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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.

Improving Outcomes With Calibration-Free Real-Time CGM in Younger Patients With T1D

Written by
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International diabetes registries repeatedly show that adolescents and young adults with type 1 diabetes (T1D) have worse A1C outcomes compared with other age groups, with direct consequence on their future complication risks. Real-time continuous glucose monitoring (RT-CGM) use has been associated with lower A1C levels, although previous studies have reported that the reduction was attenuated in younger patients.

My colleagues and I speculated that device burden (eg, finger stick testing for calibration, inaccurate sensors, and false alarms) associated with older RT-CGM technologies may have been a contributory factor and led to the suboptimal user adherence and outcomes observed in prior research. People with T1D from diverse ethnic and social backgrounds have also tended to be under-represented in device and technology studies. There is still a lack of evidence on the efficacy and usability of diabetes technologies in these under studied cohorts.

Sensor-based glucose outcomes—specifically time in range (TIR)—have recently gained traction as a measure of glycemic control beyond A1C, as A1C alone does not provide information relevant to hypoglycemia risk or glucose variability, factors that are known to impact glycemic control and quality of life in people living with T1D. TIR of 70-180 mg/dL is now accepted as an outcome of therapeutic efficacy in T1D clinical studies, and improvement in TIR has been associated with reduced risk of microvascular complications.

Calibration-Free RT-CGM vs Capillary Glucose Testing

On this background, we published a randomized cross-over design study in *Diabetes Care* that compared the efficacy of a RT-CGM system that is calibration-free and linked to a smartphone app with that of conventional self-monitoring of blood glucose (SMBG). We included adolescents and young adults aged 16–25 with poorly controlled T1D from various ethnic and social backgrounds to represent usual clinical practice.

Participants were randomly assigned to 8 weeks of RT-CGM intervention and SMBG control periods, with a 4-week wash out between these two periods. During the intervention, they installed the Dexcom G6 app on their own smartphone and were trained on using RT-CGM sensor data for decision making and insulin dose adjustments. During the SMBG period, they performed finger stick capillary glucose measurements as per usual clinical practice. The main study endpoint was the difference in TIR (70-180 mg/dL) between RT-CGM and SMBG, with secondary outcomes that included A1C and usability (% of sensor wear).

Reduced Technology Burden & Improved Glycemic Outcomes

Our study had a higher proportion of participants from diverse ethnic backgrounds compared with other T1D technology studies, with more than one-half living in areas constituting the most deprived areas of England. At baseline, they had high A1C levels (78 mmol/mol, or 9.3%) and were predominantly hyperglycemic, consistent with observations in clinical practice. We found that RT-CGM users spent an additional 2.6 hours per day with glucose levels in the normal range, compared with SMBG users. A1C was reduced by 8.5 mmol/mol, in favor of RT-CGM (Table).

The proportion of time spent hyperglycemic (glucose levels >180 mg/dL) was substantially reduced with RT-CGM by nearly 3 hours per day when compared with SMBG. This cohort had minimal hypoglycemia (<1.5% of the whole period), and thus, no statistically significant difference was found between the two groups. Use of RT-CGM in our study was relatively high compared with previous studies in this age group (sensor use was 84% of the whole study period).

We speculate that the reduced daily burden of using a calibration-free RT-CGM that is licensed for insulin dosing and linked to a smartphone app may have attributed to the higher adherence of sensor use in this age group. This higher adherence was also likely associated with the A1C reduction observed with RT-CGM use when compared with SMBG use. Further investigation is required to evaluate longer-term outcomes in this patient population.

