

first-line advanced or metastatic NSCLC. **METHODS:** A systematic literature review identified randomized controlled trials (RCTs) reporting PFS for bevacizumab-based and doublet-chemotherapy combinations. Studies were evaluated for comparability of design and patient population. Reported PFS hazard ratios (HR) were analyzed simultaneously with a Bayesian mixed treatment comparison. The base-case analysis compared BCG and BCP with grouped platinum-based doublets (PLD) and grouped nonplatinum-based doublets (NPLD). Scenario analyses explored BCP and BCG versus different combinations of doublet treatments. **RESULTS:** Eight identified RCTs, considered comparable in design and patient characteristics, allowed for a comparison between bevacizumab-based therapies and grouped doublet-chemotherapy combinations. The expected PFS HRs relative to PLD, for BCP, BCG, and NPLD were 0.66 (95% interval: 0.57; 0.77), 0.80 (0.71; 0.89), and 1.05 (0.92; 1.19), respectively. BCP and BCG were ranked as the top two most efficacious treatments in terms of PFS across all included regimens. Scenario analyses confirmed the top ranking for BCP and BCG. When BCP and BCG were compared to individual doublet chemotherapies, BCP showed the greatest benefit (HR of 0.63 [0.45; 0.88]), followed by BCG 7.5 mg/kg (0.75 [0.64; 0.87]) and BCG 15 mg/kg (0.85 [0.73; 0.99]). Further analyses confirmed the robustness of the findings. **CONCLUSIONS:** Compared to all available doublet-chemotherapy combinations, bevacizumab-based therapy is expected to be more efficacious in terms of PFS, and could therefore be considered as the first treatment option in advanced or metastatic NSCLC.

**PCN17**

**NO CONCLUSIVE EVIDENCE FROM RANDOMIZED CONTROLLED TRIALS (RCTS) FOR IMPROVED SURVIVAL WITH SECOND-LINE TREATMENT OPTIONS, IN PATIENTS WITH METASTATIC HORMONE-REFRACTORY PROSTATE CANCER (MHRPC) PREVIOUSLY TREATED WITH DOCETAXEL**

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**OBJECTIVES:** A docetaxel (D)-based regimen is recommended first-line treatment for mHRPC patients. Currently, there are no recommended second-line treatments for D pretreated patients. This study sought to identify phase II and III RCTs of second-line treatments for mHRPC in D pretreated patients to provide information regarding survival. **METHODS:** PubMed and Embase were used to perform a systematic literature review (2000–2009). Primary and secondary efficacy end points were extracted. Safety outcomes were reviewed according to grade. **RESULTS:** Among 52 records screened, three trials were included and 47 were excluded (35 not clinical trials; four not second line to D; eight not comparative or randomized). Primary end points included overall survival (OS), progression-free-survival (PFS), PSA response rate, and objective tumor response (OTR). A phase III study comparing satraplatin plus prednisone (SP) to prednisone (P) alone (n = 950, 51% post-D) was identified. Two phase II trials compared ixabepilone (ixa) with mitoxantrone plus prednisone (MP) (n = 82), and curstisen in combination with prednisone plus D (DPC) versus curstisen plus MP (MPC) (n = 42). SP demonstrated significant improvements compared to P in PSA response (25% vs. 12%,  $P < 0.001$ ), OTR (7% vs. 1%,  $P < 0.002$ ), and pain response (24% vs. 14%,  $P < 0.005$ ). Median PFS (11 weeks vs. 9.7 weeks), but median OS (66.1 weeks vs. 62.9 weeks) were similar. In the second trial (Ixa vs. MP), there was no significant improvement in either PSA response (17% vs. 20%) or OS. In the third trial, PSA response was better for DPC than MPC (40% vs. 27%); no OS data reported. Grade 3 or 4 neutropenia occurred in 54% and 63% with Ixa and MP respectively. **CONCLUSIONS:** This review found a limited number of published phase II and III RCTs second-line treatments for mHRPC in D pretreated patients. None demonstrated a survival benefit. Results should be interpreted with caution in terms of clinical benefits.

**PCN18**

**RETROSPECTIVE DATABASE ANALYSIS OF THE EFFECT OF ZOLEDRONIC ACID ON SKELETAL-RELATED EVENTS IN MEN WITH PROSTATE CANCER AND BONE METASTASES**

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**OBJECTIVES:** Patients with bone metastases from prostate cancer (PC) are at risk for skeletal-related events (SREs) including pathologic fracture, spinal cord compression, the need for radiotherapy or surgery to bone, and hypercalcemia of malignancy. Zoledronic acid (ZOL), an intravenous bisphosphonate (IVBP), has proven efficacy for reducing the incidence and delaying the onset of SREs in multiple tumor types. This retrospective study was designed to assess the fracture risk in patients receiving ZOL or no treatment, and to examine the benefit of long-term ZOL use in a real-world setting among men with PC and bone metastases. **METHODS:** Commercial and Medicare Advantage databases were used to evaluate fracture rates and medication persistence. Patients included in this analysis were  $\geq 18$  years old, had PC and bone metastasis diagnosed between January 1, 2001 and December 31, 2006, were continuously enrolled in the health plan, and had no evidence of bone metastasis or IVBP for 6 months before first infusion of ZOL. Patients were followed until discontinuation (including mortality) or study completion. Fractures were categorized as vertebral, hip, or other nonvertebral fractures. Persistence was defined as the absence of a >45-day gap between ZOL treatments. **RESULTS:** Among 4976 men (mean age, 70.9  $\pm$  9.7 years), approximately 26% received ZOL and 74% received no IVBP. Regardless

