Conference Report
ESMO 2014

HIGHLIGHTS FROM ESMO 2014
Including supporting commentary from the CARE Oncology Faculty

Members of the CARE Oncology Faculty recently attended a CARE working group meeting during the annual ESMO 2014 conference held in Madrid, Spain from September 26-30 2014. In attendance were a number of CARE Faculty Members representing a variety of tumour sites. What follows is an overview of the key abstracts and sessions from ESMO discussed at this meeting, with Canadian perspectives provided by Faculty.

The report content that follows is drawn from ESMO 2014 and is augmented with the CARE Oncology Faculty perspective and commentary.

CARE ONCOLOGY FACULTY WHO HAVE CONTRIBUTED TO THIS REPORT:

- Dr. Normand Blais, Centre Hospitalier de l’Universite de Montreal
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- Dr. Winson Cheung, BC Cancer Agency
- Dr. Ernie Mak, Princess Margaret Cancer Centre
- Dr. Stephen Chia, BC Cancer Agency
- Dr. Rob El Maraghi, Simcoe Muskoka Regional Cancer Centre
- Dr. Barbara Melosky, BC Cancer Agency
- Dr. Ralph Wong, CancerCare Manitoba
- M. Socinski et al
- E. Garon et al
- ESMO 2014. ABSTRACT 1232P.

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Spotlight on: Palliative Care

Immuno-Oncology (I-O) is an exciting topic with positive data in a number of tumour areas. Storylines covering I-O content are included in this report and are identified throughout.

Lung Cancer

Non-Small Cell Lung Cancer

ESMO 2014. ABSTRACT 1266P. Quality of life (QoL) results from the phase 3 REVEL study of ramucirumab+docetaxel (RAM+DTX) versus placebo+docetaxel (PL+DTX) in advanced/metastatic NSCLC patients (pts) with progression after platinum based chemotherapy.

E. Garon et al

Aim: RAM + DTX significantly improved overall survival and progression-free survival in pts with locally advanced or metastatic NSCLC with progression after platinum based chemotherapy. QoL data was obtained.

Conclusions: In addition to the improvement of clinical outcomes demonstrated in REVEL, the primary QoL analyses suggest that there was no detriment in QoL and pt functioning by adding RAM to DTX second line chemotherapy.

QoL is an important element to consider when managing patients with advanced lung cancer, particularly in the second-line setting, as they often have a heavy burden of symptoms. Even though there was no improvement in QoL with the addition of ramucirumab, it is encouraging to see that the benefits gained in OS were not at the expense of a detriment in QoL or patient functioning. Although targeting the VEGF-Receptor pathway in NSCLC appears to have clinical activity, the benefit is modest and it remains to be seen whether this strategy will gain popularity in a tumour site where VEGF inhibitors did not.

By reading this report, you may be eligible for credit from the Royal College of Physicians and Surgeons of Canada under Section 2: Self Learning.

— CARE Faculty Commentary
**ESMO 2014, ABSTRACT LBA45.** Antitumor activity of pembrolizumab (Pembro; MK-3475) and correlation with programmed death ligand 1 (PD-L1) expression in a pooled analysis of patients (pts) with advanced non-small cell lung carcinoma (NSCLC).

Garon, E.B. et al.

**Introduction:** Pembrolizumab (Pembro) is an anti-PDL1 antibody that has shown activity in advanced NSCLC. The correlation between tumor PD-L1 expression and antitumor activity continues to evolve. Most interesting is the duration of benefit in patients who respond. KEYNOTE-001 was presented in the oral session metastatic NSCLC as a late breaking abstract. With a large sample of 282 patients, it expands our understanding of immunotherapy in metastatic NSCLC.

**Conclusions:** Pembrolizumab is tolerable and provides antitumor activity in treatment-naïve or previously treated advanced NSCLC. Patients with strong PD-L1 tumor expression may derive particular benefit.

