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Conference: IWWM12

Ibrutinib or chemo-immunotherapy as second line treatment in Waldenstrom Macroglobulinaemia? A real-life multicentre study.

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In the setting of relapsed patients (pts) affected by Waldenström Macroglobulinaemia (WM) chemo-immunotherapy (CT) has been substantially substituted by BTKis. Previous trials have investigated efficacy and safety of BTKis in second line without a direct comparison to CT.

The aim of our retrospective study was to assess responses and outcomes with the treatment of BTKi or CT in second line.

We enrolled 169 WM pts relapsed in the period 2008-2022 from 15 FIL centres: 85 pts were treated with ibrutinib and 84 pts with CT; of whom 34 pts with BR (bendamustine-rituximab), 21 DRC (dexamethasone-rituximab-cyclophosphamide), 15 bortezomib-based regimens and 14 palliative regimens (i.e. alkylants).

The two cohorts of ibrutinib and CT showed similar basal clinical characteristics, prognostic factors, comorbidities and also times of retreatment between first and second line (42 vs 39 months, p=0.64).

Overall response rate (ORR) was achieved in 84.7% of pts after ibrutinib and in 69% after CT (p=0.026), ibrutinib pts showed a better progression free survival (PFS) than CT pts (4-y PFS of 67% vs 48%, p=0.0045; figure 1), but we did not find statistical differences in terms of time to next treatment (TTNT) and overall survival (OS); in particular 4-y TTNT was 67% for ibrutinib and 55% for CT, 4-y OS was 78% for both. ORR for both the groups was independent from presence of treatment modifications and toxicities.

Considering the 4 different groups within the CT cohort, they showed the same characteristics except for the median age at treatment (bortezomib-based: 69 yy, BR: 70 yy, DRC: 75 yy, palliative: 83 yy; p=0.007). Non-significant difference among the 4 groups was seen in terms of ORR and PFS

nor of TTNT and OS, even if we registered a better PFS for BR with a median PFS of 58.2 months, followed by bortezomib-based (PFS 53.6 mo), DRC (PFS 44.6 mo) and palliative (PFS 33.6 mo).

When comparing ibrutinib to each of the 4 CT groups, different ORR were observed in each group with Ibrutinib reporting the highest rate (84.7%; p=0.023). PFS of ibrutinib was superior to PFS of DRC, bortezomib-based and palliative regimens (p=0.028, p=0.023 and p=0.04, respectively) and it showed a trend versus PFS of BR (p=0.055). Figure 2 showed the significant trend (p=0.057) in terms of better PFS of ibrutinib in comparison to the other 4 curves. For TTNT and OS none difference was reported based on ibrutinib and type of CT.

No differences were noted in the two subgroups of ibrutinib patients who were treated with BR or DRC as first line therapy in terms of PFS, TTNT, OS, ORR and withdrawal or dose reduction due to toxicity.

Multivariate analysis found choice of the treatment (ibrutinib vs CT), beta2microglobulin and female gender as significant variables that favourably impact on PFS, choice of the treatment, age and female gender on TTNT, age and female gender on OS.

This large retrospective real-life study showed advantages of ibrutinib versus CT in terms of ORR and PFS, except for BR, but not in terms of TTNT and OS.

Figure 1: PFS of ibrutinib in comparison to the CT.

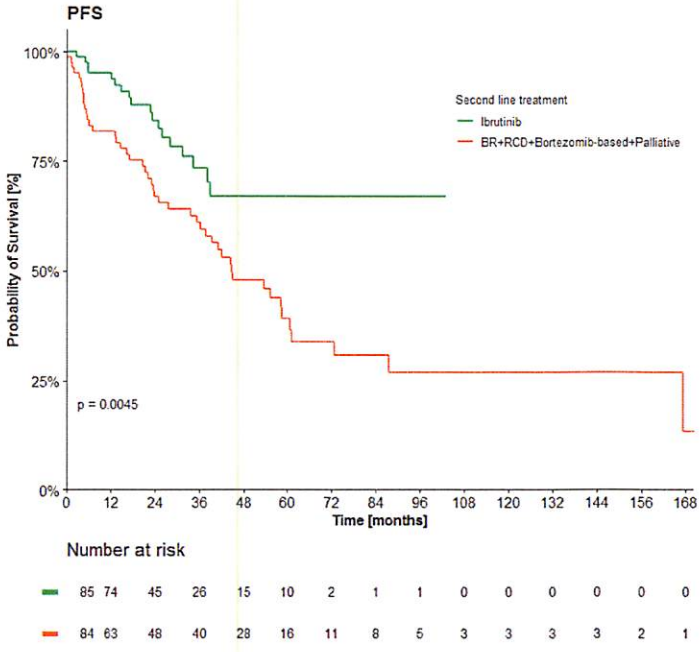

Figure 2: PFS of ibrutinib in comparison to the 4 curves of the different CT.