A randomized trial of single-dose HPV vaccination efficacy among young women

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Introduction: Single-dose HPV vaccination, if efficacious, would be tremendously advantageous; simplifying implementation and decreasing costs.

Methods: We conducted a randomized, multi-center, double-blind, controlled trial of single-dose bivalent (HPV 16/18) or nonavalent (HPV 16/18/31/33/45/52/58/6/11) HPV vaccination among 15- to 20-year-old women in Kenya. Individual participants were randomized 1:1:1 to either 1) immediate bivalent HPV vaccination and delayed meningococcal vaccination, 2) immediate nonavalent HPV vaccination and delayed meningococcal vaccination, or 3) immediate meningococcal HPV vaccination and delayed HPV vaccination. Enrollment serum was tested for HPV antibodies. Cervical swabs, collected at enrollment, months 6, 12, and 18, and vaginal swabs, self-collected at month three, were tested for HPV DNA. The modified intent-to-treat (mITT) cohort comprised participants who tested HPV antibody negative at enrollment and HPV DNA negative at enrollment and month three. The primary outcome was incident persistent vaccine-type HPV infection by month 18.

Results: Between December 2018 and June 2021, 2,275 women were randomly assigned and followed; 758 received the nonavalent HPV vaccine, 760 the bivalent HPV vaccine, and 757 the meningococcal vaccine; retention was 98%. Overall, 1,458/2,275 (64%) participants were included in the HPV 16/18 mITT cohort and 615/1,515 (40%) in the HPV 16/18/31/33/45/52/58 mITT cohorts. Thirty-eight incident persistent infections were detected in the HPV 16/18 mITT cohort: one each among participants assigned to the bivalent and nonavalent vaccine groups and 36 among meningococcal vaccine group participants; nonavalent Vaccine Efficacy (VE) was 97.5% (95%CI 81.7-99.7%, p=<0.0001), and bivalent VE was 97.5% (95%CI 81.6-99.7%, p=<0.0001). Thirty-three incident persistent infections were detected in the HPV 16/18/31/33/45/52/58 mITT cohort: four in the nonavalent group and 29 in the meningococcal group; nonavalent VE for HPV 16/18/31/33/45/52/58 was 88.9% (95%CI 68.5-96.1%, p<0.0001). The rate of SAEs was 4.5-5.2% by group.
Conclusions: In a randomized trial among young women with HPV exposure, single-dose HPV vaccine was highly efficacious.