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Misleading Advertising by Attorneys Concerning NOACs is Adversely Costly to Our Patients and Our Society

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Abstract

Over the past five years, "ambulance-chasing" attorneys have aggressively advertised for patients who have bled on a new oral anticoagulant (NOAC) or their family members. It is an infrequent day when American consumers do not see a TV advertisement saying something like: "Have you or a loved-one had a serious bleeding event while taking [fill in the NOAC]? If so, you may be entitled to monetary compensation. Call XXX, attorneys at law, and we will get you the money you deserve."

Introduction

Unlike medical presentations, whether CME or "promotional", such ads are apparently not subject to fair balance requirements. Consequent to such advertisements, many patients have discontinued NOAC therapy or have refused to start it. I have encountered such a patient on more than one occasion, mostly atrial fibrillation (AF) patients with an increased risk profile for stroke and systemic embolism (CHA₂DS₂-VASc score of 2 or higher).¹ It takes considerable effort to make them understand both the benefits and the risks of NOAC therapy and in particular, the overall antithrombotic and mortality benefits to them of being on NOAC therapy despite the risks of a bleed.

Part of such discussions with patients should involve the concepts of fair balance and of net clinical benefit. Using data from the 4 major NOAC vs warfarin pivotal AF trials²⁻⁵ and historical data from AF warfarin vs placebo trials,⁶ several calculations can be made to help them understand both what they are not being told in the advertisements they see and the consequences that may arise based upon the non-use of the NOAC.

Based upon the pivotal NOAC versus warfarin trials,²⁻⁵ assuming

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increased risk AF patients changed from NOAC to warfarin therapy: embolic events would increase by 1.1 to 2.1 %/yr; major bleeds would increase by 2.1 to 3.4 %/yr, total mortality would increase by 3.5 to 4.9 %/yr, but fatal bleeds would increase by only 0.06 to 0.5 %/yr. In other words, with a change from a NOAC to warfarin, their risk of a stroke or mortality would be much greater than would any change in fatal bleeding risk. Moreover, since warfarin reduces stroke by almost 70% and mortality by about 30% versus placebo,6 if patients changed from NOAC to no therapy or refused to start any anticoagulant, stroke rates and mortality would be correspondingly higher than the rates cited above. Given the estimate of over 8 million AF patients in the U.S. now, and the current anticoagulation paradigm using CHA2DS2-VASc, such changes have substantial adverse implications for both population health and costs. Our governmental representatives, the FDA, and the media need to recognize the consequences of such unbalanced and inadequately controlled advertising and, in my opinion, initiate appropriate regulations.

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