

further explored in a recent national review, recommending it become a regulated level of practice within the UK (The Nursing and Midwifery Council 2024). A key benefit of the role is that of enhancing capacity and capability within multiprofessional teams (Evans et al 2020). A high level of critical thinking and the ability to make complex, safe, autonomous decisions is essential (Woodman 2022). In order to do this it is important that the ACP is working to their full potential within their scope of practice (Hook and Walker 2020). In 2019, the first trainee ACP post was implemented locally in one of the largest haematological centres in the UK. This study aimed to review the impact of the role on patient flow and capacity whilst understanding the perceptions of clinical and non-clinical roles within the myeloma specialism around the role of the ACP.

Methods: A single centre study collected data over a period of 12 months quantifying outpatient appointments conducted by the ACP. In addition an electronic questionnaire was developed. Questions were aimed at identifying frequency of contact with the ACP, understanding of the role and perceptions of the impact of the role on service delivery. Target participant groups included Consultants, Registrars, Physician Associates, Clinical Nurse Specialists, ward nurses and administrative staff. Data was analysed using thematic analysis.

Results: The ACP reviewed a total of 615 patients in the outpatient setting over a 12 month period, 100 of which were new referrals with suspected myeloma or MGUS. 16 survey responses were received (40% completion rate). Responses were categorised via thematic analysis in to 7 identified themes – support, continuity, safety, enhanced capacity, clinical skills, service development and knowledge. 93.75% of respondents worked directly or indirectly with the advanced clinical practitioner. 93.75% of respondents felt they understood the advanced clinical practitioner role, however responses largely focussed on clinical skills with only 3 respondents exploring non clinical aspects of the role (research, education and leadership).

Conclusions: The role of the advanced clinical practitioner has proven to be of significant value in supporting patient care (Fowler 2018). This study suggests that locally the role has had a significant impact on capacity and patient flow, providing support to the wider multidisciplinary team. The work highlights the benefit of the advanced clinical practitioner role in myeloma, however it is proposed that further education is needed amongst the multidisciplinary team to ensure full understanding of the role.

LATE BREAKING ABSTRACTS

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Daratumumab + Bortezomib/Lenalidomide/Dexamethasone in Patients With Transplant-ineligible or Transplant-deferred Newly Diagnosed Multiple Myeloma: Results of the Phase 3 CEPHEUS Study

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Introduction: Daratumumab (DARA) has improved overall survival (OS) in 3 frontline regimens and was the first anti-CD38 monoclonal antibody approved in newly diagnosed multiple myeloma (NDMM). For transplant-ineligible (TIE) NDMM, the MAIA regimen (DARA + lenalidomide/dexamethasone [D-Rd]) is a standard of care (SOC), with a median OS of 7.5y. For transplant-eligible NDMM, the PERSEUS regimen (subcutaneous DARA [DARA SC] + bortezomib/lenalidomide/dexamethasone [D-VRd])

