

·综述·

白细胞酯酶诊断关节假体感染的意义

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摘要: 关节假体周围感染 (periprosthetic joint infection, PJI) 是关节置换术后灾难性的并发症, 一旦发生, 会给患者带来很大的心理和经济负担。所以及时且正确的诊断很重要。目前常用的诊断方法根据临床表现、影像学表现、血清与滑液标记物等制定, 随着更多的血清与滑液标记物的发现与实验, 生化指标检查日益重要, 有些滑液标记物易受到炎症的影响。近年来白细胞酯酶 (leukocyte esterase, LE) 逐渐被重视, LE 有较高的敏感性和特异性。因此, 应结合其他临床评价和辅助检查来诊断。LE 水平的影响需要进一步研究。本文综合分析目前有关滑液 LE 的临床研究, 对其在 PJI 诊断中的研究现状和临床价值进行综述。

关键词: 关节假体周围感染, 生物标志物, 滑液白细胞酯酶

中图分类号: R318

文献标志码: A

文章编号: 1005-8478 (2024) 01-0044-06

Significance of leucocyte esterase in diagnosis of periprosthetic joint infection // ZHANG Cang-xu¹, DU Wen-hao¹, ZHANG Da-hai², XIE Shi-cheng². 1. Clinical College, Jining Medical University, Jining 272067, China; 2. Department of Joint Surgery, Affiliated Hospital, Jining Medical University, Jining 272007, China

Abstract: Periprosthetic joint infection (PJI) is a catastrophic complication after arthroplasty. Once it happens, it will bring great psychological and economic burden to patients, so timely and correct diagnosis is crucial. At present, the commonly used diagnostic methods are formulated according to clinical manifestations, imaging manifestations, serum and synovial biomarkers, etc. With the discovery and experiment of more serum and synovial biomarkers, the examination of biochemical indicators become increasingly important, regardless of some synovial biomarkers easily affected by inflammation. In recent years, leukocyte esterase has been paid more and more attention, which has high sensitivity and specificity for diagnosis of PJI, despite of that other clinical evaluations and auxiliary examinations should be combined in the diagnosis. Effectiveness of leukocyte esterase for diagnosis of PJI need further research. This article comprehensively analyzes the current clinical research on synovial leucocyte esterase, and reviews its research status and clinical value in the diagnosis of PJI.

Key words: periprosthetic joint infection, biomarker, synovial fluid, leukocyte esterase

随着医学技术的不断精进, 全关节置换术是晚期髋、膝关节疾病的有效手术治疗, 其中, 假体周围感染 (periprosthetic joint infection, PJI) 是人工关节置换术后最严重的并发症之一^[1-3]。Yu 等^[4]的报道中, PJI 发病率在原发性关节置换术中为 1%, 翻修术中为 5%, 占膝关节置换术失败的 25% 和髋关节置换术失败的 16%^[5, 6]。

根据 PJI 问题第二次国际共识会议提出的 PJI 的定义^[7]。血清学指标如血清 CRP^[8]、D-二聚体^[9, 10]和红细胞沉降率^[8], 滑液指标如白细胞酯酶^[11, 12]、滑膜 α -防御素^[13, 14]、滑液白细胞计数^[8, 15], 以及多形核百分比^[8, 15]。血液标本方便且易获得, 但却易受

其他因素影响, 如其他部位感染等。近年大量文献报道滑液生物标记物在 PJI 诊断中的价值^[16]。有研究报道生物标志物比其他临床指标有更高的诊断价值^[17]。Koh 等^[18]的实验结果显示, 白细胞酯酶 (leukocyte esterase, LE) 检测对于膝关节置换术后 PJI 具有很高的诊断价值, LE 被认为是众多生物标志物中最有价值的生物标志物之一^[19]。

1 LE 的产生及作用机制

LE 是人体感染体液中的嗜中性粒细胞特异性释放的酶, 在机体发生炎性反应时, 因为多核白细胞具

有趋化性，在炎症部位积聚从而释放 LE。LE 可水解 5-溴 4-氯-3-吲哚乙酸盐，释放溴吲哚基，后者在有氧条件下可发生颜色变化，显色深度与 LE 活性成正比，可以利用生化反应来检测，这种酶类只在中性粒细胞内存在，检测阳性说明标本中有白细胞存在（或中性粒细胞），表示有炎症，但不能说明是什么病原体感染。

