

热消融术在结直肠癌肝转移瘤中的价值争论

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摘要: 肝切除术是可切除结直肠癌肝转移瘤(colorectal liver metastases, CRLM)的首选治疗方式, 但近80%的CRLM患者在初诊时不可切除。笔者所在中心认为针对不可切除或肿瘤解剖位置深在但<3cm的CRLM, 若肝切除术联合热消融术能达到无疾病证据状态(no evidence of disease, NED), 有利于患者的远期生存。但笔者2023年在日本访学期间, 了解到日本外科学者对CRLM的热消融治疗持谨慎、质疑态度, 主要基于热消融术后比较高的不完全消融率及局部复发率。但回顾既往文献, 多数中心将“不可切除”的CRLM作为热消融术的主要指征, 这可能导致不可避免的选择偏倚。国内外学者积极探索, 认为当CRLM<3cm、解剖位置深在、结节多发或分布于多个肝叶时, 单独热消融或热消融联合肝切除术在能达到NED的前提下, 具有积极意义。针对不可切除CRLM, 热消融联合化疗的远期生存也要优于单纯化疗。

关键词: 热消融术, 结直肠癌肝转移瘤

Debate on the value of thermal ablation in colorectal liver metastases

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Abstract: Hepatectomy is the preferred treatment for resectable colorectal liver metastases (CRLM), but CRLM is unresectable in nearly 80% of patients at the time of initial diagnosis. The facility where the author works believes that if hepatectomy combined with thermal ablation can achieve a no evidence of disease (NED) status for CRLM that is unresectable or in a deep anatomical location but less than 3cm in size, then this approach would be beneficial to the patient's long-term survival. However, during a visit to Japan in 2023, the author learned that Japanese surgeons are cautious and skeptical about thermal ablation to treat CRLM, mainly based on the relatively high rate of incomplete ablation and the rate of local recurrence after thermal ablation. However, a review of the literature indicates that most centers regard "unresectable" CRLM as the main indication for thermal ablation, which may lead to inevitable selection bias. Domestic and foreign scholars are actively exploring the positive value of thermal ablation alone or in combination with liver resection, predicated on achieving an NED status when the CRLM is less than 3 cm in size, the metastasis is in a deep anatomical location, and nodules are multiple or distributed in multiple lobes of the liver. For unresectable CRLM, thermal ablation combined with chemotherapy results in a better long-term survival than that of chemotherapy alone.

Keywords: thermal ablation, colorectal liver metastases

1. 引言

肝脏是结直肠癌血行转移最主要的靶器官⁽¹⁾。在结直肠癌患者的整个病程中, 有将近一半的患者会发生肝转

移⁽²⁾。肝切除术(hepatic resection, HR)是可切除CRLM患者的首选治疗方式^(3,4)。CRLM患者接受根治性HR后5年无病生存率约为20%^(5,6), 5年整体生存率(overall survival, OS)为21~58%⁽³⁾, 有报道肝脏寡转移患者HR后5年OS高达71%⁽⁷⁻⁹⁾。然而, 近80%的CRLM在初始诊断时不可切除^(10,11)。不可切除CRLM包括外科学不可切除和肿瘤学不可切除两大类。导致外科学不可切除的因素主要包括病人全身情况不能承受手术创伤、肝功能不能耐受、剩余肝体积不足等。

热消融治疗(thermal ablation, TA)主要包括射频消融(radiofrequency ablation, RFA)与微波消融(microwave ablation, MWA)。单独TA或者TA联合HR在原发性肝癌外

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科治疗中的价值得到肯定^(12,13)，但TA应用于CRLM的价值一直以来存在着争议。笔者所在中心针对部分外科学不可切除及肿瘤解剖位置深在但 $<3\text{cm}$ 的CRLM患者，采用单独TA或者TA联合HR方式，认为亦可达到NED状态，对患者预后有利。但笔者2023年在日本东京大学附属病院及国立国际医疗研究中心病院访学期间，发现日本外科医生对CRLM的TA治疗常持更谨慎甚至质疑态度，其主要顾虑在于TA术后不理想的完全消融率和比较高的局部复发率（local recurrence, LR）。本文综述国内外学者对于TA应用于CRLM的数据与观点，旨在探讨TA在CRLM中的价值。

2. TA应用于CRLM的不完全消融率与LR及其原因分析

文献报道TA用于CRLM的完全消融率为81~94%⁽¹⁴⁻¹⁷⁾，LR不一，从2%到60%^(12,16,18,19)。分析导致不完全消融和LR的原因主要有以下几方面：

