**ASC0 2020**

1. **Colorectal Cancer**

**Pembrolizumab Versus Chemotherapy for Microsatellite Instability-High/Mismatch Repair Deficient Metastatic Colorectal Cancer: The Phase 3 KEYNOTE-177 Study.** *T Andre, K-K Shiu, TW Kim, et al*
Pembrolizumab provided a clinically meaningful and statistically significant improvement in PFS versus chemo as first-line therapy for pts with MSI-H/dMMR mCRC, with fewer treatment-related AEs observed and should be the new standard of care for these pts.

**Overall survival (OS) and long-term disease-free survival (DFS) of three versus six months of adjuvant (adj) oxaliplatin and fluoropyrimidine-based therapy for patients (pts) with stage III colon cancer (CC): Final results from the IDEA (International Duration Evaluation of Adj chemotherapy) collaboration.** *AF Sobrero, T Andre, JA Meyerhardt, et al*
For the overall patient population with stage III colon cancer, 3 and 6 months of adjuvant therapy were associated with almost identical 5-year overall survival rates.
As in the prior disease-free survival analysis, a strong regimen effect was observed, demonstrating that 3 months of CAPOX is appropriate for the vast majority of patients. However, with FOLFOX, in particular for high-risk cancers, 6 months of adjuvant therapy should be considered.

**A randomized phase II/III trial comparing hepatectomy followed by mFOLFOX6 with hepatectomy alone for liver metastasis from colorectal cancer: JCOG0603 study.** *Y Kanemitsu, Y Shimizu, J Mizusawa, et al*
After resection of colorectal cancer liver metastases, the 3-year disease-free survival rate with observation alone was 41.5%; with adjuvant FOLFOX, it was 52.1%. Still, the study missed its primary endpoint, conceivably because the trial was underpowered.
This study will not and should not change the current standard of care, which is perioperative chemotherapy for resectable liver metastases.

**Short-course radiotherapy followed by chemotherapy before TME in locally advanced rectal cancer: The randomized RAPIDO trial.**
Short-course radiotherapy (SCRT) followed by delayed surgery with, in the waiting period, chemotherapy, may lead to better compliance, downstaging and fewer distant metastases. A lower rate of Disease related Treatment Failure, as a result of a lower rate of distant metastases, in high-risk LARC patients can be achieved with preoperative short-course radiotherapy, followed by chemotherapy (SCRT (5x5 Gy) with subsequent six cycles of CAPOX or nine cycles of FOLFOX4) and TME than by conventional chemoradiotherapy. In addition, the high pCR rate, achieved with the experimental treatment regimen can contribute to organ preservation. This treatment can be considered as a new standard of care.

**Total neoadjuvant therapy with mFOLFIRINOX versus preoperative chemoradiation in patients with locally advanced rectal cancer: Final results of PRODIGE 23 phase III trial, a UNICANCER GI trial.**
PRODIGE 23 investigated the role of neoadjuvant mFOLFIRINOX before preoperative (preop) chemoradiation (CRT), with TME-surgery and adjuvant chemotherapy (CT) in resectable locally advanced rectal cancer. Arm A pts received preop CRT (50 Gy, 2 Gy/fraction [fr]; 25 fr + capecitabine), surgery, then adjuvant CT for 6 months (mos). Arm B pts received 6 cycles of mFOLFIRINOX (oxaliplatin 85 mg/m$^2$, leucovorin 400 mg/m$^2$, irinotecan 180 mg/m$^2$ D1, and 5-FU 2.4 g/m$^2$ over 46 h) every 14 days, followed by the same preop CRT, surgery and 3 mos of adjuvant CT. Adjuvant CT consisted of mFOLFOX6 or capecitabine, depending on the centre's choice for all pts. Neoadjuvant mFOLFIRINOX plus CRT is safe, and significantly increased ypCR rate, DFS and MFS. OS data are not mature.

**Preliminary results of the organ preservation of rectal adenocarcinoma (OPRA) trial.**
A WW strategy for patients with locally advanced rectal cancer that achieve a clinical complete response to TNT results in organ preservation for a high proportion of patients without compromising survival. Up-front CRT followed by consolidation chemotherapy resulted in a numerically higher WW rate compared to induction chemotherapy followed by CRT.

