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# Internal Medicine

Evidence-based summaries of the latest research in internal medicine [ALERT]

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ABSTRACT & COMMENTARY

## Do Antipsychotics Help with Delirium?

*By Martin Lipsky, MD*

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**Dr. Lipsky reports no financial relationships relevant to this field of study.**

SYNOPSIS: In palliative care patients suffering from delirium, managing delirium precipitants and individualized supportive strategies alone work better than adding risperidone or haloperidol.

SOURCE: Agar MR, Lawlor PG, Quinn S, et al. Efficacy of oral risperidone, haloperidol, or placebo for symptoms of delirium among patients in palliative care: A randomized clinical trial. *JAMA Intern Med* 2017;177:34-42.

Patients in palliative care commonly experience delirium. Symptom relief is important for these patients. Crafting evidence-based strategies to address delirium optimally is crucial. Management strategies include both pharmacologic and non-pharmacologic methods. Antipsychotics remain one of the most commonly used pharmacologic treatments, yet the risks associated with their use[1] make it essential to evaluate their benefits. Agar et al[2] set out to determine if risperidone or haloperidol, administered in addition to non-pharmacologic care, provided additional benefit in reducing symptoms of delirium when compared to placebo.

The study was a double-blind, parallel-arm, dose-titrated, randomized, clinical trial conducted at 11 Australian inpatient hospice or hospital palliative care services. The study consisted of 247 participants with a mean age of 74.9 years who exhibited a life-limiting illness, delirium, and a delirium score (sum of Nursing Delirium Screen Scale behavioral, communication, and perceptual items) of 1 or more. Among the study group, 85 were women and 218 patients had cancer, making it the most common diagnosis. In the intention-to-treat analysis, 82 received risperidone, 81 received haloperidol, and 84 received placebo. Participants in the risperidone arm demonstrated significantly higher delirium scores compared to placebo (on average 0.24 units higher, 95% confidence interval [CI], 0.06-0.42; $P = 0.009$). The authors discovered similarly significant differences in the haloperidol arm. Both treatment arms experienced significantly more extrapyramidal effect, and dropout rates for the risperidone group (31

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of 82 patients) were about twice the rates of haloperidol (18 of 81 patients) and placebo (15 of 84 patients). Overall survival rate in the placebo group was better than for both the risperidone and haloperidol groups, but only the difference for those receiving haloperidol (hazard ratio, 1.73; 95% CI, 1.20-2.50; $P = 0.03$) achieved statistical significance. (Placebo vs. risperidone arm hazard ratio, 1.29; 95% CI, 0.91-1.84; $P = 0.14$).

The authors concluded that for palliative care patients presenting with delirium, management of delirium precipitants and supportive strategies alone result in lower delirium scores and shorter duration of symptoms than when adding either risperidone or haloperidol.

## ■ COMMENTARY

Antipsychotics are used commonly to alleviate the troubling behavioral symptoms associated with delirium. Despite the wide use of antipsychotics to help control behavioral symptoms, Agar et al found that not only may antipsychotics provide no benefit, risperidone and haloperidol seem to increase the intensity and duration of symptoms. Less surprising was that haloperidol use decreased overall survival. Other studies also demonstrated the dangers of antipsychotic drugs in the elderly and indicated that older patients presenting with dementia treated with atypical antipsychotics experienced about twice the mortality rate of those taking placebo.[3]

Although the first-line treatment for delirium is avoiding precipitating factors and instituting non-pharmacologic measures, antipsychotics are used commonly for uncontrolled symptoms because of their perceived effectiveness. These findings, demonstrating that those taking either risperidol or haloperidol experience less symptom relief and worsened survival, suggest that these agents should not be used to treat elderly patients suffering from delirium. The authors noted one study limitation was that few participants were younger than 65 years of age, and perhaps these drugs might demonstrate less risk and greater utility in younger patients. It is also possible that other drugs in this class may be more effective. However, even though the authors highlighted the need for further study, at this point this study suggests that antipsychotics exhibit little or no treatment role for patients in palliative care with symptoms of delirium. ■

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## ABSTRACT & COMMENTARY

# Orbiting the Truth of Heart Failure Incidence and Implications in Those with Prevalent Atrial Fibrillation

***By Cara Pellegrini, MD***

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**Dr. Pellegrini reports no financial relationships relevant to this field of study.**

SYNOPSIS: Patients presenting with atrial fibrillation are at elevated risk for the development of heart failure, typically with preserved ejection fraction, which is associated with increased risk of death and hospitalization.