2 滑液 LE 临床价值的研究现状

2.1 滑液 LE 与其他生物标志物诊断价值比较

一些标准如滑液检测是有创的、昂贵的、不方便

获得的^[20]。而 LE 是一种用于检测 PJI 的优良标志物，其特点是简单、经济、快速。最近一项大样本量研究报告称，与滑膜 WBC 计数和多形核中性粒细胞百分比（PMN%）相比，LE 的表现最佳^[21]。有荟萃分析显示，LE 条试验的敏感性和特异性分别为 0.89 (0.86~0.91) 和 0.86 (0.80~0.90)^[22]。

在 Shohat 等^[23] 的实验中，比较了 LE 和 α -防御素的敏感性、特异性、曲线下面积、阳性和阴性预测值，见表 1。在这两种滑液生物标志物的比较中， α -防御素在 PJI 的诊断中不能提供比 LE 更多的益处，两者相差不大，由于 LE 非常便宜，床旁测试也很方便，所以潜在的应用价值更大。

表 1 LE 与 α -防御素的诊断价值

Table 1 Diagnostic value of LE and α -defensin

	敏感性 (95%CI)	特异性 (95%CI)	曲线下面积 (AUC)	阳性预测值 (95%CI)	阴性预测值 (95%CI)
LE	82.1% (63.1~93.9)	98.9% (94.2~100.0)	0.905 (0.820~0.991)	95.8% (76.5~99.4)	94.9% (89.4~97.6)
α -防御素	85.7% (67.3~96.0)	96.9% (91.3~99.4)	0.913 (0.834~0.992)	89.0% (72.2~96.1)	96.0% (90.5~98.3)

在 Carli 等^[24] 的荟萃分析结果显示，203 项研究符合纳入标准，其中 170 项存在较高的偏倚风险，确定了 83 个独特的 PJI 诊断测试，并进行了 17 项荟萃分析。结果显示基于实验室的滑膜 α -防御素试验和 LE 试剂条 (2+) 表现最佳，其次是白细胞计数，滑膜 C 反应蛋白水平的测定，多形核中性粒细胞百分比的测定和 α -防御素侧流试验试剂盒。

在 Logoluso 等^[25] 的实验中，研究了 PJI 患者滑液样本中 LE 的可靠性（表 2）。结果显示，与血清 C 反应蛋白（C-reactive protein, CRP）或红细胞沉降率（erythrocyte sedimentation rate, ESR）或血清 CRP 和 ESR 的组合相比，术中 LE 试验阳性可更好地预测持续性感染。LE 测定的敏感性、特异性、阳性预测值和阴性预测值分别为 82%、99%、90% 和 97%。LE 条带测试被证明是诊断 PJI 持续性的可靠测量方法，在灵敏度和特异度方面优于血清 CRP 和 ESR 测定。条带试验为 PJI 复查期间提供了有价值的术中诊断。

表 2 各诊断指标对 PJI 诊断的可靠性
Table 2 Reliability of various diagnostic items for PJI diagnosis

	LE 条带测试	血清 CRP	ESR	血清 CRP+ESR
敏感性 (%)	82	82	55	82
特异性 (%)	99	84	87	77
阳性预测值	90	41	26	36
阴性预测值	97	94	94	96
准确度 (%)	96	82	67	-

在 Zagra 等^[26] 的研究中，比较了 LE 测定与冷冻

切片组织学的敏感性、特异性、阳性和阴性预测值（表 3）。与 FS 组织学相比，LE 测定的灵敏度更高，具有相似的特异性和诊断准确性。但 LE 具有方便、时间短和低成本的特点，使 LE 替代 FS 组织学成为可能。

表 3 LE 与冷冻切片组织学比较
Table 3 Comparison between LE and frozen section histology

结果 (%)	LE	冷冻切片组织学	P 值
敏感性	100 (82.2~100)	78.3 (55.8~92)	0.049
特异性	93.8 (86.4~97.4)	96.9 (90.5~99.2)	0.497
阳性预测值	79.3 (59.7~91.3)	85.7 (62.6~96.2)	0.423
阴性预测值	100.0 (94.9~100)	94.9 (87.9~98.1)	0.060