This is a complicated area that we are moving quickly into with metastatic NSCLC. The KEYNOTE-001 had three different doses, two different ways to assess response, and two different assays used for the PD-L1 biomarker. Although the number of patients treated at 2mg/kg were few, their responses seem as robust and durable as the higher dose, so this is the dose moving forward. (The response rate ranges between 20 and 26% for previously treated and treatment naïve respectively. Responses are durable. Side effects are few—mostly fatigue.) Overall survival is impressive at 8.2 months for the heavily untreated group and QoL is not even reached for the treatment naïve. What biomarker will be used? Likely the CTA assay with a cut off of >50% staining for pembrolizumab. We await Phase III data!

**— CARE Faculty Commentary**

![Kaplan-Meier Estimates of Survival](image)

**ESMO 2014, ABSTRACT LBA2_PR.** Gefitinib/chemotherapy vs chemotherapy in epidermal growth factor receptor (EGFR) mutation-positive non-small-cell lung cancer (NSCLC) after progression on first-line gefitinib: the Phase III, randomised IMPRESS study.

T. Mok et al.

**Aim:** Most patients (pts) with EGFR mutation-positive NSCLC respond to 1st-line gefitinib tyrosine kinase inhibitors, but later acquire resistance. The Phase III, double-blind IRESSA Mutation Positive Multicentre Treatment Beyond Progression Study (IMPRESS; NCT01544179) evaluated the efficacy/safety of continuing gefitinib plus cisplatin/pemetrexed (cis/pem) (G) vs placebo plus cis/pem (P) in pts with acquired resistance to 1st-line gefitinib.

**Conclusions:** IMPRESS is the first and only randomised Phase III study to confirm continuation of gefitinib in addition to cis/pem would be of no clinical benefit for pts with acquired resistance to gefitinib; thus the standard of care should remain doublet chemotherapy alone. The safety profile for gefitinib plus cis/pem was in line with that known.

**— CARE Faculty Commentary**

### Squamous Cell Carcinoma

**ESMO 2014, ABSTRACT 12220.** A randomized, open-label, phase II trial of afatinib (A) vs erlotinib (E) as second-line treatment of patients (pts) with advanced squamous cell carcinoma (SCC) of the lung following first-line platinum-based chemotherapy: LUX-Lung 8 (LL8).

G.Oss et al.

**Aim:** A is an irreversible Erbb family blocker that has shown promising clinical activity in pts with SCC of the head/neck and lung. Here, we report results of LL8, a phase III trial that prospectively compared A and E in pts with SCC of the lung following failure of first-line chemotherapy.

**Results:**

**— CARE Faculty Commentary**

![Kaplan-Meier Estimates of Survival](image)

**The use of chemotherapy has not been formally shown to improve overall survival in the post-TKI setting but has been considered a standard by experts. Considering the biology of this disease, many experts believed that chemotherapy may be effective against resistant clones and that continuation of the TKI during chemotherapy may prevent the reappearance of the EGFR-sensitive clones, leading to greater benefit than with chemotherapy alone. In this regard, the results of the IMPRESS study seem counter-intuitive and surprising. Although PFS was not negatively impacted by the use of gefitinib with pemetrex, the reasons why OS may be impaired by this combination were debated after the presentation of IMPRESS. Potential explanations may include the immaturity of the OS results, the imbalances in the treatment arms, as well as toxicity of the triple drug combination, perhaps leading to increased decline in performance status and/or less access to multidisciplinary treatment for this group. Of note, the phase II LUX-LUNG 5 studied paclitaxel vs paclitaxel+erlotinib in this setting and did not show differences in OS between both arms.”

**— CARE Faculty Commentary**
Conclusions: Here we present for the first time efficacy data on EVE/EXE under real world conditions. The data was defined to take place 12 months after the inclusion of the 500th patient into the documentation.


ER+ and HER2 Metastatic Breast Cancer

ESMO 2014. Abstract LBA9. Breast Cancer Treatment With Everolimus (EVE) and Exemestane (EXE) for ER+ Women: Results of the 2nd Interim Analysis of the Non-interventional Trial, BRAWO.

Fasching PA et al.

Aim: BRAWO is a German non-interventional study of 3000 patients (pts) with advanced or metastatic, hormone-receptor-positive and HER2-negative breast cancer treated with everolimus (EVE) and exemestane (EXE). Data is collected at about 400 sites. Main objectives are to extend the knowledge on a) the impact of physical activity on quality of life, b) prophylaxis and management of stomatitis in clinical routine, and c) the sequence of therapy, when EVE is used in daily clinical practice. We report the results of the 2nd preplanned interim analysis (IA) which was defined to take place 12 months after the inclusion of the 500th patient into the documentation.

