Maintenance Rituximab is associated with improved clinical outcome in rituximab naïve patients with Waldenstrom's Macroglobulinemia who respond to a rituximab containing regimen.

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Background: Rituximab alone and in combination is an important mainstay of therapy for WM. While maintenance rituximab (MRx) is often employed after induction therapy, its safety and efficacy has not been investigated in WM. **Methods:** We therefore investigated the outcome of 248 rituximab naïve WM patients who responded to a rituximab based induction therapy, including 86 (35%) patients who then received MRx. No differences in baseline characteristics, and post-induction categorical responses were observed between cohorts. Induction therapy included rituximab alone (n=79) or in combination (n=169). The median rituximab infusions during induction was 6 for both cohorts; and 8 over a 2 year period for MRx treated patients. **Results:** With a median follow-up of 37.9 months, categorical response upgrade occurred in 16/162 (10%) versus 36/86 (41.8%) of observed and MRx treated patients, respectively ($p<0.0001$). The median PFS for MRx treated patients was 56.3 versus 28.6 months for observed patients ($p=0.0001$). Improved PFS was observed despite previous treatment status ($p\leq0.001$); induction with rituximab alone ($p=0.001$), or in combination therapy ($p=0.0001$). Among patients receiving MRx therapy, the median OS was >120 months versus 116 months for patients who were observed ($p=0.0095$). Improved OS was observed despite previous treatment status ($p\leq0.001$), induction with rituximab alone ($p=0.083$) or in combination ($p=0.041$). No difference in PFS and OS for patients was observed between patients who received MRx as 1 single infusion every 3 months versus 4 weekly infusions every 6 months ($p=0.49$ and 0.38, respectively). 20.4% and 38.4% of observed and MRx patients experienced at least 1 infectious event, respectively ($p=0.0064$). Most infections involved the sinus and pulmonary tracts; all but 6 of these events were <grade 3, and there was no difference between cohorts ($p=0.718$). **Conclusions:** MRx is well tolerated and associated with improved clinical outcomes in WM patients who respond to induction with a rituximab containing regimen despite previous treatment status, treatment with rituximab alone, or in combination therapy.