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## The efficacy of adalimumab stored in plastic vials at four degrees celsius and the effect of intravitreal adalimumab on the treatment of active non-infectious ocular inflammation

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**Objective:** To prove that small amounts of adalimumab may be stored in plastic syringes for intravitreal use in active non infectious uveitis. Also report the favourable results of intravitreal adalimumab for the treatment of active uveitis. Efficacy of adalimumab stored in plastic vials at 4°C and a pilot study on the clinical effect of intravitreal adalimumab on active non infectious uveitis.

**Purpose:** Evaluate the efficacy of adalimumab repackaged into plastic polypropylene vials stored at 4°C and the efficacy and safety of intravitreal adalimumab (IVA) for treatment of active noninfectious uveitis.

**Methods:** Adalimumab refrigerated in plastic vials at 4°C for 5 weeks were used to neutralize the cytotoxic effect of recombinant human tumour necrosis factor alpha (rh-TNF- $\alpha$ ) on mouse fibrosarcoma cell line (L929 cells). Cell survival was assessed after treatment with effective dose of rhTNF- $\alpha$  and with the different concentrations of adalimumab (0.1, 1, 10  $\mu$ g/ml) stored in plastic using RTCA xCELLigence system. The inhibitory response of adalimumab was measured at one hour interval for up to 48 hours at weeks 1 and 5. In a prospective noncomparative interventional case series, eyes with active noninfectious uveitis were injected with 1.5 mg IVA at 0, 2 then every 4 weeks for total of 6 months. Change in VA, grade of inflammation (cells, haze and leakage on FA) and central retinal thickness (CRT) were recorded.

**Results:** Adalimumab (1, 10  $\mu$ g/ml) stored for 5 weeks in plastic vials was able to neutralize the cytotoxic effect of rhTNF- $\alpha$  with 100% L929 cell survival. 7 patients (13 eyes) were treated with IVA. 6 or 7 patients (12 or 13 eyes) completed 6 month treatment. 1 patient (1 eye) failed treatment with worsening VA and inflammation and was taken out of the study at visit 5. Median logMar at baseline was 0.243 (IQR=0.855) it improved to 0.049 (IQR=0.398) at 6 months. 7/12 eyes had improvement of  $\geq 2$  ETDRS lines at 6 months. At baseline, 3/13 eyes had AC cells grade  $\geq 1$ , 10/13 eyes had vit haze grade  $\geq 1$ . At 6 months, 0/12 eyes had AC grade or vit haze  $\geq 1$ . Median CRT at baseline was 317 (IQR=199) it improved to 277 (IQR=107.25) at 6 months. At baseline, 8/13 eyes had macular edema 5 of which resolved at 6 months. Median FA score at baseline was 14 (IQR=7.5) it improved to 4 (IQR=4.75) at 6 months. Using Wilcoxon Signed Rank test, the decrease in logMar, CRT and FA score at 6 months compared to baseline was significant ( $p=0.003$ ,  $0.021$ ,  $0.002$  respectively). No side effects were detected, stratifying the data to include one eye per patient revealed similar results.

**Conclusions:** Adalimumab stored in plastic vials retained its efficacy after five weeks of storage at 4°C at concentration as low as 1  $\mu$ g/ml. Furthermore, IVA was safe in this pilot study was effective in improving the VA in 7/12 eyes resolving macular edema in 5/8 eyes and decreasing AC cells, vit haze and FA score in 12 eyes while 1 patient (1 eye) failed treatment.

### Biography

Rola N Hamam is an Assistant Professor of Ophthalmology at the American University of Beirut. She is the Director of the residency training program and the medical retina fellowship training program. She received her BS degree in Biology from the American University of Beirut in 1998 and her MD in 2002. She completed her residency in Ophthalmology at the same institution then had fellowship training at Harvard University in Boston at the Beetham Eye Institute, the Massachusetts Eye and Ear Infirmary, and the Massachusetts Eye Research and Surgery Institution with Doctor C Stephen Foster until 2008. She returned to her home country and joined her Alma matter in 2009 to start the first uveitis specialty referral clinic in the country at the American University of Beirut. She is a member of several national and international societies. She has organized and lectured on ocular immunology and uveitis in many national and international conferences and scientific meetings. She is involved in multiple research projects on ocular inflammatory and infectious disease and she continues to contribute scientific publications in the field.

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