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A nationwide Italian GIMEMA survey on tandem autologous stem cell transplantation for newly diagnosed multiple myeloma patients treated with daratumumab, bortezomib, thalidomide and dexamethasone

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LETTER TO THE EDITOR

A nationwide Italian GIMEMA survey on tandem autologous stem cell transplantation for newly diagnosed multiple myeloma patients treated with daratumumab, bortezomib, thalidomide and dexamethasone

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Short title

Tandem ASCT in multiple myeloma treated with D-VTd

Authors' Contributions

C.L. and M.C. wrote the manuscript. A.P. performed survey analysis. All authors have read and agreed to the published version of the manuscript.

Conflict of Interest Disclosures

The authors declare no conflict of interest.

Data sharing statement

Original data are available in anonymous form upon request by contacting corresponding author.

Upfront quadruplets combining daratumumab (D), bortezomib (V), an immunomodulatory drug as thalidomide (T) or lenalidomide (R) and dexamethasone (d) for newly diagnosed (ND) multiple myeloma (MM) patients eligible for autologous stem-cell transplantation (ASCT) were approved by regulatory agencies based on the superiority of D-VTd and D-VRd over the standard-of-care triplets VTd and VRd, respectively.[1,2] By study design, patients enrolled in both these trials received a single ASCT which remains the gold standard strategy for transplant-eligible (TE) NDMM in the latest NCCN and EHA-EMN guidelines.[3] In these latter, European experts suggested to consider tandem (or double) ASCT for patients with high-risk cytogenetic abnormalities (HRCAs), an option supported by post-hoc analyses of randomized studies showing the superiority of tandem over single ASCT in this setting.[4,5] However, those studies included only bortezomib-based induction triplets not incorporating an anti-CD38 monoclonal antibody. Data informing the use of tandem ASCT outside clinical studies in the current real-world era of highly active quadruplet induction therapies are lacking. In addition, no Italian registry gathered useful information to address this question.

To bridge this gap, on behalf of the GIMEMA Multiple Myeloma Working Party, we conducted a retrospective, multicenter, nationwide online survey aimed at detailing the physician's choice and selection criteria of tandem ASCT for TE NDMM patients who received D-VTd induction therapy. Assessment of efficacy outcomes of tandem ASCT was out of the scope of our analysis. In Italy, D-VTd got regulatory approval on November 24th, 2021. The survey, conducted in compliance with Italian ethical standards and regulations, collected data from January 1st, 2022 to June 30th, 2024. Out of 110 affiliated hematological centers invited to participate, 66 (60%) completed the survey (Table S1) and data were included in this analysis. Over the study period, 2784 NDMM patients were deemed TE and received standard-of-care D-VTd induction therapy (Figure 1), 960 (34%) of them in 2022, 1165 (42%) in 2023, and 659 (24%) in the first six months of 2024 (Table 1). Baseline FISH results were available in 2616 (94%) patients who were mostly screened for del(17p), t(4;14) and t(14;16), while gain/amp(1q21) was assessed in a minority of them. Overall, 756 (29%) patients carried ≥1 HRCA(s), and 693 (25%) patients had R-ISS 3 disease stage. At data cut-off of April 24th, 2025, 2551 (92%) patients underwent ASCT, either single (71%) or tandem (29%) (Figure 1). Patients receiving single ASCT were 658 (36%) in 2022, 758 (42%) in 2023, and 394 (22%) from January to June 2024. Tandem ASCT was pre-planned in 987 patients (35%) and was actually received by 741 (75%) of these, including 257 (26%) patients in 2022, 346 (35%) in 2023, and 138 (14%) from January to June 2024 (Table 1). Physician's choice of tandem ASCT was based on multiple and frequently co-occurring criteria, the most common being the presence at baseline of ≥1 HRCA(s) (85%) and/or extramedullary disease combined or not with circulating tumor cells (67%) (Table 2). Advanced disease stage at diagnosis and suboptimal response to first ASCT were choice criteria of tandem ASCT in 36% and 35% of patients, respectively. Overall, 246 (25%) patients in the pre-planned tandem ASCT group did not undergo a second ASCT, 89 (9%) of these due to inadequate peripheral blood stem-cell collection and the remaining 157 patients due to other causes, including treatment-related adverse events, patients' refusal, and disease progression. At data-cut off, 1066 (38%) patients had completed D-VTd consolidation therapy, and 2136 (76.7%) had started lenalidomide maintenance therapy (Figure 1).

