Allogeneic stem cell transplantation in second complete remission for core binding factor acute myeloid leukemia: a study from the Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation

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|                                | inv(16)                | t(8;21)                | p-value |
|--------------------------------|------------------------|------------------------|---------|
| N                              | 366                    | 265                    |         |
| Age at transplantation (years) | median (range)[IQR]    | 41.9 (18.1-73.9) [30.9-50.9] | 41.5 (18-73.3) [31.6-51.2] | 0.92    |
| Year of transplantation        | median (range)[IQR]    | 2010 (2000-2014) [2007-2012] | 2009 (2000-2014) [2006-2012] | 0.49    |
| Time from diagnosis to CR1 (days) | median (range)[IQR]    | 38 (10-275) [30-49.8] 100 | 43 (10-162) [31-59.2] 97 | 0.043   |
| CR1 duration (days)           | median (range)[IQR]    | 311 (14-2380) [244-434] 109 | 341 (14-2068) [249-533] 108 | 0.08    |
| Time from CR2 to transplantation (days) | median (range)[IQR]    | 56 (7-252) [28.5-100.5] 260 | 55 (6-234) [23-88] 212 | 0.38    |
| Time diagnosis to transplantation (months) | median (range)[IQR]    | 16.5 (3.5-87.3) [13.9-21.6] 0 | 18.2 (3.9-222.9) [14.3-24.8] 0 | 0.005   |
| FLT3-ITD                       | negative               | 82 (85.42%) 14 (14.58%) 270 | 49 (80.33%) 12 (19.67%) 204 | 0.40    |
|                                | positive               |                         |         |
|                                | missing                |                         |         |
| NPM1 mutation                  | absent                 | 24 (85.71%) 4 (14.29%) 338 | 17 (94.44%) 1 (5.56%) 247 | 0.63    |
|                                | present                |                         |         |
|                                | missing                |                         |         |
|                          | no associated abnormalities |       |       |      |
|--------------------------|-----------------------------|-------|-------|------|
| ≥3 chromosomal abnormalities at diagnosis | no                          | 347   | 252   | 0.87 |
|                          | yes                         | 19    | 13    |      |
| Associated chromosomal abnormalities | t(11;23)                    | 2     | 1     |      |
|                          | abn5                        | 0     | 2     |      |
|                          | abn7                        | 8     | 2     |      |
|                          | del9                        | 0     | 5     |      |
|                          | del X or del Y              | 0     | 18    |      |
|                          | trisomy22                   | 9     | 0     |      |
|                          | trisomy 8                   | 9     | 1     |      |
|                          | hyperiploidy                | 3     | 1     |      |
|                          | hypodiploidy                | 0     | 7     |      |
|                          | other abnormalities         | 22    | 12    |      |
| Extramedullary disease at diagnosis | no                          | 131   | 68    | 0.83 |
|                          | yes                         | 17    | 8     |      |
|                          | missing                     | 218   | 189   |      |
| Patient sex              | male                        | 189   | 172   | 0.0009 |
|                          | female                      | 177   | 93    |      |
|                          | missing                     | 5     | 5     |      |
| Donor sex                | male                        | 216   | 153   | 0.80 |
|                          | female                      | 145   | 107   |      |
|                          | missing                     | 5     | 5     |      |
|                                |   |   |   |   |
|--------------------------------|---|---|---|---|
| **Sex matching**               | female to male transplant | 69 (18.9%) | 64 (24.43%) | 0.09 |
|                                | other                        | 296 (81.1%) | 198 (75.57%) |   |
|                                | missing                      | 1           | 3            |   |
|                                | **other**                    | 296 (81.1%) | 198 (75.57%) |   |
| **Karnofsky performance score**| <80%                         | 12 (3.54%)  | 4 (1.69%)    | 0.18 |
| at transplantation             | ≥80%                         | 327 (96.46%)| 232 (98.31%)|   |
|                                | missing                      | 27          | 29           |   |
|                                | **missing**                  | 3           | 3            |   |
| **Donor**                      | matched sibling              | 154 (42.08%)| 110 (41.51%)| 0.89 |
|                                | unrelated                     | 212 (57.92%)| 155 (58.49%)|   |
| **Graft source**               | bone marrow                 | 73 (19.95%) | 44 (16.6%)  | 0.29 |
|                                | peripheral blood             | 293 (80.05%)| 221 (83.4%) |   |
|                                | missing                      | 0           | 0            |   |
|                                | **missing**                  | 0           | 0            |   |
| **Molecular MRD at transplantation** | negative               | 206 (76.58%)| 137 (68.84%)| 0.06 |
|                                | positive                     | 63 (23.42%) | 62 (31.16%) |   |
|                                | missing                      | 97          | 66           |   |
|                                | **missing**                  | 97          | 66           |   |
| **Patient anti-CMV IgG at transplantation** | negative     | 132 (36.87%)| 95 (37.11%)  | 0.95 |
|                                | positive                     | 226 (63.13%)| 161 (62.89%)|   |
|                                | missing                      | 8           | 9            |   |
|                                | **missing**                  | 8           | 9            |   |
| **Donor anti-CMV IgG at transplantation** | negative | 179 (50.85%) | 127 (49.03%) | 0.66 |
|                                | positive                     | 173 (49.15%)| 132 (50.97%)|   |
|                                | missing                      | 14          | 6            |   |
|                                | **missing**                  | 14          | 6            |   |
| **In vivo T-cell depletion**    | no                           | 170 (46.45%)| 132 (50.57%)| 0.31 |
|                                | **missing**                  | 170 (46.45%)| 132 (50.57%)|   |
| Conditioning                        | yes     | missing | 196 (53.55%) | 0 | 129 (49.43%) | 4 | 0.14 |
|------------------------------------|---------|---------|--------------|---|--------------|---|------|
|                                    | myeloablative | reduced intensity | 238 (65.21%) | 127 (34.79%) | 186 (70.72%) | 77 (29.28%) | 2    |
|                                    | missing |         |              |    |              |    |      |

