# **Perspectives for Pharmacy Practice:**

Examining All the Evidence to Facilitate the Effective and Safe Use of Direct Oral Anticoagulants in Patients With NVAF Who Are Obese



## **Bibliography and References**

#### **Clinical Trials**

- Alexander JH, Andersson U, Lopes RD, et al; Apixaban for Reduction of Stroke and Other Thromboembolic Complications in Atrial Fibrillation (ARISTOTLE) Investigators. Apixaban 5 mg twice daily and clinical outcomes in patients with atrial fibrillation and advanced age, low body weight, or high creatinine: a secondary analysis of a randomized clinical trial. JAMA Cardiol. 2016;1(6):673-681.
- Boriani G, Ruff CT, Kuder JF, et al. Relationship between body mass index and outcomes in patients with atrial fibrillation treated with edoxaban or warfarin in the ENGAGE AF-TIMI 48 trial. *Eur Heart J.* 2019;40(19):1541-1550.
- Connolly SJ, Ezekowitz MD, Yusuf S, et al; RE-LY Steering Committee and Investigators. Dabigatran versus warfarin in patients with atrial fibrillation. N Engl J Med. 2009;361:1139-1151.
- Ezekowitz MD, Reilly PA, Nehmiz G, et al. Dabigatran with or without concomitant aspirin compared with warfarin alone in patients with nonvalvular atrial fibrillation (PETRO Study). Am J Cardiol. 2007;100(9):1419-1426.
- Ezekowitz ME, Parise H, Connolly SJ, et al. The use of dabigatran according to body mass index: the RE-LY experience. Eur Heart J. 2014;35:1111.
- Frost C, Nepal S, Wang J, et al. Safety, pharmacokinetics and pharmacodynamics of multiple oral doses of apixaban, a factor Xa inhibitor, in healthy subjects. *Br J Clin Pharmacol*. 2013;76(5):776-786.
- Giugliano RP, Ruff CT, Braunwald E, et al; ENGAGE AF-TIMI 48 Investigators. Edoxaban versus warfarin in patients with atrial fibrillation. *N Engl J Med.* 2013;369(22):2093-2104.
- Granger CB, Alexander JH, McMurray JJV, et al; ARISTOTLE Committees and Investigators. Apixaban versus warfarin in patients with atrial fibrillation. N Engl J Med. 2011;365(11):981-992.
- Hohnloser SH, Fudim M, Alexander JH, et al. Efficacy and Safety of Apixaban Versus Warfarin in Patients With Atrial Fibrillation and Extremes in Body Weight. Circulation. 2019;139(20):2292-2300.
- Ogata K, Mendell-Harary J, Tachibana M, et al. Clinical safety, tolerability, pharmacokinetics, and pharmacodynamics of the novel factor Xa inhibitor edoxaban in healthy volunteers. J Clin Pharmacol. 2010;50(7):743-753.
- Patel MR, Mahaffey KW, Garg J, et al; ROCKET AF Investigators. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med.* 2011;365(10):883-891.
- Stangier J, Rathgen K, Stähle H, Gansser D, Roth W. The pharmacokinetics, pharmacodynamics and tolerability of dabigatran etexilate, a new oral direct thrombin inhibitor, in healthy male subjects. Br J Clin Pharmacol. 2007;64(3):292-303.
- van Ryn J, Stangier J, Haertter S, et al. Dabigatran etexilate a novel, reversible, oral direct thrombin inhibitor: interpretation of coagulation assays and reversal of anticoagulant activity. *Thromb Haemost.* 2010;103(6):1116-1127.
- Wallentin L, Lopes RD, Hanna M, et al; Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation (ARISTOTLE) Investigators. Efficacy and safety of apixaban compared with warfarin at different levels of predicted international normalized ratio control for stroke prevention in atrial fibrillation. *Circulation*. 2013;127(22):2166-2176.

### **Guidelines and Recommendations**

- Chen A, Stecker E, A Warden B. Direct Oral Anticoagulant Use: A Practical Guide to Common Clinical Challenges. J Am Heart Assoc. 2020;9(13):e017559.
- January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused update of the 2014 AHA/ACC/HRS Guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in collaboration with the Society of Thoracic Surgeons. *Circulation*. 2019;140(2):e125-e151.
- Kirchhof P, Benussi S, Kotecha D, et al; ESC Scientific Document Group. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J. 2016;37(38):2893-2962.

- Martin K, Beyer-Westendorf J, Davidson BL, Huisman MV, Sandset PM, Moll S. Use of the direct oral anticoagulants in obese patients: guidance from the SSC of the ISTH. *J Thromb Haemost.* 2016;14(6):1308-1313.
- Martin KA, Beyer-Westendorf J, Davidson BL, Huisman MV, Sandset PM, Moll S. Use of direct oral anticoagulants in patients with obesity for treatment and prevention of venous thromboembolism: updated communication from the ISTH SSC Subcommittee on Control of Anticoagulation. J Thromb Haemost 2021;19(8):1874-1882.

#### **General Articles and Reviews**

- Hendricks AK, Zieminski JJ, Yao X, et al. Safety and efficacy of oral anticoagulants for atrial fibrillation in patients after bariatric surgery. Am J Cardiol 2020;136:76-80.
- Kido K, Shimizu M, Shiga T, Hashiguchi M. Meta-analysis comparing direct oral anticoagulants versus warfarin in morbidly obese patients with atrial fibrillation. Am J Cardiol. 2020;126:23–28.
- Kido K, Ngorsuraches S. Comparing the efficacy and safety of direct oral anticoagulants with warfarin in the morbidly obese population with atrial fibrillation. Ann Pharmacother. 2019; 53(2):165-170.
- Kushnir M, Choi Y, Eisenberg R, et al. Efficacy and safety of direct oral factor Xa inhibitors compared with warfarin in patients with morbid obesity: a single-centre, retrospective analysis of chart data. Lancet Haematol. 2019;6(7):e359-e365.
- Moll S, Crona DJ, Martin K. Direct oral anticoagulants in extremely obese patients: OK to use? Res Pract Thromb Haemost. 2019;3(2):152-155.
- Rottenstreich A, Barkai A, Arad A, Raccah BH, Kalish Y. The effect of bariatric surgery on direct-acting oral anticoagulant drug levels. Thromb Res. 2018;163:190-95.
- Russo V, Cattaneo D, Giannetti L, et al. Pharmacokinetics of direct oral anticoagulants in patients with atrial fibrillation and extreme obesity. *Clin Therap.* 2021; https://doi.org/10.1016/j.clinthera.2021.07.003
- Sandhu RK, Ezekowitz J, Andersson U, et al. The 'obesity paradox' in atrial fibrillation: observations from the ARISTOTLE (Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation) Trial. Eur Heart J. 2016;37(38):2869-2878.
- Sarode R. Direct oral anticoagulant monitoring: what laboratory tests are available to guide us? *Hematology Am Soc Hematol Educ Program*. 2019;2019(1):194-197.
- Sebaaly J, Kelley D. Direct oral anticoagulants in obesity: An updated literature review. Ann Pharmacother. 2020;54(11):1144-1158.
- Wang SY, Giugliano RP. Non-vitamin K antagonist oral anticoagulant for atrial fibrillation in obese patients. Am J Cardiol. 2020;127:176-183.
- Zhou Y, Ma J, Zhu W. Efficacy and safety of direct oral anticoagulants versus warfarin in patients with atrial fibrillation across BMI categories: a systematic review and meta-analysis. *Am J Cardiovasc Drugs*. 2020;20(1):51-60.