SOURCE: Pandey A, Kim S, Moore C, et al. Predictors and prognostic implications of incident heart failure in patients with prevalent atrial fibrillation. *JACC Heart Fail* 2017;5:44-52.

Atrial fibrillation (AF) and heart failure (HF) frequently coexist because of shared risk factors and pathophysiological mechanisms. Causality is likely bidirectional and complex. Their concurrence is associated with poor outcomes. Yet, there has not been the same focus of attention on risk stratification and prevention of HF in AF patients, as for other outcomes, such as stroke.

An important step toward that goal is the development of a greater understanding of what AF population subset is at the highest risk of developing HF. Pandey et al used a national, community-based registry of outpatients with AF (ORBIT-AF) to examine predictors and outcomes of incident HF. In addition to the primary outcome of HF incidence, they examined all-cause death, all-cause hospitalization, stroke/thromboembolism, and bleeding events. They collected demographic and medical history data, as well as insurance status, treatment strategy, and quality-of-life information. Patients presenting with prevalent HF at time of enrollment were excluded, although not patients with asymptomatic systolic or diastolic dysfunction or moderate-to-severe left ventricular hypertrophy (subclinical stage B HF); these patients were excluded in a sensitivity analysis.

The study population was largely elderly (> 70 years of age) and white, nearly half female, and mostly hypertensive with normal left ventricular ejection fraction. Of the 6,545 participants, 236 (3.6%) developed HF over a two-year follow-up period, for a rate of 1.58 per 100 person-years, markedly higher than that reported in the general population (0.2-1 per 100 person-years).

Although 64% of those who developed HF had a preserved ejection fraction (HFpEF), only 13.5% exhibited a documented drop in their ejection fraction (HFrEF); and 22.5% could not be classified due to missing ejection fraction information. Not surprisingly, older age, history of coronary artery disease, renal dysfunction, and significant valvular disease were independent predictors of HF incidence. Additionally, permanent AF, AF that is sustained and accepted by physician and patient (more end-stage AF), was associated with a 60% higher risk of HF than paroxysmal AF, and there was a 7% increased incidence of HF for each beat/minute increase in baseline heart rate.

Those who developed HF experienced significantly higher rates of all-cause death, all-cause hospitalization, and hospitalization for bleeding specifically. The authors concluded that incident HF in AF is relatively common, more likely HFpEF, predicted by AF-specific clinical characteristics, as well as traditional HF risk factors, and associated with poor long-term outcomes.

## ■ COMMENTARY

Particularly in the absence of a reduction in ejection fraction, it can be difficult to discern the true onset of heart failure in patients presenting with concomitant AF. AF alone can cause exercise limitation, left atrial enlargement, and elevation of biomarkers, such as NT-proBNP. Given the admitted inclusion of patients with subclinical stage B HF and the one-third to one-half of patients receiving diuretics at baseline, this study may have been identifying those in whom AF aided progression from subclinical to overtly clinical HF more than truly de novo HF cases. Nonetheless, the identification of a vulnerable subset of patients within the larger AF cohort is of value, as the number of people affected by these extremely prevalent conditions continues to increase.

The effect of insufficient ventricular rate control on the development of heart failure in AF patients has been debated. Although the RACE-2 (The Rate Control Efficacy in Permanent Atrial Fibrillation: a Comparison between Lenient versus Strict Rate Control II) trial did not demonstrate an increase in HF incidence in the lenient rate-control arm, there has been ongoing criticism that the study was underpowered and did not allow a long enough follow-up period to detect a potential difference.

The current registry-based study cannot ascribe causality, but does raise concerns that in the described setting — elderly patients demonstrating renal dysfunction, coronary artery disease, and more advanced AF — perhaps more stringent rate control should be considered.

There is a growing movement in AF management to treat AF earlier in the disease course and more aggressively. This appears to be truer in the HF population, as we have previously discussed, who appear to have all the more to gain with a rhythm control, and, specifically, an ablation-based strategy. In the current study, antiarrhythmic drug use was similar between the two groups, but there was a trend toward more catheter ablation in the group without incident HF.

