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外科新三联疗法治疗糖尿病足的临床观察

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摘要 目的: 观察外科新三联疗法(外科换药 - 威伐激光 - 成纤维细胞生长因子)治疗糖尿病足溃疡的临床疗效和安全性。方法: 将 57 例糖尿病足溃疡患者随机分为 2 组。对照组 28 例, 采用外科换药辅以成纤维细胞生长因子外敷治疗; 治疗组 29 例, 在对照组治疗的基础上配合威伐激光照射治疗。疗程为 8 周, 观察两组患者的治疗有效率、愈合时间和不良反应的发生情况。结果: 治疗组和对照组的有效率分别为 86.21%、57.14%, 治疗组显著高于对照组($P<0.05$); 且治疗组溃疡的愈合时间(39.40 ± 2.24 天)较对照组(50.67 ± 2.31 天)明显缩短($P<0.01$)。此外, 两组患者均无明显的不良反应发生。结论: 外科新三联疗法(外科换药 - 威伐激光 - 成纤维细胞生长因子)是治疗糖尿病足溃疡的有效方法, 且安全性好。

关键词: 威伐激光; 成纤维细胞生长因子; 三联疗法; 糖尿病足**中图分类号:** R587.2 **文献标识码:** A **文章编号:** 1673-6273(2015)19-3704-03

Clinical Observation on the Surgical New Triple Therapy in the Treatment of Diabetic Foot

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ABSTRACT Objective: To observe the clinical efficacy and safety of surgical new triple therapy (surgical dressing-WIRA laser-fibroblast growth factor) in the treatment of diabetic foot ulcer. **Methods:** 57 cases of patients with diabetic foot ulcer were selected and randomly divided into the treatment group(29 cases) and the control group(28 cases). All the patients were treated with surgical dressing and fibroblast growth factor for external application therapy. Additionally, the treatment group was irradiated with WIRA laser. Two groups were treated for eight weeks and the efficiency, healing time and incidence of adverse reactions were observed and compared between two groups. **Results:** The effective rate of treatment group and control group were 86.21%, 57.14% respectively which was significantly higher in the treatment group than that of the control group ($P<0.05$); and the ulcer healing time of treatment group was (39.40 ± 2.24) days, which was significantly shorter than that of the control group (50.67 ± 2.31 days, $P<0.01$). In addition, no obvious adverse reactions was observed in both groups. **Conclusions:** The new triple therapy of surgery (surgical dressing - WIRA laser - fibroblast growth factor) was an effective method for the treatment of diabetic foot ulcer, and is worthy of clinical application.

Key words: WIRA laser; Fibroblast growth factor; Triple therapy; Diabetic foot**Chinese Library Classification(CLC):** R587.2 **Document code:** A**Article ID:** 1673-6273(2015)19-3704-03

目前, 糖尿病是我国的高发疾病之一, 其患病率已高达 9.7%^[1], 全国有 1 亿多糖尿病患者, 其中 15%~20% 的患者因末梢神经病变、下肢动脉供血不足以及细菌感染等多种原因并发糖尿病足^[2]。经久不愈的足部溃疡和可致残的恐惧情绪, 给糖尿病患者造成了极大的心理压力, 直接影响到患者的生活质量。为了提高糖尿病的临床疗效, 降低致残率, 专家学者们纷纷尝

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试在外科常规清创换药的基础上采用多种方法对其进行治疗, 如 VSD 负压吸引、高压氧、臭氧、局部氧疗以及传统中医药外敷内服等^[3-9], 均取得了不同程度的进展。近年来, 随着激光医学的飞速发展, 应用红光、氦-氖激光、半导体激光等低强度激光治疗糖尿病足的优势也越来越明显^[10,11]。本研究创新采用外科换药联合威伐激光、成纤维细胞生长因子三者联合的方式治疗糖尿病足, 取得了较满意的疗效, 现报道如下。

1 材料与方法

1.1 一般资料

选择我院于2011年1月~2013年12月收治的糖尿病足患者57例，均为2型糖尿病，糖尿病足溃疡的病程7天至3个月，均符合WHO糖尿病足溃疡的诊断标准，按Wagner分级方法：I级18例，II级20例，III级19例。治疗前空腹血糖11.7~33 mmol/L，糖化血红蛋白7.4%~12.1%。将57例糖尿病足溃疡患者按随机表分为两组：治疗组29例，男性15例，女性14例，年龄31~65岁，平均(51.4±3.69)岁；对照组28例，男性13例，女性15例，年龄32~65岁，平均(51.1±4.08)岁。两组患者的性别、年龄、病程、空腹血糖、糖化血红蛋白以及溃疡范围、深度比较，均无统计学差异(P>0.05)，具有可比性。

排除标准：伴有胶原疾病史者、甲状腺功能亢进症者、妊娠者、营养不良者(血红蛋白<8 g/dL)、肝肾功能异常者；伴有生命体征不稳定者；以往有成纤维细胞生长因子过敏史者；其他根据临床状况及溃疡面病理情况不建议行激光治疗者。

