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The HPV Vaccine: Not Just for Young Girls and Teens

HPV INFECTION IN WOMEN OVER THE AGE OF 26 AND IMPACT OF VACCINE

Host: Dr. Lauren Streicher, Assistant Clinical Professor of Obstetrics and Gynecology at Northwestern University Medical School, the Feinberg School of Medicine.

Guest: Dr. Sharmila Makhija, the Director of Gynecologic Oncology at Emory University in Atlanta.

DR. LAUREN STREICHER:

Too late to vaccinate? the HPV vaccine for women aged 26-45.

With me today is Dr. Sharmila Makhija, the Director of Gynecologic Oncology at Emory University in Atlanta.

With the divorce rate at 50% and the association of human papillomavirus not only with cervical squamous cell carcinoma but also cervical adenocarcinoma, vulvar, vaginal, anal, bladder, and even lung cancer, the pending approval of Gardasil for women over the age of 26 is appropriate and probably long overdue, but there are a lot of questions. We know first of all that this quadrivalent vaccine protects against the four strains of HPV that are responsible for at least 70% of cervical cancers and 90% of genital warts, but we also know that the highest prevalence of HPV is in the 20- to 24-year-old women. So first of all there is an article in JAMA in February 2007 that looked at the prevalence of HPV among females in the United States and found a surprising high incidence among women older than 26. Can you comment on those findings?

DR. SHARMILA MAKHIJA:

(01:30) Yes, in fact, there was even an earlier study back in 2003 that looked at the baseline prevalence of genital warts, so having a clinical consequence of being exposed to HPV all across the age groups and what that was based on was data from privately insured women that sought treatment for genital warts. What was interesting is, as you mentioned, in the 20 to 24-year-old women that was the highest prevalence, but you continued to see incidence of genital warts above that age. What this is really actually telling us is because it is the privately insured women, this may be actually an underestimation.

DR. LAUREN STREICHER:

It is probably the tip of the iceberg when you really think about it.

DR. SHARMILA MAKHIJA:

That's right. In fact, this might be higher because a lot of women may feel uncomfortable going to their private OB-GYN and discussing an STD-related disease and going out to general clinics instead, so I think it is very important to address this issue in the older or the adult women population.

DR. LAUREN STREICHER:

Can you talk a little bit about the numbers in terms of the prevalence of HPV among these older women? Do we know?

DR. SHARMILA MAKHIJA:

Well, what's interesting is we know that the prevalence overall, there is probably about 20 million cases overall in the US that are usually quoted. Now, specifically in the adult women population, we do not have an accurate number, but what was interesting is that, and I was a part of this particular study with Merck in the adult women population which was the 24 to 45-year-old, (03:00) and when we really collected the data, these women were 25, and one of the initial issues was to find out what is the baseline prevalence in this adult population of women based on these previous studies that we just discussed. So what we found is that when we looked at the baseline prevalence in this population of women that almost two-thirds or 67% of these women were naive to any of the HPV types, so that there may be a benefit for vaccinating this group because the other studies showed that they are at risk of developing HPV.

DR. LAUREN STREICHER:

As a young woman has a competent immune system, studies suggest that about 90% of HPV infections are cleared within 2 years without any treatments at all. Is this also true of the over 26-year-old population or do you think that there is a greater likelihood of progression to invasive cancer.

DR. SHARMILA MAKHIJA:

That's actually a very good point and a point of discussion. One of my concerns about this whole thing is that a woman who is now listening to, Oh! I have HPV, I am going to get cervical cancer, that's not true. It is the persistence of this high-risk type, so not only are you exposed, are you not able to clear it, and you have a high-risk type, so you are right. The majority of these women who are exposed to HPV are going to clear this, and the other point is as you age your immune response does decline, so in fact, with your point, it is well taken, are these women actually not going to be able to fight off and are they actually at greater risk (04:30) of developing the sequelae from developing HPV. That's something that still has to be investigated and that's why this adult women population was studied with the Gardasil, and in fact, like I said before, about two-thirds of these women are naive to any of these HPV types, but in fact when they were given the vaccine, those women who were given the vaccine did not develop any of the preinvasive disease, so they are protected, it appears, from developing any of the sequelae from HPV and that's really the end point. It's not necessary do they maintain immune response or is it at the same level as a younger women. In the end, they were protected.