Additional work is needed to determine the effect of risk factor modification, including AF ablation, on HF development, but this study adds to the mounting evidence supporting the idea that halting the process of AF-induced electrical and mechanical atrial remodeling may lead to beneficial effects for mitigating the stressors that cause HF. ■

ABSTRACT & COMMENTARY

# A Healthy Lifestyle May Halve the Genetic Risk of Coronary Disease

*By Joseph E. Scherger, MD, MPH*

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**Dr. Scherger reports no financial relationships relevant to this field of study.**

SYNOPSIS: Adherence to a healthy lifestyle of no smoking, no obesity, weekly physical activity, and a healthy diet reduces the genetic risk of coronary disease by almost half for all levels of genetic risk.

SOURCE: Khera AV, Emdin CA, Drake I, et al. Genetic risk, adherence to a healthy lifestyle, and coronary disease. *N Engl J Med* 2016;375:2349-2358.

Led by the Center for Human Genetic Research and the Cardiology Division at Massachusetts General Hospital, and the Division of Preventive Medicine, Department of Medicine at Brigham and Women's Hospital in Boston, a team of investigators used four databases totaling 55,685 people with genomic information regarding risk for coronary artery disease.

Three of the databases were prospective cohorts. The Atherosclerosis Risk in Communities study included white and black participants 45-64 years of age (7,814 participants). The Women's Genome Health Study (21,222 participants) was derived from the larger Women's Health Study of health professionals (mostly nurses). The Malmo Diet and Cancer Study was comprised of 22,389 participants between 44-73 year of age. The fourth database came from the cross-sectional BioImage Study for whom genotype and covariate data were available. The parameters of the healthy lifestyle were: no current smoking, no obesity, regular physical activity, and a healthy diet according to the American Heart Association guidelines.

The authors reported three noteworthy conclusions. First, inherited DNA variation and lifestyle factors contribute independently to risk of coronary artery disease. Second, a healthy lifestyle was associated with similar relative risk reductions across each stratum of genetic risk. Third, genetic risk does not indicate a determinism that a negative outcome will occur and the genetic risk is modifiable through a healthy lifestyle.

## ■ COMMENTARY

Lifestyle matters. Most physicians know that intuitively, but it is nice to study data that demonstrate that lifestyle matters and the degree to which it affects genetic risk. Because these data are observational, they do not prove that lifestyle was the impact factor like a randomized, controlled trial would. A study of this magnitude can only look at lifestyle in the most general terms. The authors relied on self-reported information. Just three of the four factors were needed to be classified as constituting a healthy lifestyle, so some of those classified as healthy might be obese or might engage in physical activity infrequently. The nutrition recommendations matched the low-fat, high-fiber (including grains) diet recommended by the American Heart Association. This diet is under modification thanks to the loosening of restrictions on saturated fats from natural foods. Also, accumulating data have demonstrated that carbohydrates are the macronutrient most associated with overweight and obesity.[1,2]

How well are physicians trained to teach a healthy lifestyle? Is lifestyle medicine a part of the culture of American medicine, or do we overemphasize the use of medications and procedures? How skilled are we in motivational counseling? Although most of us excel in smoking cessation, we may not even put overweight or obesity on the medical problem list, know little about prescribing exercise, and have very limited nutrition education. Knowledge about lifestyle medicine is growing among physicians and the public alike, by the formation of a new organization[3] and the rapid growth in functional medicine education.[4]

Since an unhealthy lifestyle is the dominant cause of chronic illnesses, such as type 2 diabetes, overweight and obesity, hyperlipidemia, and hypertension, promoting a healthy lifestyle may enhance health and reduce the burden of disease at very low cost. We may be entering by necessity an era of lifestyle medicine. ■

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PHARMACOLOGY UPDATE

# Tenofovir Alafenamide Tablets (Vemlidy)

***By William Elliott, MD, FACP, and James Chan, PharmD, PhD***

*Dr. Elliott is Medical Director, Pharmacy, Northern California Kaiser Permanente, and Assistant Clinical Professor of Medicine, University of California, San Francisco. Dr. Chan is Associate Clinical Professor, School of Pharmacy, University of California, San Francisco.*

**Drs. Elliott and Chan report no financial relationships relevant to this field of study.**

The FDA has approved tenofovir alafenamide (TAF), a prodrug for tenofovir (TFV). TFV is a nucleoside analog reverse transcriptase inhibitor, previously approved for HIV infection, which now is approved for the treatment of chronic hepatitis B virus infections (HBV) with compensated liver disease. This provides an alternative to tenofovir disoproxil fumarate (TDF). TAF is marketed as Vemlidy.