AML, acute myeloid leukemia; IQR, interquartile range, CR1, first complete remission; CR2, second complete remission; FLT3-ITD, fms like tyrosine kinase 3 internal tandem duplication; NPM1, nucleoposmin; MRD, minimal residual disease; anti-CMV IgG, anti cytomegalovirus antibody class IgG.
Supplemental Table 2. Endpoints stratified by minimal residual disease status before transplantation – univariate analysis.

|        | relapse       | NRM       | LFS       | OS         | GRFS       |
|--------|---------------|-----------|-----------|------------|------------|
|        | 2 year results |           |           |            |            |
| MRDneg |               |           |           |            |            |
| inv(16)| 11.6% [7.6-16.5] | 21% [15.6-26.9] | 67.4% [60.8-73.9] | 71.8% [65.5-78.1] | 46.2% [39.5-53.3] |
| t(8;21)| 22.5% [15.7-30]  | 23.2% [16.3-30.9] | 54.3% [45.6-63]  | 57.4% [48.7-66.1] | 38.7% [30.1-47.3] |
| P value| 0.037          | 0.56      | 0.031     | 0.022      | 0.22       |
| MRDpos |               |           |           |            |            |
| inv(16)| 23.3% [13.5-34.7] | 22.9% [13.3-34.2] | 53.8% [41.2-66.4] | 67.1% [55.3-79]  | 30% [18.2-41.9]   |
| t(8;21)| 36% [23.5-48.7]  | 19.9% [10.5-31.4] | 43.4% [30.2-56.7] | 51.6% [38.2-65.1] | 28.2% [16.4-40]   |
| P value| 0.12           | 0.66      | 0.30      | 0.08       | 0.92       |

MRDneg, minimal residual disease negative; MRDpos, minimal residual disease positive; inv(16), acute myeloid leukemia with inv(16); t(8;21), acute myeloid leukemia with t(8;21); NRM, non-relapse mortality; LFS, leukemia-free survival; OS, overall survival; GRFS, graft-versus-host disease-free, relapse-free survival.
Supplemental Table 3. Univariate analysis of factors influencing outcomes in core-binding factor acute myeloid leukemia patients transplanted in second complete remission. Values in parentheses represent 95% confidence interval.