Over the first 30 months following the regulatory approval of D-VTd, tandem ASCT was selected by treating physicians at 66 hematological centers as the most appropriate option for 35% of patients who started induction therapy. Key selection factors were the presence at baseline of HRMM, most frequently HRCAs, and a suboptimal response to first ASCT. Interestingly, drivers of

tandem ASCT selection in this real-world setting were aligned with those of several ongoing phase 3 studies incorporating quadruplets. In part 1 of the GMMG-HD7 trial comparing VRd versus isatuximab (Isa)-VRd as induction therapy before ASCT, tandem ASCT was recommended for patients with HRCAs or failing complete response (CR) after first transplantation.[6] In addition, data from our real-world survey revealed that 75% of patients actually received tandem ASCT, a rate consistent with data from clinical studies of triplet- and quadruplet-based induction therapies.[4,5,7,8] A suboptimal yield of CD34+ cells (<4x10^6/Kg) was reported in 9% of patients. Although in the real-world setting heterogeneity exists in institutional policies and among patients, this rate is within the range reported in other studies of D-VTd and systematic reviews of D-based quadruplets.[9]

Several large retrospective registry-based studies enrolling more than 35.000 patients were published in 2025 and compared single versus tandem ASCT.[10,11] Overall, survival outcomes with single ASCT were inferior than with tandem ASCT, which was likely to mostly benefit patients failing CR after first ASCT[10,11] and to overcome HRCAs[12], although this latter finding was not uniformly confirmed.[11] In one of these studies, 26% of patients received tandem ASCT between 2017 and 2021,[10] a rate consistent with our survey conducted in the years 2022-2024. Although results from these analyses are informative, it is worth noting that most of the patients were accrued before the introduction of quadruplets including D or Isa combined with VRd. In addition, the inherent selection bias of patients who actually received tandem ASCT might have contributed to overestimate the benefits from this therapy.

Quadruplet therapies are now standard-of-care for both TE and TI patients with NDMM. In the transplant setting, their combined use with high-dose melphalan has increased the rates of CR up to approximately 90% and of MRD negativity in the range between 60% and >80%, ultimately resulting in meaningful improvements in PFS and OS.[1,2] Although the superiority of quadruplets over triplet-based therapies was established across subgroups of patients at different risk, the greatest benefit was seen for patients at standard risk. In particular, outcomes in patients with ≥2 HRCAs (some of which were included in the recent genomic re-definition of HRMM proposed by the International Myeloma Society/International Myeloma Working Group)[13] continue to remain unsatisfactory even in the contemporary era. As such, in the PERSEUS study the PFS hazard ratios for patients at standard risk and with ≥1 HRCA(s) were 0.35 ($p<0.0001$) and 0.59 ($p=0.044$), respectively, while in those with ≥2 HRCAs including gain or amp(1q21) the hazard ratio was 0.73 ($p=0.39$).[14] In line with these data are the results from a post-hoc analysis of phase 2 GRIFFIN and MASTER studies. In the GRIFFIN study of D-RVd and subsequent D-R maintenance the estimated 4-year PFS rate was 53.5% and sustained MRD negativity lasting ≥1 year was 31%.[15] Similarly, the corresponding values in the MASTER study of D-carfilzomib (K)-Rd as induction therapy before, and consolidation after, ASCT were 52% (at 3 years) and 50%.[15] Patients with ≥2 HRCAs constitute a subgroup with still high unmeet clinical need for whom room for improved outcomes beyond the use of quadruplets and single ASCT might exist.

