Simply put, no dose of alcohol is safe. Alcoholic beverages are classified by the International Agency for Research on Cancer among group I (human) carcinogens, with a dose-related increase for oral cavity, pharynx, esophagus, breast cancers beginning at the 1 to 2 drink per day level. Sherk et al[2] showed that 50% of alcohol-caused cancer deaths in Canada are experienced by those drinking within limits. In 2016, United Kingdom Chief Medical Officers wisely launched new alcohol guidelines with the term "low-risk drinking" for those who choose to drink, setting the limit at 100 g of alcohol per week for both men and women.[3] In 2019, France followed the United Kingdom. One drink a day means 112 g per week: 750 ml bottle of wine is five 150-ml glasses, as wine is 13.5% alcohol by volume (not 12 as indicated by the Centers for Disease Control and Prevention). This means a glass has 16 g of alcohol.

Finally, the use of reference number 24, a review about *Alcohol Consumption, Diabetes Risk, and Cardiovascular Disease Within Diabetes,* does not allow the claim "low to moderate alcohol consumption consistently has been shown to be associated with a reduced risk of cardiovascular disease and mortality"[1] which flew in the face of accumulating evidence from robustly designed studies avoiding selection biases.[4,5]

Semantic matters: alcohol use is now a public health crisis in the United States as it is in European countries.[6]

Disclosures

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Decrease in Reported Rates of Cardiovascular Device-Related Adverse Events During the Coronavirus Disease 2019 Pandemic

Given the disruption of cardiology practices by the coronavirus disease 2019 (COVID-19) pandemic, we sought to investigate whether the number of reports of adverse events attributed to cardiovascular medical devices changed over the course of the pandemic, specifically examining implantable cardioverter defibrillators (ICDs) and coronary drug-eluting stents (DESs). Using data from the Food and Drug Administration (FDA) Manufacturer And User Facility Device Experience (MAUDE) database, we compared weekly reported rates of adverse events for each device during the year immediately preceding the pandemic (March 2019 to March 2020) with those during the first year of the pandemic (March 2020 to March 2021). We report a 46% decrease in reported ICD-related deaths during the pandemic compared with before the pandemic, and a 27% decrease in reported coronary DES-related injuries during the pandemic compared with before the pandemic.

Because adverse event reporting plays a critical role in postmarket surveillance and risk assessment for medical devices, this report assesses the impact of the COVID-19 pandemic on the number of weekly reports of adverse events attributed to 2 cardiovascular medical devices: ICDs and coronary DESs. We used the FDA MAUDE database, which lists reports from manufacturers, distributors, clinicians, and other voluntary reporters and is publicly accessible.[1] We filtered the MAUDE data by device and adverse event type, examining malfunction, injury, and death reports with the filter "Implantable Cardioverter Defibrillator (Non-Crt)" for ICDs and the filter "Coronary Drug-Eluting Stent" for coronary DESs. Since the World Health Organization officially declared COVID-19 a pandemic on March 11, 2020,[2] we chose to record the number of reports given each week over the course of 3 years (March 2018 to March 2019, March 2019 to March 20, and March 2020 to March 2021). For clarity, March 2020 to March 2021 will be herein called "pandemic data" or "2020 to 2021," March 2019 to March 2020 will be called "prepandemic data" or "2019 to 2020," and March 2018 to March 2019 will be called "2018 to 2019." We performed paired *t* tests for the differences between weekly reported adverse event types for each event type.

Comparing the data from 2019 to 2020 with the data from 2020 to 2021, we found that there were, on average, approximately 2.6 fewer weekly reports of ICD-attributed deaths during the pandemic than there were in the prepandemic year, a decrease of approximately 45.8% (p <0.0001) (Figure 1). To determine whether this trend was isolated, we also compared the weekly reports of ICD-attributed deaths for 2018 to 2019 with the data for 2019 to 2020. In this case, we found a decrease in the average number of weekly reported ICD-attributed deaths by approximately 1.6 weekly reports between 2018 and 2019 and 2019 to 2020; however, the decrease was not as large as that from the prepandemic to the pandemic and the p value was approximately 0.0023. We also compared the differences in reported ICD-attributed deaths (prepandemic subtracted from pandemic) with the
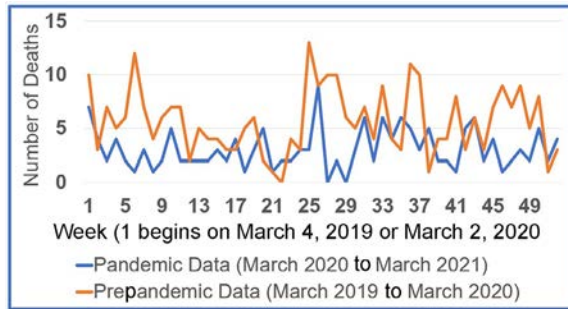
Figure 1. Weekly number of reported deaths attributed to implantable cardioverter defibrillators in FDA MAUDE database.

number of reported COVID-19-attributed deaths and found no significant correlation. We additionally examined the number of weekly reports of ICD malfunctions and ICD-attributed injuries in the pandemic year versus the prepandemic year and found no significant differences (ICD malfunctions: mean difference [pandemic − prepandemic] approximately equal to 10.8 reports, p value approximately equal to 0.19; ICD injuries: mean difference [pandemic − prepandemic] approximately equal to 9.9, p value approximately equal to 0.52).