then D-R maintenance) has shown significant progression-free survival (PFS) benefit vs SOC. The CEPHEUS study evaluated the addition of DARA SC to VRd vs VRd in NDMM patients (pts) who are TIE or for whom transplant was not planned as initial therapy (transplant deferred). Here we report for the first time the results of the CEPHEUS study. **Methods:** Pts were aged ≥ 18 y with TIE or transplant-deferred NDMM. All pts received eight 21-day cycles of VRd, followed by 28-day cycles of Rd until progressive disease (PD). Patients randomized to D-VRd received DARA SC (DARA 1,800 mg + recombinant human hyaluronidase PH20 [rHuPH20; 2,000 U/mL; Halozyme]) given QW in Cycles 1-2, Q3W in Cycles 3-8, and Q4W in Cycles 9+ until PD. The primary endpoint was overall minimal residual disease (MRD)-negativity (neg) rate (10^{-5}), among pts achieving complete response or better (\geq CR). Secondary endpoints included \geq CR rate, PFS, and sustained MRD-neg rate (≥ 12 months [mo]). **Results:** 395 pts were randomized 1:1 (D-VRd, n=197; VRd, n=198). Median age was 70 (range, 31-80) y; 28.1% had ISS stage III disease; 13.2% had high-risk cytogenetics ($t[4;14]$, $t[14;16]$, or $del[17p]$). At a median follow-up of 58.7 mo, the overall MRD-neg rate was 60.9% for D-VRd vs 39.4% for VRd (OR, 2.37; 95% CI, 1.58-3.55; $P < 0.0001$). PFS was significantly improved with D-VRd vs VRd (HR, 0.57; 95% CI, 0.41-0.79; $P = 0.0005$). Median PFS was not reached for D-VRd vs 52.6 mo for VRd; estimated 54-mo PFS rates were 68.1% vs 49.5%. \geq CR rate was 81.2% with D-VRd vs 61.6% with VRd ($P < 0.0001$) and sustained MRD-neg rate was 48.7% vs 26.3% ($P < 0.0001$). OS trended in favor of D-VRd (HR, 0.85; 95% CI, 0.58-1.24); HR was 0.69 (95% CI, 0.45-1.05) in a sensitivity analysis censoring deaths due to COVID-19. Median treatment duration was 22 months longer for D-VRd (56.3 mo) vs VRd (34.3 mo). Addition of DARA did not affect relative dose intensity of VRd. TEAEs were consistent with known safety profiles for DARA and VRd. Grade 5 TEAE rates adjusted for treatment exposure were comparable for D-VRd and VRd (0.39 vs 0.31 per 100 pt-mo). **Conclusions:** In pts with TIE or transplant-deferred NDMM, DARA SC + VRd significantly improved PFS vs VRd, reducing the risk of progression or death by 43%. D-VRd significantly increased overall MRD negativity, \geq CR rate, and sustained MRD negativity. These data, coupled with PERSEUS, demonstrate the consistent benefit of DARA + VRd vs VRd, and support DARA quadruplet therapy, with or without transplant, as a new SOC for NDMM.

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Belantamab Mafodotin in Combination with VRd for the Treatment of Newly Diagnosed Transplant Eligible Multiple Myeloma Patients: Results from the Phase II, Open Label, Multicenter, GEM-BELA-VRd Trial

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Introduction: GEM-BELA-VRd is a phase II, open label, multicenter, non-randomized single arm clinical trial evaluating belantamab mafodotin (belamaf) plus bortezomib, lenalidomide, and dexamethasone (VRD) in transplant-eligible newly diagnosed multiple myeloma (TE NDMM) patients (pts). The preliminary analyses of safety and efficacy after 4 cycles (cy) of induction were encouraging (González-Calle V et al. ASH, 2022). Here we report the results after all pts have completed 1 year of maintenance (1 yr-maint). **Methods:** 50 pts were recruited. Treatment consisted of 6 induction cy with VRd (Q4W) and belamaf 2.5 mg/kg iv (Q8W), followed by autologous stem cell transplant (ASCT). Patients also receive 2 consolidation cy with VRd (Q4W) and belamaf (at 2.5mg/kg Q8W) and maintenance with R until progression/toxicity and belamaf (Q8W) for 2 yrs (at 2.5 and 1.9 mg/kg after protocol amendment). Primary endpoint was safety (incidence of adverse events (AEs) [CTCAE v. 4.0]). Main key secondary endpoints were overall response rate (ORR), complete response rate (CR) and minimal residual disease negativity (MRD neg) rate. Cut-off date: June 1, 2024. **Results:** Median age was 56 years (27-75). Most of pts had MM Ig G kappa (64%), ECOG 0 (66%) and ISS I (64%). Besides, 12% had high LDH and 15% paraskelatal plasmacytomas. Ocular AEs were the most frequent. Among the patients with normal best correct visual acuity (BCVA) at baseline (20/25 or better), a decrease in the BCVA to 20/50 or worse occurred in 18/43 pts (41.9%) in induction; 8/43 (18.6%) in consolidation; and 11/43 (25.6%) in 1yr-maint. Blurred vision improved in all patients prior to ASCT (12 wks from last dose of belamaf). Only 1 pt had decrease of BCVA to 20/200 (2.3%), during 1yr-maint. Most common non-ocular G ≥ 3 AEs were hematological and infections. Incidence