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Non-Physician Hospital CEO Cut after Participating in Surgery

Written by
Skeptical Scalpel

A former hospital CEO was asked to resign after having been involved in a surgical procedure. He is not a licensed physician. In a statement, he said, "Recently, at the invitation of a surgeon, I entered an operating room to observe a surgical case and to support our surgical team, as many health system and hospital CEOs do throughout the nation. As the case began, the surgeon asked if I would like to make the initial incision for this surgical procedure. I regret I did so."

A subsequent article said the attorney general of the district in which this took place has asked the Tennessee Board of Medical Examiners to investigate the event for a possible "criminal violation of Title 63, Chapter 6 of the Tennessee Code." The article said the surgeon had been fired.

I can think of no reason for a hospital administrator to even be a spectator in the operating room. Contrary to his statement, it is not common for hospital CEOs to observe a surgical case in the OR. The infection risk alone would not be worth it. Since the patient apparently was not aware of the CEO's presence, a HIPAA violation may have occurred. It was once common to have device sales reps, pre-med students, and others watch cases without patients' knowledge. Now, many hospitals require informed consent for anyone outside of the normal operating room complement.

What was the CEO thinking when he accepted the surgeon's offer to make the incision? Perhaps an investigation will determine whether this was done on the spur of the moment or was planned. Why would a surgeon allow a hospital administrator to make an incision on an unknowing patient? This was clearly unethical and probably illegal. The scrub technician and circulating nurse must have assisted the CEO in donning a sterile gown and gloves. Did the CEO know anything about sterile technique? Why didn't the OR personnel question what was going on? I can't think of a single OR nurse who would have allowed this. Was this the first time the CEO had ever been in an OR? Was everyone intimidated by the presence of the CEO? Was the culture of the hospital not supportive of staff complaints about physician or administrator behavior? We know someone called the hospital's anonymous tip line, but why didn't they feel empowered to say something in the moment?

Could the CEO be successfully sued for medical battery? Because the patient suffered no physical damage, I'm not sure a plaintiff's attorney would take the case. Whether the surgeon will be sanctioned by the Tennessee Board of Medical Examiners remains to be seen.

New research was virtually presented at ESMO 2020, the European Society for Medical Oncology Virtual Congress 2020, from September 19-21. The features below highlight some of the studies that emerged from the conference.

Radiation Fails to Improve Lung Cancer Outcomes

Whether to use post-operative radiation in patients with non-small-cell lung cancer who have undergone complete resection of the cancer but still have mediastinal nodal (N2) involvement has remained unclear. To determine disease-free survival at 3 years for those in this population who received radiation, researchers enrolled patients who had been diagnosed with non-small-cell lung cancer that had been completely resected but who were also found to have N2 involvement proven by histo-cytology. Disease-free survival was achieved by 47.1% of patients who underwent radiation, compared with 43.8% of those who did not. Median disease-free survival lengths were 22.8 months in those who did not undergo radiation and 30.5 months in those who did. No statistically significant differences in overall survival were observed. Patients in the radiation group also experienced more toxicities, particularly cardiopulmonary toxicity (11% vs 5%) when compared with the control group. The first event in the disease-free survival analysis was most often recurrence of disease in the mediastinum. Of events that occurred in the control arm, 46.1% were mediastinal recurrence, compared with 25% in the radiation arm. Brain metastases occurred more often in the radiotherapy arm (23.6% vs 17.6%) than in the control arm.

Preoperative Immunotherapy Safe & Feasible in Early Stage NSCLC

Evidence indicates that neoadjuvant immunotherapy has several advantages over adjuvant immunotherapy, including higher antigen load, neoantigen release from untreated tumors that could better prime the immune system, and the opportunity to evaluate tumor response to immunotherapy. Two studies sought to better understand these potential benefits in patients with early-stage non-small cell lung cancer (NSCLC). For one, patients were treated with three courses of a PD-L1 inhibitor on days 1, 15, and 29, with surgery scheduled 2-14 days after the last infusion. Complete surgical resection was completed in 89.1% of patients, with 8.7% showing a partial radiological response, 78.3% showing stable disease, and 18.6% experiencing a major pathological response. At 1 year, 89.1% of patients were still alive and 78.2% had not relapsed. In the other study, patients with early-stage NSCLC received one injection of a different PD-L1 inhibitor 4 weeks prior to surgery. Among participants, 97% had a complete surgical resection, with 7% showing a partial radiological response, 93% achieving stable disease, 14% experiencing a major pathological response, and 41% having a pathological response. There was no correlation between radiological and pathological response. However, there was a correlation between pathological response and PD-L1 expression at baseline.

