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Editorial

Awareness of Human papilloma Virus (HPV) and its Toxicity

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INTRODUCTION

Human Papilloma Virus (HPV) lead to epidemiologically and clinically distinct form of Orpharyngeal Squamous Cell Carcinoma (OPSCC). HPV-positive OPSCCs have risk factors related to sexual behaviour whereas HPV-negative cancers strongly co-related with tobacco and alcohol usage. In addition HPV-positive patients have substantially better survival than compared with HPV-negative patients.

The population-level burden of HPV-positive OPSCC is currently unidentified and may have important implications to cancer prevention, potentially through HPV vaccination. Therefore, combined molecular epidemiologic methods that use both sensitive and specific laboratory assays with cancer surveillance methods to investigate the changes in the population-level epidemiology of OPSCC in the United States are caused by HPV infection to estimate the historical, current, and future population-level burden of HPV-positive OPSCCs.

Laboratory Analysis of (HPV) Vaccine

After tumor presence was confirmed with haematoxylin and eosin staining, serial tissue sections were produced at the Hawaii RTR by using procedures to minimize inter specimen contamination. DNA was purified from paraffin-embedded tumor tissues as previously described

Total RNA was purified by using the Roche High-Pure RNA Paraffin Kit. Following DNase treatment, RNA was reverse transcribed to cDNA by using High Capacity RNA-to-cDNA Master Mix.

Statistical Analyses of (HPV) Vaccine

BHPV assays were analysed separately. The κ statistic was used to assess agreement across assays. Characteristics of HPV-positive and HPV-negative patients were compared by using a χ^2 test. Calendar year of diagnosis was categorized into four periods: 1984 to 1989, 1990 to 1994, 1995 to 1999, and 2000 to 2004. Conclusions remained unchanged in sensitivity analyses when using single-year or 2-year categories. Trends in HPV prevalence across calendar periods were evaluated by using logistic regression, after adjustment for age, sex, race, and registry [1-10].

We anticipated loss in assay sensitivity because of the age of specimens beyond the exclusion of un-evaluable samples. Therefore, HPV prevalence in 69 cervical cancers was used to estimate sensitivity of each laboratory assay across calendar periods, assuming all cervical cancers were HPV-positive (Data Supplement). These calendar period–specific sensitivities were used to randomly resample HPV-negative tissues and assign them as HPV-positive to correct the observed prevalence (10 imputations). Trends in corrected prevalence were evaluated by using multiple imputation methods [1-10].

TOXICITY

Gardasil single-dose toxicity

Single-dose toxicity of Gardasil was assessed in 2 GLP studies in mice and rats. The dose administered intramuscular represents approximately 1200-fold excess in mice and 300-fold excess in rats of the human dose. The vaccine was well tolerated and there were no treatment-related effects on mortality, physical signs, or body weight over a 14-day observation period.

Reproductive and development toxicity

The reproductive and developmental toxicity was assessed in a study in female Sprague-Dawley rats addressing all phases of reproduction and foetal development. An immune response to the vaccine was observed, and antibodies were shown to be transferred to the offspring during gestation and also lactation. There were no adverse findings in the study.

Eco-toxicity

The environmental impact of the Gardasil vaccine would be minimal to none for the following reasons:

The HPV vaccine comprised of Virus-like Particles (VLPs) and it does not contain any live or attenuated virus. The VLPs are simply protein sub-units found in the virus capsid.

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