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Abstract Book

POTENTIAL IMPACT OF A NONVALENT VACCINE ON HPV RELATED LOW-AND HIGH-GRADE CERVICAL INTRAEPITHELIAL LESIONS

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Introduction:

Demonstration of the role of persistent infection, with high-risk (HR) human papillomaviruses (HPV) as the causal agent of cervical cancer made the development of first and second generation prophylactic vaccines. Bivalent and quadrivalent HPV vaccines are at the moment available in Europe. In 2014 is licensing a nonavalent HPV vaccine against HPV types: 6/11/16/18/31/33/45/52/58. The aim of our study was to evaluate the potential impact on HPV infection and related low- and high-grade cervical lesions (LSIL, HSIL) of the candidate nonavalent HPV vaccine, compared to the impact of the quadrivalent, in a female population living in Sicily.

Materials and Methods:

HPV genotypes was identified by Linear Array HPV Genotyping Test (Roche Diagnostics) and with the INNO-LiPA HPV assay (Innogenetics) for ambiguous HPV 52 status. Low estimates of HPV vaccine impact was calculated as prevalence of HPV 6/11/16/18/31/33/45/52/58 genotypes alone or in association but excluding presence of another HPV type; high estimate as prevalence of HPV 6/11/16/18/31/33/45/52/58 genotypes alone or in association, in presence of another HPV type.

Results:

1794 samples had a HPV positive finding. HR HPV types, alone or with LR types, were present in 1466 (81.7%) samples. 584/1794 (32.5%) samples harboured at least one of the four HPV types covered by the quadrivalent vaccine (HPV 6/11/16 and 18), while 984 (54.8%) samples harboured at least one of the genotypes included in nonavalent vaccine, implying a significantly higher estimated coverage of HPV infection from the developing vaccine than the current quadrivalent (54.8% vs 32.5%; $p < 0.001$). Of the samples with a known histological diagnosis a total of 362 cases (72.2%) of LSIL and of 58 cases (90.6%) of \geq HSIL were HPV positive. The nonavalent HPV vaccine showed increased impact on both categories of lesions, compared to the quadrivalent vaccine. Estimates of potential impact varied from 30.9% (low estimate) to 53.3% (high estimate) for LSIL, and from 56.9% to 81% for HSIL. Compared to the quadrivalent vaccine, the proportion of additional cases potentially prevented by the nonavalent vaccine was 14.4%-23.8% for LSIL, and 19%-32.8% for HSIL. The benefit of the nonavalent vaccine compared to the quadrivalent vaccine was more than 80% for both low and high impact estimates for LSIL and more than 50% for both low and high impact estimates for HSIL.

Discussion and Conclusions:

The present study confirms that the switch to a nonavalent HPV vaccine would increase the prevention of high grade cervical lesions in up to 90% of cases. Implementation of nonavalent vaccination programs could become thus a cost effective public health prevention approach, based on the potential to produce substantial incremental benefits.