**Table 1: Participant demographic data by group**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Group 1 N (column %)****N=198\*** | **Group 2 N (column %)****N=163** | **Overall****N=361** |
| **Vaccinated**67 (41.1) | **Unvaccinated**96 (58.9 ) |
| **Site** |
| Site 1 | 95 (48.0) | 53 (79.1) | 93 (96.9) | 241 (66.8) |
| Site 2 | 103 (52.0) | 14 (20.9) | 3 (3.1) | 120 (33.2) |
| **Age at colposcopy** |
| 20 years | 42 (21.2) | 17 (25.4) | 5 (5.2) | 64 (17.7) |
| 21 years | 33 (16.7) | 31 (46.3) | 5 (5.2) | 69 (19.1) |
| 22 years | 29 (14.6) | 14 (20.9) | 18 (18.8) | 61 (16.9) |
| 23 years | 39 (19.7) | 3 (4.5) | 31 (32.3) | 73 (20.2) |
| 24 years | 40 (20.2) | 1 (1.5) | 17 (17.7) | 58 (16.1) |
| 25 years | 15 (7.6) | 1 (1.5) | 20 (20.8) | 36 (10.0) |
| Mean Age (years) | 22.2 (SD 1.6) | 21.2(SD 1.0) | 23.2 (SD 1.4) | 22.3 (SD 1.6) |
| **Referral Cytology** |
| Borderline | 46 (23.2) | 19 (28.4) | 27 (28.1) | 92 (25.5) |
| Mild dyskaryosis | 86 (43.4) | 34 (50.7) | 28 (29.2) | 148 (41.0) |
| Moderate dyskaryosis | 36 (18.2) | 12 (17.9) | 28 (29.2) | 76 (21.1) |
| Severe dyskaryosis | 24 (12.1) | 2 (3.0) | 11 (11.5) | 37 (10.2) |
| Glandular neoplasia | 1 (0.5) | - | 2 (2.1) | 3 (0.8) |
| Invasive cancer | 1 (0.5) | - | - | 1 (0.3) |
| Missing | 4 (2) | - | - | 4 (1.1) |
| **Histology** |
| Biopsy not taken± | 61 (30.8) | 27 (40.3) | 20 (20.8) | 108 (29.9) |
| Normal (No CIN) | 19 (9.6) | 9 (13.4) | 10 (10.4) | 38 (10.5) |
| CIN1 | 53 (26.8) | 18 (26.9) | 24 (25.0) | 95 (26.3) |
| CIN2 | 35 (17.7) | 9 (13.4) | 23 (24.0) | 67 (18.6) |
| CIN3 | 24 (12.1) | 3 (4.5) | 14 (14.6) | 41 (11.4) |
| Invasive squamous 1a1 | 1 (0.5) | - | 1 (1.0) | 2 (0.6) |
| CGIN | 2 (1.0) | - | 4 (4.2) | 6 (1.7) |
| Unsatisfactory | 3 (1.5) | 1 (1.5) | - | 4 (1.1) |

Table 1: Comparison of participant demographics between groups."Vaccinated" women refer to women who had received 2 or more doses of the HPV vaccination. \*Group 1 includes 3 women who reported they had received the HPV vaccine. ±All cases where biopsy was not taken were because colposcopic appearances were normal.

**Table 2: Impact of HPV vaccine on colposcopic features and histology.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Unvaccinated****n/N (%)** | **Vaccinated n/N (%)** | **chi squared p-value\* (Pearson unless indicated)** |
| **Colposcopic Features** |
| Acetowhite | 231/291 (79.4) | 54/70 (77.1) | 0.623 |
| Mosaic | 129/291 (44.3) | 30/70 (42.9) | 0.791 |
| Punctation | 111/291 (38.1) | 27/70 (38.6) | 1.00 |
| Atypical Vessels | 3/291 (1.0) | 1/70 (1.4) | 0.589† |
| Iodine Negative\*\* | 101/202 (50.0) | 33/59 (55.9) | 0.442 |
| **Colposcopic Opinion** |
| High Grade\*\*\* | 99/290 (34.1) | 13/66 (19.7) | 0.027 |
| **Histology\*\*\*\*** |
| CIN2+ | 103/286 (36.0) | 13/69 (18.8) | 0.006 |
| CIN1+ | 179/286 (62.6) | 32/69 (46.3) | 0.044† |

Table 2 compares the features seen at colposcopy between all participants regardless of disease status who were vaccinated against HPV 16 and 18, and women who were not. It also compares the colposcopic opinion and histology results between these groups. In patients where biopsies were not taken, they were considered to have no disease.\*Pearson’s test used unless otherwise indicated. †Fisher’s exact test used. \*\*in 100 cases, iodine was not used. This was for a variety of reasons including patient allergy or colposcopist preference. \*\*\*High grade colposcopic opinion was appearance suggestive of CIN2+. \*\*\*\*Histology results were “unsatisfactory” for 5 unvaccinated and 1 vaccinated therefore were excluded from histology analysis.

Table 3: Impact of the vaccine and of HPV 16 on the performance of colposcopy

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Unvaccinated**(95% CI) N=294 | **Vaccinated**(95% CI)N=67 | **z-test for difference** |  | **HPV 16+**(95% CI)N=142 | **HPV 16 -**(95% CI)N=219 | **z-test for difference** |
| **Sensitivity** | 69.6(59.6-78.1) | 66.7 (35.4-88.7) | p=0.835 |  | 65.8 (53.9-76.0) | 76.3 (59.4-88.0) | p=0.251 |
| **Specificity** | 86.3 (80.2-90.7) | 92.5 (80.9-97.6) | p=0.228 |  | 75.0 (62.3-84.6) | 92.4 (87.1-95.7) | p<0.001 |
| **PPV** | 74.0 (63.8-82.1) | 66.7 (35.4-88.7) | p=0.591 |  | 75.8 (63.4-85.1) | 69.0 (52.8-81.9) | p=0.443 |
| **NPV** | 83.5 (77.3-88.4) | 92.5 (80.9-97.6) | p=0.103 |  | 64.9 (52.8-75.4) | 94.6 (89.7-97.3) | p<0.001 |

**Table 3: Predictive values of colposcopy for detecting high grade disease where histology results were considered "gold standard" and the test was colposcopic opinion. This has been done to compare predictive values between vaccinated and unvaccinated participants and between participants who are HPV 16 positive and negative.**