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Dangerous Pitfalls of Database Research

Written by
Skeptical Scalpel

Two papers using the same data about the same topic were published in the same surgical journal 1 month apart. They came up with opposite conclusions. The subject was laparoscopic appendectomy, specifically whether the placement of the excised appendix in a retrieval bag before removing it through a small incision results in fewer postoperative infections.

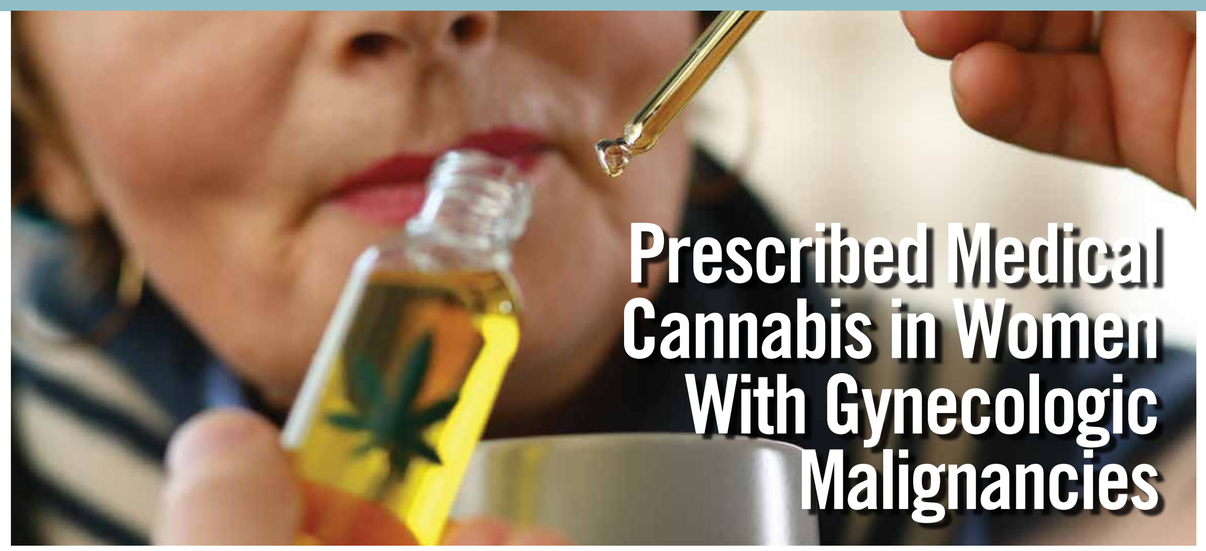
The National Surgical Quality Improvement Program (NSQIP) database for the year 2016 was used in both papers. The numbers of patients included in the studies were 11,475 in what I will call Paper A and 10,357 in Paper B. Paper A found, upon multivariable analysis, that bag use was associated with a 40% decrease in intra-abdominal infection rates. Paper B determined no statistically significant association between bag use and postoperative surgical site infection incidence.

How did both of the studies look at the same data and come up with different results? From a Viewpoint article: "… the studies use different inclusion and exclusion criteria, outcome measures, sample sizes, and covariates. These analytic decisions led to opposite findings."

The documentation of bag usage in the NSQIP database is derived from operative dictations, which may not always be accurate. For example, the Viewpoint authors reviewed data from their own institution and found when the operative note did not mention the use of a bag, the perioperative nursing log said a bag was used in 10 of 11 cases.

Abscesses most commonly occur in patients whose appendix has perforated before the operation was performed. When I asked a Viewpoint co-author how a bag could prevent abscess formation in such patients, he said, "If you are going to propose that retrieval bags reduce rates of abscess in all types of appendicitis, you have to be able to defend the biologic basis of that hypothesis." When asked if the Viewpoint called into question the value of most, if not all, database research papers, he said, "In a word, yes…. Many trainees have just enough competence with statistical software to be dangerous." However, he said many groups are performing valid health services and database research that can be trusted.

My unscientific Twitter poll found 79.8% of 168 respondents always use a retrieval bag when performing a laparoscopic appendectomy. The cost of a single-use laparoscopic retrieval bag ranges from $50 to $60. At least 250,000 appendectomies are done in the US yearly. Using a bag in every case would come to $12.5 million. It would be nice to know if bags really do prevent infections.



Prescribed Medical Cannabis in Women With Gynecologic Malignancies

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A study finds that patients perceive medical cannabis to be useful for relief of cancer and treatment-related symptoms, suggesting that it may be a reasonable alternative or adjunct therapy.

Although cannabis remains illegal in many parts of the United States, 33 states have approved medical cannabis programs as of March 2020. "With the likely expansion of medical cannabis across the US, it's important to identify whether patients with gynecologic malignancies may have symptomatic relief while using this treatment," says Gary Altwerger, MD. Unfortunately, research is lacking on the efficacy of cannabis to manage various cancer-related symptoms and has not yielded data specific to those using cannabis obtained from medical dispensaries.

