**紫杉醇脂质体联合免疫治疗晚期非小细胞肺癌的真实世界研究**

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表 1. 疾病情况 (n=100)

| 参数 | 全部(n=100) |
| --- | --- |
| 年龄(年), 平均数±SD | 64.2±8.5 |
| 性别，n(%) |  |
| 男 | 98(98.0%) |
| 女 | 2(2.0%) |
| 病理结果, n (%) |  |
| 鳞状细胞癌 | 85(85.0%) |
| 腺癌 | 4(4.0%) |
| 非小细胞癌 | 11(10.0%) |
| TNM分期, n (%) |  |
| IIIB | 32(32.0%) |
| IIIC | 5(5.0%) |
| IVA | 18(18.0%) |
| IVB | 45(45.0%) |
| EGFR, n (%) |  |
| 阴性 | 39(39.0%) |
| 阳性 | 0(0.0%) |
| NA | 61(61.0%) |
| ALK, n (%) |  |
| 阴性 | 38(38.0%) |
| 阳性 | 0(0.0%) |
| NA | 62(62.0%) |
| 紫杉醇脂质体用药周期, n (%) |  |
| 平均数(周期)±SD | 3.5±1.3 |
| 2 | 30(30.0%) |
| 3 | 19(19.0%) |
| 4 | 31(31.0%) |
| 5 | 12(12.0%) |
| 6 | 6(6.0%) |
| 7 | 1(1.0%) |
| 8 | 1(1.0%) |
| 紫杉醇脂质体剂量 |  |
| 紫杉醇总剂量(mg), median (IQR) | 720.0, (510.0, 1080.0) |
| 联合免疫用药种类, n (%) |  |
| 替雷利珠单抗 | 60(60.0%) |
| 帕博利珠单抗 | 19(19.0%) |
| 信迪利单抗 | 14(14.0%) |
| 卡瑞利珠单抗 | 4(4.0%) |
| 度伐利尤单抗 | 2(2.0%) |
| 特瑞普利单抗 | 1(1.0%) |
| 联合化疗的铂类, n (%) |  |
| 卡铂 | 91(91.0%) |
| 奈达铂 | 4(4.0%) |
| 顺铂 | 3(3.0%) |
| NA | 2(2.0%) |
|  |  |
| 联合免疫用药周期数, n (%) |  |
| 平均数(周期) ±SD | 3.4±2.4 |
| 1 | 13(13.0%) |
| 2 | 32(32.0%) |
| 3 | 25(25.0%) |
| 4 | 10(10.0%) |
| 5 | 7(7.0%) |
| 6 | 2(2.0%) |
| 7 | 3(3.0%) |
| 8 | 2(2.0%) |
| 9 | 2(2.0%) |
| 10 | 2(2.0%) |
| 12 | 2(2.0%) |
| 最佳疗效, n (%) |  |
| CR | 4(4.0%) |
| PR | 43(43.0%) |
| SD | 28(28.0%) |
| PD | 3(3.0%) |
| NA | 22(22.0%) |
|  |  |

表2平均随访时间

|  |  |  |  |
| --- | --- | --- | --- |
| 平均随访时间 |  | | |
| 平均数(月)±SD | | 9.8±5.1 |

表 3 肿瘤客观最佳疗效评价

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| CR | PR | SD | PD | ORR(95%CI) | DCR(95%CI) |
| 4(5.1%) | 43(55.1%) | 28(35.8%) | 3(3.8%) | 60.2(50.2-69.1) | 91.5(83.7,95.2) |

图1 PFS曲线[[1]](#footnote-1)

图表

描述已自动生成

表4. 中位生存分析

|  |  |
| --- | --- |
| 生存分析 |  |
| 中位生存月份(95%CI） | 11月(8.9,16.8) |

表5. 风险比(HR) 表格：

|  |  |  |
| --- | --- | --- |
|  | HR(95%CI)2 | P Value3 |
| 年龄(不大于64或大于64) | 2.07(1.07,3.99) | 0.029 |
| 性别(男或女) | 1.73(0.22,13.60) | 0.615 |
| 病理结果(鳞状或非鳞状) | 1.33(0.63,2.82) | 0.468 |
| TNM分期(III期或IV期) | 2.53(1.16,5.53) | 0.027 |
| 是否卡铂(卡铂或非卡铂) | 2.74(9.91,9.91) | 0.124 |
| ORR(到达或未到达) | 0.86(0.38,1.94) | 0.750 |
| 最大用药周期(不大于3或大于3) | 0.57(0.26,1.20) | 0.155 |
| 紫杉醇剂量(不大于794或大于794) | 0.41(0.16,1.04) | 0.065 |
| 联合免疫用药周期数(不大于3或大于3) | 1.23(0.51,2.93) | 0.573 |

