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Novel Catheter for Focused Delivery of an Agent

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The invention is a catheter that is designed to focused the application of a lytic agent near a vessel occlusion and then remove the lytic agent from the blood stream. The catheter consists of three serial elements: 1) hole to release injected lytic agent, (2) balloon that can be inflated to temporarily stop blood flow immediately distal to the thrombus and (3) some arrangement of mechanical projections within the vessel that are designed to maximize surface area. The key feature of the mechanical projections is that they are coated with a lytic binding agent.

SPECIFICATION

The catheter hole obviously provides a release point for the injected lytic agent. This agent will then come into contact with the thrombus (or other occlusion) and act to dissolve the occlusion. The balloon temporarily occludes vessel blood flow immediately distal to the vascular occlusion that is being lysed. This will allow the lytic agent to pool in the immediate vicinity of the occlusion, thus increasing both concentration of the lytic agent and duration of time that the lytic agent is in contact with the clot. After some period of time, the balloon can be deflated to restore blood flow.

The mechanical projections (see attached drawing) immediately distal to the balloon serve several functions. First and foremost, the mechanical projections (think of them as "pine trees" being radially distributed around the catheter) are coated with a lytic binding agent. T hus, when the balloon is deflated and blood flow is restored to the vessel, that volume of blood containing the lytic agent will wash over the treated projections. As this occurs, some portion of the lytic agent will be passively removed from the blood stream, thus reducing the total amount of lytic agent that will flow through the distal portions of the cerebral vasculature. This should reduce the probability of the patient suffering from intra-cranial hemorrhage, one of the primary and deadliest side affects of stroke treatment using tPa. Secondly, the exact configuration of the mechanical projections could act to either trap sections of partially lysed thrombus or crush sections of thrombus. Finally, the mechanical projections will be alternately expandable and collapsable. In its expanded state, it will be fully extended within the vessel. In its collapsed state, it will retract to within the delivery catheter.

The method of use of the catheter is envisioned to be as follows:

1. Access to major vessel (cephalic or femoral expected) gained by cut-down
2. Introduction of delivery catheter to point of occlusion
3. Insertion of catheter through occlusion, but with lytic delivery hole still proximal to occlusion
4. Deployment (inflation) of ballooon immediately distal to occlusion
5. Injection of lytic agent
6. Deployment of mechanical projections
7. Waiting period (to allow lytic agent to act on occlusion)
8. Deflation of balloon
9. Retraction of mechanical projections (thrombus trapping, thrombus fragment crushing, etc.)
10. Removal of delivery catheter.

The invention is novel in at least two ways:

(1) It uses a balloon to concentrate an injected agent in a particular section of the vessel.

(2) It uses a binding agent treatment to remove the injected agent from the blood stream.

The invention improves upon standard lysis neural catheters in that it provides a means for concentrating the lytic agent and then passively removing at least some portion of that lytic agent. One of the major problems with treatment of ischemic stroke by lytic agent is the post-treatment complication of intra-cranial bleeding from too much lytic agent (tPa) perfusing the general post-occlusion cranial vasculature. This invention seeks to provide a means for passive removal of some portion of the lytic agent, thus reducing the probability of this complication. In addition, there is a 25% reocclusion rate for tPa treatmen of ischemic stroke. Often, this re-occlusion is hastened by some portion of the thrombus remaining on the endothelial lining of the occluded vessel. By concentrating the lytic agent at the site of the occlusion, chances of total removal of the thrombus increase.