

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. ■



Estimating Shortages of Continuous Kidney Replacement Therapy During COVID-19



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Several states are projected to encounter continuous kidney replacement therapy (CKRT) shortages during the COVID-19 pandemic, according to a study. Establishing an inpatient kidney replacement therapy national registry and maintaining a national stockpile of CKRT equipment are warranted.

During the current COVID-19 pandemic, there has been a surge in patients requiring intensive care throughout the United States. "Early in the pandemic, US healthcare systems worked to increase the number of hospital beds and the availability of ventilators to care for critically ill patients with COVID-19," explains Yuvaram Reddy, MBBS. "Although serious illnesses like COVID-19 can affect the kidneys, less attention has been paid toward increasing the number of continuous kidney replacement therapy (CKRT) machines that are needed to treat critically ill patients during the pandemic."

Studies show that 5% to 7% of critically ill patients with COVID-19 will develop stage 3 acute kidney injury requiring dialysis. Anticipating this surge, healthcare systems activated crisis capacity measures for inpatient kidney replacement therapy, but the impact of these measures was largely unknown or purely anecdotal. "Without adequate data on the number of CKRT machines available and in use, it's difficult to predict how many of these machines are needed and how much of a machine shortage, if any, might be encountered," says Dr. Reddy.

Projected CKRT Machine Shortages

In a study published in the *American Journal of Kidney Diseases*, Dr. Reddy and colleagues developed mathematical models of CKRT demand and capacity in an effort to inform emergency planning, identify areas for which more data are needed, and mitigate CKRT shortages during the pandemic and in future healthcare crises. Data sources included the Institute for Health Metrics and Evaluation model, the Harvard Global Health Institute model, and published literature.

"At the peak of the early phase of the pandemic, defined as February to August 2020 for the study, our mathematical models projected a combined shortage of more than 1,000 CKRT machines, with shortages in six states—Connecticut, Maryland, Massachusetts, Michigan, New Jersey, and New York," says Dr. Reddy (Figure). "Additionally, possible shortages were projected in eight states—Arizona, Colorado, Louisiana, Nebraska,

New Mexico, Rhode Island, South Carolina, and Wyoming." In the best- and worst-case scenarios, there were shortages of CKRT machines in three and 26 states, respectively.

A National Stockpile

While the models used in the study cannot be used for county- or hospital-level decision making, the researchers reported that they may be of value in providing high-level projections of CKRT shortages. "While we sought to estimate shortages in CKRT machines on a local healthcare system level, the US currently lacks the data required to perform such an analysis," Dr. Reddy says. "Therefore, we estimated shortages at the state and national level. If policymakers worked with nephrologists to create a national data registry of the availability and use of dialysis machines across the country, it could improve future mathematical models so that we can develop better emergency preparedness plans."

The study group recommends creating a national multidisciplinary task force comprising key stakeholders from the federal government, the nephrology community, industry, and patients to improve data collection and emergency prepared-

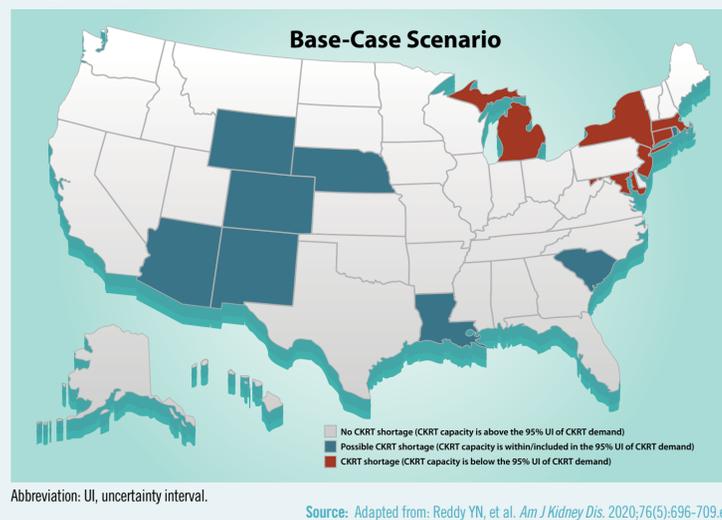
ness planning for CKRT machines. Key task force initiatives include ensuring that a national registry provides real-world data on inpatient CKRT machines, supplies, and personnel, as well as identifying approaches to creating a national stockpile of dialysis machines.

"Sharing CKRT machines across healthcare systems and developing a more robust national stockpile of these machines may help limit shortages during healthcare crises," says Dr. Reddy. Of note, as hospitals return to standard capacities when the pandemic eventually ends, there will likely be a surplus of CKRT machines. This creates a unique opportunity to repurpose these machines to provide relief for future waves of COVID-19 and other healthcare crises.

Dr. Reddy says that future research should be aimed at collecting and analyzing local hospital, healthcare system, and county-level data on the availability and use of dialysis machines. "Equipped with these data, the US can mitigate the risk and impact of CKRT shortages during current and future healthcare crises through improved emergency preparedness planning," he says. ■

Figure Base-Case Projections

The figure below is a heat map demonstrating states with continuous kidney replacement therapy (CKRT) shortages during the initial wave of the COVID-19 pandemic in the base-case scenario.