Conclusions: Here we present for the first time efficacy data on EVE/EXE under real world conditions. The data confirm the efficacy results of the pivotal phase 3 trial BOLEDO-2 (median PFS vs placebo +EXE: 7.8 months vs 3.2 months, respectively by local radiologic assessment).

**HER2+ Breast Cancer**

ESMO 2014. Abstract 3SGO_PR. Final overall survival (OS) analysis from the CLEOPATRA study of first-line (1L) pertuzumab (Ptx), trastuzumab (T), and docetaxel (D) in patients (pts) with HER2-positive metastatic breast cancer (MBC).

Swain SM et al.

Background: 808 pts with HER2-positive MBC were randomized to receive first line docetaxel, trastuzumab +/- pertuzumab. At primary analysis, pertuzumab was shown to increase progression-free survival significantly, with a strong trend to OS benefit. At a second interim analysis (May 2012) OS was improved to a degree, which was both statistically significant and clinically meaningful (HR = 0.66, 95% CI 0.52–0.84; P = 0.0008) but the median OS in patients who received pertuzumab was not reached. The results of a subsequent pre-specified OS analysis were reported at ESMO 2014.

Results: Here we present for the first time efficacy data on EVE/EXE under real world conditions. The data confirm the efficacy results of the pivotal phase 3 trial BOLERO-2 (median PFS vs placebo +EXE: 7.8 months vs 3.2 months, respectively by local radiologic assessment).

**Final OS Analysis of CLEOPATRA sets a new paradigm of treatment of HER2+ MBC**

Ptz + T + D: median 56.5 months
Pla + T + D: median 40.8 months

HR 0.68
95% CI = 0.56, 0.84
p =0.0002

Ptx + T + D: median 40.8 months
Pla + T + D: median 26 months

HR 0.64
95% CI = 0.50, 0.81
p =0.0031

HER2+ Breast Cancer

**CLEOPATRA clearly establishes docetaxel, and dual antibody targeted therapy with trastuzumab and pertuzumab, as the current standard of care in first line treatment of HER2+ MBC. The 56.5 month median OS in the pertuzumab containing arm is indeed exceptional in any MBC setting, be it HER2+ or not. The IS.7 month improvement in median OS with the addition of pertuzumab may also be an underestimate of benefit given the crossover of patients from the placebo arm. No unexpected adverse effects were seen and were similar to previous reports (increased febrile neutropenia and diarrhea observed in the pertuzumab containing arm). No increase was observed in terms of cardiotoxicity with dual anti-HER2 antibody blockade.**

There are still outstanding questions, including:

- **How will the positive CLEOPATRA trial results, with docetaxel, trastuzumab and pertuzumab, be compared to other yet to be reported HER2+/MBC 1st line studies that do not have a similar comparator study arm (e.g. MARIANNE trial)?**
- **Would similar efficacy have been demonstrated in a more heavily pretreated HER2+ MBC population (as only ~10% had received adjuvant trastuzumab, and <50% had received prior adjuvant/neo-adjuvant chemotherapy)?**
- **Can similar results and lesser toxicity be achieved with an alternate non-docetaxel chemotherapy regimen when combined with dual anti-HER2 targeted antibody therapy (e.g. venostrimab)?**
- **Would additional benefit have been observed in ER+/HER2+ subgroup if additional concomitant endocrine therapy was allowed after the docetaxel portion of treatment (median 8 cycles in both arms) was discontinued?**
- **As was seen in the NeoSphere neo-adjuvant HER2+ breast cancer trial, can we prospectively identify a group of HER2+ MBC patients who could be adequately treated with dual-HER2 antibody therapy alone, thereby avoiding chemotherapy associated potential side effects (e.g. PIK2A mutation status) and immune correlates (e.g. PD1/PDL1) from the CLEOPATRA study have yet to be reported.**
- **Lastly, while no clear advantage has been observed yet with the addition of oral TKI (lapatinib) to trastuzumab in the adjuvant setting (ALTTO), will additional benefit with dual targeted anti-HER2 antibody therapy be observed (APHINITY)?**

— CARE Faculty Commentary

References are listed on the back page.

