

CORRIGENDUM

Melphalan and prednisone versus melphalan, prednisone and thalidomide for elderly and/or transplant-ineligible patients with multiple myeloma: a meta-analysis

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Correction to: *Leukemia* (2011) 4, 689–696; doi:10.1038/leu.2010.313; published online 14 January 2011

Since the publication of the above paper, the authors have noticed an error in Table 1. The number of MP and MPT patients in 'IFM 01-01' are 116 and 113, respectively; thus, the total number of patients listed should be **229** and not 226.

This has now been amended, and the correct table is shown below.

In addition, in the abstract and in the results section, the total number of patients analyzed in all included studies was listed as 1568. It is in fact 1571.

The authors would like to apologize for any inconvenience this may have caused.

Table 1 Trial characteristics

| | <i>GIMEMA</i> | <i>IFM 99-06</i> | <i>IFM 01-01</i> | <i>NORDIC</i> | <i>HOVON 49</i> |
|---|--|---|----------------------------|---|---|
| Accrual period | 01/2002–05/2005 | 05/2000–08/2005 | 04/2002–12/2006 | 01/2002–05/2007 | 09/2002–07/2007 |
| Number of patients | 331 | 321 | 229 | 357 | 333 |
| MP | 164 | 196 | 116 | 175 | 168 |
| MPT | 167 | 125 | 113 | 182 | 165 |
| Median follow-up (months) | 38.4 | 51.5 | 47.5 | 42 | 39 |
| Inclusion criteria | > 60 yrs or any age, but transplant ineligible | 65–75 yrs or transplant ineligible if < 65 yrs | ≥ 75 yrs | Any age, but ineligible for transplant | ≥ 65 yrs, PS ≤ 3 |
| Median Age (years) | 72 | 69 | 78.5 | 74 | 72 |
| Range | 60–85 | 65–75 | 75–89 | 49–92 | 65–87 |
| ECOG performance status 3–4 (%) | 5 | 8 | 7 | 30 | 0.04 |
| Total number of cycles planned | 6 | 12 cycles q6 weeks | 12 cycles q6 weeks | Until plateau | 8 cycles q4 weeks, if ongoing response then until plateau |
| Doses | | | | | |
| M | 4 mg/m ² × 7 days | 0.25 mg/kg × 4 days | 0.2 mg/kg per day × 4 days | 0.25 mg/kg × 4 days | 0.25 mg/kg × 5 days |
| P | 40 mg/m ² × 7 days | 2 mg/kg × 4 days | 2 mg/kg per day × 4 days | 100 mg per day × 4 days | 1 mg/kg × 5 days |
| T | 100 mg per day | Dose of T not standardized, 400 mg per day maximum dose | 100 mg per day | 200 mg per day × 7 days then 400 mg per day | 200 mg per day |
| T maintenance in MPT arm | Yes, 100 mg per day until relapse/refractory disease | No | No | Yes, 200 mg per day | Yes, 50 mg per day |
| Primary End Point | RR/PFS | OS | OS | OS | EFS |
| Secondary End Point | OS Prognostic factors Toxicity frequency | PFS RR | PFS RR safety | PFS RR TTP QOL | OS RR PFS QOL |
| <i>A priori</i> sample-size calculations performed; | Yes | Yes | Yes | Yes | Yes |
| Original number of planned patients | 380 | 500 | 280 | 800 | 420 |