| Type of CBF AML | No MEDC (%) | MEDC (%) | P value |
|-----------------|--------------|----------|---------|
| inv(16)         | 19.7% (16.1-23.6) | 19.8% (14.2-26.1) | 0.83467 |
| t(8;21)         | 15.6% (12-19.6) | 25.8% (20.5-31.4) | 0.008957 |
| P value         | 0.83073       | 0.4379    | 0.6251  |

| Extramedullary disease at diagnosis | No (%) | Yes (%) | P value |
|------------------------------------|--------|---------|---------|
| No (214)                           | 21.4% (16-27.4) | 20.3% (15-26.2) | 0.6251 |
| Yes (43.6)                         | 58.2% (15-65.1) | 65.3% (51.3-68.1) | 0.95048 |
| P value                            | 0.65326 | 0.4521 | 0.21097 |

| Additional cytogenetic abnormalities | RI 2-year Probability | LFS 2-year Probability | OS 2-year Probability | GRFS 2-year Probability | cGVHD 2-year Probability | aGVHD IV-V 2-year Probability |
|--------------------------------------|------------------------|-------------------------|------------------------|--------------------------|-------------------------|------------------------------|
| no abnormality                       | 17.7% (14.4-21.3)      | 61.5% (57-65.9)         | 66.5% (62.2-70.8)       | 42.5% (38.4-47.1)        | 46.3% (41.5-50.9)        | 28.8% (24.8-32.9)            |
| abn7 (n=10)                          | 10% (0.4-38.2)         | 30% (6.2-59.3)          | 60% (29.6-90.4)         | 70% (41.6-98.4)          | 22.2% (0-49.4)           | 55.6% (16.2-82.7)            |
| ≥ 3 (n=32)                           | 34.4% (18.4-51)        | 28.1% (13.8-44.4)       | 37.5% (20.7-54.3)       | 49.6% (32.2-67.1)        | 20% (5.7-34.3)           | 44.8% (25.6-62.4)            |
| del X or Y (n=18)                    | 30.4% (10.4-53.6)      | 17.6% (4-39.2)          | 51.9% (27.6-73.6)       | 64.6% (27.6-87.6)        | 31.2% (9.1-53.4)         | 38.9% (16.6-60.9)            |
| trisomy 22 (n=9)                     | 0% (0.5-40.6)          | 11.1% (68.4-100)        | 88.9% (68.4-100)        | 71.4% (38-100)           | 71.4% (15.5-94.1)        | 11.1% (5.5-40.9)             |
| trisomy 8 (n=10)                     | 20% (40%)              | 40% (40%)               | 40% (40%)               | 20% (20%)                | 50% (50%)                | 30% (30%)                   |
|                                | other (n=34) | [2.5-49.6 | [10.5-68.9 | [9.6-70.4 | [9.6-70.4 | [0-44.8 | [15.5-77.3 | [6.2-59.3 |
|--------------------------------|--------------|-----------|------------|------------|------------|-------------|-------------|------------|
|                                |              | 30.2%     | 11.9%      | 58%        | 67%        | 42.8%       | 45.2%       | 11.8%      |
|                                |              | [15.5-46.3| [3.7-25.3  | [41.1-74.8 | [51-83]    | [25-9-59.7] | [26.8-62]   | [3.6-25.1]  |
| ≥ 3 cytogenetic abnormalities   | No           | 19%       | 20.6%      | 60.4%      | 65.9%      | 41.3%       | 46.8%       | 28.4%      |
|                                |              | [15.9-22.3| [17.4-24]  | [56.3-64.4 | [62-69.8]  | [37.2-45.4] | [42.5-51]   | [24.8-32.1]|
|                                | Yes          | 34.4%     | 28.1%      | 37.5%      | 49.6%      | 20%         | 44.8%       | 19.4%      |
|                                | P value      | 0.032235  | 0.2903     | 0.0022938  | 0.013      | 0.013759    | 0.80179     | 0.3306     |
|                                |              | [18.4-51]  | [13.8-44.4| [20.7-54.3]| [32.2-67.1]| [5.7-34.3]  | [25.6-62.4] | [7.7-34.9]  |
