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# 方右旋糖酐 40 注射液联合甘露醇治疗下肢软组织开放性损伤负压封闭引流术后患者的疗效及对血液流变学的影响 *

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**摘要 目的**:探讨复方右旋糖酐 40 注射液联合甘露醇治疗下肢软组织开放性损伤负压封闭引流(VSD)术后的治疗效果及对血液流变学的影响,为下肢软组织开放性损伤的治疗提供临床依据。**方法**:选取下肢软组织开放性损伤 VSD 术后患者 80 例,随机分为对照组和观察组各 40 例,对照组单纯应用甘露醇治疗,观察组应用复方右旋糖酐 40 注射液及甘露醇治疗,观察两组的临床疗效,比较两组治疗前后国际骨关节炎评分标准(Lequesne 指数)、视觉模拟评分法(VAS)、美国食品药品管理局(FDA)皮肤评分、Lysholm 膝关节功能评分(Lysholm)、血液流变学的变化以及不良反应发生情况。**结果**:治疗后,对照组和观察组的总有效率分别为 85.00%、97.50%,比较差异具有统计学意义($P<0.05$)。治疗后,两组 VAS 评分和 Lequesne 指数评分均降低,Lysholm 评分及 FDA 皮肤评分较治疗前显著升高($P<0.05$);治疗后,观察组 VAS 评分和 Lequesne 指数评分低于对照组,Lysholm 评分及 FDA 皮肤评分高于对照组($P<0.05$)。治疗后,两组血细胞比容较治疗前升高,全血比高切黏度、全血比低切黏度、血浆比黏度较治疗前降低($P<0.05$);治疗后,观察组血细胞比容高于对照组,全血比高切黏度、全血比低切黏度、血浆比黏度低于对照组($P<0.05$)。两组不良反应发生率比较无差异($P>0.05$)。**结论**:复方右旋糖酐 40 注射液联合甘露醇治疗下肢软组织开放性损伤 VSD 术后患者疗效确切,可减轻膝关节疼痛,促进皮肤软组织恢复,改善膝关节功能和血液流变学,安全性较好。

**关键词**:复方右旋糖酐 40 注射液;甘露醇;下肢软组织损伤;负压封闭引流;疗效;血液流变学

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# The Therapeutic Effect of Compound Dextran 40 Injection Combined with Mannitol in the Treatment of Lower Extremity Soft Tissue Open Injury and the Influence on Hemorheology after Vacuum Sealing Drainage*

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ABSTRACT Objective: To explore the therapeutic effect of compound dextran 40 injection combined with mannitol in the treatment of lower extremity soft tissue open injury and the influence on hemorheology after vacuum sealing drainage (VSD), so as to provide clinical basis for the treatment of lower extremity soft tissue open injury. Methods: 80 patients with lower extremity soft tissue open injury after VSD were selected, randomly divided into control group and observation group 40 cases each, the control group was treated with mannitol alone, the observation group was treated with compound dxtran 40 injection combined mannitol, the clinical effects of the two groups were observed, the international osteoarthritis scoring standards(Lequesne index), visual analogue score (VAS score), Food and Drug Administration (FDA) skin score, Lysholm knee function score (Lysholm), hemorheology changes and adverse reactions were compared before and after treatment. Results: After treatment, the total effective rates of the control group and the observation group were 85.00%, 97.50% respectively, the difference between the two groups was statistically significant ($P<0.05$). After treatment, VAS score and Lequesne index score of the two groups were significantly lower than before treatment, Lysholm score and FDA skin score were significantly higher than before treatment ($P<0.05$). After treatment, VAS score and Lequesne index of the observation group were lower than those of the control group, Lysholm score and FDA skin score were higher than those of the control group ($P< 0.05$). After the treatment, the hematocrit of the two groups was higher than that before the treatment, the whole blood ratio high shear viscosity, the whole blood ratio low shear viscosity, the ratio of viscosity was lower than those before treatment ($P<0.05$). After the treatment, the hematocrit of the observation group was higher than that of the control group, the whole blood ratio high shear viscosity, the whole blood ratio low shear viscosity, the ratio of viscosity were lower than those of the control group ($P<0.05$). There was no significant difference in the incidence of adverse reactions between the two groups ($P>0.05$). Conclusion: Compound dextran 40 injection combined with mannitol is effective in the treatment of patients with lower extremity soft tissue open injury after VSD, it can alleviate knee pain, promote skin and soft tissue recovery, improve knee joint function and hemorheology, it is safe.

