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## Reduced-intensity allogeneic stem cell transplantation is an effective salvage treatment for relapsed aggressive non-Hodgkin's lymphoma

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ON BEHALF OF GITMO

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We conducted a multicenter phase II trial for salvage treatment of relapsed lymphomas; 170 pts received allogeneic SCT from HLA identical sibling donors at 22 Italian centers. RIC regimen included thiotepa, fludarabine and cyclophosphamide. GVHD prophylaxis consisted of cyclosporine A and short-course methotrexate. Histologies included n=63 indolent NHL (LG-NHL) [follicular (FCL), n=27; chronic lymphocytic leukaemia/small lymphocytic lymphoma (CLL/SLL), n=32; other n=4], n=62 high-grade NHL (HG-NHL) (B-lineage lymphomas: DLCL-B, n=32; T-lineage lymphomas n=23; transformed LG-NHL n=7), n=32 HD and n=14 mantle cell lymphoma (MCL). Median age was 51 years (range, 20–69). Median number of prior regimens was 3. Eighty-four pts (49%) failed a previous auto-SCT. 117 (69%) pts had chemosensitive disease, 51 (30%) had chemorefractory and 2 had untested relapse. Forty-three pts (25%) were in CR before allo-SCT. Peripheral blood was the source of stem cells in 138 pts (81%). The actuarial probability of TRM for all pts at 100 days and 3 years was 6% and 15%, respectively. TRM at 3 years was 15%, 15%, 3%, and 35% in LG-NHL, HG-NHL, HD and MCL, respectively. On univariate analysis, there was a significantly higher TRM for older pts ( $\geq 55$  versus  $< 55$  years old, 27%

versus 8% at 3 year,  $p < 0.002$ ) and those with acute GVHD (34% versus 3% at 3 year,  $p < 0.0001$ ). Previous auto or more than 2 lines of chemotherapy and chemorefractory disease were not associated to a higher TRM. The incidence of acute and chronic GVHD was 35% and 45%, respectively. With a median follow-up of 30 months (6–78), the estimated OS and EFS at 3 years were 61% and 45%, respectively. Pts in CR at study entry had a more favourable outcome (87% versus 53% 3 year OS,  $p < 0.003$ ; 61% versus 40% 3 year EFS,  $p < 0.006$ ). The 3 year OS rates for LG-NHL, HG-NHL, HD and MCL were 67%, 68%, 34%, 43%, respectively. The one-year actuarial risk of relapse was 18%, 27%, 77% and 31% in LG-NHL, HG-NHL, HD and MCL. Interestingly, disease status at transplant influenced the relapse risk in HG-NHL and HD, but not in LG-NHL. We observed a significant difference in OS and relapse risk between FCL and CLL (OS 86% versus 56% 3 year OS,  $p < 0.01$ ; 14% versus 52% 3 year relapse risk,  $p < 0.01$ ). Of note, we did not find a significant difference in outcome among pts with DLCL-B and T-lineage lymphomas (73% versus 61% 3 year OS,  $p < 0.54$ ; 28% versus 40%,  $p < 0.35$ ). In conclusion, our data support the finding that RIC allo-SCT is a feasible and effective salvage treatment in NHL.