

chemotherapy use for the two countries with data on chemotherapy. Studying treatment details on population level in the current study was hampered by lack of data availability. A well conducted prospective study for metastatic gastric patients with special focus on quality of life is needed in the future.

**Conflict of interest:** No conflict of interest.

## Niall O'Higgins Best Abstracts Symposium

### Nial O'Higgins Award - Best Abstracts

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#### ELECTROCHEMOTHERAPY IN THE TREATMENT OF CUTANEOUS MALIGNANCY; OUTCOMES AND SUBGROUP ANALYSIS FROM THE CUMULATIVE RESULTS FROM THE PAN-EUROPEAN INSPECT DATABASE FOR 1478 LESIONS IN 691 PATIENTS (2008-2018)

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**Background:** Electrochemotherapy is a treatment for cutaneous tumors, both primary and secondary metastatic tumors. The international Network for sharing practices on Electrochemotherapy (INSPECT) group gathers information on treatment outcome in a common database with defined, outcome parameters in order to improve and guide the use of electrochemotherapy. This allowed cumulative analysis of the database over a 10 year period across the range of cutaneous histiotypes treated.

**Methods:** Twenty treatment centers across Europe participated. Treatment outcomes for 691 patients treated with electrochemotherapy for primary or secondary cutaneous tumors, with a follow-up of 45 days or more, were analyzed. Up to 7 tumor lesions were registered for each patient. Response rates were investigated in relation to primary diagnosis, tumor size, choice of electrode type and route of bleomycin administration, as well as previous irradiation in the treated lesions.

**Results:** In 691 patients, 1478 tumor lesions were treated and registered, and included in analysis. Across all histologies the overall response rate (OR) was 83% (complete response (CR) 68%, partial response rate (PR) 16%, stable disease (SD) 12%, and progressive disease 2%). For different histologies OR/CR rates were respectively: metastases of malignant melanoma 84%/67%; basal cell carcinoma 96%/81%, breast cancer metastases 74%/67%, for squamous cell carcinoma 78%/60% and Kaposi's sarcoma 97%/89%. Although response rates were uniformly high, variance was demonstrated across cancer histiotypes ( $p < 0.0005$ ) and according to size of lesion treated (greater or less than 3cm,  $p < 0.0005$ ). Hexagonal electrodes (hex) were generally used for larger tumors, but for tumors up to 3 cm it was shown that linear array electrodes (lin) provided better tumor control than hex electrodes (lin 82%, hex 73%,  $p < 0.0035$ ). Furthermore in tumors over 1 cm intravenous administration was superior to intratumoral administration ( $p < 0.0003$ ). In previously irradiated areas, responses were selectively lower for intratumoral administration. Responses were high regardless of current levels, re-iterating that electroporation is dependent on the field amplitude alone.

**Conclusions:** Electrochemotherapy is a viable option as part of the treatment algorithm for patients with cutaneous malignancy. These cumulative data endorse its efficiency across a broad range of histiotypes. An overall response rate of 83%, with a complete response rate of 67% was observed, with highest responses in basocellular carcinoma and Kaposi's sarcoma. This is the largest study on treatment of cutaneous metastases across tumor histologies, allowing detailed sub group analysis, and solidifying electrochemotherapy in context amongst the treatment options available for primary and secondary cutaneous malignancy.

**Conflict of interest other substantive relationships:** Data in the Inspect database belong to the member institutions, but the upkeep of the database is sponsored by the IGEA company. IGEA has also sponsored travel for meetings.

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#### COMPARISON OF CA125, HE4 AND ROMA TO DIFFERENTIATE MALIGNANT FROM BENIGN OVARIAN MASSES

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**Background:** CA 125, HE4 and ROMA are FDA approved test used in ovarian cancer management. Data regarding their role in differentiating malignant and benign ovarian masses suffers from heterogeneity in patient selection, test platform and cutoff values used. Better performed study would be crucial in order to assess the clinical utility of these tests.

**Methods:** This prospective study includes 188 patients presenting with ovarian masses. Serum CA 125 & HE4 levels were measured before surgery using Chemiluminescent Microparticle Immunoassay technology. ROMA values were calculated by algorithm. Histopathological correlation was done to study the ability of these tests to differentiate benign from malignant ovarian masses. Analyses were performed by the SPSS software (version 20.0). ROC curves, sensitivity, specificity and cutoff values were calculated.

