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News Letter

PCSK9 Inhibitors: Just the Basic Facts

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It is essential to understand the unmet need for LDL-C-lowering strategy beyond the statin-based therapy as a strategy for addressing lipid-related Cardiovascular disorders in patients and with Familial Hypocholesterolemia. It is the need to explore treatment options in a statin-intolerant patients to lower the LDL-C. The potential impact of PCSK9-based therapies in development in patients who require additional LDL-C reduction are currently being explored worldwide. Studies of uncommon mutations, such as the LDL-receptor mutations in familial hypercholesterolaemia have led to important therapeutic advances in the study of lipids related cardiovascular disease. Proprotein convertase subtilisin/kexin type 9 (PCSK9) is an enzyme involved in the regulation of LDL receptors and LDL cholesterol. PCSK9 via inhibition renders more receptors available to capture LDL for break down and removal from the blood thereby lowering LDL. PCSK9 inhibitors are monoclonal antibodies (MABs) bind to and inactivate a protein in the liver called PCSK9.

The PCSK9 inhibitors are a class of self injectable drugs approved in 2015 that have been shown to dramatically lower LDL cholesterol levels, by up to 60%, when combined with a statin. In fact, majority of patients on first-line treatment like statins cannot lower their cholesterol adequately at all possibly due to genetic defects or some patients stop their statin treatment due to side effects. PCSK9 inhibitors may be used alone or in combination with statins to further lower the elevated cholesterol levels for patients who cannot tolerate any statin drug due to side effects. Several PCSK9 studies report that two agents, evolocumab (Repatha) or alirocumab (Praluent), when combined with statins, lower cholesterol better than the statin alone. PCSK9 inhibitors are given by subcutaneous injection, via self-administration one or two times per month. In general, PCSK9 inhibitors have been well-tolerated, and the side effects reported are common cold, itching, flu, injection site reactions, and serious allergic reactions. These drugs are monoclonal antibodies (MABs) and could add considerable costs to statin therapy. However, this treatment is the utmost need of the high-risk patients who cannot reach adequate LDL levels with statins and may have no other options left. Results longer term phase III trials are awaited which would yield better information about efficacy and adverse effects of PCSK9 inhibitors. Hence, targeting PCSK9 in clinical practice and their genetic validation is the need of the present and future.