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Implementation of intravitreal tissue plasminogen activator injection into practice

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Why was it done?

Intravitreal tissue plasminogen activator (tPA) injection is a guideline recommendation for patients with medium, large or thick submacular hemorrhage mainly due to exudative age-related macular degeneration (AMD)[1,2]. Alteplase is a recombinant human tissue-type plasminogen activator, a glycoprotein, which activates plasminogen directly to plasmin. This treatment has not been available due to off-label use, rare demand, high price (generic unavailable, the cost uncovered by health insurance).

What was done? How was it done?

Ophthalmologists contacted the hospital pharmacy to work out a plan for two emergent cases of patients with large submacular hemorrhage in the better seeing eye. The pharmacists looked for the logistically simplest, economical affordable solution to prepare the injection in a cleanroom setting using a large volume medication vial.

The pharmacy came up with two models:

1. Compound intravitreal injection (50 µg/dose) from Actilyse 50mg vial (375 EUR) containing substance for intravenous infusion. The rest of the vial would possibly be used in neurology department during the next 24 hours. The costs would be shared based microgram use.
2. Use unregistered Actilyse cathflo 2mg vial. Application for permission and delivery would take up to 6 weeks and drug shortages would be usual. The price for 50 µg would be 65 EUR.

For the first two patients the first model was used. It was logistically complicated for the neurology department as they needed to change their everyday practice. The second model has now been introduced into practice and used for another two cases. It is accepted by the doctors and pharmacists.

What has been achieved?

Four patients have received the new treatment with intravitreal tPA in addition to the common practice of pneumatic displacement of the hemorrhage with intravitreal anti-VEGF injections or intravitreal anti-VEGF monotherapy. The treatment was well tolerated by the patients with some benefit to visual function. Pharmacy is ready to prepare tPA injections during working days.

Keywords: *intravitreal tissue plasminogen activator (tPA) injection; compounding*

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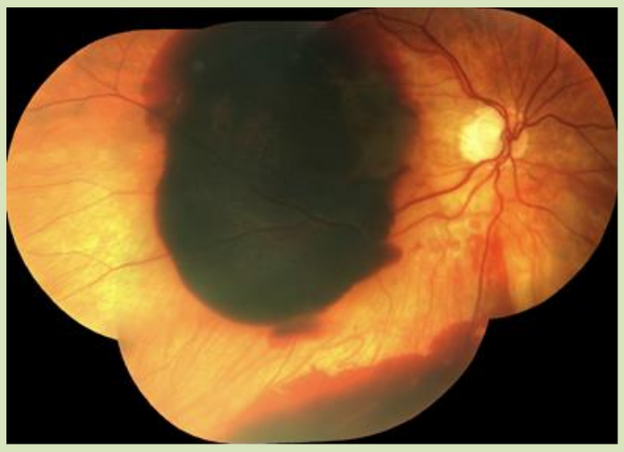
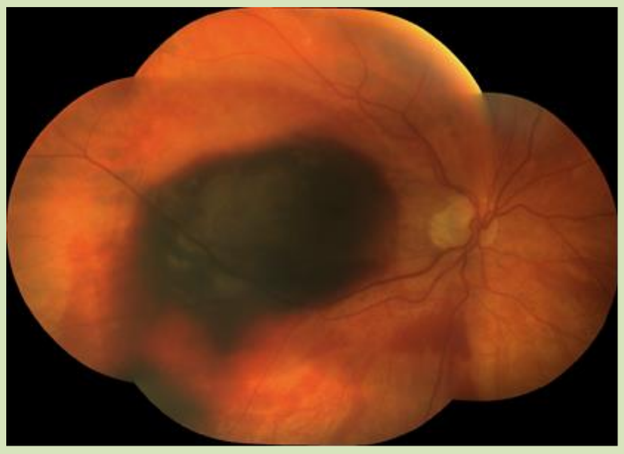
77 years old female patient has developed a large submacular hemorrhage in her right eye as a complication of exudative age-related macular degeneration (wet AMD). The patient received the following treatment for her right eye six days after the vision decreased: intravitreal tPA injection in combination with pneumatic displacement of the hemorrhage and intravitreal anti-VEGF (bevacizumab) injection.



Fundus photograph of the right eye depicting a large submacular hemorrhage. Visual acuity is counting fingers.



Fundus photograph of the same eye one month after treatment. The hemorrhage has decreased. The patient continues to receive monthly treatment with intravitreal anti-VEGF injections.

Fundus photograph of the same eye 4.5 months after treatment with tPA. The submacular hemorrhage has almost entirely resorbed. Visual acuity has improved to 0.1 on Snellen chart.

7.5 months after treatment with tPA the visual acuity has improved to 0.3 on Snellen chart.

What next?

Another hospital, the Tartu University Hospital became interested to start the same treatment. The second model was presented to their hospital pharmacy. Our ophthalmology department is now equipped to inject tPA into the subretinal space during vitrectomy to increase the efficacy of the procedure and improve patients visual outcome.

References:

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