

体外冲击波疗法治疗早中期距骨骨软骨损伤的临床研究

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摘要 目的:评价体外冲击波疗法(extracorporeal shock wave therapy, ESWT)治疗早中期距骨骨软骨损伤(osteocondral lesion of the talus, OLT)的临床疗效。**方法:**将 60 例符合要求的 Hepple I 期至 III 期 OLT 患者随机分为常规组和冲击波组, 每组 30 例。入组后 2 组患者均采用针刺、超声波治疗、踝周肌力训练、口服双氯芬酸钠肠溶片及限制患肢负重等常规疗法治疗, 冲击波组在此基础上辅以 ESWT 治疗, 2 组均治疗 5 周。比较 2 组患者治疗前及治疗结束后 2 个月的踝关节疼痛视觉模拟量表(visual analogue scale, VAS)评分、美国足与踝关节协会(American Orthopedic Foot and Ankle Society, AOFAS)踝与后足评分及病灶体积。**结果:**治疗前 2 组患者的踝关节疼痛 VAS 评分、AOFAS 踝与后足评分及病灶体积比较, 组间差异均无统计学意义($Z=0.139, P=0.709$; $Z=0.351, P=0.554$; $Z=0.184, P=0.668$)。治疗结束后 2 个月, 2 组患者的踝关节疼痛 VAS 评分均较治疗前降低[(5, 2)分, (5, 2)分, $Z=-2.828, P=0.005$; (5, 2)分, (3, 1)分, $Z=-4.902, P=0.000$], AOFAS 踝与后足评分均较治疗前提高[(69.50, 11.75)分, (72.00, 11.25)分, $Z=-4.450, P=0.000$; (68.50, 11.50)分, (78.50, 13.75)分, $Z=-4.793, P=0.000$]; 冲击波组治疗结束后 2 个月的病灶体积较治疗前减小[(1.77, 0.76) cm^3 , (1.27, 0.71) cm^3 , $Z=-4.783, P=0.000$], 常规组治疗前后病灶体积的差异无统计学意义[(1.74, 0.77) cm^3 , (1.79, 0.54) cm^3 , $Z=-0.160, P=0.873$]。冲击波组治疗结束后 2 个月的踝关节疼痛 VAS 评分低于常规组($Z=37.890, P=0.000$), AOFAS 踝与后足评分高于常规组($Z=3.944, P=0.047$), 病灶体积小于常规组($Z=15.134, P=0.000$)。**结论:**采用 ESWT 治疗早中期 OLT, 有助于缓解踝关节疼痛、改善踝关节功能、控制病灶进展。

关键词 冲击波; 距骨骨软骨损伤; 磁共振成像; 成像, 三维; 临床试验

Clinical efficacy of extracorporeal shock wave therapy on early to mid – stage osteochondral lesions of the talus

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ABSTRACT Objective: To evaluate the clinical efficacy of extracorporeal shock wave therapy (ESWT) in the treatment of early to mid – stage osteochondral lesions of the talus (OLT). **Methods:** Sixty eligible patients with Hepple I – III OLT were enrolled and randomly divided into a control group ($n=30$) and an ESWT group ($n=30$). All patients were treated with conventional intervention therapies, such as acupuncture, ultrasound therapy, periankle strength training, oral administration of Diclofenac Sodium Enteric – coated Tablets, and protection from weight bearing of the affected limb. The patients in the ESWT group received additional ESWT. The treatment lasted five weeks for all patients. The ankle pain visual analogue scale scores, American Orthopaedic Foot and Ankle Society (AOFAS) Ankle – Hindfoot Scale scores, and the volume of lesions of the two groups were compared before treatment and two months after treatment. **Results:** There was no significant difference in ankle pain VAS score, AOFAS Ankle – Hindfoot Scale score, and lesion volume between the two group before treatment ($Z=0.139, P=0.709$; $Z=0.351, P=0.554$; $Z=0.184, P=0.668$). Two months after treatment, ankle pain VAS scores of the two groups were lower ((5, 2) vs (5, 2) points, $Z=-2.828, P=0.005$; (5, 2) vs (3, 1) points, $Z=-4.902, P=0.000$) and AOFAS Ankle – Hindfoot Scale scores were higher than those before treatment ((69.50, 11.75) vs (72.00, 11.25) points, $Z=-4.450, P=0.000$; (68.50, 11.50) vs (78.50, 13.75) points, $Z=-4.793, P=0.000$). In the ESWT group, the lesion volume was reduced two months after treatment ((1.77, 0.76) vs (1.27, 0.71) cm^3), $Z=-4.783, P=0.000$, and there was no significant difference in lesion volume of the control group before and after treatment ((1.74, 0.77) vs (1.79, 0.54) cm^3), $Z=-0.160, P=0.873$. Compared with the control group two months after treatment, the ESWT group showed reduced ankle pain VAS score ($Z=37.890, P=0.000$), higher AOFAS Ankle – Hindfoot Scale score ($Z=3.944, P=0.047$), and smaller lesion volume ($Z=15.134, P=0.000$). **Conclusion:** In the treatment of early to mid – stage OLT, ESWT can relieve ankle pain, improve ankle function, and control lesion progression.