COVID-19 Associated With Rising Burnout Numbers Among Oncologists

Evidence suggests that the impact of the COVID-19 pandemic on the wellbeing of oncologists has the potential for serious negative consequences on work, home life, and patient care. To investigate this impact, the ESMO Resilience Task Force collaboration conducted two online surveys of oncology professions (survey 1: April/May, survey 2: July/August 2020). Statistical analyses were used to examine differences between the survey respondents, associations, and predictors of wellbeing/distress, burnout, and COVID-19 job performance. With 1,520 participants from 101 countries, survey 1 found that 25% were at risk for distress, with 38% reporting feeling burnout and 66% not able to perform their job to pre-COVID-19 levels. Differences in wellbeing and job performance between countries were related to COVID-19 mortality rates. Main predictors of wellbeing, burnout, and job performance were resilience and changes to work hours. Still undergoing analysis, survey 2 results suggest that overall wellbeing and burnout rates have worsened over time, whereas job performance has improved. Among those completing both surveys, burnout rates rose from 22% to 31%.

Dual AR/AKT Blockade Effective in mCRPC With PTEN Loss

Research suggests that approximately 40% to 50% of metastatic castration-resistant prostate cancer (mCRPC) tumors show loss of the AKT phosphate PTEN, which leads to hyperactivation of the oncogenic PI3K/AKT signaling pathway. Other studies show that, due to reciprocal cross talk, blockade of the androgen receptor (AR)-activated pathway activates the PI3K/AKT signaling pathway, enabling prostate cancer cell survival. Therefore, PTEN loss in mCRPC is associated with worse prognosis and reduced benefit of AR blockade. To evaluate the efficacy and safety of an AKT inhibitor with a combination AR inhibitor (dual AR/AKT blockade) in patients with previously untreated mCRPC, investigators randomized asymptomatic or mildly asymptomatic patients to dual AR/AKT blockade or placebo plus the combination AR inhibitor (controls). Patients were stratified to PTEN loss as determined by immunohistochemistry (≥50% of the tumor cells having no detectable PTEN staining). Median radiographic progression-free survival (rPFS) was statistically significantly better in the dual AR/AKT blockade arm when compared with controls (18.5 months vs 16.5 months). In patients with PTEN loss, median rPFS was 19.1 months in the dual AR/AKT blockade arm, compared with 14.2 months in controls. However dual AR/AKT was associated with more toxicity when compared with placebo, leading to dose reduction in 39.9% (vs 6.2%) and discontinuation in 21.1% (vs 5.1%).

No Benefit With Hysterectomy After Intraoperative Node Detection

The optimal management of patients with intraoperatively detected positivity of pelvic lymph nodes remains unclear. With the combination of extensive surgical dissection in the pelvis followed by pelvic radiotherapy shown to be associated with high morbidity rates, investigators sought to determine whether radical hysterectomy completion improves oncological outcomes of such patients, researchers analyzed oncological outcome and major prognostic factor data on patients with cervical cancer who were found upon operation to be LN positive and referred for primary surgery with a curative intent at 51 institutions in 19 countries from 2005-2015. Patients were grouped by those with completion or abandonment of the planned hysterectomy. Prognostic factors were balanced between the groups and included tumor size and type and disease stage. No significant differences were observed between the groups in risk of recurrence (hazard ratio [HR], 1.154), local recurrence (HR, 0.836), or mortality (HR, 1.064). No cohort was found upon subgroup analyses to have a survival benefit with radical surgery completion. Across all participants, increasing FIGO stage and tumor size of 4 cm or larger were identified as major prognostic factors for recurrence and survival.