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A Physician's Guide to Surviving COVID Winter

By Rada Jones, MD

How can you survive this winter holding on to your temper, family, and job? Look out for #1. That's you. To care for others, you must care for yourself first. That's not selfish. That's smart. To protect those who need you, you must stay healthy and sane. How? These are my tips.

1 | Set rules for others and for yourself | Your sleep should be sacred. So should whatever time off you can schedule.

2 | Enlist help | So many grateful folks want to help healthcare workers. Your neighbors may be glad to walk your dog, run some errands, or grab a gallon of milk.

3 | Prioritize yourself | Pay someone to plow, buy groceries online, hire a housekeeper to save time for the things that really matter.

4 | Schedule time for yourself | To exercise, meditate, pray, journal—whatever helps fill your well.

5 | Shut off the TV | Whether you're Democrat or Republican, you won't enjoy the news. Watch Hallmark, the Nature Channel, or the Food Channel. Watching food is fun, and it won't make you fat.

6 | Go outdoors | There's magic in nature and sunlight, whatever's left of it. Hike, snowshoe, and allow your lungs to breathe the real air instead of the reconditioned germs they allow you in the hospital.

7 | Say no | That's a survival technique. Say no to parties, hugging strangers, doing things you shouldn't, and protecting others' feelings. Let them take care of their feelings. You take care of yourself.

8 | Cut yourself some slack | You aren't perfect. Nobody is. You'll make mistakes, gain a few pounds, step on some toes, maybe even lose it at times. So what? Just do the best you can.

9 | Read a book | Remember those things made of paper? You turn a page and land in a new world?

10 | Be careful with alcohol and substance use | They may feel good at the moment, but you'll be worse off in the long run.

11 | Watch old movies that make you laugh.

12 | Take a break from social media | Picking fights with random strangers won't help your mental health. Cut off those who hurt you.

13 | Get a cat | They have nine lives; that's why they are masters of survival. They ignore all unpleasantness, and they'll show you how. And they're the best nap helpers.

14 | Communicate | Ask your coworkers how they handle the stress. They may teach you something, and if they don't, sharing the burden will help you both.

15 | Seek help before you lose it | Check out the CDC's resources on stress and coping.

16 | Pat yourself on the back | You're a darn hero! In recycled PPE, instead of shining armor, you saved fair maidens of all genders, ages, and persuasions. With a vaccine in sight, there's a light at the end of the tunnel.

Wishing you all health, joy, and happiness. See you all on the other side.

Rada Jones is an emergency physician and can be reached at her self-titled site, RadaJonesMD.com, and on Twitter @jonesrada. She is the author of *Overdose*.

In Case You Missed It Fine Particulate Matter Linked to Increased Prevalence of CKD

Fine particulate matter (PM_{2.5}) is associated with an increased prevalence of chronic kidney disease (CKD) and albuminuria in the general population in China, according to a study published in the *Journal of the American Society of Nephrology*. Researchers examined the association between long-term exposure to ambient PM_{2.5} and CKD prevalence in China in a representative sample of 47,204 adults from the China National Survey of CKD. The annual exposure to PM_{2.5} was estimated at each participant's address. The 2-year mean PM_{2.5} concentration was 57.4 µg/m³, varying from 31.3 to 87.5 µg/m³. There was a positive association for a 10-µg/m³ increase in PM_{2.5} with CKD prevalence (odds ratio [OR], 1.28) and albuminuria (OR, 1.39). These associations were significantly stronger in urban versus rural areas, in men versus women, in participants younger than 65 versus aged 65 and older, and in those without versus with comorbidities. "The risk started to increase at PM_{2.5} concentrations well below the Chinese ambient air quality standards, suggesting that air quality control should be more stringent in China," the study authors write. "These findings offer important evidence to inform policymakers and public health practices in lowering the risk of CKD associated with exposure to ambient PM_{2.5} pollution."

Donor Kidney Biopsies Do Not Aid Transplant Outcome Prediction

Use of kidney biopsy results from deceased donor kidneys does not improve prediction of allograft survival, according to a study published in the *Journal of the American Society of Nephrology*. Investigators conducted a population-based study involving patients who received a deceased donor kidney that had been biopsied before implantation in France and Belgium. Kidneys that had been acquired from deceased US donors for transplantation and were discarded due to low organ quality were also studied. Adding donor histology did not significantly improve prediction of long-term allograft failure in the development cohort of 1,629 kidney recipients at two French centers. The lack of improved accuracy from adding histology was confirmed in an external validation cohort from two Belgian centers. Of 1,103 US kidneys discarded due to histologic findings, about 45% could be accurately matched to very similar kidneys that had been transplanted in France; the allograft survival rates of these discarded kidneys were expected to be 93.1%, 80.7%, and 68.9% at 1, 5, and 10 years, respectively. "These results add to a growing body of evidence that a ready opportunity exists for US centers to increase the number of kidney transplants by adopting evidence-based standards for organ acceptance," the authors write. ■

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