Keywords shock wave; osteochondral lesion of the talus; magnetic resonance imaging; imaging, three – dimensional; clinical trial

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距骨骨软骨损伤(osteochondral lesion of the talus, OLT)是由于创伤或反复劳损引起踝关节周围生物力学环境改变,使胫骨或腓骨与距骨滑车挤压撞击,从而导致距骨关节软骨和软骨下骨损伤的一种疾病^[1-2]。OLT 的发生率较高^[3],也是导致踝关节慢性疼痛的主要原因。若治疗不及时或治疗不当,OLT 可进展为距骨坏死,甚至发生塌陷,进而导致踝关节畸形,最终使患者丧失日常生活能力。对于早中期 OLT,临床可选择限制负重、物理治疗及踝周肌力训练等非手术方法治疗^[3],但存在治疗周期长、成功率低^[4]等问题。对于非手术治疗无效或中晚期 OLT,临床多采用微骨折术、逆行和顺行钻孔术、软骨移植术等手术方法治疗^[5],但也存在费用高、患者接受度差、可发生医源性神经和关节软骨损伤等问题。体外冲击波疗法(extracorporeal shock wave therapy, ESWT)具有治疗周期短、无创伤、并发症少、费用低廉等优点,已被临床证明具有软骨保护作用^[6-7]。为此,本研究对 ESWT 治疗早中期 OLT 的临床疗效进行了观察,并基于 MRI 病灶三维模型测量病灶体积,以评价临床疗效,现总结报告如下。

1 临床资料

1.1 一般资料 选择 2018 年 12 月至 2020 年 12 月在四川省骨科医院住院治疗的早中期 OLT 患者进行研究。试验方案经医院医学伦理委员会审查通过。

1.2 诊断标准 根据文献拟定 OLT 诊断标准:①踝关节负重时可出现踝关节疼痛、活动轻度受限及关节卡顿、交锁等表现^[8];②经 MRI 检查确诊^[9]。

1.3 纳入标准 ①符合上述诊断标准;②年龄 20~65 岁;③Hepple 分期为 I 期至 III 期^[10];④同意参与本研究,签署知情同意书。

1.4 排除标准 ①合并严重心脑血管疾病、出血性疾病、凝血功能障碍、肿瘤者;②患侧小腿深静脉血栓形成,且病程 < 4 周者;③正在使用免疫抑制剂者;④孕妇;⑤有精神疾病病史者。

2 方法

2.1 分组方法 采用随机数字表将符合要求的患者随机分为冲击波组和常规组。

2.2 治疗方法 入组后 2 组患者均采用常规疗法治疗,冲击波组在此基础上辅以 ESWT 治疗。

2.2.1 常规疗法 针刺:取解溪、太溪、昆仑、悬钟及阿是穴,留针 20 min,每日 1 次。超声波治疗:探头对

准患者踝穴病灶痛点,强度 1.2 W,每次 10 min,每日 1 次。踝周肌力训练:在同一位高年资康复治疗师指导下进行训练。口服药物:口服双氯芬酸钠肠溶片(北京诺华制药有限公司),每次 25 mg,每天 2 次。以上疗法均治疗 3 周。此外,还需限制患肢负重 5 周。

2.2.2 ESWT 保持踝关节极度跖屈,充分暴露距骨顶骨软骨损伤处,结合压痛点及 MRI 检查结果标定治疗位置。选用 MASTERPULS MP100 分散式冲击波治疗仪(STORZ 公司),设置压力场 0.1~0.4 MPa,频率 5~8 Hz,每次选择 2~3 个治疗点,每个点冲击 1000~1500 次,共冲击 2000~3000 次。间隔 7 d 后进行下一次治疗,共治疗 3 次。