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## 前言

随着我国城市现代化的发展，交通伤、工伤及自然灾害等突发事件日益上升，下肢软组织损伤的发病率逐年递增[1]。如何保存肢体软组织血运，重建其组织结构与恢复肢体功能是目前骨科创伤学科、整形外科及烧伤重建科等面临的主要临床挑战[2]。负压封闭引流(VSD)是目前临床常用于治疗创面软组织损伤的一种新疗法，是在负压创面治疗技术( negative pressure wound therapy，NPWT)基础上发展起来的，这种治疗理念已经验证了其成功治疗软组织损伤、软组织感染及糖尿病足坏疽的有效性[3,4]，但在临床治疗中发现，许多应用 VSD 术后的患者仍然存在创面周围软组织瘢痕化，而瘢痕化与软组织水肿及微循环代谢不良有关[5]。甘露醇作为有效的消肿药物，成功地应用于脑外伤、肢体创伤及复合伤等疾患[6]。复方右旋糖酐 40 注射液，系国家食品药品监督管理局 2004 年批准的代血浆产品，于 2007 年投入市场，属于新一代晶胶结合的代血浆产品，具有快速、高效扩容、显著改善微循环、平衡电解质、预防调整酸中毒、渗透性利尿等作用[7]。目前有关复方右旋糖酐 40 注射液能否应用于下肢软组织损伤，特别是接受 VSD 手术治疗后的患者的报道较少。因此，本文采用复方右旋糖酐 40 注射液联合甘露醇治疗下肢软组织开放性损伤 VSD 术后患者，为下肢软组织损伤 VSD 术后患者的优化治疗提供临床依据。

## 1 资料与方法

### 1.1 一般资料

选取 2016 年 9 月 ~2019 年 9 月我院收治的 80 例下肢软组织损伤 VSD 术后患者，所选患者受伤程度中度或重度，且具备创伤的典型症状与体征。纳入标准：①符合下肢软组织开放性损伤的诊断标准[8] (包括软组织脱套伤、钝挫伤、撕裂伤及切割伤等)；②有明显外伤史；③接受入院清创 VSD 自体植皮修复术；④入选前 2 周内未使用相关药物治疗或采取医疗手段者。 排除标准：①上肢、脊柱及骨盆部位软组织损伤；②合并心脑血管、肝、肾、血液系统等危及生命的疾病及精神障碍者；③重度软组织毁损伤接受截肢术的患者；④对复方右旋糖酐 40 注射液及甘露醇过敏者。将入选的病例按照随机数字表法分为对照组与观察组，每组各 40 例。其中对照组男、女分别为 25 例、15 例，平均年龄 (46.13±8.15) 岁；平均病程 (20.10±28.85) 天。观察组男、女分别为 28 例、12 例；平均年龄 (46.08±7.82) 岁；平均病程 (21.65±27.86) 天。两组患者均积极配合治疗，治疗期间无脱落病例。两组基线资料比较差异无统计学意义 ($P$>0.05) 。

### 1.2 治疗方法

VSD 术后，对照组给予静脉点滴 20%甘露醇，每日 2 次；观察组在对照组的基础上给予静脉点滴复方右旋糖酐 40 注射液，每日 2 次，每次均为 500 mL，两组均连续治疗 8 天。

### 1.3 观察指标

1.3.1 疗效评价 治疗后评价两组患者的临床疗效，其中临床控制：治疗后，患膝无疼痛及肿胀，关节活动正常；显效：治疗后患者疼痛、肿胀症状明显缓解，关节活动逐渐恢复正常；有效：治疗后患者疼痛、肿胀症状有所缓解，关节活动有所改善；无效：治疗后患者症状无改变或加重，总有效率＝(临床控制＋显效＋有效) / 总例数[9]。

1.3.2 相关评分 于治疗前、后采用国际骨关节炎评分标准 (Lequesne 指数)[10]、Lysholm 膝关节功能评分(Lysholm)[11]、视觉模拟评分法 (VAS)[12]、美国食品药品管理局 (FDA) 皮肤评分[13]评价患者的膝关节功能、疼痛和皮肤软组织恢复情况，使用 Lequesne 指数评分对膝关节的局部症状体征和功能活动进行评价，分值越低代表关节功能越好；Lysholm 评分评价患者膝关节活动恢复情况，分值越高代表患者关节活动恢复越好。VAS 评分评估患者膝关节静息疼痛，分值越低代表疼痛感越轻；FDA 皮肤评分评价患者皮肤软组织恢复情况，分值越高代表患者恢复越好。

1.3.3 血液流变学指标 分别于治疗前、后静脉采血 4 mL，用血流变分析仪测定两组患者血细胞比容、全血比高切黏度、全血比低切黏度、血浆比黏度等血液流变学指标。

