Gardasil® Immunization Effects on Laryngeal Papillomatosis: A Preliminary Study

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ABSTRACT

The potential role of the adjuvant use of Gardasil® vaccine (series of three injections) in the treatment of recurring laryngeal papillomatosis (RPP) was evaluated in an adult population of 18 cases (12 m & 6 f, age range 37-79) being treated by one laryngologist with a long term meticulous CO2 laser removal every two-to-three months and than at double intervals, until no visible papillomas was observed by transoral magnified laryngovideostroboscopy (LVS), and when visual findings were questionable, verification was done by MDL with microscopic visualization. Thus each patient’s history was used as their control. Of the 18 cases, nine (5 m and 4 f) were still positive at the last in-office post final vaccination exam, while the remaining nine (7 m and 2 f) were negative for papilloma at stroboscopic exam at the last post final vaccination office visit. When the results of LVS were questioned, patients were visualized by MDL.

INTRODUCTION

Several trends were observed and need to be discussed; use of Gardasil® vaccine (series of three injections) in the adult population of 18 cases (12 m & 6 f) were negative for papilloma per apparent results. Based on this sample, it can represent chance or a trend. ironically, all these adjuvant therapies produce disappointing or only marginal improvement to the basic surgical debulking results. To improve on our CO2 laser surgical results, we routinely paint the operated field with podophyllin after CO2 laser removal2, and now in addition we tried a new adjuvant treatment, namely the use of the HPV vaccine Gardasil® (Merck) given by the patient’s family physician10,11 and approved for prevention of genital warts, cervical, vaginal, and vulvar cancer targets papovavirus types 6, 11, 16 and 18. Papova virus types 6 and 11 cause most RRP.

RESULTS

Of the 18 cases, nine (5 m and 4 f) were still positive at the last in-office post final vaccination exam, while the remaining nine (7 m and 2 f) were negative for papilloma at stroboscopic exam at the last post final vaccination office visit. When the results of LVS were questioned, patients were visualized by MDL.

The remaining five cases that were positive for papilloma at the time of the last injection later became negative, and remained negative between 8-27 months post the last Gardasil® injection. For these five cases the duration form the last injection until they became negative was between 4 and 25 months.

The results also showed a reduction in the papilloma clusters count detected upon recurrence by either LVS or by MDL microscopy. In addition to the slower re-growth, recurrence also seems to be located mostly in the same area or in the area adjacent to the original location, indicating a trend for restricted spread.

In summary, our preliminary results, though intriguing and encouraging, are not unequivocal with regard to efficacy of Gardasil® vaccine’s role in the adjuvant treatment of laryngeal papillomatosis. A search for laryngeal papillomatosis (papova virus 6 and 11) specific vaccine generation is needed and research is encouraged.

DISCUSSION

Several trends were observed and need to be discussed;
1. Most interesting ins the 50/50 split in apparent results. Based on this sample, it can represent chance or a trend.
2. Gender imbalance in favor of male patients observed here is artificial (although gender make-up in our cohort does reflects national statistics of male to female advantage ratio of ad novo adult onset cases) and is based on the larger number of males participating in the study.

Our preliminary data suggest some benefit from Gardasil® vaccination in adult patients with recurrent laryngeal papillomatosis regardless of gender, age or onset timing of papillomatosis. Since no side effects were encountered by any of the 18 cases, a larger study focused on longer follow-up preferably with a vaccine designed specifically for the papova virus types 6 and 11 and with mapping by high-speed imaging is advised.

CONCLUSIONS

Ongoing clinical evaluation via MDL at the time of the CO2 laser removal and after none visible and by laryngovideostroboscopy (LVS) and objective voice evaluation12, was done in 18 consenting adult patients (12 m & 6 f, age range 37-79) with recurrent laryngeal papillomatosis, each receiving three Gardasil® immunizations over 6 months, and treated by the same laryngologist over time, with meticulous CO2 laser removal every two-to-three months and than at doubling intervals, and then yearly until no visible papillomas was observed. Hence, each participating Gardasil® patient served as his/her own control since all had multiple prior excisions. Each patient underwent an exam using acoustics and transoral rigid magnified LVS visualization of the glottis, subglottis and supraglottic area including epiglottis throughout the course of the entire treatment period. Instead of using Derkay’s score13, we used our own index that included papilloma cluster count and mapping per LVS1. In all, we followed these 18 cases for the duration of 45 months post initial injection. But, because some of these cases came from our long-term patient pool, the longest follow-up for this series of 18 patients was close to eight years.

METHODS AND MATERIALS

Ongoing clinical evaluation via MDL at the time of the CO2 laser removal and after none visible and by laryngovideostroboscopy (LVS) and objective voice evaluation12, was done in 18 consenting adult patients (12 m & 6 f, age range 37-79) with recurrent laryngeal papillomatosis, each receiving three Gardasil® immunizations over 6 months, and treated by the same laryngologist over time, with meticulous CO2 laser removal every two-to-three months and than at doubling intervals, and then yearly until no visible papillomas was observed. Hence, each participating Gardasil® patient served as his/her own control since all had multiple prior excisions. Each patient underwent an exam using acoustics and transoral rigid magnified LVS visualization of the glottis, subglottis and supraglottic area including epiglottis throughout the course of the entire treatment period. Instead of using Derkay’s score13, we used our own index that included papilloma cluster count and mapping per LVS1. In all, we followed these 18 cases for the duration of 45 months post initial injection. But, because some of these cases came from our long-term patient pool, the longest follow-up for this series of 18 patients was close to eight years.

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