2.3 疗效评价方法 比较 2 组患者治疗前及治疗结束后 2 个月的踝关节疼痛视觉模拟量表(visual analogue scale, VAS)评分、美国足与踝关节协会(American Orthopedic Foot and Ankle Society, AOFAS)踝与后足评分^[11]及病灶体积。

病灶体积通过基于 MRI 的病灶三维模型测量。采用 GE SIGNA 1.5T MRI 系统扫描患者踝关节,选用 3D-Cube Sequence 扫描模式,重复时间 600 ms、回波时间 15 ms、矩阵 256×256、视场 256 mm×256 mm、层厚 1.0 mm。将扫描获取的 DICOM 格式图像导入 Mimics 20.0 软件,建立病灶三维模型(图 1),并测量病灶体积。

2.4 数据统计方法 采用 SPSS24.0 软件进行数据统计分析。2 组患者性别的组间比较采用 χ^2 检验;年龄、病程、体质量指数的组间比较均采用独立样本 t 检验;踝关节疼痛 VAS 评分、AOFAS 踝与后足评分及病灶体积的组间比较均采用 Mann-Whitney U 检验,组内比较均采用 Wilcoxon 秩和检验。检验水准 $\alpha = 0.05$ 。

3 结果

3.1 分组结果 共纳入 60 例 OLT 患者,每组 30 例,2 组患者的基线资料比较,差异无统计学意义,有可比性(表 1)。

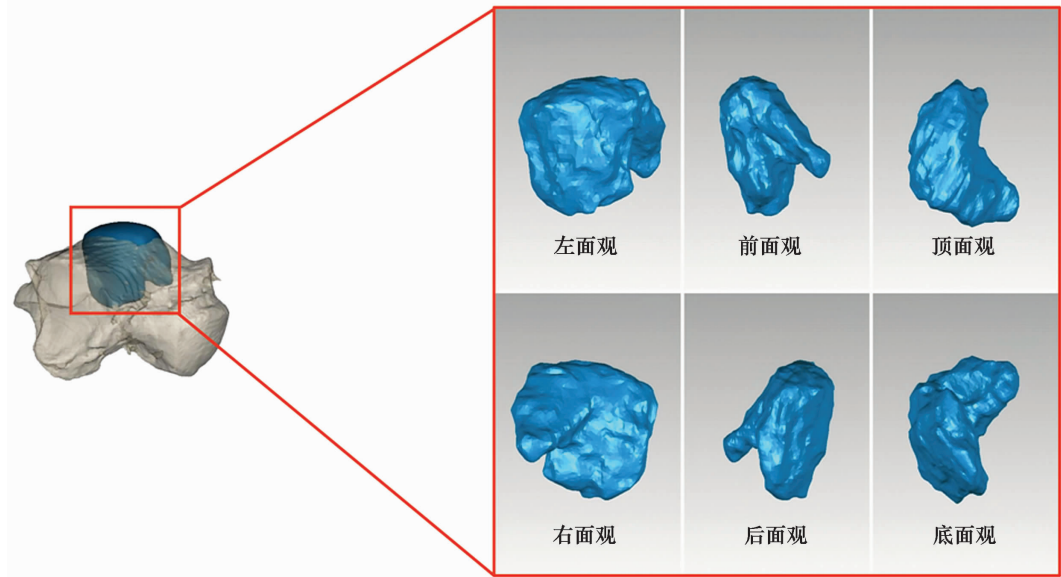
3.2 疗效评价结果 治疗前 2 组患者的踝关节疼痛 VAS 评分、AOFAS 踝与后足评分及病灶体积比较,组间差异均无统计学意义。治疗结束后 2 个月,2 组患者的踝关节疼痛 VAS 评分均较治疗前降低、AOFAS 踝与后足评分均较治疗前提高;冲击波组治疗结束后

2 个月的病灶体积较治疗前减小,常规组治疗前后病灶体积的差异无统计学意义。冲击波组治疗结束后 2 个月的踝关节疼痛 VAS 评分低于常规组、AOFAS 踝与后足评分高于常规组、病灶体积小于常规组。见表 2 至表 4。典型病例 MRI 见图 2。

4 讨论

距骨表面 60% 以上被软骨覆盖,而透明软骨内

无血管、神经,且不可再生,这限制了距骨软骨的愈合潜力^[12]。距骨软骨的营养几乎全部来自踝关节滑液和软骨下骨面血运。但距骨本身的血供也较为脆弱,这进一步弱化了距骨软骨损伤后的愈合能力^[13-14]。此外,与下肢其他负重关节相比,距骨软骨厚度相对较薄,抵御外力的能力较差。Shepherd 等^[15]的研究显示,踝关节的软骨厚度为 0.7 ~ 1.2 mm,而膝关节