The CARE Breast Cancer Faculty will next meet at SABCS 2014 in San Antonio, TX from December 9th-13th.

More news to follow in the CARE at SABCS 2014 report!
ESMO 2014, ABSTRACT S47P. Impact of baseline efficacy on efficacy and safety of first-line panitumumab (pmab) + FOLFIRI4 vs FOLFIRI4 alone. 

J. Douillard et al.

Aim: Data from PRIME showed pmab + FOLFIRI4 to be an effective and tolerable first-line treatment for patients (pts) with RAS WT metastatic colorectal cancer (mCRC). However, treatment outcomes can differ in pts of differing age.

Results:

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Overall Survival (OS)</th>
<th>Progression-Free Survival (PFS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pt&lt;65</td>
<td>HR 0.748 (0.584–0.949)</td>
<td>HR 0.655 (0.536–0.832)</td>
</tr>
<tr>
<td>Pt≥65</td>
<td>HR 0.797 (0.581–1.109)</td>
<td>HR 0.879 (0.646–1.193)</td>
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</table>

Conclusions: In subgroup analyses of RAS WT pts from PRIME, pmab + FOLFIRI4 appears to offer benefit over FOLFIRI4 alone both in pts <65 and ≥65 yr. Analysis of efficacy in the ≥75 yr population was limited by pt numbers and more research is needed to assess treatment benefit in these pts.

Hepatocellular Carcinoma

ESMO 2014, ABSTRACT 728P. Final analysis of overall survival per subgroup of HCC patients in the prospective, non-interventional INSIGHT study treated with sorafenib.

T. Ganett et al.

Aim: INSIGHT is a prospective, non-interventional study, conducted in Germany and Austria with hepatocellular carcinoma (HCC). The objectives of this study are the evaluation of safety and efficacy under practice conditions in both hospitals and private practices. Enrollment into INSIGHT is not restricted to a particular tumor stage.

Conclusions: Results of mOS in pts with HCC treated under daily practice conditions in hospitals and private practices confirms the general efficacy of Sorafenib and gives further insight into survival of pts with CHILD B, BCLC stage A/B, age ≥65, etiology of HCC and a relevant subgroup of patients treated longer than 40 weeks. Further demographic data, efficacy and safety results will be presented.
Genitourinary Cancer

The abstract content/visuals that follow are drawn from the ESMO 2014 meeting, with Canadian perspectives provided by the CARE GU Faculty.

ESMO 2014. ABSTRACT 771P. Analysis of overall survival (OS) with docetaxel in men with different prognostic risk factors treated with cabazitaxel and prednisone (Cbz + P) after docetaxel (D) in the TROPIC trial.

B. Tombal et al.

Aim: TROPIC (NCT00417079) showed improved OS for Cbz + P vs. mitoxantrone (Mtx) + P in pts with metastatic castration-resistant prostate cancer (mCRCP). Cbz + P had a manageable safety profile similar to other chemotherapies (ctx). A novel prognostic model using TROPIC and SPARC trial data was developed to predict and validate OS in men with mCRCP progressing during/after D and scheduled to receive second-line ctx. The model identified 9 factors: presence of pain, measurable disease or visceral disease; ECOG PS; time since last D; time from first hormone therapy; haemoglobin (Hb); prostate-specific antigen (PSA); and alkaline phosphatase (ALP). The aim of this study was to explore the activity of Cbz + P in pts with different numbers of prognostic factors.

Conclusions: Increasing numbers of poor prognostic factors were associated with worse OS. Cbz + P improved OS vs Mtx + P regardless of the number of poor prognostic factors present.

ESMO 2014. ABSTRACT 767P. External-beam radiation therapy (EBRT) use and safety with radium-223 dichloride (Ra) in patients (pts) with castration-resistant prostate cancer (CRPC) and symptomatic bone metastases (mets) from the ALSYMPCA trial.