| Molecular CR at transplantation | No           | 29.3%     | 21.5%      | 49%        | 59.9%      | 29.2%       | 48.9%       | 27.2%      |
|                                |              | [21.2-37.8| [14.5-29.4| [39.8-58.2]| [50.8-68.9]| [20.8-37.5] | [39.3-57.9] | [19.6-35.4]|
|                                | Yes          | 16.2%     | 22.2%      | 61.6%      | 65.8%      | 42.9%       | 45.9%       | 29.5%      |
|                                | P value      | 0.0028876 | 0.49498    | 0.046352   | 0.4667     | 0.014591   | 0.61705     | 0.71792    |
|                                |              | [12.4-20.4]| [17.8-26.8| [56.3-66.9]| [60.7-71]  | [37.4-48.4] | [40.1-51.5] | [24.7-34.4]|
|                                |              | 0.41534   | 0.16296    | 0.64058    | 0.97605    | 0.24469    | 0.89203     | 0.84125    |
| WBC at diagnosis, median 28.9 G/l| ≤ median     | 21.9%     | 16.9%      | 61%        | 67.1%      | 35.9%       | 48.3%       | 29.4%      |
|                                |              | [15.9-28.5| [11.6-23]  | [53.7-68.5]| [59.8-74.3]| [28.4-43.4] | [40.2-55.9] | [22.6-36.4]|
|                                | > median     | 16.5%     | 22.4%      | 61.1%      | 66.4%      | 45.2%       | 47.7%       | 30%        |
|                                | P value      | 0.41534   | 0.16296    | 0.64058    | 0.97605    | 0.24469    | 0.89203     | 0.84125    |
|                                |              | [11.4-22.5]| [16.4-28.9]| [53.7-68.4]| [59.3-73.5]| [37.6-52.7]| [39.8-55.1]| [23.3-37]  |
|                                |              | 0.41534   | 0.16296    | 0.64058    | 0.97605    | 0.24469    | 0.89203     | 0.84125    |
| Patient age, median 41.7 years | ≤ median     | 17.9%     | 21.2%      | 60.7%      | 66.5%      | 39.9%       | 48.5%       | 30%        |
|                                |              | [13.8-22.5| [16.8-26.1]| [55.1-66.3]| [61.1-71.9]| [34.2-45.7]| [42.4-54.4]| [24.9-35.2]|
|                                | > median     | 21.7%     | 20.7%      | 57.6%      | 63.6%      | 40.4%       | 45%         | 25.9%      |
|                                | P value      | 0.14708   | 0.9807     | 0.29435    | 0.39368    | 0.95855    | 0.34313     | 0.27792    |
|                                |              | [17.2-26.5]| [16.3-25.4]| [52-63.2]  | [58.1-69]  | [34.8-46]  | 0.34313     | 0.27792    |
| Patient sex                    | Male         | 21.4%     | 20.3%      | 58.3%      | 65%        | 40%         | 46.5%       | 28.7%      |
|                                |              | [17.2-25.9| [16.2-24.7]| [53-63.5]  | [59.9-70.1]| [34.6-45.3]| [40.9-52]   | [24.1-33.5]|
|                                | Female       | 17.8%     | 21.9%      | 60.3%      | 65%        | 40%         | 47%         | 27%        |
|                                |              | [13.4-22.7]| [17.1-27.1]| [54.3-66.2]| [59.1-70.8]| [34.3-46.5]| [40.5-53.2]| [21.7-32.5]|
|                                | P value      | 0.16887   | 0.63076    | 0.52692    | 0.72766    | 0.70516     | 0.92355     | 0.66892    |
| Donor sex | Male | Female | P value | Median 2010 | ≤ median | ≥ median |
|-----------|------|--------|---------|-------------|----------|----------|
| Male      | 20.3% [16.3-24.6] | 19.9% [15-25.2] | 0.94983 | [19.2-28] | 17.1% [12.6-22.2] | 0.2524 |
| Female    | 23.5% [19.2-28] | 17.1% [12.6-22.2] | 0.2524 | [23.5-28] | 19.9% [15-25.2] | 0.94983 |
| P value   | 0.94983 | 0.2524 | 0.071864 | 0.136 | 0.179 |