\*重点事件是所有患者的PFS

表6. 不良反应总结

|  |  |  |  |
| --- | --- | --- | --- |
|  | 例次 | 人数 | 发生率(%) |
| 所有AE | 403 | 91 | 91% |
| 大于等于3级AE | 69 | 34 | 34% |

表7. 不良反应名称及细节

| 参数 | | 全部(n=100) | |
| --- | --- | --- | --- |
| 不良反应名称, n (%) | 1 – 4级发生率 | | 大于3级发病率 |
| 白细胞计数降低 | 26(26.0%) | | 9(9.0%) |
| 贫血 | 25(25.0%) | | 1(1.0%) |
| 中性粒细胞计数下降 | 24(24.0%) | | 16(16.0%) |
| 丙氨酸氨基转移酶增高 | 21(21.0%) | | 3(3.0%) |
| 天冬氨酸氨基转移酶增高 | 19(19.0%) | | 1(1.0%) |
| 血胆红素升高 | 18(18.0%) | |  |
| 疲劳 | 17(17.0%) | | 3(3.0%) |
| 咳嗽 | 17(17.0%) | |  |
| 食欲下降 | 15(15.0%) | | 3(3.0%) |
| r-谷氨酰转移酶增高 | 14(14.0%) | | 1(1.0%) |
| 呕吐 | 12(12.0%) | | 5(5.0%) |
| 疼痛 | 11(11.0%) | | 2(2.0%) |
| 恶心 | 11(11.0%) | | 2(2.0%) |
| 血小板计数下降 | 10(10.0%) | | 1(1.0%) |
| 呃逆 | 10(10.0%) | | 5(5.0%) |
| 发热 | 9(9.0%) | |  |
| 低钠血症 | 9(9.0%) | |  |
| 脱发 | 8(8.0%) | |  |
| 碱性磷酸酶增高 | 8(8.0%) | |  |
| 眩晕 | 8(8.0%) | | 2(2.0%) |
| 高钙血症 | 7(7.0%) | |  |
| 血乳酸脱氢酶升高 | 7(7.0%) | |  |
| 腹泻 | 7(7.0%) | |  |
| 胸痛 | 7(7.0%) | | 4(4.0%) |
| 便秘 | 7(7.0%) | | 1(1.0%) |
| 低白蛋白血症 | 7(7.0%) | |  |
| 皮疹 | 6(6.0%) | | 2(2.0%) |
| 咯血 | 6(6.0%) | |  |
| 低钾血症 | 5(5.0%) | |  |
| 皮肤瘙痒 | 3(3.0%) | |  |
| 牙龈疼痛 | 3(3.0%) | |  |
| 头痛 | 3(3.0%) | |  |
| 失眠症 | 3(3.0%) | | 3(3.0%) |
| 咽喉疼痛 | 3(3.0%) | | 2(2.0%) |
| 呼吸急促 | 3(3.0%) | | 2(2.0%) |
| 高钠血症 | 2(2.0%) | |  |
| 血红蛋白增高 | 2(2.0%) | | 1(1.0%) |
| 腹痛 | 2(2.0%) | |  |
| 肌酐升高 | 2(2.0%) | |  |
| 放屁 | 2(2.0%) | |  |
| 声嘶 | 2(2.0%) | |  |
| 吞咽困难 | 2(2.0%) | |  |
| 口干 | 2(2.0%) | |  |
| 口咽疼痛 | 2(2.0%) | |  |
| 低镁血症 | 2(2.0%) | |  |
| 血清淀粉酶增高 | 1(1.0%) | |  |
| 肌酸激酶增高 | 1(1.0%) | |  |
| 肌肉疼痛 | 1(1.0%) | |  |
| 潮热 | 1(1.0%) | |  |
| 流行性样感冒症状 | 1(1.0%) | |  |
| 心悸 | 1(1.0%) | |  |
| 外周感觉神经障碍 | 1(1.0%) | |  |
| 嗳气 | 1(1.0%) | |  |
| 嗜睡 | 1(1.0%) | |  |
| 味觉障碍 | 1(1.0%) | |  |
| 听力下降 | 1(1.0%) | |  |
| 空腔疼痛 | 1(1.0%) | |  |
| 体重减轻 | 1(1.0%) | |  |
| 低钙血症 | 1(1.0%) | |  |

1. 除非另有说明

   2 年龄不大于64，性别女，病理结果非鳞状，III期，非铂类，ORR未到达，最大用药周期不大于3，紫杉醇剂量不大于794，和联合免疫用药不大于3 重新编码为0，剩余为1。EGFR和ALK 全部数据均为阴性，故全标为0，因此不在列表中。

   3 P Value 来自于 cox proportional hazard 模型的Wald test检验基于系数估计值符合正态分布。 [↑](#footnote-ref-1)