2.2 滑液 LE 在服用抗生素患者中的诊断价值

在 Shahi 等^[27] 的研究中，共纳入 121 例根据肌肉骨骼感染协会确诊的 PJI 而接受髋关节或膝关节置换术的患者。所有患者进行了 LE 试纸条测试。一组患者 (32%) 在检查前服用抗生素，而另一组患者 (68%) 在检查后 2 周内未接受抗生素治疗。收集 LE 试纸条试验、ESR、CRP、滑膜白细胞计数和多形核中性粒细胞 (polymorphonuclear neutrophils, PMN) 百分比，并进行比较（表 4）。

与未接受抗生素治疗的患者相比，接受抗生素治疗的患者，血清中位 ESR (85 mm/h vs 67 mm/h, $P=0.009$)，CRP (16.5 mg/L vs 12.9 mg/L, $P=0.032$)，滑膜白细胞计数 (45 675 细胞/ μ L vs 9 650 细胞/ μ L, $P<0.001$) 和 PMN 百分比 (93% vs 88%, $P=0.004$) 均显

著降低。此外，抗生素组中，只有 LE 敏感性变化不大，其余的所有试验的敏感性均降低，ESR（抗生素队列中为 79.5%，而无抗生素队列中为 92.7% [假阴性结果的相对风险 (RR) : 2.8, $P=0.04$]，CRP (64.2% vs 81.8%, RR: 1.9, $P=0.03$)，WBC 计数 (69.3% vs 93.4%, RR: 5.0, $P<0.001$)，PMN 百分比 (74.4% vs 91.5%, RR: 3.0, $P=0.01$) 和 LE (78% vs 83%, RR: 1.6, $P=0.17$)。抗生素组的阴性培养率较高，为 30.7%，而无抗生素组为 12.1% ($P=0.015$)。

表 4 实验室测试抗生素组和无抗生素组诊断敏感性的比较
Table 4 Comparison of diagnostic sensitivity between the antibiotic group and the antibiotic free group in laboratory tests

诊断测试	抗生素组 (%)	无抗生素组 (%)	假阴 RR 值	P 值
LE	77.8	83.1	1.3	0.170
血清 ESR	79.5	92.7	2.8	0.040
血清 CRP	64.2	81.8	1.9	0.030
滑液白细胞计数	69.3	93.4	5.0	<0.001
滑液中性粒细胞百分比	74.4	91.5	3.0	0.010
滑液细菌培养	69.3	87.9	2.5	0.015

此项研究表明，过早使用抗生素会损害 PJI 的标准诊断测试结果，导致假阴性结果显著增加。然而，在这项研究中，LE 试纸条试验即使在抗生素给药的情况下也保持了诊断性能。在 PJI 的诊断性病情检查前给予抗生素会干扰诊断，LE 试纸条试验可用作诊断 PJI 的可靠诊断标志物。还有研究表明，因为它不受抗生素的影响，可用于帮助确定分阶段修订方法后再植入是否可能成功^[28]。

表 5 条形试验分析测试诊断 PJI 的准确性
Table 5 Accuracy of PJI diagnosis by bar test analysis

	LE 试纸++或+++	葡萄糖试纸	LE 试纸 (++或+++) 联合葡萄糖试纸
敏感性 (95%CI)	0.67 (0.54~0.81)	0.57 (0.42~0.71)	0.50 (0.36~0.64)
特异性 (95%CI)	0.91 (0.85~0.97)	0.88 (0.81~0.94)	0.98 (0.95~1.01)
阳性预测值 (95%CI)	0.78 (0.65~0.90)	0.68 (0.51~0.86)	0.92 (0.80~1.03)
阴性预测值 (95%CI)	0.86 (0.79~0.92)	0.81 (0.74~0.89)	0.80 (0.73~0.87)
阳性似然比 (95%CI)	7.41 (3.13~11.66)	4.67 (1.23~8.09)	24.63 (17.62~31.64)
阴性似然比 (95%CI)	0.40 (0.32~0.48)	0.50 (0.41~0.58)	0.51 (0.43~0.60)

