groups was 5 mg. 35/54 AM patients (64.8%) developed stomatitis of any grade (CTCAE grade 1 27.8%; grade 2 20.4%; grade 3 11.1%) compared with 13/23 AM+S patients (56.5%) (CTCAE grade 1 30.4%; grade 2 17.4%; grade 3 8.6%); $P = 0.49$. There was no difference between the frequency of grade 2–3 stomatitis between the AM group (31.5%) and the AM+S group (26.1%); $P = 0.67$. Stomatitis was an early toxicity in both groups, occurring during cycle 1 in almost 70% of patients in the AM group and the AM+S group. Everolimus was discontinued due to stomatitis in 12% of patients in both groups.

Conclusion: The addition of a betamethasone mouthwash did not reduce the rate of everolimus-related stomatitis. The rate of grade 2–3 stomatitis was significantly higher in our study (26.1%) than reported in the SWISH clinical trial with the dexamethasone mouthwash (2%). This audit highlights the significant challenges that still exist with administering everolimus in the real-life clinical setting.

References

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A Real-world Analysis of the Treatment of HER2+ Metastatic Breast Cancer (mBC) Beyond First-line HER2-directed Therapies

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Purpose: The treatment of HER2+ mBC is clinically challenging and treatment algorithms continue to be updated based on clinical trial outcomes. Challenges to treatment sequencing include prior exposure to HER2-directed therapies, including exposure in the neoadjuvant/adjuvant setting. We interrogated our Sussex Cancer Network mBC dataset to determine real-world patterns in HER2+ disease responses.

Methods: Clinical coding was used to identify patients treated by the breast oncology team for HER2+ mBC between 2014 and 2017. Clinical notes, radiology and chemotherapy e-prescribing records were used to collect histopathological, treatment and survival data.

Results: In total, 86 patients were treated for HER2+ mBC, of which 34.8% ($n = 30$) presented with *de novo* HER2+ mBC. In the first-line setting, 79% of patients ($n = 68$) received HER2-directed therapies, of which 51% ($n = 35$) received docetaxel/trastuzumab/pertuzumab, 38% ($n = 26$) received other cytotoxic agents, i.e. paclitaxel, capecitabine, vinorelbine, and the remaining 11% ($n = 8$) received endocrine treatment in combination with HER2-targeted therapies. Patients received a median of 2.5 lines (1–8) of treatment. Sixty per cent ($n = 52$) received second-line therapies on progression, of which chemotherapy in combination with HER2-directed therapies (57.6%, $n = 30$) and endocrine-only (21%, $n = 11$) were the most commonly used treatment modalities. The median overall survival for this HER2+ patient group was 34 months. Survival analysis indicates that continuity of systemic therapy correlates with median overall survival, i.e. one line (15.5 months, $n = 31$), two to three lines (26.7 months, $n = 33$) and more than three lines (38.8 months, $n = 20$). Interestingly, a difference in median overall survival was observed between patients with *de novo* mBC (44.4 months, $n = 30$) when compared with patients previously treated for early breast cancer (19.5 months, $n = 56$), suggesting that disease recurrences following exposure to trastuzumab may be associated with poorer outcomes influenced by alternate pathways of resistance.

Conclusion: This analysis indicates that continuing beyond three lines of treatment may be beneficial to overall survival, while contributing to the argument that treatment plans for HER2+ mBC need to be individualised, factoring in the timeline of previous exposure to HER2-targeted therapies. Predictive biomarkers could play a role in predetermining resistance/response and aid in rationalising treatment plans. Our onward analysis will assess the influence of the hormone receptor status in the treatment responses of HER2+ mBC.

Prospective Observational Study in Patients with Metastatic Breast Cancer Involving the Central Nervous System (PRIMROSE)

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Purpose: Central nervous system (CNS) involvement from breast cancer is an increasing clinical problem and is associated with a poor prognosis. Incidence of CNS metastasis and response to treatment varies by breast cancer subtype and no breast cancer-specific CNS metastasis guidelines currently exist to help guide management. Treatment options include surgery, stereotactic and whole brain radiotherapy, systemic and intrathecal therapies. There is a need to understand how current treatment paradigms affect CNS metastasis outcomes across subtypes, and generate data to inform future practice guidelines.

Methods: This prospective, multicentre observational study aims to register patients diagnosed with CNS involvement secondary to breast cancer throughout the UK and will collect data relating to the primary breast cancer and extracranial metastatic disease, presentation and diagnosis of CNS metastasis and CNS-directed treatment outcomes. The primary outcome is measurement of overall survival from the time of diagnosis of CNS metastasis. Secondary outcomes include prevalence of brain metastasis by subtype and progression-free survival (local/brain relapse versus relapse at other sites) following therapy. Inclusion criteria are female or male patients with breast cancer of any subtype, with histologically or radiologically confirmed breast cancer involving the CNS or diagnosis of a paraneoplastic syndrome. This is a trainee-led study involving specialist registrars training in medical oncology, clinical oncology, pathology and neurosurgery. Study sites cover major cancer centres and peripheral centres throughout the UK. The study will be registered at individual sites according to local trust policy. Subjects will be identified via breast cancer clinical teams, acute oncology services, neuroradiologists, neurosurgical multidisciplinary teams and radiotherapy referrals. Data will be recorded and stored on a centralised data system, RedCap, in compliance with ICH-GCP. Data collection will start early 2019 and the first database lock for evaluation of number and data spread will be carried out after 8 months.

Results: N/A (study in progress).

Conclusion: N/A (study in progress).

Role of Primary Chemotherapy in Women with Biopsy-proven Lymph Node-positive Breast Cancer

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Purpose: Women with lymph node-positive early breast cancer who achieve a good response to primary chemotherapy could potentially avoid axillary node clearance (ANC) and proceed to sentinel lymph node biopsy (SLNB) [1]. This would reduce the risk of significant lymphoedema. We have previously reported response rates in the axilla following primary chemotherapy in our population [2]. We now report on 30 patients who had a marker clip inserted in the lymph node prior to primary chemotherapy. At the time of breast surgery, patients either underwent ANC or SLNB with at least three lymph nodes removed, including the marker clip, to enable accurate assessment of response.

Methods: This was a retrospective single-centre study. We examined the records of all patients, through the Guy's Breast Cancer Database and chemotherapy prescribing system, who had node-positive breast cancer, marker coil in the axilla and primary chemotherapy from October 2016 to October 2017.

Results: We identified 30 patients with lymph node-positive disease, who had primary chemotherapy. At the time of surgery, 7/30 had a pathological complete response (pCR) in the axillary lymph node. Of these, 5/7 patients