Q&A WITH DR. MEDLAW

As a urologist, I am very sensitive to my patients' need for privacy. However, I was really surprised when a new patient got very nasty with my receptionist because he was asked to sign in on a sheet at the front desk. He was carrying on about how this is a HIPAA violation because other patients signing in can see his name. I thought that a sign-in sheet is actually acceptable under HIPAA.

It is, as is announcing a patient's name in the waiting room to tell them that they are the next to see you or saying their name in the hearing of other patients or visitors. Under HIPAA, these revelations of PHI are considered incidental to medical care.

However, you should be doing your part to minimize that revelation. Start with the fact that PHI is an identifier coupled to a medical fact. All that a sign-in sheet alone therefore reveals is that someone is your patient, so make sure to not expand it beyond that—why the patient is there should never be included. Using a peel-off type of sign-in sheet is also a good idea—while not a HIPAA requirement, it does make patients feel more protected and avoids a situation like this.

Similarly, when discussing a patient where others might overhear, keep your voice low, and when calling a patient in from the waiting room do not mention the reason that they are there. For example, your MA saying "Mr. Joe Smith, come with me please" is acceptable but "J.S., we are ready for your cystoscopy" is not, because the issue is not the completeness of the name but the association of that identifier to the specific personal medical fact.

Having these as policies in your employee manual will stand you in good stead if you ever have to defend against a complaint from a troublesome patient.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney. It originally appeared on SERMO, which retains all rights to it.

In Case You Missed It

Coffee Linked to Reduced Disease Progression, Death in CRC

For patients with advanced or metastatic colorectal cancer (CRC), coffee consumption is associated with reduced risk of disease progression and death, according to a study published in *JAMA Oncology*. Researchers examined the association between coffee consumption and disease progression and death in a study involving 1,171 patients with previously untreated locally advanced or metastatic CRC. Among participants, 93% had died or had disease progression. The researchers observed an association between increased coffee consumption and a decreased risk for cancer progression and death (hazard ratios for one-cup/day increment, 0.95 [95% confidence interval (CI), 0.91 to 1.00; P = 0.04 for trend] and 0.93 [95% CI, 0.89 to 0.98; P = 0.004 for trend], respectively). The multivariable hazard ratios for overall survival and progression-free survival were 0.82 (95% CI, 0.67 to 1.00) and 0.82 (95% CI, 0.68 to 0.99), respectively, for participants who consumed two to three cups of coffee compared with those who did not drink coffee. Patients consuming four or more cups of coffee had multivariable hazard ratios of 0.64 (95% CI, 0.46 to 0.87) and 0.78 (95% CI, 0.59 to 1.05) for overall and progression-free survival, respectively. "Incorporating coffee drinking into treatment strategies for patients with CRC has practical appeal, but such recommendations require further research," write the authors of an accompanying editorial.

Cancer Treatment Affects COVID-19-Related Mortality

Cancer patients treated one to three months prior to COVID-19 diagnosis and those treated with chemoimmunotherapy have the highest 30-day mortality, according to a study presented at the annual meeting of the European Society for Medical Oncology. Study investigators examined outcomes related to systemic cancer treatment within 1 year of laboratory-confirmed severe acute respiratory syndrome coronavirus 2 infection. Data were analyzed for 3,920 patients as of July 31, 2020. The study team found that 42% of the patients received systemic anticancer treatment within 12 months and 159 distinct medications were administered. Patients treated within 1-3 months prior to COVID-19 had the highest rates of COVID-19-associated complications; all-cause mortality was 26% in this group. By most recent treatment type, 30-day mortality was 20%, 18%, 17%, 29%, 20%, and 11% for chemotherapy, immunotherapy, chemoradiotherapy, chemoimmunotherapy, targeted therapy, and endocrine therapy, respectively. The standardized incidence ratio for mortality was lowest for endocrine treatments and highest for chemoimmunotherapy or chemotherapy less than two weeks before COVID-19 diagnosis. Targeted agents within 3-12 months also had a high standardized incidence ratio. Mortality was 14% for patients untreated in the year prior to COVID-19 diagnosis. "Targeted therapies, especially those causing immune cell depletion, used one to three months before [the diagnosis of] COVID-19, are associated with very high mortality, up to 50%," a co-author said in a statement.