

加药环境与加药器具对输液不溶性微粒污染的影响

徐学君, 徐德琴, 汪 滢, 邹若飞 (武警安徽省总队医院, 合肥 230041)

摘要: 考察加药环境与加药器具对输液不溶性微粒的影响。取一次性使用无菌加药器具, 分别在净化洁净室和病房治疗室, 模拟加药, 按《中国药典》, 以光阻法测定样品中的不溶性微粒, 与未模拟加药的输液比较, 在病房治疗室和净化洁净室制备的样品中, $\geq 10\mu\text{m}$ 的不溶性微粒均有显著增加 ($P < 0.05$), $\geq 25\mu\text{m}$ 的不溶性微粒均增加不明显 ($P > 0.05$); 病房治疗室制备的样品与净化洁净室制备的样品比较, $\geq 10\mu\text{m}$ 的不溶性微粒增加显著 ($P < 0.05$), $\geq 25\mu\text{m}$ 的不溶性微粒增加不明显 ($P > 0.05$)。病房治疗室内加药环境及一次性加药器具可使输液中 $\geq 10\mu\text{m}$ 的不溶性微粒明显增加。

关键词: 一次性使用无菌注射器; 输液; 不溶性微粒

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The Impact of Pollution of Insoluble Particles Caused by Dosing Environment and Drug Infusion Devices

Xu Xuejun, Xu Deqin, Wang Ying and Zou Ruofei (Armed Police Corps Hospital in Anhui Province, Hefei 230041)

ABSTRACT The impact of pollution of insoluble particles caused by dosing environment and drug infusion devices was studied. Take one-time use of sterile equipment and simulate medicine, respectively in the purification clean room and ward treatment rooms clean room. According to the "Chinese Pharmacopoeia", samples of insoluble particles by photoresist were determined, and compared to not simulated drug infusion. In the ward treatment rooms clean room and the purification clean room, the insoluble particles of $\geq 10\mu\text{m}$ were significantly increased ($P < 0.05$), the insoluble particles of $\geq 25\mu\text{m}$ were not significant increased ($P > 0.05$). Compared the samples of the ward treatment rooms clean room and purification clean room, $\geq 10\mu\text{m}$ particulate matter increased significantly ($P < 0.05$), and $\geq 25\mu\text{m}$ insoluble particles increase was not significant ($P > 0.05$). ward drug treatment room plus a one-time environment and increase drug infusion devices enable $\geq 10\mu\text{m}$ in the insoluble particles increased significantly.

KEY WORDS one-time use of sterile syringes; infusion; insoluble particles

输液中的不溶性微粒进入人体后, 可引起静脉炎、肺水肿等反应, 严重危害人体的健康, 已引起高度重视。1985年版《中国药典》开始对大容量注射剂的不溶性微粒限度有具体规定^[1], 2005年版《中国药典》, 对大容量注射剂和小容量静脉用注射剂的不溶性微粒限度均做了具体规定^[2]。在临床输液治疗中, 因不溶性微粒引起的各种反应时有发生, 文献也有相应报道, 药物配伍后, 由于药物本身的 pH 值、药物浓度和其它条件的变化, 药物相互作用, 发生分解、聚合、沉淀等反应, 导致不溶性微粒增加^[3]。本实验主要对非药物配伍即加药环

境与加药器具对输液不溶性微粒的影响情况进行探讨, 现将实验结果报告如下。

1 材料与方法

1.1 仪器与试剂

SHJ 净化工作台 (上海净化设备厂); GWJ-4 智能微粒测定仪 (天津天大天发科技有限公司); 一次性使用无菌注射器 (20mL, 批号 060610; 10mL, 批号 060606; 5mL, 批号 060729; 2mL, 批号 060206; 1mL, 批号 040620; 常州市鹤寿医用器材厂); 一次性使用输液器 (批号 060515, 常州市鹤寿医用器材厂)。5% 葡萄糖注射液