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Postremission Therapy in Adult Acute Myeloid Leukemia (AML): A Randomized Comparison between High Dose Ara-C Therapy and Conventional Consolidation Therapy (JALSG AML 201 Study). Shuichi Miyawaki,[1] Shigeki Ohtake,[2] Shin Fujisawa*,[2] Hitoshi Kiyoi*,[2] Katsuji Shinagawa,[2] Noriko Usui,[2] Koichi Miyamura,[2] Miki Nishimura*,[2] Yasushi Miyazaki,[2] Kazuhiro Nishii,[2] Tadashi Nagai,[2] Takahisa Yamane*,[2] Masafumi Taniwaki,[2] Masatomo Takahashi,[2] Fumiharu Yagasaki*,[2] Yukihiko Kimura*,[2] Norio Asou,[2] Sumihisa Honda*,[2] Kazunori Ohnishi,[2] Tomoki Naoe,[2] Ryuzo Ohno.[2] *[1]Leukemia Research Center, Saiseikai Maebashi Hospital, Maebashi, Gunma, Japan; [2]Japan Adult Leukemia Study Group, Japan.*

Between 2001 and 2005, JALSG conducted a randomized study to assess the optimal post remission therapy for adult AML in the first CR. JALSG AML201 enrolled 1064 previously untreated AML patients (pts) aged 15-64 yrs. The induction therapy consisted of cytarabine (Ara-C 100mg/m2 day1-7) and idarubicin (IDR 12mg/m2 day1- 3) (arm A) or cytarabine (100mg/m2 day1-7) and daunorubicin (DNR 50mg/m2 day1- 5) (arm B). If the patients did not achieve remission after the first induction therapy, then the same therapy was given once more. Pts were categorized into good, intermediate or poor risk groups by risk factors based on the criteria established in previous JALSG AML studies. All CR pts were stratified according to the induction, the number of courses of induction, age and karyotype and were randomly assigned to the high dose Ara-C (HDAC) post remission regimen (arm C) or the conventional JALSG post remission regimen (arm D). Arm C: the three courses of HDAC which consisted of Ara-C 2.0g/m2 q12h day1-5, arm D: the first course consisted of Ara-C 200mg/m2 day1-5+ mitoxantrone (MIT) 7mg/m2 day1-3, 2) Ara-C 200mg/m2 day1-5+ DNR 50mg/m2 day1-3, 3) Ara-C 200mg/m2 day1-5+ aclarubicin (ACR) 20mg/m2 day1-5, 4) Ara-C 200mg/m2 day1-5+ etoposide (ETP) 100mg/m2 day1-5 + vincristine (VCR) 0.8mg/m2 day 8 + vindesine (VDS) 2 mg/m2 day10.
Results: Of the 1064 pts registered, 1057 pts (median age: 47 years) were evaluable. 825 pts (78%) achieved CR after one or two courses of induction therapy. Of the 825 pts in CR, 781 pts were assigned to arm C or arm D. The 4-year OS rate of arm C was 61.6% while that of arm D was 62.8% (p=0.58). The 4-year RFS rate of the CR patients was 42.8% in arm C and 40.8% in arm D (p=0.65). Among the good risk group, the 4-year OS rate of arm C was 77.0% while that of arm D was 75.8 % (p=0.40), and the 4-year RFS rate of arm C was 54.6% while that of arm D was 53.1% (p=0.71). Among the intermediate risk group, the 4-year OS rate of arm C was 63.2% while that of arm D was 65.7% (p=0.78), and the 4-year RFS rate of arm C was 38.7% while that of arm D was 42.2% (p=0.63). Among the poor risk group, the 4-year OS rate of arm C was 36.3% while that of arm D was 34.1% (p=0.71), and the 4-year RFS rate of arm C was 25.9% while that of arm D was 6.6% (p=0.17). In the CBF leukemia group, the 4-year OS rate of arm C was 79.4% while that of arm D was 66.5% (p=0.09), and the 4-year RFS rate of arm C was 57.7% while that of arm D was 43.7% (p=0.14). Among the young group (<50yrs), the 4-year OS rate of arm C was 66.5% while that of arm D was 66.2% (p=0.37), and the 4-year RFS rate of arm C was 43.9% while that of arm D was 45.6% (p=0.32). Among the old group (>=50 yrs), the 4-year OS rate of arm C was 53.4% while that of arm D was 57.7% (p=0.90), and the 4-year RFS rate of arm C was 39.1% while that of arm D was 33.8% (p=0.67).
Conclusion: The conventional post remission therapeutic regimen established by JALSG consisting of 4 courses of consolidation was thus found to be as effective as the three courses of HDAC therapy. To further confirm these results, a longer follow-up is therefore needed.
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