ABSTRACTS

RESEARCH Podium Presentations

Podium Session I: Cancer Outcomes Research

C01 Stats and colorectal cancer: is there a link?

Clancy Z1, Keith SW2, Rabiniwicz C3, Gagne J4, Maio V5

1Thomas Jefferson University, Philadelphia, PA, USA; 2Brigham and Women’s Hospital, Harvard Medical School, Boston, MA, USA

OBJECTIVES: Studies evaluating the association between statins and colorectal cancer (CRC) have used various methods to address bias and have reported mixed findings. We sought to assess the association in a large cohort of residents in Emilia-Romagna, Italy, using multiple methods to address different sources of confounding. We also sought to explore potential effect measure modification by sex.

METHODS: We conducted a retrospective population-based new-user cohort study using the 2003-2010 longitudinal healthcare database of Emilia-Romagna, Italy. This comprehensive database contains information on healthcare services rendered to the population, including hospital, outpatient pharmacy and specialty data. We identified all initiators of statins; initiators of glucocorticosteroids served as the comparison group to account for confounding by healthy user bias. We followed patients longitudinally to identify CRC cases in hospital discharge data. We used multivariable Cox regression analyses to adjust for confounding by CRC risk factors and we conducted a sensitivity analysis using propensity score matching and inverse probability of treatment weighting among those who received statins.

CONCLUSIONS: Reflecting a crude incidence rate of 222.2 cases per 100,000 person-years. After multivariable adjustment, initiators of statins had a lower incidence rate of CRC than compared to initiators of glucocorticosteroids (hazard ratio, 0.79; 95% CI, 0.69 to 0.90). In sex-stratified analyses we observed a protective effect in men (hazard ratio, 0.77; 95% CI, 0.67 to 0.88) but not in women (hazard ratio 0.96; 95% CI, 0.82 to 1.1). Results were similar in propensity score analyses.

C02 Development of a patient-reported outcome instrument in brain metastases: the brain metastases symptom and impact questionnaire (BASIQ)

Lasch KE1, Ganguli A2, Bonthapally V2, Pompilus F1, Delbecque L1, Fitzgerald K1, Ray S2

1Abbott Laboratories, Abbott Park, IL, USA; 2Brigham and Women’s Hospital, Harvard Medical School, Boston, MA, USA

OBJECTIVES: Patient-reported outcomes (PRO) instruments currently used for patients with brain metastases (BM) have not been developed with adequate patient input from the appropriate population. The objective of this study was to develop a new PRO in this population. METHODS: The BASIQ was developed according to the FDA PRO Guidance. A literature review, seven expert interviews, and 19 in-depth interviews with BM patients were conducted to identify the symptoms and impacts of BM important to this population and generate an initial version of the BASIQ. Twenty face-to-face cognitive interviews (CIs) were conducted to assess the content validity of the BASIQ and to assess the understandability, relevance, wording, and importance of items and, if necessary, revise it. RESULTS: The initial 23-item BASIQ included a 7-item event log with a yes/no response (assessing vision, reading, nausea, numbness, needing to stay in bed, falling, fainting), 7-item daily symptom section (assessing severity of headache, memory, balance, physical weakness, dizziness, tiredness, energy) on an 11-point NRS, and a 9-item impact section (assessing performing certain words, putting ideas into words, staying focused on a topic, walking, understanding words read/heard, following a story in a book/on TV, doing things around the house, bathing, dressing). During the CIs, most of the patients reported that the instrument was easy to understand, of adequate length and format and did not contain any difficult words. Based on the CIs, items were deleted, modified, or included as impacts rather than symptoms. A revised 18-item BASIQ used a 24-hour recall period and an 11-point NRS assessing severity. CONCLUSIONS: Robust qualitative methods used to identify the symptoms and impacts of patients with BM led to the development of a much needed PRO measure in BM. Additional qualitative and quantitative research is planned to further support the use of the tool in clinical research.