J. O'Sullivan et al.

Aim: Bone mets in CRPC frequently cause symptomatic skeletal events (SSEs) requiring EBRT for pain. In ALSYMPCA, Ra, a first-in-class α-emitter, improved overall survival and delayed time to first SSE (Parker NEJM 2013). This post hoc study analyzed ALSYMPCA pts with EBRT for bone pain before randomization and during treatment (tx).

Conclusions: Ra delays the need for EBRT for bone pain vs pbo. Prior EBRT does not appear to affect need for EBRT for bone pain in pts receiving Ra. EBRT use does not affect the Ra favorable safety profile.

ESMO 2014. ABSTRACT 768P. External-beam radiation therapy (EBRT) use and safety with radium-223 dichloride (Ra) in patients (pts) with castration-resistant prostate cancer (mCRCP) and symptomatic bone metastases (mets) from the ALSYMPCA trial.

C. Higano et al.

Aim: In the PREVAIL trial, enzalutamide, an androgen receptor signaling inhibitor, significantly improved overall survival (OS) (HR, 0.77; p < 0.0001) and radiographic progression-free survival (rPFS) (HR, 0.99; p < 0.0001) compared to placebo in chemotherapy-naive men with metastatic castrate-resistant prostate cancer (mCRCP). Patients with visceral metastases have worse prognosis, which is heavily subject to bias and study case selection, suggests to consider visceral disease in mCRCP.

Conclusions: Visceral metastases were permitted in the PREVAIL trial of men with chemotherapy-naive mCRCP. Enzalutamide was active in this small group of patients; post-hoc analyses showed benefit vs placebo on OS, rPFS, and secondary endpoints. Response rates were higher for LSG vs liver metastases. These results support androgen receptor signaling as an important target in prostate cancer with visceral metastases.

ESMO 2014. ABSTRACT 770P. Updated analysis of OS at 3 years of enzalutamide (Enz) in patients (pts) progressing during/after docetaxel (D) in the TROPIC trial.

F. de Bono et al.

Aim: TROPIC (NCT00417079) showed OS benefit for Enz vs D in pts with mCRCP progressing during/after D. Median OS was 17.8 months in the Enz + D group vs 10.2 months in the D group (HR, 0.71; p < 0.0001) and rPFS was 18.9 months in the Enz + D group vs 6.6 months in the D group (HR, 0.35; p < 0.0001). The updated analysis at 3 years showed even greater benefit for Enz + D, with median OS of 30.0 months in the Enz + D group vs 15.6 months in the D group (HR, 0.67; p < 0.0001).

Conclusions: Enz improves OS, rPFS, and time to radiographic progression in pts with mCRCP progressing during/after D.

CARE GU Faculty Update - mCRPC

The CARE GU Faculty has met over the course of the year at conferences including ASCO, GU ASCO, and ESMO. They meet with the intent of reviewing key news and data from these conferences, considering how they apply to the Canadian landscape. The main focus of the group has predominantly been on the management and treatment of mCRCP. Work to date by the group includes the development of educational initiatives such as conference outputs, needs assessments and a CARE Suggested Treatment Algorithm/Guidance for mCRCP (see below for more details).
ESMO 2014. ABSTRACT B850. Randomized, dose-ranging phase II trial of nivolumab for metastatic renal cell carcinoma (mRCC)  R.J. Motzer et al.

Aim: Nivolumab, a fully human IgG4 programmed death-1 immune checkpoint inhibitor antibody, has shown encouraging survival and manageable safety in pretreated mRCC patients (pts). This phase II trial (NCT01354431) assesses 3 nivolumab doses in mRCC pts pretreated with targeted VEGF pathway agents. We previously reported no dose response relationship with 3 doses of nivolumab (primary objective). Here we present updated overall survival (OS) and duration of response (DOR) data.

Conclusions: In this phase II trial nivolumab was associated with encouraging efficacy, with no dose response relationship observed for PFS or DOR. Median OS range was 18.2-25.5 months; longer median OS was reported at 2 and 10 mg/kg. The safety profile of nivolumab was acceptable for all doses with no grade 3-4 pneumonitis observed.