Further treatment intensification by incorporating D-KRd induction and consolidation into tandem ASCT followed by D-R maintenance for up to 2 years was explored in the phase 2 IFM 2018-04 study for patients with HR NDMM, 60% of whom carried ≥2 HRCAs.[7] The rates of CR and MRD negativity following the second ASCT were 81% and 97%, respectively, and the 30-month PFS and OS rates were 80% and 91%, respectively. In the phase 3 MIDAS study, TE NDMM patients with MRD positivity (10^{-5} sensitivity) after Isa-KRD induction therapy were randomized to subsequent consolidation with single ASCT and 2 additional cycles of Isa-KRd or double ASCT.[8] At the time of reporting, the rate of post-consolidation MRD negativity at a sensitivity of 10^{-6} was 32% in tandem

ASCT group and 40% in the single ASCT-Isa-KRd group, but data on sustained MRD negativity and PFS were not mature.

This survey provides real-world insights into clinical practice patterns in Italy in the management of TE NDMM patients in the contemporary era of quadruplets. According to physician's choice, tandem ASCT was the most appropriate option for approximately one third of TE NDMM patients treated with standard-of-care D-VTd induction, a real-world finding not available so far. Candidates to tandem ASCT were mostly selected based on the presence of HR characteristics at baseline, reflecting the European guidelines that recommend tandem ASCT as the only treatment modification option for HRMM. Consistently with other studies, the second ASCT was actually received by 75% of patients, confirming the feasibility of this procedure even after an intensified induction therapy. Whether tandem ASCT might be an alternative to, or even part of, an intensified treatment program including extended induction, consolidation and maintenance therapy for patients with HRMM is currently under evaluation in ongoing studies. The number of centers participating in our survey was representative of the broader physician population and reflects real-world behavior, assuring generalizability of results. Although we cannot exclude possible selection bias, patients' characteristics were likely to be representative of the general population. In addition to these strengths, the retrospective nature of the survey represents a limitation of our analysis.

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Table 1. Transplant-eligible newly diagnosed multiple myeloma patients' disposition per year.

	2022	**2023**	**2024***	**Total**
Patients with TE NDMM treated with D-VTd induction, n	960	1165	659	2784
Patients treated with D-VTd induction who received single ASCT, n	658	758	394	1810
Patients treated with D-VTd induction who received tandem ASCT, n	257	346	138	741
Patients treated with D-VTd induction who received single or tandem ASCT, n	915	1104	532	2551

*from January 1st, 2024, to June 30th, 2024.

TE NDMM: transplant-eligible newly diagnosed multiple myeloma; D-VTd: daratumumab, bortezomib, thalidomide, dexamethasone; ASCT: autologous stem-cell transplantation.

Table 2. Criteria of choice of tandem ASCT in participating centers.

Criteria of choice of tandem ASCT	**Centers (n=66)**
Presence at baseline of HRCA, n (%)	56 (85)
EMD and/or circulating plasma cells, n (%)	44 (67)
Advanced disease stage at baseline*, n (%)	24 (36)
Suboptimal response to first ASCT**, n (%)	23 (35)
Others, n (%)	9 (14)

ASCT: autologous stem-cell transplantation; HRCA: high-risk chromosomal abnormalities, including del(17p), t(4;14), t(14:16), gain/ampl(1q21), and del(1p); EMD: extramedullary disease.

