap and provide baseline data, we evaluated the prevalence and type distribution of HPV, including HR and LR types, among Egyptian women attending routine gynaecological examinations in different age strata, and documented awareness of HPV infection and health-related behaviours for HPV infection.

2. Methods

2.1. Study design and population

This multicenter, observational study was carried out at two hospitals (Al Kasr Al Aini University Hospital, Cairo, and Ain Shams University Hospital, Cairo) and an outpatient clinic (Alexandria University Hospital, Alexandria) between October 2010 and August 2011. The study hospitals are tertiary university hospitals and treat patients within their catchment areas as well as patients from primary healthcare centres and secondary hospitals (including regional hospitals).

Women aged ≥ 18 years undergoing routine gynaecological examination and willing to provide a cervical sample were enrolled. Known diagnoses of immunosuppression, previous HPV vaccination, hysterectomy, pregnancy, or referral for an abnormal cervical sample were all reasons for exclusion. Two validated questionnaires were completed by all subjects enrolled: one on 'health-related behaviours' to solicit information about smoking, marriage history (e.g., age at first marriage), contraception, and reproductive history (parity), and the other to elicit information on HPV awareness, in order to assess the level and accuracy of understanding regarding the cause, transmission, and prevention of HPV infection. These 'knowledge-attitudes-practices' questionnaires were designed by a multi-disciplinary team. The questionnaires were initially tested on 50 women in a short interview lasting for approximately 20 min and were subsequently provided to all enrolled women by the investigators.

2.2. Sample collection and laboratory procedures

Cervical samples were collected by a gynaecologist/trained health practitioner using a cytobrush and placed in a liquid-based cytology medium (Thinprep, Hologic, Inc.). A 2-ml sample was subsequently stored at -20°C and analyzed for the presence of HPV DNA using Linear Array HPV genotyping at Al Mokhtabar Laboratory, Cairo, Egypt. This technique, based on the L1 consensus primer PGMY09/11 for PCR amplification of HPV DNA and reverse-line blot hybridization, was used for the detection of 37 individual HPV genotypes.¹⁷

2.3. Statistical analyses

The primary objective was to describe the overall prevalence and types of HPV (including multiple infections) among

women ≥ 18 years of age. Secondary objectives were to investigate HPV type prevalence amongst women in different age groups and to describe health-related behaviours. Based on an overall HPV prevalence of 15%¹⁶ and allowing for 10% of non-evaluable samples, to give an overall estimate of HPV prevalence with 95% confidence and a precision level of 0.035, a total of 440 subjects were required, with at least 80 in each age-group (18–24, 25–34, 35–44, 45–54, and ≥ 55 years of age). The percentage of HPV-positive women in each category was tabulated with corresponding exact 95% confidence intervals (CI). A description of subject characteristics (i.e., educational level, age at first marriage, number of marital partners, parity, and smoking status) and HPV status is provided, including the 95% confidence intervals for the prevalence of these characteristics. All statistical analyses were undertaken using SAS version 9.2 statistical analysis software.

2.4. Ethical considerations

The study was approved by the National Ethics Committee of the Egyptian Ministry of Health and was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization Guidelines for Good Clinical Practice. Informed consent was obtained from all eligible women before starting the study.

3. Results

3.1. Study population

Of the 1156 women aged ≥ 18 years who visited the practice, a total of 490 provided a cervical sample and were enrolled in the study. Cervical samples were not collected or tested in 47 cases, leaving 443 women in the final analysis, all of whom completed both questionnaires. The mean \pm standard deviation (SD) age of women was 39.3 ± 14.0 years and the majority (78.6%) lived in urban areas. The baseline characteristics of women enrolled in the study are shown in Table 1.

Table 1
Baseline characteristics (N=443^a)

Characteristics	Categories	n ^b	n ^c	%	95% CI (LL–UL)
Education level	No formal education	88	7	8.0	3.3–15.7
	Primary	140	17	12.1	7.2–18.7
	Secondary	143	15	10.5	6.0–16.7
	Post-secondary/university	72	7	9.7	4.0–19.0
Parity	0	87	10	11.5	5.7–20.1
	1–2	153	14	9.2	5.1–14.9
	3–5	183	18	9.8	5.9–15.1
	≥ 6	20	4	20.0	5.7–43.7
Age at first marriage, years	≤ 16	20	0	0.0	0.0–16.8
	17–19	173	21	12.1	7.7–18.0
	20–22	155	17	11.0	6.5–17.0
	≥ 23	95	8	8.4	3.7–15.9
Number of marital partners	1	419	41	9.8	7.1–13.0
	2–5	24	5	20.8	7.1–42.2
Smoking status	No	422	42	10.0	7.3–13.2
	Yes	21	4	19.0	5.4–41.9

95% CI, exact 95% confidence interval; LL, lower limit; UL, upper limit.

^a Number of subjects whose cervical samples were tested.

^b Number of subjects whose cervical samples were tested and who answered the health-related behavior questionnaire.

^c Number of HPV-positive subjects in the given category.

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