We examined adverse event data for coronary DESs and found that there were, on average, approximately 14.3 fewer weekly reported coronary DES-attributed injuries during the pandemic year than in the prepandemic year, a decrease of approximately 27.3% (p <0.0001) (Figure 2). The comparison between 2018 and 2019 and 2019 to 2020, although showing a decrease in the average number of reported coronary DES-attributed injuries by approximately 1.4 reports from 2018 to 2019 to 2019 to 2020, did not yield a statistically significant result (p value approximately equal to 0.63). We again compared the differences in weekly coronary DES-attributed injuries (prepandemic subtracted from pandemic) with the weekly number of COVID-19 deaths but found no significant correlation. Our statistical analyses for coronary DES-attributed malfunctions and deaths did not yield significant differences (coronary DES malfunctions: mean difference [pandemic − prepandemic] approximately equal to −3.0, p value approximately equal to 0.44; coronary DES deaths: mean difference [pandemic − prepandemic] approximately equal to 1.0, p value approximately equal to 0.38).

In summary, our examination of the FDA MAUDE database revealed that the reported rates of ICD-attributed deaths and coronary DES-attributed injuries significantly decreased during the pandemic. There are several potential explanations for the observed decreases. One explanation is that fewer cardiovascular devices were implanted during the pandemic because of undertreatment, leading to fewer adverse events. An Italian study of 84 arrhythmia centers revealed that 92.9% of centers reported a significant reduction in ICD implantation for primary prevention in the first 2 months of the 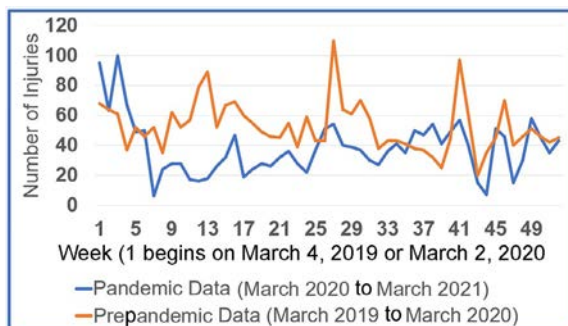pandemic.[3] Similar trends have been recorded in Catalonia,[4] Greece,[5] Iran,[6] and Romania.[7] The early stages of the pandemic were also associated with a 23.4% reduction in hospital admissions for acute coronary syndromes in two Italian high-volume centers,[8] with similar trends in Austria[9] and China.[10] A study in the United States of 9 high-volume centers revealed a 38% reduction in ST-segment cardiac catheterization laboratory activations,[11] with a similar trend in Spain.[12] Another explanation is that there was a lower burden of arrhythmia and major coronary events during the pandemic. A US study of 2,458 patients with ICDs demonstrated a 32% reduction in ventricular arrhythmias needing device therapies during the pandemic.[13] However, a different US study of 14,665 patients with ICDs demonstrated an increase in defibrillator shocks in 3 major cities during the pandemic.[14] A third explanation is that the observed decrease in ICD-attributed deaths and coronary DES-attributed injuries is a result of underreporting, thus raising concerns about adverse event surveillance during the pandemic. Further investigation is needed to determine the extent of cardiovascular undertreatment, underreporting, or both during the COVID-19 pandemic.

Disclosures

The authors have no conflicts of interest to declare.

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Figure 2. Weekly number of reported injuries attributed to coronary drug-eluting stents in FDA MAUDE database.

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Effect of SARS-COV-2 Diagnosis on Individuals with Preexisting Chronic Heart Failure

The effect of SARS-COV-2 diagnosis on individuals with pre-existing chronic heart failure long-term outcomes is still poorly understood. The researchers aimed to determine whether there exists a difference in all-cause mortality between patients with a SARS-COV-2 diagnosis that received a pre-existing chronic heart failure diagnosis compared with those that did not have a diagnosis of chronic heart failure that contracted SARS-COV-2. Established research has connected poor outcomes to the previous history of heart failure.[1]

The researchers queried the Trinetx (Covid-19 Research Network) which is composed of 63 health care organizations. They analyzed the data from January 20, 2020, to June 1, 2021, and identified n = 508,524 cases between the ages of 18 and 90 years with n = 21,274 with a previous history of heart failure which was defined using the International Statistical Classification of Diseases, Tenth Revision (ICD) 10 Code I50 and n = 487,240 patients with no previous diagnosis of heart failure. Descriptive statistics were used to measure the association between the 2 groups. A propensity score matching of a 1:1 was performed to match on the covariates (age, male, female, White, Black, Hispanic, hypertension, diabetes, coronary artery disease, chronic obstructive pulmonary disease, personal history of smoking, personal history of alcohol dependence, body mass index). The researchers were able to well match n = 20,428 of 20,428 over 550 days.

The researchers identified n = 508,514 patients aged 18 to 90 with differing ages between the 2 groups with chronic heart failure with average of (68.5 ± 13.8 vs 47.7 ± 17.9 p <0.001) compared to the group without chronic heart failure. The chronic heart failure group were more males (54.1% vs 44.5%, p <0.001) White (60.4% vs 54.9%, p <0.001), Black (21.7% vs 13%, p <0.001), hypertension (77.8% vs 24.2%, p <0.001) diabetes (50.7% vs 11.8%, p <0.001), coronary artery disease (44.4% vs 4%, p <0.001), personal history of smoking (24.0% vs 6%, p <0.001), personal history of alcohol dependence (3.4% vs 1.0%, p <0.001), body mass index (32.1 ± 8.37 vs 30.7 ± 7.45, p <0.001). Patients in the chronic heart failure group had a higher mortality of (15.3% vs 6.7%, p <0.001) A log-rank test also illustrated that those with a chronic heart failure diagnosis had a lower survival rate of (75.1% vs 89.6%, p <0.001) with a confirmed hazard of (2.73, p = 0.02).