## INDICATIONS

TAF is indicated for the treatment of chronic HBV with compensated liver disease.[1]

## DOSAGE

The recommended dose is 25 mg once daily with food.[1] Patients should be tested for HIV infection prior to initiation of therapy. TAF is available as 25 mg tablets.

## POTENTIAL ADVANTAGES

TAF provides a more efficient delivery of TFV to the liver, requiring one-tenth of the dose of TDF.[2] It is also less likely to affect bone mineral density and cause decline in renal function.[1]

## POTENTIAL DISADVANTAGES

Glycosuria (≥ 3+) and elevation of LDL-cholesterol (> 190 mg/dL) were numerically higher with TAF (5% vs. 1% and 4% vs. < 1%) compared to TDF.

## COMMENTS

TFV, as a chemical entity, exhibits poor membrane permeability; thus, it is unable to be converted intracellularly to active tenofovir diphosphate (TFV-DP). TDF was the first approved prodrug for TFV. It is metabolized intracellularly to TFV and subsequently to TFV-DP. However, it has been associated with reduced renal function and decreased bone mineral density due to high system exposure. TAF, a new prodrug, has improved passive permeability and is actively transported into the liver cells, providing pharmacologically active TFV-DP at one-tenth the oral dose and 90% lower systemic exposure.[2] The efficacy and safety of TAF were evaluated in two randomized, double-blind, active-controlled, non-inferiority, 48-week studies.[1] Subjects (n = 1298) were treatment-naïve and treatment-experienced adults presenting with chronic HBV with compensated liver disease. Study one included subjects who were HBeAg-negative who were randomized 2:1 to TAF 25 mg (n = 285) or TDF 300 mg (n = 140). Study two included subjects who were HBeAg-positive (n = 581, n = 292). Twenty-one percent were treatment-experienced in study one and 26% in study two. The primary efficacy endpoint was the proportion of subjects with plasma HBV DNA levels < 29 IU/MmL. Secondary endpoints were proportion of subjects with ALT normalization, HBeAg loss, and seroconversion in study one and HBeAg loss and seroconversion in study two. Treatment successes were 94% vs. 93% in study one and 64% vs. 67% in study two, and noninferiority criteria was met. Numerically, normalization of ALT and serological improvements (loss of HBeAg and seroconversion) were higher for TAF. Common adverse reactions, such as headache, abdominal pain, fatigue, cough, nausea, and back pain, were similar between TAF and TDF. Changes in estimated glomerular filtration rate showed a median decrease from baseline of 1.2 mL/min for TAF vs. 5.4 mL/min. BMD declines of ≥ 5% at the lumbar spine occurred in the TAF arm compared to 20% for the TDF arm. Switching from TDF to TAF showed improvement in BMD and renal function in HIV subjects.[3] Seven of 866 subjects on TAF experienced elevated amylase levels and associated symptoms (e.g., nausea, biliary pancreatitis, pancreatitis), but none were associated with TDF. The wholesale cost for TAF and TDF is the same — $978 per 30-day supply.

## CLINICAL IMPLICATIONS

Chronic hepatitis B affects up to 2.2 million people in the United States. The American Association for the Study of Liver Diseases recommends pegylated interferon, entecavir, or TFV as preferred initial therapy for adults suffering from immune-active chronic hepatitis B.[4] TAF provides an effective and potentially safer option than TDF for the treatment of hepatitis B. Long-term safety in terms of fracture risk and renal toxicity has not been established. ■

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# Clinical Briefs

By Louis Kuritzky, MD

## Orthostatic Changes in BP Among Hypertensives

SOURCE: Townsend RR, Chang TI, Cohen DL, et al. Orthostatic changes in systolic blood pressure among SPRINT participants at baseline. *J Am Soc Hypertens* 2016;10:847-856.

Upon standing from a sitting or supine position, compensatory changes in heart rate and vascular tone maintain both systolic blood pressure and diastolic blood pressure fairly consistently. Postural changes in blood pressure of more than a 20 mmHg drop in systolic blood pressure or a 10 mmHg drop in diastolic blood pressure (or both) within three minutes of standing are defined as orthostatic hypotension, although only a minority of individuals with measurable orthostatic hypotension experience any clinical manifestations such as dizziness, lightheadedness, or falls. On the other hand, orthostatic hypotension has been associated with worsened cardiovascular outcomes, even when asymptomatic.