1.2 治疗方法

1.2.1 全身治疗 所有患者予糖尿病饮食，使用胰岛素或口服降糖药控制血糖至正常或接近正常范围；静脉应用改善微循环药物；同时予调脂降压、营养神经治疗，伴感染者首选广谱抗生素，药敏结果出来后据药敏结果给予相应敏感抗生素治疗。

1.2.2 局部治疗 对糖尿病足Wagner分级为II级、III级患者进行外科清创，先用双氧水冲洗溃疡面，而后再用生理盐水进行第二次冲洗，局部形成脓腔及窦道者尽早切开引流。对照组用重组牛碱性成纤维细胞生长因子(贝复济，63000 IU/15 ml，珠海亿胜生物制药有限公司)，首先将纱布覆于溃疡面上，并将溶

解好的药液喷敷于纱布，以药液不溢出为度，有窦道者将药液喷于引流条上，填塞至伤口内，适当包扎，1次/日，剂量每次150 AU/cm²。治疗组则在对照组治疗的基础上联合威伐激光：德国威伐WIRA® R光治疗系统(德国海特公司Hydrosun Irradiator 500)照射足部溃疡面，波长560 nm~1400 nm，功率750 W，30分钟/次，1次/天，治疗光源距患处25 cm，疗程8周。

1.3 疗效判定

痊愈：经治疗后溃疡面完全愈合；显效：溃疡面缩小50%以上；有效：溃疡面缩小50%以下；无效：溃疡面无变化或扩大，甚至致残。总有效率=(痊愈例数+显效例数)/总病例数×100%。同时观察并记录溃疡面愈合所需时间及不良反应的发生情况。

1.4 统计学处理

应用SPSS17.0软件进行统计学处理，计量资料采用独立样本的t检验，计数资料及率的比较采用χ²检验，以P<0.05为差异有统计学意义。

2 结果

治疗组的总有效率为86.21%，对照组的总有效率为57.14%，治疗组显著高于对照组(P<0.05)；治疗组溃疡面愈合病例的愈合时间为(39.40±2.24)天，对照组为(50.67±2.31)天，治疗组溃疡愈合时间明显短于对照组(P<0.01)，见表1、表2。在为期8周的治疗中，两组患者均未发生明显不良反应。

表1 两组临床疗效的比较(例)

Table 1 Comparison of the clinical therapeutic effect between two groups(Case)

Group	Case	Recovery	Excellence	Improvement	Uselessness	Efficiency(%)
Treatment group	29	15	10	4	0	86.21
Control group	28	9	7	12	0	57.14

表2 两组溃疡面完全愈合患者愈合时间的比较(天)

Table 2 Comparison of the healing time of ulcer between two groups(day)

Group	Cured cases	Healing time
Treatment group	15	39.40±2.24
Control group	9	50.67±2.31

3 讨论

治疗糖尿病足溃疡是一个漫长的过程，少则数月，多至余年，很多患者因不堪忍受痛苦中断甚至放弃了治疗。因此，寻求一种既能缩短病程，又具有较好临床疗效的方法迫在眉睫。

威伐光是由卤素光经过WIRA系统后，形成波长范围为560 nm~1400 nm的高能量“彩虹之光”，囊括了红光、超激光和近红外光，其功率最大可达750 W，可穿透深达7 cm的皮肤深层组织，具有促进溃疡愈合，帮助组织修复，缓解疼痛等多种“彩虹效应”。其治疗原理^[12-17]是通过波长为620 nm~660 nm的能量光谱提升细胞线粒体利用氧的能力，增强酶促反应，促进DNA、RNA以及白蛋白、免疫球蛋白的合成，诱使细胞再

生，发挥促进组织修复的作用；还可使白介素增加，抗原表达减少，从而发挥减少炎性渗出和免疫调节的作用；波长为760 nm~1400 nm的能量光谱属近红外波段，有较强的穿透性，可使能量束深达病灶基底。此外，威伐光中810 nm的光谱可通过减少5-羟色胺等介质的释放，使交感神经兴奋降低，因此还具有止疼的功效。糖尿病足溃疡面深浅不一，最深可达肌层，应用成纤维细胞生长因子(rb-bFGF)外敷于创面，有促进上皮、真皮、成纤维、血管内皮等多种细胞的修复和再生作用，并可促进毛细血管的再生，改善局部的血液循环，从而加速创面的愈合作用^[18-20]。

本研究通过对糖尿病足溃疡清创换药外科治疗，辅以威伐高能量“彩虹之光”，再以成纤维细胞生长因子外敷的新三联疗法，治疗有效率高达86.21%，明显高于外科换药辅以成纤维细胞生长因子外敷治疗，且溃疡愈合时间明显缩短，治疗中亦未发现明显副作用，患者耐受性好。这表明外科换药联合威伐激光及成纤维细胞生长因子--外科新三联疗法治疗糖尿病足溃疡的疗效好，安全性高，是治疗糖尿病足溃疡的有效新方法，值得临床推广应用。

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