## 2. Genito-urinary cancers

**Impact of PSMA-targeted imaging with 18F-DCFPyL-PET/CT on clinical management of patients (pts) with biochemically recurrent (BCR) prostate cancer (PCa): Results from a phase III, prospective, multicenter study (CONDOR).**

**Background:**
Current imaging modalities are inadequate for localizing and characterizing occult disease in men with BCR PCa, particularly in pts with low PSAs (<2 ng/mL). There is a need for improved diagnostic imaging to better inform treatment planning. $^{18}$F-DCFPyL (PyL) is a novel PET imaging agent that binds selectively with high affinity to PSMA, which is overexpressed in PCa cells.
**Methods:**
Men ≥18 years- with rising PSA after definitive therapy and negative or equivocal standard of care imaging (e.g., CT/MRI, bone scintigraphy) were enrolled. A single 9 mCi (333 MBq) ± 20% dose of PyL was injected, followed by PET/CT 1-2 hours later. Primary endpoint was correct localization rate (CLR), defined as percentage of pts with a 1:1 correspondence between at least one lesion identified by PyL-PET/CT and the composite standard of truth: pathology, correlative imaging, or PSA response. The trial was successful if the lower bound of the 95% confidence interval (LLCI) for CLR exceeded 20% for two of three independent, blinded central PyL-PET/CT reviewers. The secondary endpoint, impact of PyL-PET/CT on clinical management of pts was based on the treating physician's documented clinical plans before and after PyL-PET/CT.
**Results:**
208 men (median PSA 0.8 [0.2 - 98.4] ng/mL) underwent PyL PET/CT. The study achieved its primary endpoint: CLR of 84.8% to 87.0% among the three PyL-PET/CT readers; the LLCI for CLR by all three reviewers was >77%. Here we report the clinical impact. Based on local radiology assessment, PSMA-avid lesion(s) were identified in 69.3% (142/208) of pts. 63.9% (131/205) had a change in intended management after PyL-PET/CT, of which 78.6% (103/131) were attributable to positive PyL finding(s) and 21.4% (28/131) to negative PyL scans. Changes included: salvage local therapy to systemic therapy (n=58); observation before initiating therapy (n=49); noncurative systemic therapy to salvage local therapy (n=43); and planned treatment to observation (n=9). PyL was well tolerated with one drug-related SAE (hypersensitivity) and the most common AE being headache (n=4; 1.9%).**Conclusions:**PSMA-targeted PyL-PET/CT detected and localized occult disease in most men with BCR presenting with negative or equivocal conventional imaging. PyL-PET/CT led to changed management plans in the majority of pts, thus providing evidence that clinicians find PSMA PET imaging useful in men with recurrent or suspected metastatic PCa.

**TheraP: A randomised phase II trial of $^{177}$Lu-PSMA-617 (LuPSMA) theranostic versus cabazitaxel in metastatic castration resistant prostate cancer (mCRPC) progressing after docetaxel: Initial results (ANZUP protocol 1603).**

**Background:**
LuPSMA is a radiolabeled small molecule that delivers therapeutic β-radiation to PSMA-expressing tumors. Encouraging efficacy and safety has been shown in non-randomized studies of mCRPC. TheraP is a randomized phase II trial comparing LuPSMA vs cabazitaxel in men with mCRPC progressing after docetaxel.
**Methods:**
Men with mCRPC, and imaging with $^{68}$Ga-PSMA-11 and $^{18}$F-FDG PET/CT that confirmed high PSMA-expression and no sites of FDG-positive/PSMA-negative disease, were randomly assigned (1:1) to LuPSMA (6-8GBq q6weeks up to 6 cycles) vs cabazitaxel (20mg/m$^2$ q3weeks up to 10 cycles);

