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An investigator-initiated, open-label, single-center, proof-of-concept-study of Omalizumab in patients with poorly controlled acute Urticaria

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Approximately 20~30% of the general population experiences at least one episode of urticaria in their lifetime. Research has also shown that itch, the dominant symptom in most patients with acute urticaria, severely interferes with sleep and daily activities, and has a detrimental impact on the quality of life. This prospective, interventional, single-arm open-label trial recruited 20 consecutive patients aged 20-75 years with a diagnosis of acute urticaria persistant (wheals between 3 days ~ 6 weeks) and baseline urticaria activity score (UAS) \geq 4 despite oral/intravenous antihistamines with or without systemic corticosteroid therapy who attended our clinic between January 2015 and October 2015. At day 0, patients received a single dose of 300 mg of Omalizumab subcutaneously. Treatment with Omalizumab resulted in mean UAS decrease from 5.0 ± 0.8 at baseline to 1.6 ± 2.1 at day 7. Compared with baseline, a statistically significant reduction in UAS had been observed since day 1, and continued through week 6 (Figure 1). Ten patients (50%) achieved complete remission (UAS=0 or UCT=16) at day 7 of Omalizumab therapy. As with the primary efficacy outcome, similar improvements were also observed for ISS, UCT, and DLQI. The mean change from baseline in ISS was -0.15, -0.8, -1.30, -1.35, -1.45 at days 1, 3, 5, 7 and week 6, respectively. Mean DLQI score also decreased by 16.4 points at day 7 after Omalizumab treatment. Similar with UAS, sustained therapeutic improvement in ISS, UCT, and DLQ was also observed till week 6. The mean of the patients' percentage improvements in UCT and DLQI was 75.1% and 55.6 % at day 7, respectively. Our study demonstrated that despite significantly improved symptoms and quality of life in patients with acute urticaria after Omalizumab treatment, a rapid control was observed in a minority.

Biography

Hsien-Yi Chiu is an attending physician of dermatology department and research scientist at the Institute of Biomedical Engineering, College of Medicine and College of Engineering, National Taiwan University. He has contributed significantly to a number of important studies on immune-related skin disorders, including urticarial and psoriasis.

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