ESMO 2014. ABSTRACT B35P. Updated OS analysis, multivariate and QTWIST analysis of a randomized sequential open-label study (SWITCH) to evaluate efficacy and safety of sunitinib (SU) / sunitinib (SU) versus SU/SO in the treatment of metastatic renal cell cancer (mRCC) (ID 5193).  C. Eichelberg et al.

Aim: Results of the sequential randomized phase III SWITCH study comparing SU/SO and SU/SO have been reported previously (ASCO GU 2014, abstract 393) showing no significant difference in the primary endpoint, total PFS (HR 1.01), nor the secondary endpoints, overall survival (OS; HR 1.0) and 1st-line PFS (HR 1.19). We report here the results of an updated overall survival (OS) analysis, a multivariate analysis and QTWIST analysis (all post-hoc).

Conclusions: In this updated OS analysis there was no significant difference between the two sequential treatments concerning OS. In addition, the time without specific AE's of grade 3/4 (QTWIST) was not significantly different. A multivariate analysis showed that slowly progressing pts and those who started on sunitinib were more likely to reach 2nd line on study treatment.

ESMO 2014. ABSTRACT L829-PR. Afatinib versus methotrexate as second-line treatment for patients with recurrent and/or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) who progressed after platinum-based therapy: results of the randomised, open-label, phase III trial LUX-Head & Neck 1  J. Machiels et al.

Aim: Pts with R/M HNSCC who progress after first-line platinum-based therapy have a poor prognosis with no defined standard treatment. Afatinib is an orally available ErbB family blocker that irreversibly blocks EGFR, HER2, ErbB3 and ErbB4 signalling. In a randomised, proof-of-concept phase II trial, afatinib showed promising anti-tumor activity in pts with R/M HNSCC progressing after platinum regimens. LUX-Head & Neck 1 is a phase III trial designed to compare afatinib with methotrexate in R/M HNSCC pts following progression on platinum-based chemotherapy.

Conclusions: In this phase III trial, second-line afatinib significantly improved the primary endpoint of PFS and delayed deterioration of PROs vs MTX, with a manageable safety profile, in patients with R/M HNSCC after failure of platinum-based therapy. Machiels JPH, Haddad RI and Fayette J contributed equally to this work.

ESMO 2014. ABSTRACT L831. A phase Ib study of pembrolizumab (Pembro; MK-3475) in patients (Pts) with human papilloma virus (HPV) positive and negative head and neck cancer (HNC)  L. Chow et al.

Aim: The highly selective, anti-PO-1 humanized monoclonal antibody pembrolizumab has shown antitumor activity in several solid tumors, including HNC. We present updated safety, tolerability, and antitumor activity of pembrolizumab for recurrent/metastatic HNC (Clinicaltrials.gov: NCT01848834).

Results:

<table>
<thead>
<tr>
<th></th>
<th>Overall N = 61*</th>
<th>HPV+ n = 25*</th>
<th>HPV− n = 36*</th>
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</thead>
<tbody>
<tr>
<td>ORR, n (%)</td>
<td>11 (22)</td>
<td>4 (20)</td>
<td>7 (19)</td>
</tr>
<tr>
<td>Median PFS (95% CI), wk</td>
<td>9.3 (8.0-20.1)</td>
<td>11.2 (8.0-41.7)</td>
<td>8.1 (7.9-15.6)</td>
</tr>
<tr>
<td>Median OS (95% CI), mo</td>
<td>12.6 (8.2-12.6)</td>
<td>NR (9.6-NR)</td>
<td>9.5 (3.9-12.6)</td>
</tr>
</tbody>
</table>

*ORR and PFS were evaluated in the 56 pts (20 HPV+, 36 HPV−) who received ≥ 1 pembro dose and had measurable disease per RECIST v1.1 by investigator review

Conclusions: Pembrolizumab is safe and tolerable and shows antitumor activity in both HPV+ and HPV− advanced HNC. These findings support further development of pembrolizumab in advanced HNC.

The CARE GU Faculty will next meet at the ASCO GU Cancers Symposium being held in Orlando, FL from February 26th-28th 2015 to continue development/update this and other CARE GU initiatives.