Townsend et al reported on baseline data from the SPRINT trial, which collected data on orthostatic blood pressure changes in 8,662 participants at baseline. Overall, 7% (n = 634) of enrollees demonstrated orthostatic hypotension, although the element by which they met the diagnostic criteria for orthostatic hypotension varied: 294 subjects met systolic blood pressure criteria, 227 met diastolic blood pressure criteria, and 113 met both.

No one has suggested that asymptomatic orthostatic hypotension requires treatment. On the other hand, symptomatic orthostatic hypotension places patients at risk for falls with subsequent consequences such as hip fractures, leading to increased mortality.

Because patients may not always be forthcoming about symptoms referable to orthostatic hypotension, more routine measurement of orthostatic blood pressure changes in hypertensive patients may help identify those at risk. ■

## Atopic Dermatitis Associated with Smoking

SOURCE: Kantor R, Kim A, Thyssen JP, Silverberg JI. Association of atopic dermatitis with smoking: A systematic review and meta-analysis. *J Am Acad Dermatol* 2016;75:1119-1125.

Atopic dermatitis is a chronic, often lifelong disorder affecting people of all ages. In addition to troublesome cosmetic effects, the pruritus of atopic dermatitis has been demonstrated to be extremely disruptive to sleep in children, and often requires systemic antihistamine treatment for control.

A lifelong requirement for periodic treatment with topical steroids and/or topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus) is not uncommon for mild-to-moderate sufferers. Severe atopic dermatitis may require systemic treatments, including immune modifiers such as cyclosporine.

Smoking has been demonstrated to be associated with atopic dermatitis. The association was found to be statistically significant in children and adults. Of particular concern, smoking in the home was associated with atopic dermatitis in passively exposed children.

There is some predictability within families with an atopic diathesis (i.e., common presence of atopic disorders such as asthma, allergic rhinitis, and eczema) that children are more likely to develop atopic dermatitis. In addition to the many other good reasons to stop smoking, we can add an increased incidence of atopic dermatitis. ■

## An Action Plan for Eczema

SOURCE: Sauder MB, McEvoy A, Ramien ML. Prescribing success: Developing an integrated prescription and eczema action plan for atopic dermatitis. *J Am Acad Dermatol* 2016;75:1281-1283.

Many clinicians may be familiar with the concept of an action plan in reference to asthma management. National guidelines suggest that providing patients with a stratified plan to address intensification of their asthma treatment regimen based on symptoms and measurements of peak flow rates may enhance control.

Recently, similar advice has been offered — and supported by favorable outcomes from a randomized, controlled trial — for patients suffering from atopic dermatitis.

The proposed atopic dermatitis action plan features three 'zones' (green, yellow, and red), similar to asthma action plans. In the green zone, eczema is 'under control,' and patients should continue their daily moisturizer, possibly with use of their topical steroid and/or topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus). The yellow zone indicates worsening eczema, which calls for increased dosing of steroids or calcineurins. The red zone indicates uncontrolled eczema, which indicates that clinician contact is appropriate and a prescription for stronger corticosteroids is needed. At this point, action plans for eczema are a fairly new concept. It is anticipated that such action plans will evolve as we learn more about their efficacy in enhancing patient self-care and timely consultations. ■

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## CME QUESTIONS

1. **Which is the best strategy to treat a palliative care patient presenting with delirium?**
   a. Managing delirium precipitants and supportive strategies alone
   b. Managing delirium precipitants and supportive strategies combined with risperidone as needed
   c. Managing delirium precipitants and supportive strategies combined with haloperidol as needed
   d. Managing delirium precipitants and supportive strategies combined with using either haloperidol or risperidone as needed based on clinical response

2. **Heart failure in atrial fibrillation patients is usually associated with:**
   a. a rapid heart rate.
   b. preserved left ventricular ejection fraction.
   c. permanent atrial fibrillation.
   d. All of the above

3. **Which of the following is *not* associated with a reduction of risk for coronary artery disease?**
   a. Regular physical activity
   b. Not smoking
   c. Following safety precautions such as seatbelts, etc.
   d. Not being obese

## CME OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- describe new findings in the differential diagnosis and treatment of various diseases;
- describe the advantages, disadvantages, and controversies surrounding the latest advances in the diagnosis and treatment of disease;
- identify cost-effective treatment regimens;
- explain the advantages and disadvantages of new disease screening procedures.