**Results:** Total 58 benign and 130 malignant ovarian tumors were found. The values of CA 125, HE4 & ROMA were significantly higher in malignant compared to benign masses in both pre and postmenopausal group ( $p < 0.05$ ). In premenopausal females Z test showed similar diagnostic between the markers, CA 125 and HE4 (AUC: 0.965 vs. 0.938,  $Z = 0.72$ ,  $p = 0.474$ ), CA 125 and ROMA (AUC: 0.965 vs. 0.914,  $Z = 1.19$ ,  $p = 0.235$ ) and also in HE4 and ROMA (AUC: 0.938 vs. 0.914,  $Z = 1.17$ ,  $p = 0.240$ ). In postmenopausal females, Z test showed significantly higher diagnostic of ROMA compared to CA 125 (AUC: 0.901 vs. 0.975,  $Z = 2.15$ ,  $p = 0.032$ ) while not differed between CA 125 and HE4 (AUC: 0.901 vs. 0.975,  $Z = 1.55$ ,  $p = 0.122$ ), and HE4 and ROMA (AUC: 0.975 vs. 0.975,  $Z = 0.00$ ,  $p = 1.000$ ). In premenopausal females chances of malignancy was higher if CA 125 > 77 U/ml or HE4 > 62.1 and ROMA value of > 13.3% pmol/L was found. In postmenopausal females with CA 125 > 259 U/ml or HE4 > 124 pmol/L and ROMA value of > 76% had high chances of malignancy in ovarian masses.

**Conclusions:** Diagnostic accuracy of each test is different according to the menopausal status. Overall accuracy of these three markers in premenopausal female is similar. In postmenopausal females HE4 measurement in addition to CA125 and calculating ROMA value is beneficial. We suggest

using ROMA values in clinical practice in these patients especially in setting when there is discordance between clinical, radiological imaging and CA 125 values to appropriately manage the patients.

**Conflict of interest:** No conflict of interest.

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### MAPPING OF THE FUNCTIONAL ANATOMY OF LYMPHATIC DRAINAGE TO THE AXILLA IN EARLY BREAST CANCER: A COHORT STUDY OF 933 CASES

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**Background.** The aims of this study were to investigate the correlation between lymphatic drainage and the sentinel lymph node (SLN) status of the subregions in the context of the clinico-pathological parameters of the tumour and the coverage of the axillary volumes by standard and high tangential fields (STgF and HTgF) for whole breast radiotherapy and axillary reverse mapping (ARM).

**Materials and methods.** This was a retrospective study of prospectively collected data of 933 women with early breast cancer and clinically negative axillary status. Patients underwent breast surgery and sentinel lymph node biopsy (SLNB) followed by axillary lymph node dissection (ALND) in SLN-positive cases. The subregional localisation of the SLN(s) was identified and registered intraoperatively and completed with the clinic-pathological characteristics of the breast tumour afterwards. All recorded parameters were statistically analysed. In node-positive patients treated with breast-conserving therapy in whom the SLNs were found in the anterior or posterior axillary subregions (Level I), the axillary volumes (Levels I, II and III) were contoured using the Radiation Therapy Oncology Group contouring atlas (n=61). All patients (n=61) had 3D-conformal RT. The breast was irradiated with two opposing tangential fields with 6 MV photons. The STgF upper margin was generally the base ( $\pm 1$  cm) of the clavicle. HTgF consisted of a superior border placed at the inferior edge (or below maximum 2 cm) of the humeral head.

**Results.** None of the examined characteristics of the primary breast cancer had a significant correlation with the subregional localisation of the SLN. The correlation between the localisations of the positive SLNs and the breast tumour was significant ( $p=0.031$ ). In 91.1% (n=797) of the cases, the SLN appeared in the anterior, posterior or central subregions.

