

New Score Allows Early Prediction of AMI Readmission Risk

A new “AMI READMITS” score—based on renal function, diabetes, and low blood pressure, among other factors in the first 24 hours in the hospital—identifies patients at high risk of readmission after acute myocardial infarction, reports a study in the open-access *Journal of the American Heart Association*.

Using data from consecutive AMI hospitalizations to six diverse Texas hospitals in 2009–2010, the researchers sought to develop a pragmatic model to predict the risk of all-cause, nonelective hospital readmission within 30 days. The model was derived using data on 826 patients, 13% of whom were readmitted within 30 days. Two separate AMI-specific models were de-

veloped and evaluated: a “first-day” model using only data from the first 24 hours in the hospital and a “full-stay” model including data from the full hospital stay.

The first-day model, called AMI READMITS, consisted of seven predictors: renal function (serum creatinine greater than 2 mg/dL), elevated brain natriuretic peptide, age, history of diabetes, nonmale sex, absence of timely percutaneous coronary intervention; and systolic blood pressure less than 100 mm Hg. This score provided good discrimination, C-statistic 0.75, and identified a broad range of risk categories, with average risks of 2.1% to 41.1% by decile. About one-third of patients classified as high risk (AMI READMITS score 20 or

higher) had 30-day readmission, compared to 2% of those classified as low risk (score 13 or lower).

The full-stay model added three further predictors: intravenous diuretic use, anemia at discharge, and discharge to postacute care. However, it provided minimal net reclassification improvement and calibration. Both models appeared to have better performance compared to other models.

Readmission after AMI is a common problem, but current models have modest predictive value and do not provide readily actionable data to reduce risk. The new AMI READMITS score is a parsimonious model that includes clinically relevant risk factors and provides actionable data

to identify patients at high risk of readmission during their first 24 hours in the hospital. The researchers note, “[C]linical severity measures directly related to the AMI (shock, heart strain or failure, renal dysfunction) and timely percutaneous coronary intervention were strong predictors of readmission risk” [Nguyen OK, et al. Predicting 30-day hospital readmissions in acute myocardial infarction: the AMI “READMITS” (renal function, elevated brain natriuretic peptide, age, diabetes mellitus, nonmale sex, intervention with timely percutaneous coronary intervention, and low systolic blood pressure) score. *J Am Heart Assoc* 2018; 7:e008882. DOI: 10.1161/JAHA.118.008882]. ■

Renal Denervation for Persistent Hypertension on Medications: Randomized Trial

Renal denervation safely reduces blood pressure in patients with uncontrolled hypertension who continue taking antihypertensive medications, reports a trial in *The Lancet*.

The SPYRAL HTN-ON MED trial enrolled 487 adults with uncontrolled hypertension at 25 centers in Asia, Australia, Europe, and North America. All had un-

controlled hypertension, including an ambulatory systolic BP of 140 to 170 mm Hg despite at least 6 weeks on stable doses of one to three antihypertensive medications. After renal angiography, patients were randomly assigned to catheter-based renal denervation of the main renal arteries and branches or a sham procedure with sensory masking.

All procedures were performed by an experienced proceduralist following a detailed treatment plan.

At follow-up visits, patients underwent 24-hour ambulatory BP monitoring, as well as urine and blood tests to assess adherence to prescribed medications. The current paper presents a proof-of-concept analysis of

the first 80 patients treated: 38 assigned to renal denervation and 42 to the sham control procedure. The main efficacy outcome was change in ambulatory BP from baseline to 6 months, with a prespecified requirement for the patient to remain on the same antihypertensive drug regimen during this time. Major

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JYNARQUE™ (tolvaptan)

experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Use in Patients with Hepatic Impairment: Because of the risk of serious liver injury, use is contraindicated in patients with a history, signs or symptoms of significant liver impairment or injury. This contraindication does not apply to uncomplicated polycystic liver disease which was present in 60% and 66% of patients in TEMPO 3:4 and REPRISSE, respectively. No specific exclusion for hepatic impairment was implemented in TEMPO 3:4. However, REPRISSE excluded patients with ADPKD who had hepatic impairment or liver function abnormalities other than that expected for ADPKD with typical cystic liver disease.

Use in Patients with Renal Impairment: Efficacy studies included patients with normal and reduced renal function. TEMPO 3:4 required patients to have an estimated creatinine clearance ≥ 60 mL/min, while REPRISSE included patients with $eGFR_{CKD-Epi}$ 25 to 65 mL/min/1.73m².

OVERDOSAGE: Single oral doses up to 480 mg (4 times the maximum recommended daily dose) and multiple doses up to 300 mg once daily for 5 days have been well tolerated in trials in healthy subjects. There is no specific antidote for tolvaptan intoxication. The signs and symptoms of an acute overdose can be anticipated to be those of excessive pharmacologic effect: a rise in serum sodium concentration, polyuria, thirst, and dehydration/hypovolemia.

No mortality was observed in rats or dogs following single oral doses of 2000 mg/kg (maximum feasible dose). A single oral dose of 2000 mg/kg was lethal in mice, and symptoms of toxicity in affected mice included decreased locomotor activity, staggering gait, tremor and hypothermia.

In patients with suspected JYNARQUE overdose, assessment of vital signs, electrolyte concentrations, ECG and fluid status is recommended. Continue replacement of water and electrolytes until aquaresis abates. Dialysis may not be effective in removing JYNARQUE because of its high binding affinity for human plasma protein (>98%).

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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