Robert Gattone

From: Robert Gattone
Sent: Thursday, March 20, 2008 9:22 AM
To: 'Subir.Nag@kp.org'
Subject: RE: Oncology Institute of Greater Lafayette

Dr. Nag,

Thank very much for your thorough and prompt response.

Sincerely,

Bob

From: Subir.Nag@kp.org [mailto:Subir.Nag@kp.org]
Sent: Wednesday, March 19, 2008 6:46 PM
To: Robert Gattone
Subject: Re: Oncology Institute of Greater Lafayette

March 19th, 2008
Mr. Gattone:
Here are my responses to the following questions.
1. "Assessment of probable deterministic effects of the radiation exposure on the individual":

Response: The underdosage to the inferior vagina, which is part of the area at risk for microscopic disease, increases the risk of tumor recurrence.

2. Do you agree with the licensee's assertion that, while cancerous tissue had been present on the posterior vaginal wall, it had been surgically resected before the HDR treatment, inferring that, since the cancerous tissue was surgically resected prior to HDR treatment, a radiation underdosage to that area would not result in a tumor recurrence? If not, why not?

Response: While cancerous tissue in the posterior vaginal wall had been surgically resected before the HDR treatment, the entire upper two-third of vagina including the posterior vaginal wall and especially the tumor bed is at risk for recurrence due to microscopic disease. This is the reason for prescribing the HDR boost (700 cGy x 3 to 6 cm / upper two-third of vagina). Hence, radiation underdosage to the tumor bed, (even after resection) and the inferior vaginal wall would increase the risk of tumor recurrence.

3. Do you agree with the licensee's assertion that the inferior-posterior vaginal wall was close enough to the cervix such that it was in the area of overtreatment rather than the area of underdose? If not, why not?

Response: The exact location of the tumor in the posterior vaginal wall has not been accurately documented. It has been variously described as "lesion at the posterior vaginal wall 3 cm from the apex at 6 o'clock position" and "0.3 cm lesion along the posterior vaginal wall". Irrespective of the exact location of the lesion, the entire upper two-third of vagina including the posterior vaginal wall is at risk for recurrence due to possible microscopic disease. The anterio-superior vaginal wall was definitely over irradiated. The posterio-superior vaginal wall would also have been over-irradiated if it were not shielded. However due to the clinical decision to shield the posterior half of the vagina to reduce the rectal dose, there was a 91.8% dose reduction from the shielding. Hence instead of over-irradiation, there was probably a resultant 89% underirradiation of the posterio-superior vaginal wall. However, I agree with the licensee's assertion that the use of a rectal shield to reduce the rectal dose is a physician decision and not related to the medical event.

In summary, the effect of the medical event, as modified by the medical decision to shield the posterior half of the vagina, is as follows:
1. The anterio-superior vagina was overdosed by about 30%.

2. The anterio-inferior vagina was underdosed by about 50%.
3. The posterior-superior vagina was overdosed by about 30% if shielding is not taken into consideration. However, because of the medical decision to shield the posterior half of the vagina, the posterior-superior vagina was actually underdosed by 89%.
4. The posterio-inferior vagina was underdosed by about 50% if shielding is not taken into consideration. However, because of the medical decision to shield the posterior half of the vagina, the posterior-inferior vagina was actually underdosed by about 96%.
5. No matter how one looks at it, there was definitely a medical event.

Subir

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