stratified by disease burden (>20 vs ≤20 sites), prior novel antiandrogens (NAA; abiraterone or enzalutamide), and study site. The primary endpoint was PSA response rate (PSA50-RR) defined by ≥50% reduction. Secondary efficacy endpoints included PSA-progression-free survival (PSA-PFS) and overall survival (OS). Data cut-off was 31DEC19 at this first pre-specified analysis.
**Results:**
200 (median age 72 y, prior NAA 91%, >20 lesions 78%) of 291 PET screened men were randomised to LuPSMA (N=99) or cabazitaxel (N=101). 17 patients withdrew or died before receiving study treatment (1 LuPSMA vs 16 cabazitaxel). The PSA50-RR was higher in those assigned LuPSMA than cabazitaxel (65/99 [66%; 95%CI 56-75] vs 37/101 [37%; 95%CI 27-46]; P<0.001). At a median follow-up of 11.3 months, LuPSMA significantly improved PSA-PFS (HR 0.63, 95%CI 0.45-0.88, P=0.007; 143 events with next pre-specified analysis planned after 170 events). Efficacy results were similar when analyses were restricted to per-protocol treated men. OS data remains immature (57 deaths). Grade III-IV adverse events (AEs) occurred in 31/98 (32%) LuPSMA-treated men vs 42/85 (49%) in cabazitaxel-treated men. Discontinuations for toxicity occurred in 1/98 (1%) LuPSMA vs 3/85 (4%) cabazitaxel-treated. There were no treatment-related deaths.**Conclusions:**In men with docetaxel-treated mCRPC, LuPSMA was more active (PSA50-RR) than cabazitaxel with relatively fewer G3-4 AEs and PSA-PFS favoring LuPSMA.

**A phase II multicenter study of stereotactic radiotherapy (SRT) for oligoprogression in metastatic renal cell cancer (mRCC) patients receiving tyrosine kinase inhibitor (TKI) therapy.**

**Background:**
SRT is increasingly considered to delay the need to change systemic therapy in metastatic cancer patients who develop oligoprogression. This prospective phase II study evaluated the use of SRT in the setting of mRCC patients who developed oligoprogression while on 1st or 2nd line TKI therapy
**Methods:**
IMDC favourable or intermediate risk mRCC patients (pts) who had previous stability or response on ≥ 3 months of TKI therapy were eligible if they developed radiographic progression of ≤ 5 metastases. The oligoprogressive tumours were treated with SRT while other metastases which were stable or responding to TKI therapy were left alone. TKI therapy was temporarily stopped during SRT, and the same TKI drug then resumed. Endpoints included local control of the irradiated lesions, progression free survival (PFS), overall survival (OS), and cumulative incidence of changing systemic therapy after study entry.
**Results:**
37 pts (median age 63, IMDC favourable 12, intermediate 25) with 57 oligoprogressive tumours were enrolled. 35 pts were on sunitinib and 2 on pazopanib. Median duration of TKI therapy prior to study entry was 18.6 months. 4 pts had IL-2 therapy prior to a 2$^{nd}$ line TKI. 21 pts had a solitary oligoprogressive tumour, while 17 pts had 2-3 oligoprogressive tumours treated with SRT. Median biological effective dose ($BED_{10}$) was 72 Gy, corresponding to an SRT dose of 40 Gy in 5 fractions. Irradiated tumour sites were the following: 21 lung/pleural, 15 bone, 7 lymph node, 4 adrenal, 4 liver, 3 brain, 2 spleen, and 1 pancreas. At a median followup of 11.6 (1.8-53.5) months the median PFS from study entry was 9.6 months (95%CI 7.4-20.5) with the vast majority of progression occurring outside of the irradiated areas. The 2-year local control of the irradiated tumours was 96%. The 2-year OS from study entry was 77%. The cumulative incidence of changing systemic therapy was 47% at 1 year and 75% at 2 years, with a median time to a change in systemic therapy of 12.6 months. There were no grade 3-5 SRT related toxicities.**Conclusions:**To our knowledge, this is the first prospective evaluation of the use of SRT for oligoprogressive metastatic cancer. Local control of irradiated oligoprogressive mRCC tumours was high. After delivering SRT, mRCC patients did not need a change in their systemic therapy for a median of 1 year, effectively increasing the PFS of their TKI therapy. This novel approach should be studied in patients with oligoprogression on immunotherapy.

