



Why We Need the Lede, in Both Journalism & Medicine



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In journalism, the “lede” is the first part of a news story. A good lede contains the key points and gives the general idea of the article. Ledes are also crucial in medicine.

When healthcare professionals communicate with each other, we use ledes all the time. Let’s say a doctor is working in a clinic and is sending a university student to the emergency department. The doctor is concerned that the student could have meningitis. The patient—let’s call him John Doe—is confused and has a fever. His blood pressure is low, but his heart rate is high. After calling 911, the doctor calls the ED to communicate that the patient is coming in an ambulance. The charge nurse answers the phone. Consider the following two scenarios and which has a better lede?

“I just sent an unstable, 21-year-old male to your department because I’m concerned he could have meningitis. His blood pressure is 86/52 and his heart rate is 120. His temperature is 102.2, he is confused, and his neck is stiff. His name is John Doe and he will be there in 5 minutes. The ambulance just left with him.”

OR

“A patient came into my office this afternoon. His name is John Doe, and he is 21. He started feeling unwell yesterday after he got home from basketball practice. His roommates brought him to my office today because John became confused. When I checked John’s blood pressure, it was low, and his heart rate was high. His neck was stiff and his temperature was up, so I think it could be meningitis. He just left here in an ambulance and he should arrive to you soon.”

In the first example, the charge nurse knows from the first sentence that John’s condition is serious. Already, she is thinking about the next steps, who she needs to notify, and the supplies they will need. The word “unstable” gives a hint about John’s level of sickness. The specific numbers describing his blood pressure, heart rate, and temperature give an idea of the severity of his illness.

In the second example, it is not clear until the end of the paragraph that the doctor is thinking that John could have meningitis. A couple of unnecessary sentences may not seem like that much extra time, but in medicine, time can be crucial, especially in emergencies. ■



“You are just fine. This prescription’s for me!”

Hormone Therapy for Subclinical Hypothyroidism



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Previous studies indicate that subclinical hypothyroidism affects up to 10% of the adult population and is associated with symptoms such as tiredness, low mood, and weight gain among the estimated 13 million Americans with the condition, for whom the prevalence is higher in women and the elderly. Relatively limited evidence exists from randomized clinical trials (RCTs) to guide therapy of subclinical hypothyroidism. Systematic reviews have been inconclusive, and clinical practice guidelines have varied regarding recommendations for management.

For a study published in *JAMA*, Martin Feller, MD, MSc, and colleagues assessed whether the use of thyroid hormone therapy is associated with improvements in general quality of life or thyroid-related symptoms among patients with subclinical hypothyroidism. The study investigators also assessed tiredness, depressive symptoms, cognitive function, blood pressure, and BMI.

A Striking Null Result

Dr. Feller and colleagues reviewed data from randomized clinical trials that compared thyroid hormone therapy with placebo or no therapy in non-pregnant adults with subclinical hypothyroidism. Two reviewers independently evaluated eligibility based on titles and abstracts of all retrieved studies. Overall, 21 studies included 2,192 adults (Table). Study size ranged from 20 to 737 participants; mean age from 32 to 74 years; percentage of women from 46% to 100%; and baseline mean thyrotropin values from 4.4 mIU/L to 12.8 mIU/L.

After a treatment range of 3 to 18 months, thyroid hormone therapy was associated with decreasing the mean thyrotropin value into the normal reference range when compared with placebo (range, 0.5-3.7 mIU/L vs 4.6-14.7 mIU/L) but was not associated with benefits in general quality of life or thyroid-related symptoms. Overall, risk of bias was low, and the quality of evidence assessed with the GRADE tool was judged moderate to high.

“We observed a striking null result, (ie, no benefit of thyroid hormone therapy) regarding any of the outcomes we analyzed,” says Dr. Feller. “Our results imply that patients with subclinical hypothyroidism need generally not to be treated with thyroid hormones. It is our hope that international guidelines will be updated, taking into account our findings, and that our findings will spare millions of patients with subclinical hypothyroidism from taking a daily, futile therapy.”