| Donor and recipient sex matching | Female to male | Other | P value | Median 2010 | ≤ median | ≥ median |
|---------------------------------|----------------|-------|---------|-------------|----------|----------|
| Female to male                  | 21.9% [15-29.6] | 19.4% [16-23.1] | 0.5376 | [15.9-22.9] | 22.5% [18.8-26.3] | 0.22135 |
| Other                            | 23.1% [17-27.5] | 17.7% [13.6-22.3] | 0.071864 | [20.6-22.9] | 21.1% [17.1-25.4] | 0.89372 |
| P value                          | 0.5376 | 0.071864 | 0.2135 | 0.22135 | 0.22135 | 0.22135 |

| Patient anti-CMV IgG | Negative | Positive | P value | Median 2010 | ≤ median | ≥ median |
|-----------------------|----------|----------|---------|-------------|----------|----------|
| Negative              | 23.1% [17-27.5] | 18% [14.2-22.1] | 0.071864 | [15.5-26.3] | 21.1% [17.1-25.4] | 0.89372 |
| Positive              | 22.5% [17.9-27.5] | 17.7% [13.6-22.3] | 0.071864 | [15.7-24.8] | 21.2% [16.7-26.1] | 0.49007 |
| P value               | 0.071864 | 0.071864 | 0.89372 | 0.89372 | 0.89372 | 0.89372 |

| Donor anti-CMV IgG | Negative | Positive | P value | Median 2010 | ≤ median | ≥ median |
|---------------------|----------|----------|---------|-------------|----------|----------|
| Negative            | 22.5% [17.9-27.5] | 17.7% [13.6-22.3] | 0.071864 | [15.7-24.8] | 21.2% [16.7-26.1] | 0.49007 |
| Positive            | 22% [17.4-25.2] | 17% [13.6-22.3] | 0.071864 | [15.7-24.8] | 21% [16.7-26.1] | 0.49007 |
| P value             | 0.071864 | 0.071864 | 0.49007 | 0.49007 | 0.49007 | 0.49007 |

| Karnofsky performance score at transplantation | KPS<80 | KPS≥80 | P value | Median 2010 | ≤ median | ≥ median |
|------------------------------------------------|-------|-------|---------|-------------|----------|----------|
| KPS<80                                          | 12.5% [1.8-34.2] | 20.3% [17-23.8] | 0.7175 | [23.3-71.9] | 19.8% [16.5-26.5] | 0.0018721 |
| KPS≥80                                          | 37.5% [13.8-61.2] | 62% [55.7-64.1] | 0.0026102 | [13.8-61.2] | 66.1% [61.7-70.2] | 0.0026872 |
| P value                                         | 0.7175 | 0.7175 | 0.0018721 | 0.0018721 | 0.0026102 | 0.0026872 |