A Society of Gynecologic Oncology clinical practice statement notes a paucity of literature regarding the indication, use, and effects of medical cannabis in this patient population. "As restrictions on cannabis use continue to be eased, more research is needed to help guide gynecologic oncologists in their clinical practice and management of women with gynecologic malignancies who may benefit from medical cannabis," says Dr. Altwerger.

A Closer Look

For a study published in *Gynecologic Oncology Reports*, Dr. Altwerger, Emily Webster, and colleagues surveyed 31 women with gynecologic cancers who were prescribed medical cannabis by a gynecologic oncologist. Respondents, most of whom had stage III or IV disease, completed a 43-item survey to explore their experiences with medical cannabis. "Of note, 75% of patients in our study either never used cannabis before the study or tried it only once in the past," Dr. Altwerger says.

Among participants, 83% perceived medical cannabis to be effective in relieving cancer- and treatment-related symptoms, according to Dr. Altwerger. "Respondents reported using medical cannabis for a variety of reasons, including decreased appetite, insomnia, and neuropathy," he says (Figure). "Most patients used medical cannabis to manage more than one symptom. We also found that the majority of patients felt medical cannabis was equivalent or superior in efficacy to other traditional medications, like opioids and anxiolytics, for cancer-related symptoms. Furthermore, the majority felt the side effect profile was better or equal to these other therapies."

About two-thirds of patients who used medical cannabis for pain reported a reduction in opioid use. "That patients felt they needed less opioids when using medical cannabis is important from a population health perspective as the fight against the opioid epidemic continues," says Webster. Dr. Altwerger says the finding that medical cannabis was associated with less neuropathy is also critically important. "Neuropathy can be a difficult side effect of chemotherapy and has a serious impact on quality of life," he says. "In severe cases, it can cause patients to stop or change chemotherapy. Medical cannabis use may help mitigate the need to change therapy by relieving this symptom."

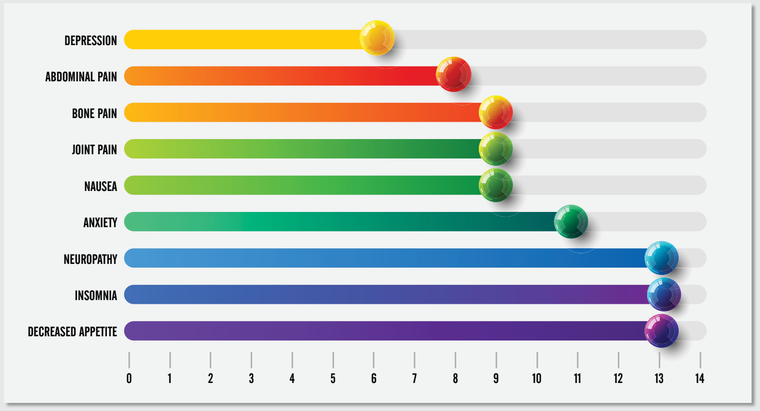
Important Implications

The study data suggest that medical cannabis may be a reasonable alternative or can serve as an adjunct to medications frequently used for cancer- or treatment-related symptoms. "Our findings emphasize the need to keep treating patients holistically," says Webster. However, Dr. Altwerger laments that although this is a helpful finding for patients, "unfortunately, we lack randomized controlled trials to guide our use of medical cannabis, preventing medical cannabis from becoming a universally accepted treatment across the US."

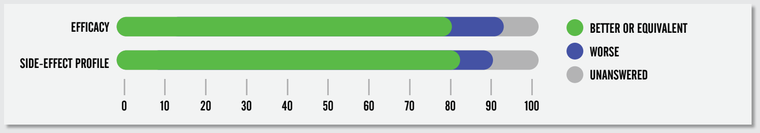
With more research, Dr. Altwerger hopes that data will emerge to inform discussions on what is known about medical cannabis so patients with gynecologic cancer can choose what is right for them. "Grassroots efforts are needed to overcome stereotypes and preconceived notions associated with medical cannabis," he says. "Another hindrance is the legal restriction from the government's classification of cannabis as a Schedule 1 substance, along with heroin and ecstasy. We hope our study will show how medical cannabis can benefit our patients. These data serve as a springboard for future randomized control trials in medical cannabis. We have a duty to offer evidence-based recommendations to guide this type of therapy."

Figure Reasons for Medical Cannabis Use

In a survey of 36 patients with gynecologic malignancies regarding their reason for medical cannabis use, 77% reported using medical cannabis for management of more than one symptom. The figure below depicts the most common reasons for use.



In addition, the figure below shows that the majority of patients believed efficacy and safety with medical cannabis was better or equivalent to other medications for relief of cancer and treatment-related symptoms.



Source: Adapted from: Webster EM, et al. *Gynecol Oncol Rep.* 2020;34:100667.