**Primary analysis of a phase II study of metastasis-directed ablative therapy to PSMA ($^{18}$F-DCFPyL) PET-MR/CT defined oligo-recurrent prostate cancer.**

**Background:**
Despite maximal local therapies (MLT) (radical prostatectomy followed by radiotherapy [RT]), 20-30% of men will progress to incurable prostate cancer (PCa). Most recurrences in this scenario are characterized by rise in PSA with negative bone scan (BS) and computed tomography (CT). We conducted a phase II trial for men with rising PSA after MLT using $^{18}$F-DCFPyL (PSMA) PET-MR/CT followed by metastasis-directed therapy (MDT) to PET positive foci. We report the results of our primary analysis.**Methods:**Patients with rising PSA (0.4-3.0 ng/mL) after MLT, negative BS/CT and no prior salvage ADT were eligible. All patients underwent PSMA PET-MR and PET-CT. Those with limited disease burden amenable to MDT underwent either stereotactic ablative RT (SABR) or surgery (lymph node dissection). No ADT was used. The primary endpoint was biochemical response rate (complete [undetectable PSA] or partial [PSA decline ≥50% from baseline]) following MDT. A Simon's two-stage study design was employed. Estimated time of delay in salvage ADT was calculated using the Kaplan-Meier method. Toxicity was prospectively recorded (CTCAE v4.0).
**Results:**
After a median of 63 months (range 3-180) post MLT, 72 patients underwent PSMA PET-MR/CT with median PSA 0.98 ng/mL (range 0.4-3.1). Sixteen patients had negative and 56 had positive PET-MR/CT scans, of which 37 (51%) were amenable to MDT. The median number of treated lesions was 2 (range 1-5). Of the treated patients, 30 (81%) had miT0N1M0 disease, 2 (5.5%) had miT0N1M1a, 2 (5.5%) had miT0N0M1a and 3 (8%) had miT0N0M1b. Twenty-seven patients underwent SABR (median 30 Gy in 3 fractions) and 10 had surgery. At a median of 11 months (range 1-29) post MDT, 8 patients (22%) had complete (CR) and 14 (38%) had partial (PR) responses. Among the 8 CRs, 5 had surgery and 3 had SABR; of the 14 PRs, 2 had surgery and 12 had SABR. The estimated median delay in salvage ADT for the entire cohort, PR and CR subgroups was 13 months (IQR 8-20), 16 months (IQR 13-20) and 30 months (IQR not reached), respectively. Two grade 2+ toxicities were observed, both in surgical patients: deep venous thrombosis and ureteric injury requiring stent placement.
**Conclusions:**
$^{18}$F-DCFPyL PET-MR/CT has high detection rates (78%) in men with rising PSA after MLT. We observed a favorable therapeutic index with MDT (60% response rate) for patients with metachronous PSMA-unveiled oligometastatic PCa following MLT. Phase III studies using validated intermediate clinical endpoints are needed before integration into routine practice

## 3. Breast cancer

**Primary analysis of KAITLIN: A phase III study of trastuzumab emtansine (T-DM1) + pertuzumab versus trastuzumab + pertuzumab + taxane, after anthracyclines as adjuvant therapy for high-risk HER2-positive early breast cancer (EBC).** *N Harbeck, S-A Im, CH Barrios, et al*
Take-Home Message

- Negative trial.
- The control remains the standard of care.

**Three-year follow-up of neoadjuvant chemotherapy with or without anthracyclines in the presence of dual HER2-blockade for HER2-positive breast cancer (TRAIN-2): A randomized phase III trial.**
The 3-year follow-up of the TRAIN-2 study confirms the results of the primary outcome that anthracylines do not improve efficacy and are associated with clinically relevant toxicity. A neoadjuvant carboplatin-taxane based regimen with dual HER2-blockade can be considered in all stage II-III breast cancer patients, regardless of hormone receptor and nodal status.

