Paclitaxel exposure in vascular device not linked to mortality

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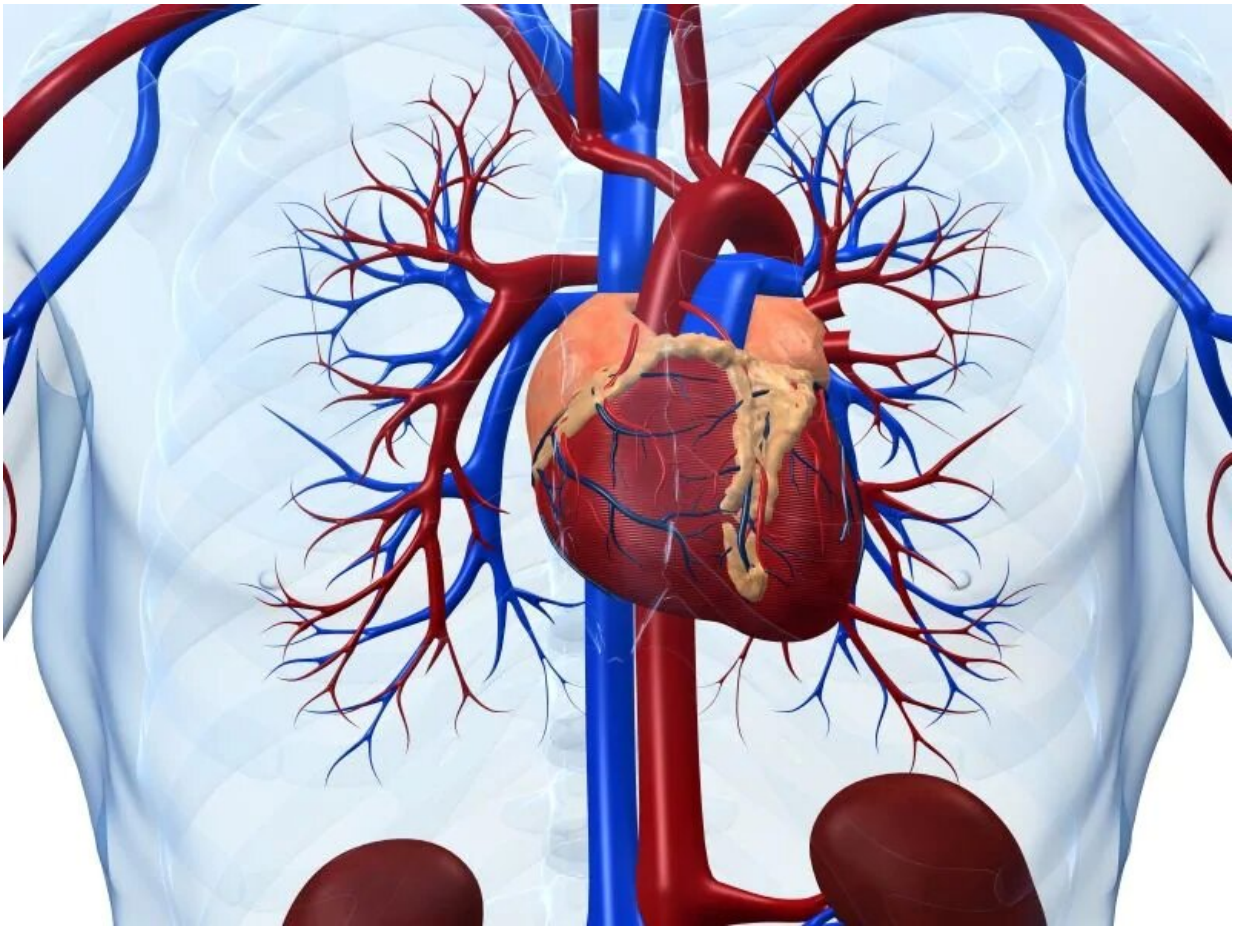

(HealthDay)—Exposure to paclitaxel in drug-coated balloons used in

procedures for the treatment of symptomatic femoropopliteal peripheral arterial disease is not associated with mortality, according to a study published online Jan. 25 in the *Journal of the American College of Cardiology*.

Peter A. Schneider, M.D., from Hawaii Permanente Medical Group in Honolulu, and colleagues conducted an independent patient-level meta-analysis of 1,980 patients with up to five years of follow-up in an effort to examine the correlation between paclitaxel exposure and mortality. Data were included from four prospective studies of paclitaxel drug-coated balloons (DCB; 1,837 patients) and uncoated percutaneous transluminal angioplasty (PTA; 143 patients).

The researchers found that all-cause mortality did not differ significantly between patients treated with DCB and PTA through five years (9.3 versus 11.2 percent; P = 0.399). An independent clinical events committee did not adjudicate any deaths as device-related. Nominal paclitaxel dose was stratified by low, middle, and upper tertiles, with mean doses of 5,019, 10,007.5, and 19,978.2 µg, respectively. Through five years, the three groups did not differ significantly in all-cause mortality.

"Results from this independent patient-level meta-analysis show no difference in mortality between DCB and PTA at five years and no correlation between varying levels of paclitaxel exposure and mortality," the authors write. "Data transparency and additional analyses are needed to better understand how other factors influence long-term outcomes in this complex patient population."

Several authors disclosed financial ties to medical technology companies, including Medtronic, which funded the analysis.

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