| Year of transplantation, median 2010 | ≤ median | 19.8% [15.8-24.2] | 20.9% [16.7-25.3] | 59.3% [54.1-64.5] | 65% [60-70.1] | 42.3% [36.9-47.6] | 48.3% [42.7-53.7] | 28.7% [24.3-31.9] |
|> median                                       | 19.8% | 21.3% | 58.8% | 64.9% | 37.2% | 44.7% | 27% | 28.7% |
| Condition                        | Median                | P value          |
|---------------------------------|-----------------------|------------------|
| Time from diagnosis to CR1,     | ≤ median 39 days      | 0.86894          |
|                                 | > median              | 0.51948          |
|                                 |                       | 0.7491           |
|                                 |                       | 0.75484          |
|                                 |                       | 0.28024          |
|                                 |                       | 0.33187          |
|                                 |                       | 0.45657          |
| CR1 duration,                   | ≤ median 318 days     | 0.0067452        |
|                                 | > median              | 0.3257           |
|                                 |                       | 0.453            |
|                                 |                       | 0.21993          |
|                                 |                       | 0.54701          |
|                                 |                       | 0.37179          |
| Time from CR2 to transplantation,| ≤ median 56 days      | 0.36312          |
|                                 | > median              | 0.97782          |
|                                 |                       | 0.41071          |
|                                 |                       | 0.32318          |
|                                 |                       | 0.26791          |
|                                 |                       | 0.05578          |
| Time from diagnosis to          | ≤ median 17 months    | 0.013632         |
| transplantation,                | > median              | 0.21426          |
|                                 |                       | 0.48203          |
|                                 |                       | 0.28012          |
|                                 |                       | 0.34122          |
| Donor                           | Matched sibling       | 3.2283e-05       |
|                                 | Unrelated             |                  |
|                                 |                       |                  |
|                                 |                       |                  |
| Conditioning intensity          | MAC                   | 0.6424           |

P values are given for each comparison, with values less than or equal to the median indicated in bold.
|                    | RIC 25.9% [19.9-32.2] | RIC 18.4% [13.3-24.2] | RIC 55.6% [48.6-62.6] | RIC 61.5% [54.7-68.4] | RIC 40.9% [34-47.9] | RIC 47.4% [40-54.4] | RIC 21.6% [16.1-27.7] |
|--------------------|------------------------|------------------------|------------------------|------------------------|---------------------|---------------------|------------------------|
| **RIC**            |                        |                        |                        |                        | 0.0023561           | 0.28638             | 0.17549                |
| **P value**        |                        |                        |                        |                        | 0.21936             | 0.6978              | 0.8531                 |
| **Graft source**   |                        |                        |                        |                        |                     |                     |                        |
| Bone marrow        | 18.9% [12.2-26.8]      | 21.9% [14.8-29.9]      | 59% [49.9-68.2]        | 65.3% [56.4-74.1]     | 44.3% [34.9-53.6]   | 37.1% [28.4-46.2]    | 36% [27.3-44.8]        |
| Peripheral blood   | 0.34853                | 0.90128                | 0.62518                | 0.91932                | 0.22462             | 0.039322            | 0.037095               |
| **P value**        |                        |                        |                        |                        | 0.024458            | 0.45092             | 0.24087                |
| **in vivo T-cell depletion** |                   |                        |                        |                        |                     |                     |                        |
| No                 | 16.7% [12.7-21.3]      | 22% [17.4-27]          | 61.2% [55.5-66.8]      | 66.6% [61.1-72]       | 33.9% [28.3-39.5]   | 55.9% [49.7-61.6]    | 32.7% [27.4-38.1]      |
| Yes                | 22.6% [18.1-27.4]      | 20.2% [15.9-24.9]      | 57.1% [51.5-62.6]      | 63.5% [58.1-68.9]     | 46.1% [40.5-51.8]   | 37.7% [32.1-43.3]     | 23.6% [19-28.4]        |
| **P value**        | 0.024458               | 0.45092                | 0.24087                | 0.84598                | 0.0036315           | 3.7709e-05          | 0.014416               |

MEDC, EBMT detailed reporting form with additional patient and treatment information; Rl, relapse incidence; NRM, non-relapse mortality; LFS, leukemia-free survival; OS, overall survival; GRFS, graft-versus-host disease-free, relapse-free survival; cGVHD, chronic graft-versus-host disease; aGvHD II-IV acute graft-versus-host disease, grades II to IV; CBF AML, core-binding factor acute myeloid leukemia; abn 7, chromosome 7 abnormalities including monosomy or partial deletion; ≥3, three or more accompanying chromosomal abnormalities; del X or Y, deletion of chromosome X or Y; trisomy 22, trisomy of chromosome 22; trisomy 8, trisomy of chromosome 8; CR complete remission; WBC, white blood cell count; anti-CMV IgG, anti cytomegalovirus antibody class IgG; CR1, first complete remission; CR2, second complete remission.