An Extensive Analysis

According to Dr. Feller, other experts in the field speculate that thyroid hormone therapy could lower the risk for cardiovascular events. “We mainly focused on patient-centered outcomes, such as quality of life and thyroid-related symptoms,” he says. “We could not analyze cardiovascular events or mortality, because only one of the 21 included trials reported on cardiovascular events; they were not powered for this outcome, and

follow-up periods were too short. To determine whether thyroid hormone therapy could lower the risk for cardiovascular events, a large randomized controlled trial with a multi-year follow-up would be needed.”

Additionally, Dr. Feller says that the 21 trials the research team analyzed included a limited number of patients with subclinical hypothyroidism who had a thyrotropin greater than 10 mIU/l (in general, about 10% of patients with subclinical hypothyroidism have a thyrotropin >10 mIU/l). They did not find evidence that this minority benefits from thyroid hormone therapy, but to confirm

this lack of benefit, an additional randomized trial would be needed.

“In my experience, many physicians treating patients with subclinical hypothyroidism find it hard to accept that there is no benefit of thyroid hormone therapy for this patient population,” says Dr. Feller. “In their daily clinical practice, many of these patients seem to benefit from thyroid hormones. However, given the futility of thyroid hormone therapy in randomized clinical trials, I believe that the benefit some patients experience from thyroid hormone therapy outside randomized clinical trials is just due to a placebo effect.” ■

Table Select Trial Characteristics

Characteristics of 21 randomized clinical trials on thyroid hormone therapy for subclinical hypothyroidism in adults.

Source	Country	No. participants	Mean age, years	Percent women	Intervention	Hypothyroid symptoms at baseline, intervention vs control
Stott, et al. 2017	Netherlands, Switzerland, United Kingdom, Ireland	737	74	54	Levothyroxine vs placebo	ThyPRO hypothyroid symptom score: 17.5 vs 16.9
Zhao, et al. 2016	China	369	55	73	Levothyroxine vs no intervention	NR
Najafi, et al. 2016	Iran	60	34	85	Levothyroxine vs placebo	Mean number of hypothyroid symptoms per participant: 4.8 vs 5.1
Ersoy, et al. 2012	Turkey	60	46	97	Levothyroxine vs no intervention	NR
Aghili, et al. 2012	Iran	60	34	85	Levothyroxine vs placebo	Mean number of hypothyroid symptoms per participant: 3.2 vs 3.7
Reuters, et al. 2012	Brazil	71	50	87	Levothyroxine vs placebo	Zulewski score (only change from baseline reported)
Cabral, et al. 2011	Brazil	32	46	100	Levothyroxine vs no intervention	NR
Parle, et al. 2010	United Kingdom	94	74	61	Thyroxine vs placebo	NR
Nagasaki, et al. 2009	Japan	95	65	100	Levothyroxine vs placebo	NR
Teixeira, et al. 2008	Brazil	60	48	95	Levothyroxine vs placebo	NR
Razvil, et al. 2007	United Kingdom	100	54	82	Levothyroxine vs placebo	ThyDQoL (only change from baseline reported)
Jorde, et al. 2006	Norway	69	62	46	Thyroxine vs placebo	Mean number of hypothyroid symptoms per participant: 4.0 vs 4.0
Iqbal, et al. 2006	Norway	64	64	48	Thyroxine vs placebo	NR
Caraccio, et al. 2005	Italy	23	32	91	Levothyroxine vs placebo	NR
Yazici, et al. 2004	Turkey	45	40	84	Levothyroxine vs placebo	NR
Monzani, et al. 2004	Italy	45	37	82	Levothyroxine vs placebo	NR
Kong, et al. 2002	United Kingdom	40	50	100	Thyroxine vs placebo	Overall, 83% reported fatigue, 80% reported weight gain
Caraccio, et al. 2002	Italy	49	35	86	Levothyroxine vs placebo	NR
Monzani, et al. 2001	Italy	20	32	90	Levothyroxine vs placebo	NR
Meier, et al. 2001	Switzerland	66	57	100	Levothyroxine vs placebo	Billewicz score: -25.7 vs -28.3
Cooper, et al. 1984	United States	33	54	97	Levothyroxine vs placebo	Mean number of hypothyroid symptoms per participant: 21. Vs 2.4

Source: Feller M, et al. *JAMA*. 2018;320(13):1349-1359.

Medical Economics

SMARTER BUSINESS. BETTER PATIENT CARE.