蓝色区域为病灶三维重建模型及各方向观察的形态。

图 1 基于 MRI 的距骨骨软骨损伤病灶三维模型

表 1 2 组距骨骨软骨损伤患者基线资料

组别	样本量/ 例	性别/例		年龄/ ($\bar{x} \pm s$, 岁)	病程/ ($\bar{x} \pm s$, 周)	体质量指数/ ($\bar{x} \pm s$, $\text{kg} \cdot \text{m}^{-2}$)
		男	女			
常规组	30	18	12	46.76 ± 4.69	6.63 ± 3.06	24.89 ± 4.58
冲击波组	30	14	16	47.56 ± 5.32	6.90 ± 2.85	25.27 ± 5.08
检验统计量		$\chi^2 = 1.071$		$t = 0.617$	$t = 0.348$	$t = 0.299$
P 值		0.301		0.540	0.729	0.766

表 2 2 组距骨骨软骨损伤患者治疗前后踝关节疼痛视觉模拟量表评分

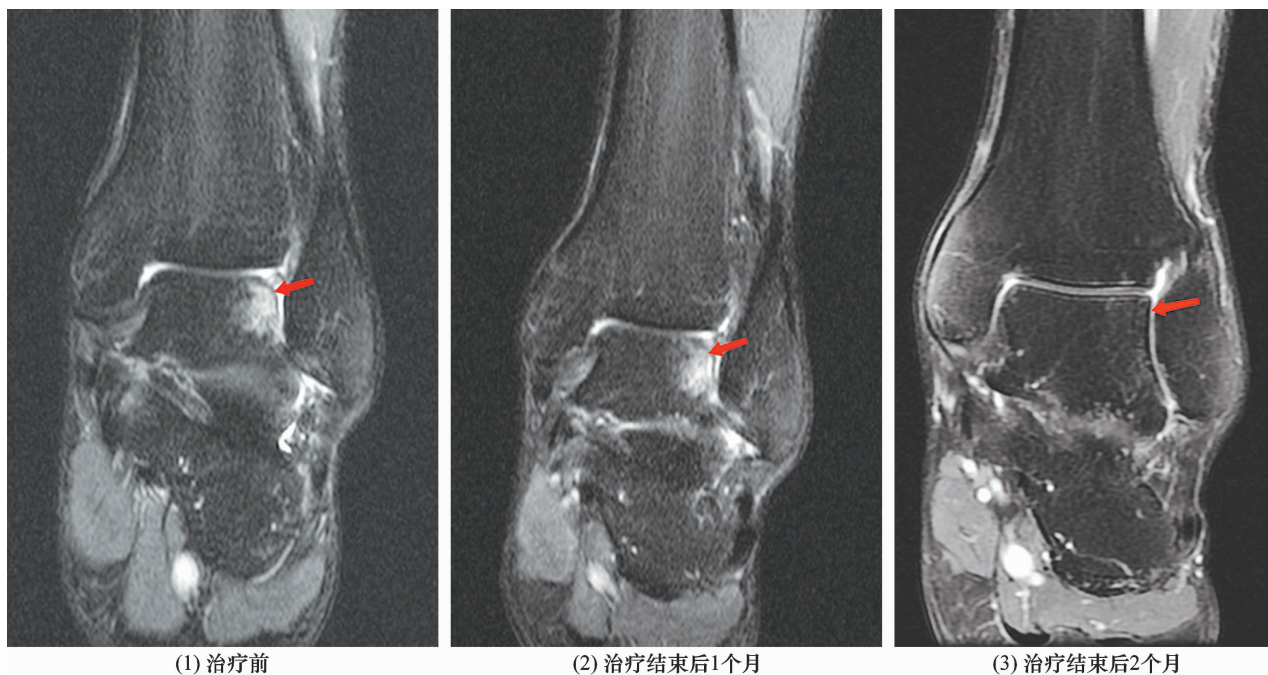
组别	样本量/例	踝关节疼痛视觉模拟量表评分/(M, Q, 分)		Z 值	P 值
		治疗前	治疗结束后 2 个月		
常规组	30	5, 2	5, 2	-2.828	0.005
冲击波组	30	5, 2	3, 1	-4.902	0.000
Z 值		0.139	37.890		
P 值		0.709	0.000		

