Nivolumab治疗化疗后进展的晚期食管鳞状细胞癌患者的疗效分析：一项单臂回顾性研究

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Title: **The efficacy of Nivolumab in patients with chemotherapy-refractory metastatic esophageal squamous cell carcinoma:A single-arm retrospectively study**

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摘要: 目的:回顾性分析PD-1单抗（Nivolumab）在化疗后进展的晚期食管鳞癌患者中的疗效及安全性。方法：研究入组化疗后进展的食管鳞状细胞癌患者接受Nivolumab单药治疗，3 mg/kg，静脉输注大于30分钟，每2周重复一次，治疗至疾病进展或不能耐受。主要研究终点为客观缓解率（ORR）及安全性，次要研究终点为无进展生存（PFS）和总生存（OS）。结果：2016年1月至 2018年1月，共27例患者接受了Nivolumab单药的治疗,客观缓解率（ORR）为7%，疾病控制率（DCR）为63%。治疗相关1-2级不良反应及发生率为：皮疹4例（15%）、转氨酶升高3例（11%）、肺炎3例（11%）、腹痛2例（7%）、腹泻2例（7%）、高胆红素血症2例（7%）、皮肤血管瘤2例（7%）、甲状腺功能减退2例（7%）、血肌酐升高1例（4%）。3-4级不良事件及发生率分别为：皮肤血管瘤1例（4%）、咳嗽1例（4%）、血小板减少1例（4%）及贫血1例（4%）。未观察到与治疗相关死亡事件的发生。中位无进展生存（mPFS）为2.8月（95%CI：2.2~3.4月），中位总生存（mOS）为5.6月（95%CI：4.1~7.1月）。结论：免疫检查点抑制剂Nivolumab在化疗后进展的晚期食管鳞癌的治疗中，疾病控制率高，不良事件发生率低，可作为食管鳞癌患者后线治疗的选择进一步探索。

Abstract: Objective:To analyze the safety and efficacy of programmed death receptor-1 monoclonal (Nivolumab) in patients with metastatic esophageal squamous cell carcinoma who were confirmed progressionafter chemotherapy.Methods:Patients with metastasis esophageal squamous cell carcinoma who experience disease progression after chemotherapyreceived the treatment of Nivolumab,3 mg/kg,intravenous infusion over 30 minutes,repeated every 2 weeks,until disease progression or intolerance.The primary endpoints wereobjective response rate (ORR) and safety.The secondary endpoints were progression-free survival (PFS) and overall survival (OS).Results:From January 2016 to January 2018,a total of 27 patients met the criteria.They received Nivolumab as subsequent treatment.The objective response rate (ORR) and disease control rate (DCR) was 7% and 63%,respectively.Treatment related grade 1-2 adverse eventswere rash(15%),elevated transaminase (11%),pneumonia (11%),abdominal pain (7%),diarrhea (7%),hyperbilirubinemia (7%),cutaneous hemangioma (7%),hypothyroidism (7%) and hypercreatinemia (4%).Grade 3-4 treatment related adverse events included cutaneous hemangioma (4%),cough (4%),thrombocytopenia (4%) and anemia (4%).No treatment-related death was observed.The median progression-free survival (mPFS) and median overall survival (mOS) was 2.8 months (95%CI:2.2~3.4 months) and 5.6 months (95%CI:4.1~7.1 months).Conclusion:Nivolumabhad high disease control and low incidence of adverse events in chemotherapy-refractory metastatic esophageal squamous cell carcinoma.It could be an effective and safetreatment option for patients with advanced esophageal squamous cell carcinoma.And further exploration is essential in the future.

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