1.3.4 不良反应 详细记录两组治疗期间恶心、头晕头痛、便秘等不良反应发生情况

### 1.4 统计学处理

所得数据资料采用 SPSS 20.0 软件分析处理，组内、组间计量资料采用 $\bar{x}\pm s$ 表示，比较选用 t 检验；计数资料采用百分率表示，比较使用 $\chi^2$ 检验，$P$<0.05 表明差异有统计学意义。

## 2 结果

### 2.1 两组疗效比较

治疗后，观察组总有效率高于对照组 ($\chi^2$ =3.914, $P$=0.048)，见表 1。

### 2.2 两组各项评分比较

两组治疗后 VAS 评分和 Lequesne 指数评分较治疗前均

表 1 两组临床疗效比较

Table 1 Comparison on clinical curative effect between two groups

| Groups | n | Clinical control | Excellent | Valid | Invalid | Total effective rate |
|---|---|---|---|---|---|---|
| Control group | 40 | 1 | 22 | 11 | 6 | 85.00% |
| Observation group | 40 | 2 | 31 | 6 | 1 | 97.50% |

有降低，且治疗后观察组低于对照组，Lysholm 评分及 FDA 皮肤评分较治疗前均有升高，且治疗后观察组高于对照组（$P<0.05$），见表 2。

表 2 两各组评分比较($\bar{x}\pm s$, 分)

Table 2 Comparison on scores between two groups($\bar{x}\pm s$, score )

| Groups | n | Time | VAS score | Lysholm score | Lequesne index score | FDA skin score |
|---|---|---|---|---|---|---|
| Control group | 40 | Before treatment | 5.12±1.93 | 50.29±3.36 | 15.23±3.68 | 1.21±0.19 |
| | | After treatment | 4.59±1.24* | 75.26±4.86* | 13.86±2.52* | 6.39±1.84* |
| Observation group | 40 | Before treatment | 5.19±1.53 | 50.35±2.73 | 15.31±3.51 | 1.17±0.23 |
| | | After treatment | 3.35±1.06*▲ | 83.59±3.24*▲ | 10.55±2.04*▲ | 10.81±1.85*▲ |

Note: *$P<0.05$ vs same group before treatment, ▲$P<0.05$ vs control group after treatment.

### 2.3 两组血液流变学指标比较

治疗后，两组血细胞比容较治疗前升高，全血比高切黏度、全血比低切黏度、血浆比黏度较治疗前降低（$P<0.05$）；治疗后，观察组血细胞比容高于对照组，全血比高切黏度、全血比低切黏度、血浆比黏度低于对照组（$P<0.05$），见表 3。

表 3 两组血液流变学指标比较($\bar{x}\pm s$)

Table 3 Comparison of hemorheology indexes between the two groups($\bar{x}\pm s$)

| Groups | n | Time | Hematocrit (%) | Whole blood ratio high shear viscosity (mPa·s) | Whole blood ratio low shear viscosity (mPa·s) | Ratio of viscosity (mPa·s) |
|---|---|---|---|---|---|---|
| Control group | 40 | Before treatment | 32.89±3.23 | 4.76±0.82 | 10.73±1.43 | 2.62±0.52 |
| | | After treatment | 39.36±5.42* | 4.22±0.42* | 9.78±1.23* | 1.82±0.56* |
| Observation group | 40 | Before treatment | 32.86±3.21 | 4.96±0.86 | 10.81±1.38 | 2.68±0.56 |
| | | After treatment | 56.23±7.48*▲ | 3.09±0.42*▲ | 9.26±0.73*▲ | 1.26±0.31*▲ |

Note: *$P<0.05$ vs same group before treatment, ▲$P<0.05$ vs control group after treatment.

### 2.4 安全性评价

观察组患者出现头痛头晕 2 例，恶心 2 例，便秘 1 例，不良反应发生率为 12.50%；对照组患者出现头痛头晕 1 例，恶心 1 例，便秘 1 例，不良反应发生率为 7.50%；所有上诉患者症状较轻微，经对症治疗后缓解。两组不良反应发生率比较差异无统计学意义（$\chi^2=0.556$, $P=0.456$）。