DR. LAUREN STREICHER:

And, what about the impact of tobacco on this population?

DR. SHARMILA MAKHIJA:

Yes, very much so. With any type of disease, you know it is not only just being exposed to one risk factor, it is the compilation of a multitude of all of these. So you are exposed to HPV at high risk, you can't clear it and then you are a smoker. We know that cervical cancer, that's a huge risk factor, and so now whether or not smoking and getting the vaccine does that change anything? we don't know, but we do know on the adult women population, 75% of those women were nonsmokers.

DR. LAUREN STREICHER:

And you talked about who has already been exposed, and this is a huge issue because we know, of course, that the most effective time to vaccinate is prior exposure and if you think it is hard to find a 20-year-old virgin, try finding a 40-year-old virgin, but the original (06:00) clinical trials for Gardasil looked at the likelihood of a young sexually active woman being naive to at least one virus type and found that there was a near 0.1% of the sexually active population that had been exposed to all 4 viral subtypes, which of course led to the rationale for not testing for the presence of HPV subtypes prior to vaccination. So the big question is in the older population that has had this opportunity for increased exposure over time:

1. Do we know the percentage that are naive to 1, 2, 3, or 4 subtypes.
2. What's the likelihood that a woman has already been exposed to all 4 subtypes, and that gets us back to the original question is it too late to vaccinate.

DR. SHARMILA MAKHIJA:

These are all excellent points and in fact that's what was one of the main goals for the testing in the adult women, and frankly, I will just tell you, I ran both types. I ran this 16 to 26-year-old population as well as the adult women, so what would happen is the mothers would come and say please vaccinate my daughter on this trial, but I want to receive it, so there was a great concern that women who are already seeking out help or guidance with this. So here you can't just go straight to vaccinating that population of women without testing. So we previously discussed that the baseline prevalence was still that 67% were naive to any of the types and what we found were that very similar to the young adult women that were 16 to 26-year-olds, (07:30) as you mentioned, only 0.1% were exposed to all 4 types. In the adult population of women that were 25-45 years of age, that number was 0.4%. So there is a need for the vaccination in that group because they are not exposed to all 4 types.

DR. LAUREN STREICHER:

And, it also confirms what we are doing with the younger women that there is no reason to test all the women for prevalence of subtypes prior to vaccination.

DR. SHARMILA MAKHIJA:

That's absolutely right. I think that as you get older, you want to know what type they are having and I can understand I have patients that ask that all the time, but that's very costly and there is no need for that.

DR. LAUREN STREICHER:

Dr. Makhija, I think it's unrealistic to think that catch-up vaccinations are going to incur in the entire 26 to 45-year-old population and many have suggested that it might be appropriate to use risk factors to predict who would most benefit so what are your thoughts on this and can you comment on which risk factors are known to make an older woman more likely to benefit?

DR. SHARMILA MAKHIJA:

Well, I think that just to back up that the FDA approval age for this vaccine is currently 9 to 26-year-old women and the ACIP (Advisory Committee for Immunization Practice) recommends vaccinating 11 to 12-year-olds and the catch up is actually 13 to 26. So we almost look it as two different populations, you have the young women and then you have the adult women that are the 25- 45-year-olds. So in my mind at least as someone who helped run the trials, (09:00) it's a whole different category, so I have almost considered them to not be in a catch-up vaccination group, albeit their own population of women that need vaccination and part of that too is what we discussed before that we saw that they are mostly naive to all 4 types and could benefit from receiving it and/or are at high risk for developing HPV in the future.

DR. LAUREN STREICHER:

But what are those risk factors, if you are going to identify a particular at-risk population.

DR. SHARMILA MAKHIJA:

I think that it's hard to just say, okay, well if you are not in a monogamous relationship, you should be vaccinated because in a very practical manner when you are taking care of patient, I think it is very uncomfortable or hard for them to explain to you, well I had an affair or my husband was cheating on me, I might be exposed to this. Socially, it has changed where you are seeing women that are now in a divorce situation or dating again at an older age or delaying marriage until they are a little bit older, so I think those women in general are at risk.

DR. LAUREN STREICHER:

I would like to thank my guest Dr. Makhija who has enlightened us on the scope and burden of HPV infection in women over the age of 26 and how the HPV vaccine can impact this population.