Results.—Step 1 has been completed. Baseline characteristics of pts in Step 1: Mean (SD) age 59 (±14) yrs; 6 M/6F; 9 newly diagnosed, 3 relapsed pts; anti-MPO+ 7 (58%) pts; anti-PR3+ 6 (50%) pts; mean (SD) screening s-creat 119.4 (±40.5) µmol/L. No SAEs related to CCX168 occurred in Step 1. No rescue CS was required in the treatment period. One subject’s disease flared up during the follow-up period upon review, an external data monitoring committee recommended continuation to Step 2. Eight of 12 pts have been enrolled in Step 2 so far. One patient’s disease flared up prompting rescue CS. The trial is still blinded.

Discussion.—The partial CS withdrawal step of this Ph 2 trial has been completed successfully and the full CS withdrawal step is ongoing.

Conclusion.—The oral CSAR antagonist CCX168 could become a new treatment for patients with ANCA vasculitis.

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Lack of efficacy of tocilizumab in mucocutaneous Behçet’s syndrome: Report of two cases
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Introduction.—Behçet’s syndrome (BS) is a rare multisystem inflammatory disease. The treatment of BS consists of immunomodulating agents and biologics. Tocilizumab, an IL-6 inhibitor, has shown efficacy in BS patients with resistance to other therapies disease [1,2].

Methods.—We present hereby two patients of Norwegian ancestry with severe mucocutaneous BS who failed to respond to treatment with the IL-6 inhibitor tocilizumab.

Results.—

– A 55-year-old woman was primarily treated with high doses of glucocorticosteroids with regression of mucocutaneous disease. However, the addition of colchicine, methotrexate, azathioprine, anti-TNF-a led to either short efficacy or side effects. After the first infusion of tocilizumab, a deterioration of mouth and genital ulcers was observed and the patient was admitted to the internal medicine ward with severe retrosternal pain. The pain responded promptly to a combination of analgesics and 20 mg of prednisolone.

– A 26-year-old woman with mucocutaneous BS received initially high to moderate doses of corticosteroids. On the other hand, corticosteroid-sparing treatment with cyclosporine, azathioprine, colchicine, methotrexate, anti-TNF-a led to incomplete response or improper toxicity. Tocilizumab treatment was started and she received 3 monthly infusions, in total. Partial response was seen during the first two infusions, however, immediately after the third infusion the painful genital ulcers recurred.

Discussion.—Our report comes in contrast with others that described efficacy of tocilizumab in severe neurological and ocular BS. It appears that IL-6 is a major contributor in the inflammation observed in neurological and ocular BS through stimulation of proliferation of Th-17 cells [3]. Nevertheless, in mucocutaneous BS the pathogenesis may be somewhat different with different cytokine profile than the other phenotypes of BS [3]. This may explain the inefficacy of tocilizumab in mucocutaneous BS.

Conclusion.—Tocilizumab may be ineffective in the treatment of mucocutaneous BS.

References

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P208
Improving the quality and safety of intravenous cyclophosphamide (IV CYC): A regional audit of a best-practice protocol
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Introduction.—Following the 2009 Department of Health report “Chemotherapy Services in England: Ensuring quality and safety” a regional best-practice protocol for the use of IV CYC was developed. The protocol contains IV CYC regimes with trial evidence, guidance on steroid tapering and improving host defence. We audited the protocol standards and outcome of IV CYC use.

Methods.—Retrospective notes review of all patients at three centres commencing IV CYC between April 2010 and April 2012.

Results.—Sixty-seven patients received IV CYC (41 at Trust 1, 11 at Trust 2 and 15 at Trust 3). Mean age was 59 years. Indications were: Systemic Vasculitis 37 (GPA 16, EGPA 4, MPA 5, CNS vasculitis 3, other Vasculitis 9); SLE 5; Scleroderma 6; IBD 16; Other CTD 3. Most Vasculitis patients received the IV CYC protocol currently being used in the MICYC trial. All SLE patients received the Euro-Lupus regime. Doses were adjusted for age in 85% and renal function in 100%. Anti-emetics and Mesna were prescribed in 100%. Counselling and consent were documented in > 90%. Formal disease activity assessment and vaccinations were recommended in 48 and 46% respectively, with some variation between centres. Twenty-five percent of patients had a documented infection during treatment, most commonly LRTI or oral candida. Thirty-eight percent had an adverse event (AE) whilst on CYC; 27% could be attributable to CYC. The most common AE was nausea ± vomiting in 10%. There were four deaths during treatment; one could be attributable to CYC. Three patients did not complete the treatment course (1 withdrew consent, 1 AE, 1 primary inefficacy).

Discussion.—Most patients completed the treatment course. Infections were common, but usually mild, with no admissions for neutropenic sepsis. Areas for improvement include: improved formal assessment of disease activity, documentation of immunization status, and continued need to communicate with patients and primary care.

Conclusion.—The regional protocol is being followed well in most domains. It has enabled standard evidence based regimes to be used across units.

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