Using HTgF, Level I was completely included in the fields in 65.6% (40/61) of the cases. With STgF, the complete coverage was 0% (HTgF versus STgF,  $p<0.0001$ ). Using HTgF, Level II was completely included in the fields in 6.6% of the patients (4/61), but with STgF, the rate was 0% (HTgF versus STgF,  $p=0.1198$ ). The coverage of Level III was very poor.

A total of 281 (30.1%) SLNs were found within one of the apical, lateral or posterior subregions and 22.4% (n=63) of them were positive, meaning that 6.8% of all cases had one positive lymph node in the expected ARM lymph node regions.

**Conclusion.** A SLN is more than likely to be present in the anterior, posterior and central axillary subregions. Tangential fields allow only limited coverage of the axillary volumes. In some patients, using HTgFs with the accurate definition of axillary nodal levels ensures adequate coverage of Level I volume. Preserving the lateral subregion during ARM may increase the possibility of understaging.

**Conflict of interest:** No conflict of interest.

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### EORTC 1409 GITCG / ESO 01 - A PROSPECTIVE COLORECTAL LIVER METASTASIS DATABASE WITH AN INTEGRATED QUALITY ASSURANCE PROGRAM (CLIMB): PRIMARY ANALYSIS OF VARIATIONS IN

### EUROPEAN CLINICAL PRACTICES AND SURGICAL COMPLICATIONS AFTER COMPLEX LIVER METASTASIS SURGERIES

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**EORTC & ESO** developed an infrastructure for surgical quality assurance (QA) in clinical trials (SURCARE) to advance the surgical research agenda in Europe. The first project is CLIMB, a prospective study to benchmark practices for unresectable or borderline resectable colorectal liver metastasis (CRLM) surgery. Quality indicators included multidisciplinary team (MDT), use of biomarker testing, type of chemotherapy regimen, imaging used pre-surgery and complications rates.

CLIMB included 14 specialized centers in 9 countries. Eligible patients were registered after MDT & pre-surgery. Primary endpoint was 30 & 90 day surgical complication rate (Clavien-Dindo Classification). Onsite visits and central review ensured prospective data collection of current practices per country on biomarker testing, imaging, chemotherapy & liver surgery. Over all complication rates until post-op day 90 were analyzed. Trend of complications will be given to sites with at least 10 postop patients. Long-term outcome, correlation of complication with recurrences & overall survival will be reported when all patients will have been followed for 2 years after registration.

Among 210 patients registered, 126 (60%) who had at least one liver surgery were analyzed. 73% had left-sided or rectal primary tumor, 95.2% had synchronous primary and liver metastasis, 19.8% had extra-hepatic lesions and CRLM. An MDT with liver surgeon, oncologist and radiologist assessed patients with a median of 30.5 days from last MDT to surgery. AT, FR, BE, DE, ES performed biomarker testing for 70-100% of their patients while < 40% was done in NL or SW. 122 (96.8%) received pre-surgery chemotherapy with a median duration of 4.9 months. Among those, 86.9% used only 1 regimen, usually FOLFOX. Only 65.1% received targeted therapy, with >70% from BE, FR, AT and ES in contrast to SW with only 5.6%. Median time interval of last pre-surgery imaging was 34.5 days. Among those with pre-surgery image data (87.7%), 54.1% received less than CT scan with MRI while 45.9% received at least CT with MRI (mostly in AT & NL). Most patients (N = 95, 75.4%) had one stage liver surgery while 30 (23.8%) had two stage liver surgery, 10 of whom had ALPSS. Over-all complication rates for one stage surgery were 53.7% (95% CI 43%- 64%), 17.9% (95% CI: 11%-27%) with grade $\geq 3$  and 93.3% (95% CI: 78%- 99%) for two stage surgery, 46.7% (95% CI: 28%- 66%) with grade $\geq 3$  including two deaths. Infections, bile leak, post hepatectomy liver failure grade A, fluid retention and anemia were most commonly reported.

**CLIMB** prospectively collected data on upfront unresectable CRLM surgery. Two-stage surgery had more Clavien-Dindo grade $\geq 3$  complications. Harmonizing standards in MDT evaluation, biomarker testing and imaging may improve outcomes. **SURCARE** will use these indicators to develop trials with enhanced QA methods to improve cancer surgery.

**Conflict of interest:** No conflict of interest.