

Off-label use of ultrasound contrast agents for carotid ultrasound imaging Information Sheet

General indications for the procedure:

The ultrasound examination of the carotid artery is indicated based on the physician's clinical assessment. The use of ultrasound contrast agents may provide clearer images of the carotid arteries.

Ultrasound contrast agents for carotid imaging are considered an off-label indication. This term "off label" means that the manufacturer has not requested FDA approval for this product at this time. Historically, the off-label use of Optison™, has been approved as an ultrasound contrast agent for heart imaging, which began in 1997 following FDA approval. Since that time, over 1.5 million patient injections have been safely performed. Optison™ has been safely used for carotid ultrasound exams at Rush University Medical Center since 2001 (over 1000 patient exams). Similarly, ultrasound contrast agents have been used for carotid artery imaging in other hospitals, including those in the USA, Italy, China and Germany.

The advantage of using Optison™ with a standard carotid ultrasound exam include the following: (1) improvement in the detection of atherosclerosis disease (plaques and ulcers which may lead to strokes); (2) enhancement of the carotid artery wall thickness which indicates premature cardiovascular disease; and (3) detection of plaques and the related blood vessels associated with heart attacks and strokes (termed, vasa vasorum).

The description of the procedure:

The procedure requires a standard intravenous line through which the ultrasound contrast agent will be delivered. Approximately one teaspoonful of the contrast agent will be used and this procedure will add about 10 minutes to the overall procedure time.

Risks/benefit of the procedure:

The use of Optison™ as an ultrasound contrast agent is not to be used in patients with a history of prior drug reactions to Optison™, allergies to blood products or with a history of a right to left shunt. The package insert describes serious cardiopulmonary reactions in patients with pulmonary hypertension or unstable cardiopulmonary conditions. These reactions may be increased among patients with pulmonary hypertension or unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, serious ventricular arrhythmias or respiratory failure, including patients receiving mechanical ventilation). Of the reported adverse reactions following the use of Optison™ most frequently reported were headache (5.4%), nausea and/or vomiting (4.3%), warm sensation or flushing (3.6%), and dizziness (2.5%).

The potential benefits of using Optison™ as a contrast agent include improved diagnostic accuracy of detecting early cardiovascular heart disease (atherosclerosis).

Procedure Alternatives, if any:

Alternative choices include performing the study without ultrasound contrast agents, or using CT scans, cerebral angiography or MRI and similar dyes.

Probable consequences of refusing the procedure:

The ultrasound images performed without the use of Optison™ may not be of sufficient quality to detect cardiovascular heart disease (atherosclerosis) and therefore, additional testing may be required.

Person(s) performing the procedure:

The procedure will be performed by a member of the Rush Hospital staff who is specifically trained in carotid ultrasound imaging.