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Problem statement: Recruitment to de-escalation trials is challenging because of strong patient and clinician preferences and worry around 'under-treatment'. ATNEC is a phase III, randomised (1:1), multi-centre trial to assesses whether axillary treatment can be de-escalated, post-surgery, in T1-3N1M0 breast cancer patients who have no residual nodal disease post-neoadjuvant chemotherapy. Understanding why patients do/do not wish to participate is important as it can influence recruitment strategies.
Methods: ATNEC has registered 168 patients of which 58 have been randomised against the 1900 target. The patient experience sub-study uses semi-structured interviews to explore how patients process information about the trial and their decision to take part.
Results: Fifteen trial participants have been interviewed and talked openly about their personal cancer pathway and their decision-making process regarding the trial.
Initial analysis suggests that participation is often altruistic:
'…there wasn't really much of a decision to make…. I just thought to myself, well, anything that I can do to try and help people in the future then…. why wouldn't I do that? *[TNO 0001]*
Understanding of lymph nodes and axillary treatment ranges from a little:
Interviewer: *'And before that did you have any understanding of why……they might want to take out lymph nodes from under your arm?'* Participant: *'Uh, I think I'm gonna say no to that.' [TNO 0011]*
to a lot:
'…what I understood from that was the lymph nodes are really, really good at holding on to the cancer for like a really long time.' *[TNO 0001]*
All participants interviewed who have been randomised to no further axillary treatment have said they are happy with this allocation. One participant randomised to receive axillary radiotherapy is concerned about potential side-effects: *'I'm having great reservations about going ahead and having radiotherapy.' [TNO 0035]*
Conclusion: Patients taking part in the ATNEC trial do not appear to be worried about de-escalation of treatment. Apart from altruism, a reduction of potential treatment side-effects is a key motivating factor for participation. Patients who decline randomisation may have a preconceived treatment preference possibly guided by initial contact with the clinical team; exploring information exchange and understanding is key to successful recruitment.

MONITORING OF BREAST CANCER TREATMENT RESPONSE BY ANALYSIS OF BREAST CANCER-DERIVED EXTRACELLULAR VESICLES

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Funding source: NSW Cancer Council Grant
Problem statement: Extracellular vesicles (EVs) are nanoscale biomaterials used for cell-to-cell communication where signals for proliferation and resistance are passed between tumour cells and their environment. EVs may therefore be a powerful circulating tumour marker that can be used to predict and monitor for treatment response and resistance. However, due to technical challenges, limited clinical studies have been performed to date to validate the utility of EVs as a tumour marker.
Methods: We developed a novel portable microfluidic device that overcomes significant technical challenges of EV analysis. It is a portable microfluidic chip where EVs can be simply pulled from the blood and subsequently analysed on-chip. The whole process takes less than an hour. Breast cancer patients from St Vincent's Hospital Melbourne are enrolled into the study. Bloods from pre-, during- and post- systemic or surgical therapy are collected and have their EVs analysed.
Results: The level of breast cancer derived EVs from patients 1-week post curative surgery dropped significantly, demonstrating the utility of using EVs as a monitoring tool for disease burden. It may be used clinically to monitor for disease response in treatment monitoring group and disease recurrence in the surveillance group. As well as concentration, EVs' phenotype also changed during systemic therapy, indicating the possibility of using EVs to monitor for treatment resistance.
Conclusion: This study demonstrated the utility of using EV as a tumour marker to monitor breast cancer treatment response. It also validated the novel microfluidic device as an accurate tool for EV capture and analysis. The portable nature of the device means EV analysis may be performed by any pathology lab and not limited to tertiary centres. With longer term study, we aim to identify unique EV changes associated with treatment resistance.

ENHANCED TOXICITY WITH TRASTUZUMAB EMTANSINE AND CONCURRENT ADJUVANT RADIOTHERAPY: NON-CONSECUTIVE CASE SERIES

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Background: Trastuzumab emtansine (T-DM1) has recently been approved for adjuvant treatment in patients with HER2-positive early breast cancer with residual invasive disease after receiving neoadjuvant chemotherapy plus HER2-targeted therapy. Many of these patients are likely to also undergo adjuvant radiotherapy treatment (RT) however there is little published data regarding the safety of these concurrent therapies.
Case presentation: We now report on 5 cases at our institution where enhanced radiotherapy toxicity was observed when adjuvant RT was delivered during treatment with T-DM1. Cases 1, 2 and 3 experienced varying degrees of enhanced pulmonary toxicity inclusive of early onset radiation pneumonitis, recurrent radiation pneumonitis despite appropriate treatment, and out of field radiation pneumonitis.
Cases 4 and 5 experienced unexpected skin toxicity. With one case of prolonged radiation dermatitis followed by telangiectasia formation and one case of breast cellulitis requiring hospital admission.
Discussion: This further supports the hypothesis that T-DM1 may actually be a radiation sensitiser due to its microtubule inhibitor emtansine component. Further studies are recommended to assess the potential toxicities when combining these treatments. We advise clinicians to remain vigilant of unexpected toxicities and consider the potential risks in patient management of adjuvant RT when combined with T-DM1.