检测。

在 Li 等^[33]的研究中，93 例患者包括 38 例 PJI 和 55 例非感染病例。LE 条带试验的敏感性和特异性分别为 92.1% (95% CI 77.5% ~97.9%) 和 96.4% (95% CI 86.4% ~99.4%)。在 Kuo 等^[34]和 Levent 等^[35]的研究中，LE 是 PJI 诊断优秀的次要标准。在

3 LE 检测

3.1 方法及现状

LE 筛选试验的吸引力在于它给药迅速且获取成本低廉。诊断 PJI 的挑战之一是目前缺乏可用的床旁

Grzelecki 等^[36]的研究中，证明了两种 LE 试纸均具有较高的准确性。在 Shohat 等^[23]的实验中验证了 LE 可以区分 PJI 病例与非感染病例，P 值均小于 0.001。

3.2 检测时间的选择

术前关节穿刺是应用较多的方法，术前关节活检也是常用的检测方法。LE 试纸检测的样本多样，包括血液和多种体液样本，受多方面影响，而且检测术前术中均可进行。在 Salar 等^[37]的报道中，用抽吸或活检进行床旁 LE 试验有很好的效果。在 Abdelbary 等^[38]的研究中，如果关节抽吸产生湿抽，强烈建议使用 LE 条带进行床旁检测，读数为++或更大表示 PJI；下面读数++之后应进行一项实验室的滑膜测试。

LE 的问题之一是测试结果取决于技术。例如，在抽吸物被血液污染时，外科医生常使用离心来减少红细胞的存在，这可能会影响分析条带的结果。Li 等^[39]建议在解释 LE 条测试结果时，应考虑离心的影响。对于没有离心的情况，建议使用++作为正阈值，而对于使用离心的患者，阈值应同时降低为++和+。

有作者认为，颜色的深度比滑膜细胞计数等定量标记更主观，也有医生不建议使用 LE，认为其不具有高敏感性，有研究表明其敏感性可能低至 72.4%^[40]。但这种敏感性可能是由于读取 LE 条太早。因为在 Tan 等^[41]的实验结果显示 LE 条带测试结果受时间和离心的影响。对于未离心的样品，测试发现应用后 5 min 是读取 LE 条的最佳时间。不能否认离心机的使用，因为这是目前解决样品混合问题的有效方法。所以建议在离心后 10 min 作为读取 LE 条的最合适时间。

Zheng 等^[42]认为使用自动化、定量和 AI 对 LE 条带测试进行解释可能会提高 PJI 诊断的准确性，特别是以 AI 为代表的新技术的发展，有希望将 LE 带测试进行改进，来弥补 LE 条带测试在 PJI 诊断中作为高精度床旁检测的不足。

4 展望

PJI 一直是关节置换术后较难处理的并发症之一，及时正确的诊断能使患者早治疗，节省治疗费用的同时获得良好预后。现在国内外许多学者研究 LE 与 PJI 的关系，LE 试纸对 PJI 诊断价值的实验较多，在多数研究报道中 LE 诊断 PJI 具有较高的敏感性和特异性。

本文总结了滑液 LE 诊断 PJI 的一些临床研究。发现目前临幊上 LE 对 PJI 的诊断仍存在一些缺点：(1) 研究多按照 MSIS 诊断标准进行分类，有些研究标准不统一；(2) 有研究表明 LE 联合其他指标会提高敏感性与特异性，有一些 LE 与 α-防御素对 PJI 诊断的比较，LE 与其他滑液生物标志物的比较较少，目前 LE 联合其他滑液及血清标志物对诊断 PJI 的研究也较少；(3) LE 应用较多的是 LE 试纸检测，方便并且廉价，但 LE 检测在使用的条状试剂方面缺乏标准化，并且在排除血性样品时限制了样品量，是否有 LE 相关的更好的测试方法^[43]；(4) 样本中混有血液等物质时往往使 LE 条带试验的结果不可读，而离心的时间长短也有待系统性地研究。

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(收稿:2022-10-27 修回:2023-06-29)

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(本文编辑: 宁桦)

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(收稿:2023-01-29 修回:2023-07-31)

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