**Phase III trial of metronomic capecitabine maintenance after standard treatment in operable triple-negative breast cancer (SYSUCC-001).** *XI Wang, S-S Wang, H Huang, et al*
Take-Home Message

- Maintenance capecitabine therapy improved distant disease–free survival after standard therapy. These results confirm the CREATE-X benefit after neoadjuvant chemotherapy in patients with less than a pCR.
- Should it be given to all patients? We await the full analysis.

**KEYNOTE-355: Randomized, double-blind, phase III study of pembrolizumab + chemotherapy versus placebo + chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer.** *J Cortes, DW Cescon, HS Rugo, et al*
Take-Home Message

- There was a benefit in terms of progression-free survival with pembrolizumab in patients with a combined positive score for PD-L1 expression of >10%.
- We await details to see if different chemo backbones show a similar benefit.

**Meta-analysis of cyclin-dependent kinase (CDK) 4/6 inhibitors with endocrine therapy versus endocrine therapy alone on progression-free survival (PFS) and overall survival (OS) for metastatic breast cancer (MBC).** *R Kunwor, R Baniya, MM Abu-Khalaf, et al*
Take-Home Message

- This meta-analysis evaluated progression-free survival and overall survival with three CDK 4/6 inhibitors—palbociclib, ribociclib, and abemaciclib—used in HR+/HER2− metastatic breast cancer. The meta-analysis included 8 phase II and III randomized controlled trials (RCTs) comparing CKD4/6 inhibitors plus endocrine therapy versus endocrine therapy alone in a total of 4338 patients with HR+/HER2− metastatic disease. The pooled hazard ratio for progression-free survival in the 8 RCTs was 0.55 (P < .00001). The pooled hazard ratio for overall survival in the 8 RCTs was 0.75 (P < .00001).
- The meta-analysis confirmed the enhanced progression-free survival benefit of CDK 4/6 inhibitors plus endocrine therapy. The pooled hazard ratio of all 8 RCTs showed an overall survival benefit.

**Biomarker data from KATHERINE: A phase III study of adjuvant trastuzumab emtansine (T-DM1) versus trastuzumab (H) in patients with residual invasive disease after neoadjuvant therapy for HER2-positive breast cancer.** *C Denkert, C Lambertini, PA Fasching, et al*
Take-Home Message

- These investigators conducted an exploratory analysis of potential biomarkers of treatment response in patients with residual invasive disease after neoadjuvant therapy for HER2-positive breast cancer randomized to receive adjuvant trastuzumab emtansine (T-DM1) or trastuzumab. PIK3CA mutation status was not associated with outcomes in either treatment arm. The clinical benefit of T-DM1 over trastuzumab was observed across all single-gene and immune gene-signature subgroups. In the trastuzumab treatment arm only, high versus low HER2 expression was associated with less favorable outcomes while high versus low PD-L1 expression was associated with more favorable outcomes.
- The benefit associated with the use of T-DM1 in this population appeared to be independent of all the biomarkers assessed

**TBCRC 048: A phase II study of olaparib monotherapy in metastatic breast cancer patients with germline or somatic mutations in DNA damage response (DDR) pathway genes (Olaparib Expanded).** *NM Tung, ME Robson, S Ventz, et al*
Take-Home Message

- In this proof of principle study, PARP inhibitor olaparib monotherapy showed a clinically meaningful response in patients with metastatic breast cancer with somatic BRCA1/2 or germline PALB2 mutations but not in those with ATM or CHEK2 mutations.

**Tucatinib versus placebo added to trastuzumab and capecitabine for patients with previously treated HER2+ metastatic breast cancer with brain metastases (HER2CLIMB).** *NU Lin, RK Murthy, CK Anders, et al*
Take-Home Message

- In this cohort of the HER2CLIMB trial, the results of the exploratory efficacy analyses of tucatinib added to trastuzumab and capecitabine in HER2-positive patients with brain metastases are reported.
- There was a large improvement in brain events with the addition of tucatinib, a 67% reduction in the risk CNS progression, and prolonged overall survival.