2.1. CRLM无包膜

不同于肝细胞癌，CRLM无包膜，呈浸润性生长。CRLM的实际大小术前难以准确评估⁽²⁰⁾；

2.2. 肿瘤 $>3\text{cm}$

肿瘤 $>3\text{cm}$ 被认为是LR的危险因素^(15,21,22)。Hammil等人报道 $<3\text{cm}$ CRLM经过TA治疗后的LR为3%， $3\sim5\text{cm}$ 为4%⁽²³⁾，而 $>5\text{cm}$ CRLM的TA治疗后LR在27~45%之间^(23,24)。分析原因可能跟TA的有效消融范围、 $>3\text{cm}$ 肿瘤的生物活性等因素相关。

2.3. 病灶特殊的解剖位置

(1) 靠近主要血管或者肝蒂的CRLM 由于血液流动的热沉效应，消融血管旁肿瘤更加困难。Qin⁽²⁵⁾、Wong⁽²⁶⁾等认为病灶位于血管旁是术后LR的危险因素。Jiang⁽²⁷⁾等研究报道当病灶位于 $\geq 3\text{mm}$ 血管周围时，将导致消融不完全，是术后LR的独立危险因素。Wada^(25,28,29)等报告肿瘤直接接触主要肝静脉时，TA后LR达到42.9%。

(2) Wada⁽²⁸⁾等同时认为病灶位于肝后上段（第1、7、8段）且 $>15\text{mm}$ 是LR的独立危险因素，考虑与以下几个因素相关：7段病灶位置深、穿刺针道长导致穿刺难度大、术中超声评估穿刺针道及消融边缘困难；8段肿瘤尤其是靠近膈顶穹隆位置时，需要较小的穿刺角度和较长的穿刺距离，均有可能导致消融不完全；1段肿瘤位置深且被主要血管包绕，穿刺针道长且受限，同时为减少胆管热损伤风险，1段肿瘤的消融边缘也受到限制。

(3) 病灶位于包膜下 可能是影响CRLM治疗效果的另一个因素。位于包膜下的CRLM在消融技术上存在困难，肝包膜附近CRLM在TA时不能获得足够的消融边缘，甚至可能对邻近结构造成热损伤，如横膈膜和胃肠道、出血或肝外肿瘤扩散⁽³⁰⁻³⁴⁾。但该技术困难理论上可通过腹腔镜或开腹手术解决。

2.4. 术中难以即时准确评估消融边缘

与HR术中肿瘤切缘的宽度与OS的延长相关相似，TA的消融边缘与剩余肿瘤细胞的活性相关，足够的消融边缘是TA实现局部肿瘤控制的关键决定因素⁽³⁵⁻³⁸⁾。Kurilova、Wada等^(28,39)认为 $>1\text{cm}$ 的消融边缘能提供良好的肿瘤控制，但是增加了部分患者胆道并发症的发生率。最小消融边缘 $\leq 5\text{mm}$ 被认为是消融不完全的重要危险因素⁽³⁰⁾。但不同于HR时切缘的直观测量，消融边缘仅能通过影像来评估。受病灶与周围组织信号强度、密度、回声相似导致的分辨率不足或干扰、术中多方位立体评估难度大等因素影响，术中术后准确评估消融边缘存在困难。

2.5. 不同的消融方式（RFA vs. MWA）

TA治疗CRLM相关文献中，多使用RFA⁽⁴⁰⁻⁴³⁾，MWA相较于RFA，理论上具有以下优势：受热沉效应的影响较小⁽³⁸⁾，具有更快的消融时间、更大的消融区域、更高的瘤内温度和更完全的凝固性坏死⁽⁴³⁻⁴⁵⁾。Correa-Gallego等⁽⁴⁶⁾学者统计分析认为，与RFA相比，MWA后LR更低。

3. 较高的不完全消融率及LR预示着比较差的生存预后，但TA的患者选择指征存在选择偏倚

一项meta分析⁽⁴⁷⁾显示，HR治疗CRLM的3年OS和5年OS分别为55~82%、23~66%，而RFA治疗CRLM的3年OS和5年OS分别为32~84%、17.9~49%，提示HR的3年OS（RR: 1.377,95%CI: 1.246~1.522）、5年OS均显著优于RFA组（RR: 1.474,95%CI: 1.284~1.692）。

