

Best Medical Treatment: What About the COMPASS Trial Strategy?

O Melhor Tratamento Médico: Onde Tem Lugar a Estratégia do Ensaio COMPASS?

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Palavras-chave: Aspirina/uso terapêutico; Doença Arterial Coronária/tratamento farmacológico; Doença Arterial Periférica/tratamento farmacológico; Inibidores da Agregação Plaquetária/uso terapêutico; Rivaroxabana/uso terapêutico

We read with interest the paper by Lopes *et al* reporting data about 'best medical treatment' (BMT) in patients admitted to a vascular surgery department. BMT was defined as treatment with antithrombotic and lipid-lowering treatment and, when appropriate, antihypertensive, and anti-diabetic drugs.¹ However, the anti-thrombotic drug chosen was not specified and the reasons for not being on BMT were not detailed. Unlike in clinical trials, real-world patients can present a significant number of uncontrollable variables that could influence both therapeutic decisions and outcomes.

We would like to call attention to a topic only briefly mentioned by the authors – the COMPASS trial strategy.²

In 2017, the COMPASS trial showed that using aspirin plus low-dose rivaroxaban in patients with stable atherosclerotic vascular disease reduced cardiovascular death, stroke, or myocardial infarction by 24%. Even when considering the bleeding risk, combination therapy had a net clinical benefit of 20%.²

Therefore, we considered it would be interesting to specify which antithrombotic strategy is chosen in these high-risk patients. In fact, most vascular surgery patients have peripheral artery disease (PAD) and hence meet inclusion criteria to start the COMPASS strategy. However, it is important to be aware of the broad exclusion criteria of this treatment (Table 1). We also hypothesize that therapeutic conservatism and physicians' resistance to change,³ in addition to the last two years of the COVID-19 pandemic, may have reduced physicians' adherence to this new treatment strategy.⁴

To perceive how many patients met criteria to start the COMPASS strategy² we did an exploratory, observational, retrospective, and cross-sectional study. On a randomly selected day, the electronic records of all inpatients of the internal medicine department were screened. Inclusion and exclusion criteria of the COMPASS trial were applied. Ethics committee approval was waived due to the retrospective design and focus on data collected from electronic

Table 1 – Inclusion and exclusion criteria of COMPASS trial

Inclusion criteria	Exclusion criteria
Peripheral artery disease	
Previous bypass surgery or percutaneous angioplasty revascularization OR	High risk of bleeding
Previous amputation for arterial vascular disease OR	Stroke within 1 month or any history of hemorrhagic or lacunar stroke
History of intermittent claudication AND (≥ 1): - An ankle/arm BP ratio < 0.90 , or peripheral artery stenosis ($\geq 50\%$) OR	Severe heart failure with known ejection fraction $< 30\%$ or New York Heart Association (NYHA) class III or IV symptoms
- Previous carotid revascularization or asymptomatic carotid artery stenosis $\geq 50\%$	Glomerular filtration rate < 15 mL/min
	Need for dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or oral anticoagulant therapy
Coronary artery disease	Non-cardiovascular disease that is associated with poor prognosis (e.g., metastatic cancer)
≥ 65 years old; OR	History of hypersensitivity or known contraindication for rivaroxaban/ aspirin
< 65 years old AND	Systemic treatment with strong inhibitors of both CYP3A4 and p-glycoprotein (e.g. ketoconazole, ritonavir), or strong inducers of CYP3A4 (e.g. rifampicin, rifabutin, phenobarbital, phenytoin, and carbamazepine)
- atherosclerosis or revascularization involving at least 1 one additional vascular bed (e.g., the aorta, arterial supply to the brain, gastro-intestinal tract, lower limbs, upper limbs, kidneys);	
OR	Any known hepatic disease associated with coagulopathy
- or at least 2 additional risk factors:	
- Current smoker;	
- Diabetes mellitus;	
- Glomerular filtration rate < 60 mL/min;	
- Heart failure;	
- Non-lacunar ischemic stroke ≥ 1 month ago.	Subjects who are pregnant or breastfeeding

BP: blood pressure

databases as part of patients' routine care.

Forty-eight patients (52% male) with a mean age of 74.8 ± 16.4 years-old were analyzed and 19% (n = 9) met criteria to start this strategy – of which 55% (n = 5) had coronary artery disease and 45% (n = 4) had PAD.

Nonetheless, only 4% (n = 2) were eligible when considering exclusion criteria. The most frequent exclusion criteria were the use of full dose oral anticoagulation due to atrial fibrillation, followed by poor medical prognosis. One of the patients was excluded due to being treated with clopidogrel, which could be switched to aspirin plus low-dose rivaroxaban to meet the COMPASS strategy, since it could have more clinical benefit.²

We consider that it is important to raise physicians' awareness to the inclusion and exclusion criteria of this new preventive strategy in order to potentially apply it in clinical practice.

AUTHORS CONTRIBUTION

SRJ, MA: Study design and conception. Data collection and analysis. Drafting, critical review and approval of the manuscript.

ARL: Data analysis. Drafting, critical review and approval of the manuscript.

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PROTECTION OF HUMANS AND ANIMALS

The authors have followed the protocols of their work center on the publication of data. The data was anonymized and none of the authors had access to patient identification. The study was conducted in accordance with the Helsinki Declaration updated in 2013.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

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