**Alpelisib (ALP) + fulvestrant (FUL) in patients (pts) with PIK3CA-mutated (mut) hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced breast cancer (ABC) previously treated with cyclin-dependent kinase 4/6 inhibitor (CDKi) + aromatase inhibitor (AI): BYLieve study results.** *HS Rugo, F Lerebours, E Ciruelos, et al*

Take-Home Message

- Results of this study support the use of alpelisib plus fulvestrant for patients with HR+, HER2– PIK3CA-mutated advanced breast cancer who were previously treated with CKD4/6 and aromatase inhibitors.
- The clinical benefit rate of 50.4% supports use of this regimen after progression on CDK 4/6.

**PARSIFAL: A randomized, multicenter, open-label, phase II trial to evaluate palbociclib in combination with fulvestrant or letrozole in endocrine-sensitive patients with estrogen receptor (ER)[+]/HER2[-] metastatic breast cancer.** *MR Borrego, J Gavilá, M Sampayo-Cordero, et al*

Take-Home Message

- Palbociclib plus fulvestrant did not improve progression-free survival compared with palbociclib plus letrozole in this group of patients with endocrine-sensitive HR+, HER2– metastatic breast cancer, and 41% had de novo metastatic disease.

**Primary results of NRG Oncology / NSABP B-43: Phase III trial comparing concurrent trastuzumab (T) and radiation therapy (RT) with RT alone for women with HER2-positive ductal carcinoma in situ (DCIS) after lumpectomy.** *R Rabinovitch, DS Parda, SA Seaward, et al*

Take-Home Message

- Women with ductal carcinoma in situ (DCIS) resected by lumpectomy were randomized to receive radiation therapy (RT) alone or concurrent trastuzumab (T) and RT. The hazard ratio for the risk of ipsilateral breast tumor recurrence (IBTR) in the T+RT group compared with the RT-alone group was 0.81 (P = .26). The annual IBTR event rate was 0.99% per year in the RT group versus 0.80% per year in the RT+T group.
- The addition of T to RT was associated with a modest and nonsignificant reduction in the risk of IBTR compared with RT alone, but this did not meet the protocol objective of a reduction of 36%

**Randomized trial of a collaborative palliative and oncology care intervention to improve communication about end-of-life care in patients with metastatic breast cancer.** *JS Temel, B Moy, AE-Jawahri, et al*

Take-Home Message

- Patients with metastatic breast cancer and clinical indicators of a poor prognosis were randomized to receive collaborative palliative and oncology care with five structured palliative care visits or standard care. The rate of documented end-of-life care discussions was 67.2% in the intervention group versus 40.7% in the group receiving usual care (P = .006). There was no difference in reported quality of life or mood between the two groups.
- The use of this new model improved communication and documentation of end-of-life discussions, and further study is warranted to evaluate the impact on subsequent healthcare utilization.

4. **Lung cancer**

**Nivolumab + ipilimumab versus platinum-doublet chemotherapy as first-line treatment for advanced non-small cell lung cancer: Three-year update from CheckMate 227 Part 1.** *SS Ramalingam, TE Ciuleanu, A Pluzanski, et al*

Take-Home Message

- In this study, patients with stage IV recurrent non–small cell lung cancer (NSCLC) and PD-L1 expression of 1% or higher were randomized to receive nivolumab with ipilimumab, nivolumab alone, or chemotherapy. OS at 3 years was 33%, 29%, and 22% in the nivolumab plus ipilimumab, nivolumab, and chemotherapy groups, respectively; PFS was 18%, 12%, and 4%. Patients with complete or partial response at 6 months had longer OS with nivolumab plus ipilimumab compared with chemotherapy.
- Nivolumab plus ipilimumab provided long-term OS benefit in patients with NSCLC, and patients with PD-L1 ≥1% who achieved complete or partial response at 6 months had higher OS benefit with nivolumab plus ipilimumab compared with chemo

5. **Symptoms and Survivorship**

**Multisite randomized trial of integrated palliative and oncology care for patients with acute myeloid leukemia (AML).** *A El-Jawahri, T William LeBlanc, A Kavanaugh, et al*