More news to follow in the CARE at GUCS 2015 report!
One of the primary goals of the various CARE Faculties has been the consideration of therapy to optimize patient outcomes. In alignment with this goal, CARE Faculty has begun to focus/ build on palliative care concepts and the positive impact it has on patient QoL.

Palliative care was also a prominent topic at the ESMO 2014 conference. Key storylines, as identified and covered by CARE Faculty member Dr. Ernie Mak can be found below:


A. Affatato et al.

**Background.** Recently many authors have hypothesized that early palliative care (EPC) in patients with cancer could improve survival, quality of life or symptoms control. To confirm this datum, we have recently completed a systematic review of literature with meta-analysis of randomized clinical trials.

**Conclusions.** Our data confirm that EPC could improve quality of life of patients with advanced cancer. The datum, that is significant by a clinical point of view, is modest by a statistical point of view, with a negligible impact to the relatively well status of these patients. Also the inevitable modality to explain the heterogeneity in the use of PS in oncological patients in Austrian palliative care units which cannot be explained by dose associated variables. Since the use of PS is associated with significant ethical issues, training of physicians and implementation of an Austrian nation-wide guideline is mandatory.

**ESMO 2014, ABSTRACT 1347P.** Key Interventions of Palliative Cancer Care (KI-PCC) - patient perceived need and remembered delivery by health-care professionals (HCP): A prospective, longitudinal, multicenter study.

N. Magaya-Kalbermatten et al.

**Aim.** The integration of PC-in oncology is challenging, particularly in resource-restricted and regulatory discharge settings with variable training of HCPs. To identify gaps and in a second step to improve care of advanced, incurable cancer patients (pts), we collect a "reality map" of KI-PCCs and quality indicators (GI).

**Conclusions.** Our data suggest a substantial gap between perceived need for and delivered KI-PCCs, without rapid change after 1 month.

This review confirms that early Palliative Care has the potential to improve quality of life. The modest clinical significance may be due to the relatively well status of these patients. Also the inevitable variability in service or support provided from different Palliative Care programs may have an impact. It would be important to look at multi-centre trials in the future to elucidate the true benefit of early Palliative Care referral. The second study highlights the disparity between the need for and the actually provided support in Palliative care. Although there is likely recall bias in this sample, there remains a very real service gap due to available resource. Future studies can help to determine which components in early Palliative Care generate the largest impact so interventions can be prioritized according to support in the region.

--- CARE Faculty Commentary

**ESMO 2014, ABSTRACT 1348P.** A nationwide survey on palliative sedation for terminally ill cancer patients by the Austrian Palliative Care (AUPAC) study group.

S. Schür et al.

**Aim:** Palliative sedation (PS) is defined as the controlled use of sedative drugs to alleviate unbearable suffering caused by refractory symptoms. Intractable distress longing for subsequent sedating treatment may frequently occur especially in oncological patients in the terminal phase of illness. Application of this approach requires special expertise but consensus on best practice is achieved incompletely. The aim of this study was to assess the current practice of PS in Austria.

**Conclusions:** There is a considerable heterogeneity in the use of PS in oncological patients in Austrian palliative care units which cannot be explained by dose associated variables. Since the use of PS is associated with significant ethical issues, training of physicians and implementation of an Austrian nation-wide guideline is mandatory.

**ESMO 2014, ABSTRACT 1353P.** Active palliation and new treatment strategies for malignant ascites using KM-CART

K. Matsuzaki et al.

**Aim:** To improve the symptoms of refractory ascites, we have developed a novel cell-free and concentrated ascites refluxion therapy (KM-CART). KM-CART is easier to use and can be applied for massive malignant ascites. The effectiveness of KM-CART in alleviating symptoms, and the application of cancer cells recovered by KM-CART in personalized medicines are hereby reported.

**Conclusion:** The KM-CART system was considered easy to use and very safe, and the recovery of large volumes of autologous proteins was thought to have improved general status, nutrition, and immune status, as well as subjective symptoms. In addition, the recovered cancer cells were able to be used for drug sensitivity tests and immune cell therapy, indicating the potential for new treatment strategies for malignant ascites in the future.

