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Standard dosing and delivery of Nal-IRI + 5-FU/LV

Hi. This is Dr. Wang-Gillam. I will be talking about a new drug that is approved in pancreas cancer, that is nanoliposomal irinotecan (nal-IRI) in patients who progressed in gemcitabine-based regimens. Based on the NAPOLI-1 study, nanoliposomal irinotecan plus 5-FU/leucovorin (5-FU/LV) has resulted in superior overall survival compared to 5-FU/leucovorin alone. In patients who progressed on gemcitabine-based regimens, the overall survival was 6.1 months with a combination regimen compared to 4.2 months in the 5-FU/leucovorin arm. The regimen was given every two weeks with 5-FU/leucovorin 2400 mg/m^2 over 46 hours and nal-IRI 70 mg/m^2. There is no 5-FU bolus in this regimen. The side effects include neutropenia, but more commonly was diarrhea, vomiting, nausea, decreased appetite, and hypokalemia. This is also along the typical side effects we see with irinotecan. I do check patients UGT1A1 genotype. If a patient has 7/7 genotype, nal-IRI will be starting as one level dose reduction, which will be 50 mg/m^2. If patient tolerates it well, that drug can be dose-escalated to full dose. I think those patients need to be closely monitored for their GI symptoms, including aggressively supporting their IV hydration and potassium. Overall, it is a tolerable regimen that has evidence supporting the use in patients who progress on a gemcitabine-based regimen.