## 3 讨论

软组织是构成骨骼肌肉系统不可分割的一部分，其不仅提供对骨骼天然保护屏障，同时也提供骨与软骨生长发育的关键营养，以调控其生理功能需要[14]。因皮肤、筋膜、肌肉等损伤的软组织缺失对骨再生与修复造成不可逆性伤害，越来越多的研究集中在开放性骨折的骨修复技术，例如 MIPPO 微创技术、Hybrid 骨外固定技术及计算机辅助导航、虚拟手术等[15,16]，但是常忽略了软组织损伤修复的相关研究。因此，如何加强软组织损伤再生与修复显得非常迫切与重要。Schultz GS 提出 TIME 原则指导处理伤口愈合，清除坏死组织与纠正湿性失衡是伤口管理的两个核心目标[17]。自德国学者采用 NPWT 技术治疗开放性骨折以来，一些学者也按照此原理，采用 VSD 成功地治疗各类开放性骨折、骨髓炎、糖尿病足坏死及感染性骨不愈合等[18,19]。基于 NPWT 原理的 VSD 技术的治疗优势日益凸显，而且这项技术在不同国家进行了推广。NPWT 的作用原理是通过将吸引装置与特殊的伤口敷料连接建立负压系统，使创面处于负压状态并充分引流渗液，清除坏死组织，降低创面细菌数量，从而达到创面治疗目的[20]。与临床常规开放式换药相比，该技术具有更换敷料次数少、创面组织愈合快、降低感染风险等优势，但也存在一些缺点，如负压周期性长、引流时间长等，这些因素也会影响伤口愈合[21]。

目前，大多数 VSD 技术应用于下肢开放性伤口损伤的处理，相对于其他部位损伤，下肢的损伤类型、机制、致伤原因有所不同[22]。如何消除软组织水肿与促进其微循环重建是 VSD 技术应用的核心，也是临床上需要解决的问题之一，以往应用 VSD 后可在伤口周围组织出现水肿、瘢痕化的现象，而且去除 VSD 敷料后伤口周围压痕、瘢痕化现象比较常见[23]。某些部位的软组织长期处于缺血状态下，也会出现无复流现象，原因可能是溶栓过程中产生的血凝块、血小板栓阻塞微血管，这也是造成血流再灌注失败的主要原因[24]。

甘露醇溶液静脉滴注后进入血液循环后，通过扩充血容量，可降低全血黏度，但大量使用甘露醇可引起体内甘露醇积聚，血容量迅速大量增多，且甘露醇外渗可致组织水肿、皮肤坏死，临床上需注意其量的控制[25]。复方右旋糖酐 40 富含钠、钙、钾等离子，是由右旋糖酐 40 和乳酸林格组成的晶胶复合体[26]。脉滴注后进入血液循环在红细胞表面形成带有负电荷外膜的短链分子桥，使红细胞之间相互排斥，起到预防红细胞聚集的作用；同时复方右旋糖酐 40 可以抑制血小板表面活化标识 GP IIb/IIIa 受体的表达，起到防止血小板粘附的作用，通过以上三条路径，从整体上改善人体微循环，增强组织灌注，预防静脉血栓的形成[27,28]。本研究显示观察组治疗总有效率高于对照组，且

观察组治疗后 VAS 评分和 Lequesne 指数评分低于对照组，Lysholm 评分及 FDA 皮肤评分高于对照组，可见采取复方右旋糖酐 40 注射液联合甘露醇治疗方案，能有效缓解患者疼痛、肿胀症状，促进膝关节功能恢复。原因可能是在甘露醇补充血容量的基础上，联合复方右旋糖酐 40 注射液治疗既能满足血容量的补充，同时其所含的乳酸钠经代谢生成碳酸氢离子，可增加碱储备，有利于机体酸碱平衡，从而对机体康复有促进作用[29]。本研究显示，两组治疗后血细胞比容较治疗前升高，全血比高切黏度、全血比低切黏度、血浆比黏度较治疗前降低，且观察组上述指标优于对照组，可见采取复方右旋糖酐 40 注射液联合甘露醇治疗方案能有效改善软组织开放性损伤 VSD 术后患者血液流变学。分析其原因，甘露醇注射液与复方右旋糖酐 40 注射液联合使用，两种药物均可起到增加血容量的作用，降低全血黏度，同时复方右旋糖酐 40 注射液可通过胶体渗透压组织，加快创面组织水分吸收，降低红细胞压积，改善血液微循环，抑制血栓形成[30]。此外，本研究也显示，两组用药不良反应症状均较轻微，不良反应发生率经比较无统计学差异，可见采取复方右旋糖酐 40 注射液联合甘露醇治疗的安全性较好。

综上所述，复方右旋糖酐 40 注射液联合甘露醇治疗下肢软组织开放性损伤 VSD 术后患者疗效确切，可减轻膝关节疼痛，促进皮肤软组织恢复，改善膝关节功能和血液流变学，安全性较好。本研究亦存在一定的不足，如未对下肢软组织损伤患者的炎性细胞因子、基质金属蛋白酶、血栓素和 6- 酮 - 前列腺素F1a 等生化指标进行动态监测，这也许是未来研究将改善的方向。

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