--- CARE Faculty Commentary

**ESMO 2014, ABSTRACT 1353EP.** Cancer cachexia: Perspectives of health care professionals.

M. Muscatioli et al.

**Aim:** The majority of cancer patients develop cancer cachexia (CC). CC is a debilitating and life-threatening, multifactorial condition that is characterized by altered metabolism and reduced food intake, contributing to weight loss (mainly lean body mass). Existing treatment approaches are limited in their ability to treat CC, while too little is currently done to prevent it. Surveys were carried out to gain insights on the current perspectives of health care professionals (HCPs) on CC.

**Conclusions:** The results of these surveys indicate that, although CC is still not equally defined among HCPs, it is perceived as a condition which negatively impacts on QoL and risk of side effects, and it need of new, effective, preventive, and therapeutic strategies. Furthermore, increasing awareness of CC and its detrimental consequences appears mandatory among HCPs in order for new treatments to be cost-effective.

**ESMO 2014, ABSTRACT 1354SPD.** Phases II trial of epidermal growth factor ointment for patients with erlotinib-related skin effects.

S. Oh et al.

**Aim:** The efficacy of the epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor erlotinib has been demonstrated in patients with non-small cell lung cancer (NSCLC) and pancreatic cancer (PC). Dermatologic reactions can be a surrogate marker for the efficacy of erlotinib and they can result in dose modification. Such reaction can cause significant physical and psycho-social discomfort to patients. In the present study, we evaluate the effect of epidermal growth factor (EGF) ointment on erlotinib related skin effects (ERSEs).

**Conclusions:** This is the first large-scale prospective study of the treatment of ERSEs. Based on the results, the EGF ointment is effective for ERSEs, regardless of gender, age, type of tumor, and dosage of erlotinib. The EGF ointment frequently improved all kinds of symptoms of ERSEs (NCT01593995).

**ESMO 2014, ABSTRACT 13540.** Fatigue (F) and anemia scores for overall survival (OS) prognosis (ID 2554).

Y. Gornadha et al.

**Background.** F is an adverse reaction related both to disease and treatment in cancer patients (pts). Incidence of F episodes and anemia could be expressed using scores which association with OS could be useful for treatment management.

**Conclusions:** A linear score of anemia and fatigue PSS were simple and efficient predictors of overall survival. They could be monitored to help clinicians in fatigue and anaemia management.

It would be interesting to see if the severity of fatigue is correlated to the types and the number of previous chemotherapy. This score may be a tool to prompt health care professionals to initiate discussions on goals of care and encourage Palliative Care referrals, especially in patients with a poor anticipated prognosis.

--- CARE Faculty Commentary

**ESMO 2014, ABSTRACT 1352P.** Phase II trial of epidermal growth factor ointment for patients with erlotinib-related skin effects.

S. Oh et al.

**ESMO 2014, ABSTRACT 1353P.** Cancer cachexia: Perspectives of health care professionals.

M. Muscatioli et al.

**ESMO 2014, ABSTRACT 1354SPD.** Phase II trial of epidermal growth factor ointment for patients with erlotinib-related skin effects.

S. Oh et al.
ABOUT THE CARE ONCOLOGY FACULTY

The CARE (Community Academic Research Education) Oncology Faculty is a national group of oncologists from across Canada who gather, discuss and address gaps in knowledge, to develop education initiatives.

The vision of the CARE Oncology Faculty is to share opinions and update Canadian specialists with news and developments from key conferences framed in a Canadian perspective.

The mission of the CARE Oncology Faculty is to enhance medical education with the explicit goal of improving patient outcomes.

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2. Final overall survival (OS) analysis from the CLEOPATRA study of first-line (1L) pertuzumab (Ptz), trastuzumab (T), and docetaxel (D) in patients (pts) with HER2-positive metastatic breast cancer (MBC). Swan SM et al. Abstract 3500_PR. ESMO 2014
4. First results from the phase III ALTOO trial (BIG 2-06; NCT0 [Alliance] N063D) comparing one year of anti-HER2 therapy with lapatinib alone (L), trastuzumab alone (T), their sequence (T-L), or their combination (T+L) in the adjuvant treatment of HER2-positive early breast cancer (EBC). Piccart-Gebhart MJ et al. J Clin Oncol 32:5s, 2014 (suppl; abstr LBA4)

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