表 3 2 组距骨骨软骨损伤患者治疗前后美国足与踝关节协会踝与后足评分

组别	样本量/例	美国足与踝关节协会踝与后足评分/(M, Q, 分)		Z 值	P 值
		治疗前	治疗结束后 2 个月		
常规组	30	69.50, 11.75	72.00, 11.25	-4.450	0.000
冲击波组	30	68.50, 11.50	78.50, 13.75	-4.793	0.000
Z 值		0.351	3.944		
P 值		0.554	0.047		

表 4 2 组距骨软骨损伤患者治疗前后病灶体积

组别	样本量/例	病灶体积/(M, Q, cm^3)		Z 值	P 值
		治疗前	治疗结束后 2 个月		
常规组	30	1.74, 0.77	1.79, 0.54	-0.160	0.873
冲击波组	30	1.77, 0.76	1.27, 0.71	-4.783	0.000
Z 值		0.184	15.134		
P 值		0.668	0.000		



箭头指示处为病灶区域。

图 2 Hepple II 期距骨骨软骨损伤体外冲击波法治疗前后 MRI

的软骨厚度为 1.5 ~ 2.6 mm。距骨及其软骨的这些特点,导致其容易出现继发性损伤。

本研究中,治疗后常规组患者的踝关节疼痛和关节功能均有所改善,但病灶体积却没有明显改变。这主要是因为针刺、超声波治疗、踝周肌力训练、口服药物以及限制负重等常规治疗方法均聚焦于缓解踝关节疼痛症状、改善踝关节功能,其本身并不具备促进 OLT 病灶修复的作用。冲击波组在常规疗法的基础上辅以 ESWT,治疗后患者的踝关节疼痛、踝关节功能及病灶体积均较治疗前明显改善,且效果优于常规组。其原因可能包括以下几点:①ESWT 能够通过抑制 P 物质的释放缓解疼痛^[16]。②ESWT 可直接作用于感觉神经末梢,提高疼痛阈值,阻止疼痛信号的产生和传播^[17]。③ESWT 一方面通过对损伤区域的重复机械刺激,使治疗区域发生微损伤并激活软骨保护机制^[18];另一方面这种机械刺激,又可影响软骨细胞中的一些机械敏感信号通路,从而加速软骨细胞增殖,延缓其退变^[19]。④OLT 后软骨下骨水肿可引发

距骨内压力升高,静脉高压,血液循环障碍,使软骨下骨小梁骨折和缺血性骨坏死风险增加,一旦发生上述情况可导致软骨下骨质塌陷,使距骨软骨失去支撑,进而加重软骨损伤。本研究纳入的病例均为早中期 OLT,未发生距骨塌陷。此阶段的治疗除致力于促进软骨损伤修复外,另一个重要目标则是提高软骨下骨骨密度,预防距骨塌陷,防止踝关节畸形的发生。ESWT 可作用于软骨下骨,延缓其结构改变^[20],并且通过上调增殖细胞核抗原和骨形态发生蛋白-2 诱导成骨^[21],增加软骨下骨骨密度,预防骨质塌陷。

既往对 ESWT 疗效的争议,部分原因与相关研究缺乏客观疗效指标有关。因此,本研究创新性地应用基于 MRI 病灶三维模型测量病灶体积。以往研究中基于二维影像测量 OLT 病灶大小,会因治疗前后所选取 MRI 层面、踝关节扫描平面角度、MRI 扫描层厚不一致等因素导致测量结果出现偏差。另外,相关研究在病灶边界的分割时均依靠人工识别,但 MRI 图像具有模糊和不均匀的特点,会导致测量结果出现偏

差。这些因素最终导致研究结果可靠性不足,引发争议。King 等^[22]将 OLT 病灶测量分为传统测量和计算机辅助测量 2 组,发现传统测量组所获得数据较计算机辅助测量组偏差值可达 864%。针对以上情况,本研究基于 MRI 图像建立病灶三维模型,进行观察、测量,避免了基于二维影像数据测量所存在的问题,使研究结果更为可靠。此外,本研究在病灶边界分割过程中,运用 Mimics 软件的勘察剖面线功能进行后处理,提取病灶边界灰度值标本,完成病灶灰度值区间的界定,将病灶边界从二维影像数据中逐帧精准分割出来。这种半自动交互式分割法,能够解决医学影像图像分割数据量大、分割要求高等问题,有效规避了人工识别导致的偏差,可精确重建病灶三维模型,从而确保了 OLT 病灶体积测量数据的准确性。

本研究的结果提示,采用 ESWT 治疗早中期 OLT,有助于缓解踝关节疼痛、改善踝关节功能、控制病灶进展。

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