Table Glycemic Outcomes

Day & Night	RT-CGM	SMBG	Paired Mean Difference (95% CI)*	*P* Value
Time spent at glucose level (%)				
70-180 mg/dL	35.7 ± 13.5	24.6 ± 9.3	11.1 (7.0-15.2)	<0.001
>180	61.7 ± 15.1	73.6 ± 10.4	-11.9 (-16.4, -7.4)	<0.001
>300	21.7 ± 14.4	33.4 ± 16.5	-11.7 (-16.8, -6.6)	<0.001
<70	1.45(0.40-4.08)	0.58 (0.20-3.50)		0.055
<63	0.65 (0.18-2.32)	0.25 (0.04-2.15)		0.111
<54	0.28 (0.05-1.16)	0.06 (0.00-0.99)		0.102
A1C change (%)	-0.53 ± 0.74	0.24 ± 0.69	-0.76 (-1.1, -0.4)	<0.001
A1C change (mmol/mol)	-5.9 ± 8.0	2.6 ± 7.5	-8.5 (-12.4, -4.6)	<0.001
Mean glucose (mg/dL)	219.7 ± 37.6	251.9 ± 36.3	-32.2 (-44.5, -20.0)	<0.001
SD of glucose (mg/dL)	85.3 ± 14.1	90.0 ± 11.3	-4.6 (-9.0, -0.3)	0.037
CV of glucose	39.3 ± 5.6	36.3 ± 6.3	3.0 (1.0-4.9)	0.006

Data are mean ± standard deviation or median (interquartile range).
*Normally distributed data are presented as mean differences of values (RT-CGM minus control phase). A positive value indicates that the measurement was higher during the RT-CGM phase than during the SMBG phase.
Abbreviations: CV, coefficient of variation; RT-CGM, real-time continuous glucose monitor; SD, standard deviation; SMBG, self-monitoring of blood glucose.
Source: Adapted from: Thabit H, et al. *Diabetes Care.* 2020;43(10):2537-2543.

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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 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, and on Twitter @jonesrada. She is the author of Overdose.

In Case You Missed It

Monitors Identify Heart Rate Patterns During Nocturnal Hypoglycemia in T1D

Findings from an exploratory study published in *Metabolites* support that heart rate modifications occur during nocturnal hypoglycemia in pediatric patients with type 1 diabetes (T1D) whose blood glucose was detected by flash glucose monitoring devices and heart rate was measured by wrist-worn fitness trackers. With a combination of information from blood glucose and heart rate measurements having been proposed to investigate heart rate changes related to nocturnal hypoglycemia episodes in pediatric patients with T1D, researchers sought to examine whether such measurements could help improve hypoglycemia prediction. Children and adolescents with T1D were monitored for an average of 194 days using the above-noted devices to compare heart rate values recorded in the hour before nocturnal hypoglycemia episodes with those recorded during sleep intervals without hypoglycemia. Behavior after nocturnal hypoglycemia was also investigated. Among participants, 67% showed a statistically significant difference between the before-hypoglycemia and the no-hypoglycemia heart rate distributions. In each of these cases, the before-hypoglycemia heart rate median value was higher than the no-hypoglycemia heart rate median value. In nearly all cases, heart rate values remained higher after the hypoglycemia episode when compared with no-hypoglycemia sleep intervals.

App Fills the Gap in Care for Hispanic Women With Prior Gestational Diabetes

A smartphone app developed to pilot test a culturally tailored, bilingual (Spanish/English) lifestyle program to reduce risk factors for type 2 diabetes in Hispanic women with gestational diabetes mellitus (GDM) in the prior 5 years has the potential to fill the gap in care experienced by this patient population, according to study published in *JMIR Formative Research*. With a lack of mobile health programs to reduce these risk factors in this patient population, despite the high prevalence of smartphone ownership in these women, study investigators sought to develop the above-noted app (¡Hola Bebé, Adiós Diabetes!), examine its usability and acceptability, and assess its short-term effectiveness in increasing self-efficacy for healthy eating and physical activity and in decreasing weight. App features include are educational modules on healthy eating and physical activity; personal action plans; motivational text messages; weight tracking; recipes; and tiered rewards. Statistically significant improvements were observed in self-efficacy for physical activity and for healthy eating, while weight decreased but not significantly. Data revealed a high level of user engagement and supported the app's acceptability and usability.

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