**defined as ISS 3 and/or R-ISS 3 disease stage. **defined as less than very good partial response (VGPR).*

Figure 1: TE NDMM patients' disposition across the survey. *TE NDMM: transplant-eligible newly diagnosed multiple myeloma; D-VTd: daratumumab, bortezomib, thalidomide, dexamethasone; ASCT: autologous stem-cell transplantation.*

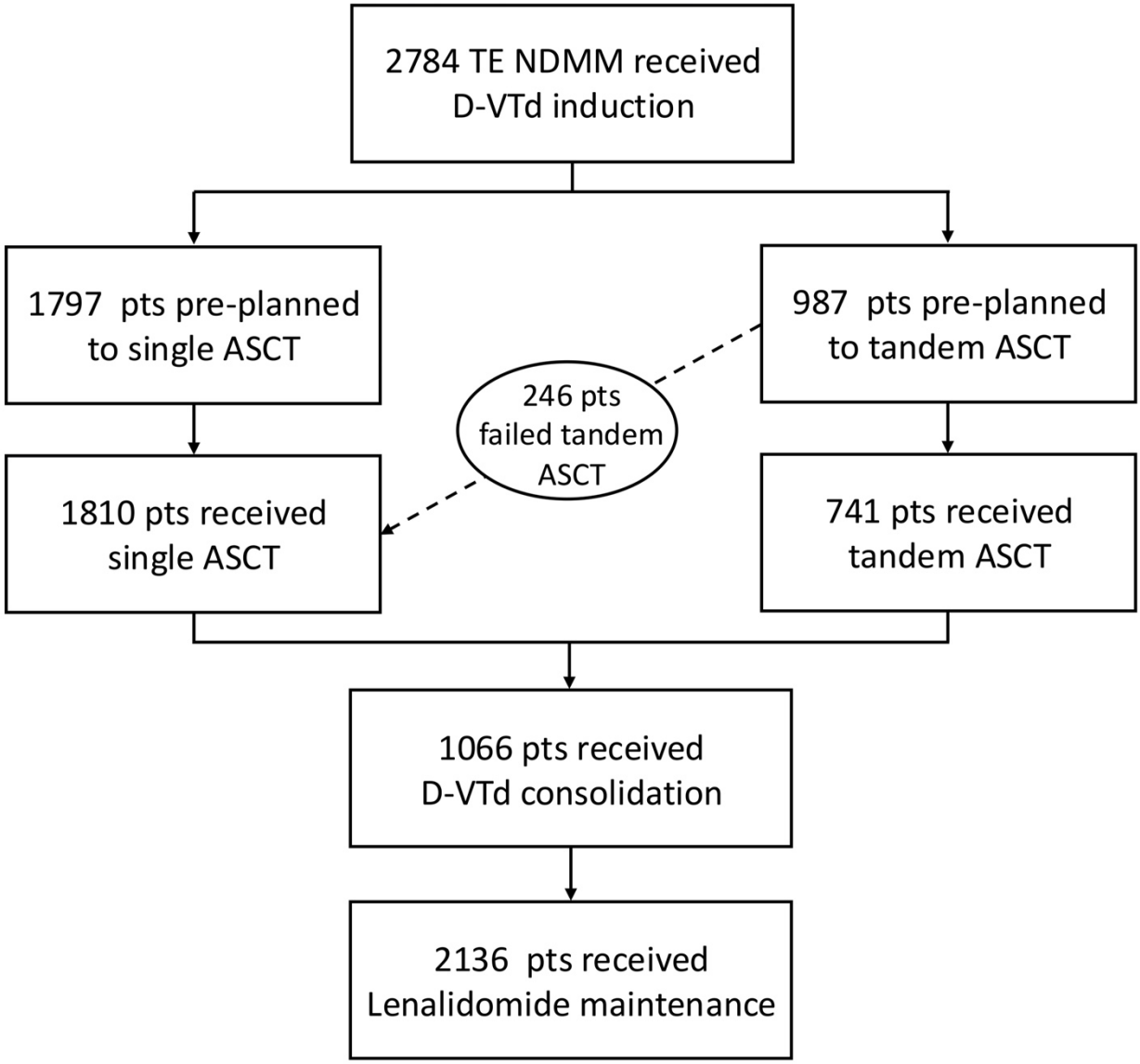

Table S1. List of 66 participating centers.

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