MedicalXpress

Why we need to fund newer blood-thinning agents to prevent strokes

November 18 2014

Care gaps are emerging due to disharmony between healthcare reimbursement policies and evidence-based clinical guideline recommendations, cautions a group of Canadian physicians. Writing in the *Canadian Journal of Cardiology*, they use the example of stroke prevention in atrial fibrillation (AF) to make a case for engaging with policy-makers to address the growing barriers to patients' access to optimal care.

Stroke is a costly disease, imposing a significant human, societal, and economic burden. AF affects about one in eight people over age 75 and increases the risk of stroke five-fold by causing local blood clots in the heart that can break off and go to the brain. These strokes can be prevented by blood-thinning drugs ("anticoagulants"). Traditionally, the only effective blood-thinning available for AF was based on a compound (warfarin) that inhibits the production in the body of vitamin-K dependent clotting factors.

Warfarin was originally introduced (and is still employed) as a rat poison, and requires very careful use and close safety monitoring in humans. A newer set of compounds, which act directly on clotting factors (called "Direct Acting AntiCoagulants," or DOACs), has been introduced over the last few years. DOACs are simpler to use than warfarin and clinical trials consistently show that they are safer; however, they cost more. Thus, while national guidelines like those of the Canadian Cardiovascular Society generally recommend the preferential use of DOACs, government healthcare funders have been

reluctant to provide patients with unrestricted access based on physician prescription.

Stroke in the setting of AF carries an 80% probability of death or disability. In Canada, healthcare expenditures are the single largest category of public expenses with a growth rate that overshadows the rate of economic growth. A recent Canadian stroke costing study reported the average overall cost per patient of the first year of stroke as over CAN$74,000. The initial three months accounted for just over half the overall cost and was driven primarily by hospitalization and rehabilitation. Subsequent costs, such as continuing rehabilitation, homecare, and paid caregivers, contribute substantially to the overall cost of stroke to society. Thus, any extra costs of paying for DOACs must be weighed against the overall health expenditure savings that they produce via their superior value in stroke prevention.

"Although two-thirds of AF-related strokes are preventable with appropriate anticoagulation drugs, these have historically been under-prescribed and poorly managed for the Canadian population with AF," says lead investigator James A. Stone, MD, PhD, Clinical Professor of Medicine at the University of Calgary. "National and international guidelines endorse these drugs as first line therapy for this indication. However, no Canadian province has provided these drugs on an unrestricted basis. These decisions appear to be founded on silo-based cost assessment - the drug costs rather than the total system costs - and thus overlook several important cost-drivers in stroke."

While national guidelines in Canada endorse DOACs (dabigatran, rivaroxaban, and apixaban) in preference to warfarin for stroke prevention and reduction of the risk of intracranial bleeding, and hence the first line therapy for this indication, the Canadian Agency for Drugs and Therapeutics in Health (CADTH) has recommended that these agents receive reimbursement only if warfarin cannot be used (e.g., due

to allergy) or after an initial attempt with warfarin therapy has been unsuccessful.

"This places healthcare providers in an awkward position," says Dr. Stone. "They are required to treat many patients in a manner that is discordant with national guidelines and this may have a deleterious clinical impact given recent evidence of heightened risk of both ischemic stroke and bleeding in the first month of initiating warfarin therapy."

According to the authors, CADTH appears to have considered only direct costs such as drug acquisition, the cost of anticoagulation level management itself, treatment costs for bleeding, and avoidable stroke, rather than a more global assessment that includes the cost of the outcome to the patient and indirect costs such as costs associated with undergoing blood clotting assessment, lost productivity due to stroke, and longer-term expenses of caring for individuals who have experienced stroke.

"It is within our personal and professional capacity to direct our efforts at prevention of diseases such as stroke that have such significant human and economic consequences. Appropriate anticoagulation of individuals with AF is an extremely effective means of accomplishing this," notes Dr. Stone.

"Cost containment is essential. However, we must ensure that we consider a complete assessment of costs when we make policy decisions and not limit the scope to select budget silos, and ensure that all stakeholders can understand how and why funding decisions are made. We have a responsibility to our patients to engage with policy-makers in addressing and resolving this barrier to optimal patient care. There needs to be a collaborative approach between funding agencies and clinical practice guideline groups in an effort to clearly defined clinical practice

strategies, in any preventative or disease treatment paradigm, that lead to the best cost utility," he concludes.

More information: "Aligning Health Care Policy With Evidence-Based Medicine: The Case for Funding Direct Oral Anticoagulants in Atrial Fibrillation," by James A Stone, MD, PhD; Karen Earl, MSc; Blair J O'Neill, MD; Mukul Sharma, MD, MSc; Thao Huynh, MD, MSc PhD; Kori Leblanc, PharmD; Richard Ward, MD; Philip A Teal, MD; and Jafna L Cox, BA, MD, DOI: dx.doi.org/10.1016/j.cjca.2014.08.002. Published in the *Canadian Journal of Cardiology*, Volume 30/Issue 10 (October 2014)

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