Providing Patients Record Access

This article was originally published in *Medical Economics* and is written by Keith Loria.

Many physicians aren’t aware that, with limited exceptions, HIPAA gives patients the right to get copies of all of their medical records and allows them to see all original medical records, usually at a medical provider’s office.

Shuhan He, MD, an emergency medicine physician at Massachusetts General Hospital, says one of the most common misconceptions is that patients somehow are limited in obtaining their own medical records because of HIPAA.

“Many smaller practices actually use it as a way to prevent patients from accessing their own records for fear of mishandling data in some capacity,” he says. “What I always emphasize is that the legislation itself was called the Health Insurance Portability and Accountability Act. The rule actually encourages patients to access their own information and move it between practices, even if providers and healthcare entities are required to protect that information at a higher burden.”

Providing the Records

Anwar A. Jebran, MD, a third-year internal medicine resident at Weiss Memorial Hospital in Chicago suggests practices use systems that are compatible with interoperability standards such as HL7 FHIR, an interface for exchanging electronic health records, which would eliminate much of the manual workload associated with accessing records.

“For practices without that, having a system to handle these requests with posted timelines works well,” he says. “Corroborating information with the patient before adding it to their health records is also a good practice of verbally sharing the patient’s health records and then giving them the option of either receiving a copy or managing their own documents.”

Money Matters

The HIPAA Privacy Rule permits a covered entity to charge a reasonable, cost-based fee that covers certain limited labor, supply, and postage costs that may apply in providing an individual with a copy of medical records in the form and format requested or agreed to by the individual.

However, the laws for copying medical records vary from state to state in terms of fees. For instance, in Florida, searches for medical records are \$1 per search per year, \$1 per printed page, and \$2 for microfilm. But it gets more complicated when you cross state lines.

The law is very clear. People have a right to their data, Jebran says. ■

To read the unabridged version, visit www.medicaleconomics.com.

Schizophrenia & Insulin Resistance

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Although research indicates that patients with schizophrenia are at increased risk for impaired glucose metabolism when compared with the general population, the comorbidity between the two conditions cannot be fully explained by known risk factors, such as obesity, smoking, stress, or antipsychotic medication. Previous family and genome-wide studies suggest that the co-occurrence between schizophrenia and impaired glucose metabolism might be due to shared genetic factors, but the biological mechanisms underlying this association remain unknown.

For a study published in *JAMA Psychiatry*, my colleagues and I examined the association between insulin resistance, schizophrenia polygenic risk, and response to treatment in drug-naïve schizophrenia patients and matched healthy individuals while controlling for demographic (age, gender, BMI), lifestyle (smoking, alcohol, and cannabis use) and clinical (psychopathology scores, medication) factors. Schizophrenia polygenic risk scores (PRS) were calculated based on 108 genome-wide significant schizophrenia loci from the Illumina Infinium PsychArray Bead-Chip genotyping data imputed using IMPUTE2/SHAPEIT. The updated Homeostasis Model Assessment (HOMA2) was used to infer IR, β -cell function, and insulin sensitivity from clinical measurements of fasting serum glucose and insulin levels. Switching antipsychotic medication at least once during the initial 12 months of treatment was used as a heuristic long-term treatment outcome measure.

We found that insulin resistance was significantly correlated with schizophrenia PRS, with higher genetic risk of schizophrenia associated with increased insulin resistance. Patients with higher insulin resistance were more likely to switch medication during the first year of treatment, implying lower clinical response. Indeed, the HOMA2-IR was positively associated with schizophrenia PRS in patients with schizophrenia but not in the control group. Baseline HOMA2-IR was significantly associated with switching antipsychotic medication during the initial 12 months of treatment. Of the patients for whom complete follow-up information was available, all patients who at baseline satisfied the fasting insulin criteria for IR ($\geq 25 \mu\text{U/mL}$) required changing medication within the first year of treatment. However, schizophrenia PRS was not significantly associated with medication switching status.

Our results suggest that insulin resistance and schizophrenia are genetically linked and that patients with schizophrenia presenting with insulin resistance might constitute a distinct patient subgroup. Because these patients show diminished response to antipsychotic medication, they might require personalized treatment tailored to their endophenotype. ■

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