

#20 SAFETY AND EFFICACY OF RETEPLASE FOR THE TREATMENT OF ARTERIAL OCCLUSIVE DISEASE

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Purpose: To evaluate the safety and efficacy of Reteplase (r-PA) in arterial thrombolysis for upper and lower extremity occlusive disease.

Materials and Methods: From November 2000 to February 2004, Reteplase was used to treat arterial occlusions in 81 patients (median age 58.5 ± 13.3 yrs, 56.8 % male, 80.2% smokers, 74 lower extremity, 7 upper extremity). Catheter-directed intra-thrombus thrombolysis was performed with Reteplase (0.5 u/hr) continuous infusion. Mechanical thrombectomy (angiojet) was performed in 61% (n=50). Limb ischemia acuity was class II in 91.4% (n=74) and class I in 8.6% (n=7). Safety was evaluated by major and minor complication rates. Efficacy was evaluated with regards to thrombus dissolution, limb salvage, and amputation-free survival. Thrombus burden was measured from pre-lysis arteriogram using the volume of a cylinder derived from the diameter and length of the thrombus burden. Thrombus burden was then divided equally into 3 groups (low burden $<32 \text{ cm}^3$, moderate burden $32-241 \text{ cm}^3$, high burden $\geq 242 \text{ cm}^3$).

Results: The 81 patients received Reteplase therapy (median = 10.3 ± 5.3 units, 19.5 ± 7.4 hours) followed by next day arteriogram to confirm successful thrombus removal. Technical success, as defined as 50% thrombus dissolution, was achieved in 96.2% (n=78) of cases. Kaplan-Meier Life table analysis revealed primary patency rates of 76.3%, 60.1% and 51.6%, which were achieved at one month, six months and one year respectively. However, higher rates were seen with limb salvage (88.9%, 80.2% and 73.1% at one month, six months and one year) and amputation-free survival (86.4%, 76.4%, and 69.7% at one month, 6 months and one year). Overall survival rates were 97.5% at one month, 93.0% at six months and 90.7% at one year. Thrombus burden revealed a trend towards decreasing patency, limb salvage and amputation-free survival at six months and one year with increasing thrombus burden, although data did not reach statistical significance. Thirty-day complication rate was 18.5% (n=15) with a major complication rate of 6.2% (n=5) including two deaths, one compartment syndrome, one retroperitoneal hematoma, and one groin hematoma requiring transfusion. Minor complication rate was 12.3% (n=10) and included five patients showing a transient increase in creatinine, four access hematomas and one thigh hematoma not requiring transfusion. There were no intracranial hemorrhage complications noted.

Conclusion: Our data suggest that Reteplase can be used to treat arterial occlusive disease in a safe and efficacious manner, as is shown by the low risk of bleeding complications, high limb salvage rates and low mortality rates in this study.