Table 1 (Continued)

| | GIMEMA | IFM 99-06 | IFM 01-01 | NORDIC | HOVON 49 |
|--|---|--|---|---|---|
| Accrual | Recruitment stopped at 331 patients as clear ORR advantage of MPT noted on interim analysis | Recruitment stopped at 447 patients as clear OS advantage of MPT noted on unplanned interim analysis | Recruitment stopped at 232 patients because of survival advantage of MPT in IFM 99-06 trial and because MPT was officially made available to HDT ineligible NDMM patients | Accrual stopped at 357 patients; effective power reduced from 80 to 72% to detect HR of 1.4 | Accrual stopped at 344 patients based on other publication reports indicating superior effect |
| Study design | Open labeled; ITT | Open labeled; ITT | Placebo-controlled design, ITT | Placebo-controlled design, ITT | Open labeled; ITT |
| ORR (%) | | | | | |
| MP | 85 | 35 | 31 | 66 (including MR) | 45 |
| MPT | 51 | 76 | 62 | 71 (including MR) | 66 |
| CR | | | | | |
| MP | 4 | 2 | 1 | 4 | NR |
| MPT | 16 | 13 | 7 | 13 | NR |
| CR+VGPR | | | | | |
| MP | 15 | 7 | 7 | 7 | 8 |
| MPT | 45 | 47 | 21 | 23 | 28 |
| PFS (months) | | | | | |
| MP | 14.5 | 17.8 | 18.5 | 14 | 21 |
| MPT | 21.8 | 27.5 | 24.1 | 15 | 33 |
| OS (months) | | | | | |
| MP | 47.6 | 33.2 | 29 | 32 | 31 |
| MPT | 45 | 51.6 | 44 | 29 | 40 |
| Grade 3–4 Toxicity ^a (%) | | | | | |
| PN | | | | | |
| MP | 0 | 0 | 2 | 1 | 4 |
| MPT | 10 | 6 | 2 | 6 | 23 |
| Venous Thromboembolism | | | | | |
| MP | 2 | 4 | 3 | 8 | 0 |
| MPT | 11 | 12 | 6 | 8 | 3 |
| Neutropenia | | | | | |
| MP | 17 | 26 | 9 | 20 | NR |
| MPT | 16 | 48 | 23 | 25 | NR |
| Infection | | | | | |
| MP | 2 | 9 | NR | 10 | 18 |
| MPT | 10 | 13 | NR | 15 | 28 |
| Constipation | | | | | |
| MP | 0 | 0 | 10 (≥Grade 2) | 6 | NR |
| MPT | 6 | 10 | 17 (≥Grade 2) | 3 | NR |
| DVT Prophylaxis | Not initially, but started in Dec 2003; LMWH with first 4 cycles | No routine prophylaxis recommended | No routine prophylaxis recommended | No routine prophylaxis recommended | Not initially; Jan 2005 LMWH with MPT and ASA with T maintenance |
| Response criteria | EBMT/IBMTR | Own definitions, VGPR also included | Own definitions, VGPR also included | Own definitions, MR and VGPR also included | Own definitions, VGPR also included |
| Median duration of T therapy (months) | 9.6 | 11 | 13.5 | 7.7 for those living longer than 1 year | 8.4 months as maintenance |
| Total dose of M if completed assigned schedule at recommended maximum dose | 4 mg/kg | 12 mg/kg | 9.6 mg/kg | Incalculable ^b | Incalculable ^b |

Abbreviations: ASA, aspirin; CR, complete response; DVT, deep vein thrombosis; EFS, event-free survival; EBMT/IBMTR, European bone marrow transplantation/international bone marrow transplantation registry; ECOG, Eastern cooperative oncology group; GIMEMA, Gruppo Italiano Maligne Ematologiche dell'Adulto; HDT, high dose therapy; HOVON, Hemato-Oncologie voor Volwassenen Nederland; IFM, Intergroupe Francophone du Myélome; ITT, intention to treat; LMWH, low molecular weight heparin; MR, minor response; M, melphalan; MPT, melphalan, prednisone and thalidomide; NDMM, newly diagnosed multiple myeloma; NR, not reported; ORR, overall response rates; OS, overall survival; P, prednisone; PN, peripheral neuropathy; PFS, progression-free survival; PR, partial response; QOL, quality of life; RR, response rate; TTP, time to progression; T, thalidomide; VGPR, very good partial response; Yrs, Years.

^aNational Cancer Institute Common Toxicity Criteria.

^bAs melphalan was given until plateau.