of fracture site, ZOL reduced the fracture rate compared with no IVBP (5.9 vs. 8.5 per 100 person-years;  $P = 0.0003$ ). Longer persistency with ZOL was associated with a reduced fracture rate (trend test,  $P = 0.0179$ ). The mortality rate was also significantly lower in ZOL patients versus patients receiving no IVBP (6.2 vs. 9.4 per 100 person-years;  $P = 0.0018$ ). **CONCLUSIONS:** In men with bone metastases from PC, ZOL was associated with a significantly lower fracture rate and mortality compared with no IVBP. Furthermore, longer persistency with ZOL was associated with a lower fracture rate.

**PCN19**

**SYSTEMATIC REVIEW OF ENDOSCOPIC SUBMUCOSAL DISSECTION VERSUS ENDOSCOPIC MUCOSAL RESECTION FOR EARLY GASTRIC CANCER**

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**OBJECTIVES:** Endoscopic submucosal dissection (ESD) allows en bloc resection of the entire lesion which permits higher curative resection rate, lower local recurrence, and consequently, increases quality of life by minimizing the resection size compared to endoscopic mucosal resection (EMR). While ESD has been implemented in most university hospitals in Korea currently, potential complications of ESD like hemorrhage and perforation waver over the therapeutic decision on the ESD for early gastric cancer patients as well as the reimbursement decision-making. The study aims to address both effectiveness and safety outcomes of ESD versus EMR in early gastric cancer by systematic review. **METHODS:** MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and Koreamed were searched using primary key words: "stomach neoplasm" and "endoscopic submucosal dissection" and "endoscopic mucosal resection." To assess the quality of selected studies, the methodological approach of Scottish Intercollegiate Guidelines Network were used. Five effectiveness-relevant and three safety-relevant outcome measures were extracted. Bibliography management and meta-analysis for each outcome were conducted using Review Manager 5.0. **RESULTS:** Three nonconcurrent cohort studies and nine retrospective cohort studies were identified. Meta-analyses showed significantly greater effectiveness of ESD as compared to EMR for en bloc resection (OR = 8.43, 95% CI: 5.20–13.67), complete resection (OR = 8.54, 95% CI: 4.44–16.45), curative resection (OR = 2.56, 95% CI: 1.68–3.91), local recurrence (RR = 0.13, 95% CI: 0.04–0.40), and all-cause mortality (RR = 0.65, 95% CI: 0.08–5.38). While intraoperative bleeding (RR = 2.16, 95% CI: 1.14–4.09) and perforation risk (RR = 3.58, 95% CI: 1.95–6.55) were significantly greater for ESD, overall bleeding risk (RR = 1.22, 95% CI: 0.76–1.98) and longer resection time (RR = 1.55, 95% CI: 0.74–2.37) were not significantly different between ESD and EMR. **CONCLUSIONS:** Considering bleeding risk was not significantly different between ESD and EMR, and the perforation risk usually does not lead to life-threatening disease, the effectiveness benefit of ESD can outweigh the overall harm compared to EMR on condition that ESD was performed by surgeons with certain experiences.

**PCN20**

**MAINTENANCE ERLOTINIB VERSUS PEMETREXED FOR THE TREATMENT OF NON-SMALL CELL LUNG CANCER: INDIRECT COMPARISON APPLYING REAL-LIFE OUTCOMES**

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**OBJECTIVES:** Recent clinical trials have established superior efficacy of both erlotinib and pemetrexed as first-line maintenance therapies for metastatic non-small cell lung cancer (mNSCLC) over placebo. Results indicated that erlotinib improved survival for all histology types and pemetrexed improved survival in nonsquamous patients. To date, there have been no head-to-head trials directly comparing the two agents. An indirect comparison analysis was performed to examine the relative efficacy of these two treatment regimens as maintenance treatment options following platinum-based first-line therapy. **METHODS:** An adjusted-matched indirect analysis approach was used to compare overall survival (OS) estimates in mNSCLC patients treated with erlotinib from SATURN versus pemetrexed patients from JMEN. Patient distributions of key characteristics between the two studies were unbalanced; JMEN trial patients had a better prognosis at baseline. Patient distributions observed in the pemetrexed study for race and smoking status were used to match erlotinib-treated patients using patient-level data from the SATURN trial, employing an adjusted matching approach to make the populations more comparable. A distribution of survival outcomes was derived from each of 1000 repeated random matching samples of the SATURN data, with 95% confidence intervals (CI) around the mean of the aggregate of all observed median OS survival estimates generated by ordering the outcome measures and identifying the 2.5 percentile observations. To indirectly compare treatments, the median ratio (MR) for OS was calculated to approximate the hazard ratio. **RESULTS:** The estimated median OS after adjusted-matching was 13.9 months (95% CI 10.9–16.8) for erlotinib, compared with the published median OS reported for pemetrexed of 13.4 months (95% CI: 11.9–15.9). Erlotinib patients had similar median OS compared to pemetrexed patients with an MR of 0.96 (0.95, 1.09). **CONCLUSIONS:** Erlotinib and pemetrexed are similarly efficacious in first-line maintenance NSCLC differing in other parameters than efficacy such as tolerability, administration, and patient convenience.