Take-Home Message

- This study evaluated the effect of integrated palliative and oncology care on quality of life (QOL), mood, post-traumatic stress (PTSD) symptoms, and end-of-life (EOL) outcomes in patients with acute myeloid leukemia (AML). AML patients were randomly assigned to receive either integrated palliative and oncology care (n = 86) or usual oncology care (n = 74), and were then assessed for their QOL, mood, and PTSD symptoms at baseline and weeks 2, 4, 12, and 24. Patients receiving integrated palliative and oncology care reported significantly better QOL (107.59 vs 116.45; P = .039) and less depression (7.20 vs 5.68; P = .021), less anxiety (5.94 vs 4.53; P = .018), and fewer PTSD symptoms (31.69 vs 27.79; P = .009) at week 2, with these effects sustained up to week 24. Patients receiving palliative care were also more likely to report discussing their EOL care preferences with their clinicians.
- For AML patients receiving intensive chemotherapy, integrated palliative and oncology care led to significant improvements in patients' QOL, psychological distress, and EOL care. Palliative care should be considered for patients with AML.

**A randomized trial of a palliative care intervention for patients on phase I studies.** *TJ Smith, V Chung, MT Hughes, et al*

Take-Home Message

- This study evaluated a palliative care intervention for patients with solid tumors in a randomized trial, where patients enrolled in phase I therapeutic trials were compared as a usual care group with a palliative care intervention (PCI) group at two study sites. The PCI assessed quality of life (QOL) and symptoms, discussed the care plan, and provided two nurse-delivered teaching sessions. Patients were followed for 24 weeks, with 12 weeks as the primary outcome point. The PCI cohort, when compared with the usual care cohort showed less psychological distress (1.9 vs 1.2; P = .03) and a trend toward improved QOL (3.7 vs 1.6; P = .07), with differences between sites.
- PCI improved QOL outcomes and distress in patients participating in phase 1 trials, indicating the benefit of increased use of palliative care in these patients and in supporting transitions from treatment to supportive care.

**ACUFOCIN: Randomized clinical trial of ACUpuncture plus standard care versus standard care alone FOr Chemotherapy Induced Peripheral Neuropathy (CIPN).** *AM Wardley, D Ryder, V Misra, et al*

Take-Home Message

- This study evaluated the efficacy of acupuncture when used with standard care (Acu +SC) to reduce the symptoms of chemotherapy-induced peripheral neuropathy (CIPN). In this phase II clinical trial, patients experiencing CIPN grade ≥2 and reporting a "most troublesome" CIPN symptom score of ≥3 were randomized to Acu+SC or SC-alone groups. After 10 weeks, in the Acu+SC group, 67% of patients achieved a reduction of ≥2 points compared with 33% of patients in the SC-alone group (aOR, 4.3; P < .001); 51% of patients achieved a CIPN success grade (≤1) in the Acu+SC group compared with 7% of patients in the SC-alone group (aOR, 13.1; P < .001).
- A 10-week course of acupuncture significantly improved symptoms of CIPN, supporting further investigation of the use of acupuncture for CIPN within a phase III trial.

**Effect of a tailored exercise intervention during or after chemotherapy on cardiovascular morbidity in cancer patients.** *GGFGF van der Schoot, HL Ormel, N-DL Westerink, et al*

Take-Home Message

- This study evaluated whether exercise intervention started during chemotherapy (early group) is superior to exercise started after completion of chemotherapy (late group) at reducing treatment-related cardiovascular morbidity. Patients with testicular cancer, breast cancer, colon cancer, or non-Hodgkin's lymphoma were randomized to a 24-week aerobic and resistance exercise intervention started during chemotherapy (n=131) or after completion of chemotherapy (n=135). Compared with the late group, patients in the early group had a significantly reduced decline in $VO_2$ peak and quality of life (QoL) at diagnosis post chemotherapy (T1). Patients in the early group experienced reduced general and physical fatigue at T1; but, at post-exercise intervention (T2), $VO_2$ peak, QoL, and general and physical fatigue were comparable between groups, and baseline levels were regained.
- Exercise initiated at the start of chemotherapy may be effective in reducing a decline in $VO_2$ peak, QoL, and fatigue. However, after completion of the exercise intervention, baseline levels of these parameters are regained