Dealing With Non-Compliant Patients: Using Facts in Your Defense

The following is a continuation of the MedLaw column in the January issue.

If, despite your best efforts, your patient suffers a poor outcome and you are being sued for malpractice, you would ideally like to stop the process before it reaches the courtroom. To that end, your attorney would file a Motion for Summary Judgment, asking the judge to dismiss the case as a matter of law because the plaintiff cannot meet their burden of proof. The plaintiff would be required to "lay bare their proof" that it was actually your conduct that was the proximate cause of the harm.

The judge may decide the Motion on papers alone or may hold a hearing at which the attorneys can offer argument but there will not be any witnesses called. Your "witness" will, therefore, be the medical record. Courts generally loathe to deny a plaintiff their day in court, and so the record must be very clear as to the patient's resistance to your efforts to work with them and your informing them of the serious consequences of their non-compliance and of the likelihood that it would cause the very harm that they then suffered.

If this Motion fails and the matter proceeds to trial, you still have strong defenses to raise based on the patient's non-compliance:

- Contributory negligence is an archaic defense that is still retained in few jurisdictions. It holds that a plaintiff who has any fault at all in their injuries may not recover damages for those injuries. If you are in one of those jurisdictions, your ability to demonstrate that patient non-compliance contributed at all to the claimed harm will bar any recovery against you.
- Comparative negligence does exactly what its name implies: it compares the level of fault for each side. In some jurisdictions, no amount of plaintiff fault bars recovery, and in others, there is a cut-off beyond which the plaintiff is barred. If a case goes through, any recovery will be offset by the proportion of the plaintiff's fault. In any comparative negligence jurisdiction, patient non-compliance will be a critical issue, because even if the case is not barred and the patient wins, damages will be reduced.

The plaintiff's duty of mitigation applies to the conduct of the patient after a harm has been recognized. Plaintiffs must show that they did what they reasonably could to minimize the effect that the negligence for which they are suing had on them. Even if you do have actionable liability for an error of your own, a patient non-compliant with well-advised recommendations for correction comes into evidence and acts as a damages offset.

When dealing with a persistently non-compliant patient, think ahead to how you would counter a malpractice claim when you create the record. A clear contemporaneous record of the patient's ongoing non-compliant conduct despite your efforts to have them act in a medically responsible way is the key to a solid defense.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney.

In Case You Missed It

Oral Contraceptives Protect Against Ovarian, Endometrial Cancer

Oral contraceptives have a lasting protective effect against ovarian and endometrial cancer, according to a study published in *Cancer Research*. Researchers conducted an observational study involving 256,661 women from the UK Biobank, born between 1939 and 1970, to clarify the time-dependent effects between long-term oral contraceptive use and cancer risk. The cumulative risk for cancer over the timespan of the study and instantaneous risk were measured by the odds ratio (OR) and hazard ratio (HR), respectively. Compared with never users, ever users had lower odds of ovarian cancer and endometrial cancer (ORs, 0.72 and 0.68, respectively); the association was stronger with longer use. When limiting follow-up to age 55, increased odds of breast cancer were seen (OR, 1.10); but this finding was not seen for the full timespan. A higher HR for breast cancer was seen in former users immediately (no more than 2 years) after discontinued oral contraceptive use (HR, 1.55), while for ovarian and endometrial cancer, the protective effect remained significant up to 35 years after last use of oral contraceptives. "It was clear that women who had used oral contraceptive pills had a much lower risk of developing both ovarian and endometrial cancer," a coauthor stated. "A decreased risk was still detected up to 30-35 years after discontinuation."

Hospitalization Up for Black Gynecologic Cancer Patients With COVID-19

Black gynecologic oncology patients with COVID-19 are more likely to require hospitalization and have a disproportionate rate of death, according to a study published in *Cancer*. Investigators abstracted data from gynecologic oncology patients with COVID-19 infection among eight New York City area hospital systems. COVID-19-related hospitalization and mortality were analyzed using a multivariable mixed-effects logistic regression model. Overall, 34.7% and 65.3% of the 193 patients who had gynecologic cancer and COVID-19 were black and non-black, respectively. The researchers found that compared with non-blacks, black patients were more likely to require hospitalization (71.6% vs 46.0%). Overall, 41.2% of the 34 patients who died from COVID-19 were black. Among those who were hospitalized, black patients were significantly more likely than non-black patients to have three or more comorbidities (81.1% vs 59.2%); to reside in Brooklyn (81.0% vs 44.4%); to live with family (69.4% vs 41.6%); and to have public insurance (79.6% vs 53.4%). Among those younger than 65, black patients were more likely to need hospitalization compared with non-black patients in a multivariable analysis (odds ratio, 4.87). "COVID-19 infection outcomes experienced by black women highlight pre-existing disparities and call for multi-faceted attention to address these longstanding differences in health outcomes among patients with gynecologic cancer," the authors write."