## [IN FUTURE ISSUES]

Amyloid PET Imaging in the Diagnosis of Dementia

Cardiovascular Event Rates and Mortality

Iron Deficiency Anemia Associated with Hearing Loss

Internal Medicine [ALERT]

# ECG Review

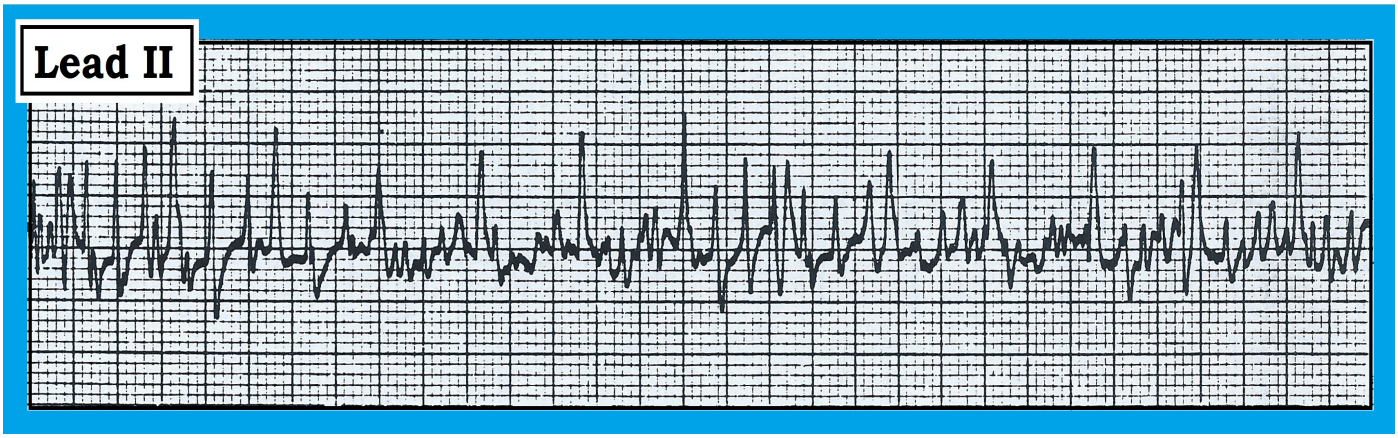
By Ken Grauer, MD

*Professor Emeritus in Family Medicine, College of Medicine, University of Florida*

Dr. Grauer is the sole proprietor of KG-EKG Press, and publisher of an ECG pocket brain book.

## Should This Patient Be Cardioverted?

The lead II rhythm strip shown in the figure below was obtained from an older adult patient on telemetry. Should the patient be immediately cardioverted?




Although at first glance, this tracing prompted much concern on the telemetry unit, prompt cardioversion is not the optimal initial intervention. Instead, there is much baseline aberration with spurious-looking complexes that occur at a rate of more than 300/minute in parts of the tracing. No real tachyarrhythmia exhibits a ventricular rate this fast in adults.

The first thing to do when confronted with a potentially worrisome tracing such as this is to check the patient. Doing so revealed that the patient was coughing vigorously at the time this tracing was recorded. The artifact totally disappeared as soon as the patient stopped coughing.

Artifact is common in clinical practice. At times, it may be extremely difficult to distinguish artifact from a real tracing. The consequences of mistaking artifact for ventricular tachycardia (as was almost done for the tracing in the figure) are not trivial. Patients have been shocked, and investigative procedures (such as cardiac catheterization) have been ordered. Remember the following:

Check on the patient first. If the patient is alert and hemodynamically stable, then the rhythm is far less likely to be ventricular tachycardia.

The most likely causes of artifact simulating ventricular tachycardia are inconsistent skin-electrode contact and body movement (scratching, tremor, shivering, coughing, hiccups, brushing teeth, writhing in bed, interference from a mechanical device, etc.).

ECG features that suggest artifact as the cause include geometric appearance (unphysiologic vertical deflections) that are unpredictably irregular, often at exceedingly rapid rates. On a 12-lead tracing, one often inexplicably sees highly unusual deflections in some leads, but not in others. Identifying an underlying regular rhythm that is undisturbed by artifactual deflections provides proof that the phenomenon is not real.

For further discussion about this case, please visit: http://bit.ly/2jT37f4.