PERIVASCULAR ANTI-INFLAMMATORY THERAPY FOR VENOUS THROMBOSIS

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 63/086,228 filed October 1, 2020, which is incorporated herein by reference.

[0002] The subject matter of the present application is related to the subject matter of U.S. Application No. 16/977,355, filed on September 1, 2020, which is a national phase entry of International Application No. PCT/US19/22054, filed on March 13, 2019, which claims priority from U.S. Provisional Application No. 62/642,743, filed on March 14, 2018, which are incorporated herein by reference

BACKGROUND

[0003] Individuals having deep vein thrombosis (DVT) or blood clots in blood vessels may experience post-thrombotic syndrome (PTS). PTS has been associated with local venous inflammation and changes in levels of inflammatory factors. Individuals with DVT may experience PTS even after compression therapy, pharmaceutical treatments, or thrombolysis or interventional or open surgical procedures to treat the DVT. Symptoms of PTS may include sensations of leg heaviness, pulling, or fatigue, leg pain, and limb swelling. As such, a local delivery of agents that target the inflammatory response may reduce the symptoms of PTS and provide a useful treatment for PTS.

SUMMARY

[0004] Disclosed herein are device, methods, and kits for treatment of post-thrombotic syndrome (PTS) in an individual. Provided herein are device, methods, and kits for treatment of symptoms from resulting from deep vein thrombosis (DVT) or blood clots in blood vessels in an individual. Described herein are device, methods, and kits to reduce or resolve inflammation that is present with PTS and/or venous thromboembolism, including but not limited to DVT and pulmonary embolism (PE).

[0004a] In one aspect, the present disclosure refers to a use of a therapeutic composition in the manufacture of a medicament for reducing progression to post-thrombotic syndrome (PTS) in a subject, wherein the therapeutic composition comprises an anti-inflammatory agent and a therapeutic dosage of the anti-inflammatory agent ranges from about 0.1 mg per cm of a thrombosed segment to about 10 mg per cm of the thrombosed segment, and wherein the therapeutic composition is to be delivered into a perivascular tissue at or near the thrombosed segment using a therapeutic delivering catheter, and wherein the therapeutic delivering catheter is to be advanced within a lumen of a vein affected by DVT to or near the thrombosed segment

of the vein, and wherein the vein is identified in the subject affected by deep vein thrombosis (DVT) currently or previously and/or is at risk for progressing to PTS.

[0004b] In another aspect, the present disclosure refers to a system for use in reducing progression to post-thrombotic syndrome (PTS) in a subject affected by deep vein thrombosis (DVT) currently or previously and/or is at risk for progressing to PTS, the system comprising: a therapeutic composition comprising an anti-inflammatory agent; a catheter configured to be placed within a vein affected by deep vein thrombosis (DVT) in the subject, wherein the catheter is to be advanced within a lumen of the vein affected by DVT to or near the thrombosed segment of the vein; an expandable element at a distal end of the catheter, wherein the expandable element is inflatable from an involuted contracted configuration; and an injection needle coupled to the expandable element, wherein expanding the expandable element advances the injection needle in a direction transverse to a longitudinal axis of the catheter to puncture wall of the vein at or near a thrombosed segment of the vein, and wherein, when the needle has punctured the wall of the vein, the needle delivers an amount of the therapeutic composition to a perivascular tissue at or near a thrombosed segment of the vein, the amount being therapeutic to reducing progression to PTS, wherein the therapeutic dosage of the anti-inflammatory agent ranges from about 0.1 mg per cm of the thrombosed segment to about 10 mg per cm of the thrombosed segment.

[0005] Provided herein are methods of reducing progression to post-thrombotic syndrome (PTS) in a subject, the method comprising: (a) identifying a vein in the subject affected by deep vein thrombosis (DVT) currently or previously and/or is at risk for progressing to PTS; (b) advancing a therapeutic delivering catheter within a lumen of the vein affected by DVT to or near a thrombosed segment of the vein; and (c) delivering a therapeutic composition into a perivascular tissue at or near the thrombosed segment using the therapeutic delivering catheter, wherein the therapeutic composition comprises an anti-inflammatory agent and a therapeutic dosage of the anti-inflammatory agent ranges from about 0.1 mg per cm of the thrombosed segment to about