日本结肠癌和直肠癌学会2019年结肠直肠癌治疗指南⁽⁴⁸⁾指出，关于TA有效性的报道较少，由于TA治疗CRLM伴随着LR高风险，应尽可能考虑切除。对于可切除CRLM，手术切除是标准治疗方法，因此不推荐TA作为首选的治疗方法；对于不可切除CRLM，全身治疗是标准治疗，因此也不推荐TA用于不可切除的病变。

然而，回顾既往文献报告⁽⁴⁹⁻⁵³⁾，发现多数中心将不可切除的CRLM作为TA的主要指征，这可能导致不可避免的选择偏倚。不可切除因素主要包括健康状况不佳、剩余肝脏功能储备不足、病灶数目多或散在分布于多个肝叶、病灶位于特殊部位如靠近大血管而对手术不耐受等。因此HR往往实施于条件比较好的患者，而TA往往应用于条件不佳患者。其次，HR可以更好地进行术中分期和术后病理评估，有助于优化术后化疗和生物治疗策略⁽⁴⁷⁾。以上因素均有可能是导致TA治疗CRLM疗效劣于HR的原因。一项由国际消融术专家小组撰写的立场文件显示，荟萃分析15篇论文中接受RFA治疗的1613例CRLM患者，从首次TA日期开始，平均3年OS为50%（37~77%），平均5年OS为31%（17~51%）。几乎所有的研究都在不可切除的患者中使用RFA，但RFA应用于潜在可切除疾病的患者时，5年OS增加到50%⁽⁵⁴⁾。

4. TA应用于CRLM的积极价值

目前鲜有在同等基线条件下TA对比HR治疗CRLM的相关临床研究。但国内外学者积极尝试，认为针对CRLM的治疗，TA在以下几个方面具有积极价值：

4.1. 针对<3cm CRLM

Gillams等⁽⁵⁴⁾分析认为, TA应用于CRLM, 局部肿瘤进展率随着肿瘤大小的减小而持续降低, 目前最常用的分界点为3cm。Tez等⁽⁵⁵⁾认为<3cm CRLM开放RFA术后的局部复发率相当于HR。对于合并其他全身疾病不能耐受HR或不愿手术患者, TA是一个适宜的选择方案。

4.2. 针对解剖位置深在的CRLM

对于解剖位置深在的CRLM, HR需要牺牲比较多的正常肝实质。若考虑TA可达到NED, 则TA治疗可以保存尽可能多的残肝体积⁽⁵⁶⁾。

4.3. TA联合化疗 vs. 单纯化疗

对于不可切除CRLM, TA联合化疗患者的远期生存要优于单纯化疗患者⁽⁴⁰⁾。文献显示, TA联合化疗可以帮助延长不可切除CRLM患者的OS, 3年OS可达37~77%, 5年OS可达17~51%, 而同期仅接受化疗的不可切除CRLM患者5年OS接近0%⁽⁵⁴⁾。一项旨在研究初始不能手术CRLM患者系统化疗同时增加TA的随机对照试验(EORTC-CLOCC)⁽⁵²⁾显示: RFA联合化疗组的30个月OS为61.7% (95%CI: 48.2~73.9%), 而单独化疗组为57.6% (95%CI: 44.1~70.4%)。经过9.7年的中位随访, RFA联合化疗组OS要显著优于单纯化疗组(HR = 0.58; 95%CI: 0.38~0.88), 其中RFA联合化疗组的8年OS为35.9%, 而单独化疗组为8.9%。联合化疗组的中位DFS显著延长, 为16.8个月(95%CI: 11.7~22.1), 而单独化疗组的中位DFS为9.9个月(95%CI: 9.3~13.7), HR为0.63(95%CI: 0.42~0.95, $p=0.025$)。

4.4. 针对多个结节或分布于多个肝叶的CRLM, TA联合HR

ESMO⁽⁵⁶⁾指南将≥5个结节患者定义为交界可切除, 认为不能单纯用HR处理。wada等⁽²⁸⁾将≥5个结节的CRLM患者分为可切除组(虚拟残肝体积≥30%)和不可切除组(虚拟残肝体积<30%), 通过回顾性分析认为: 积极的外科治疗(TA和/或HR)处理交界可切除或不可切除的CRLM, 能达到一个较好的远期生存, 可切除组和不可切除组患者的3年生存率分别为51.4%和44.6%。5年生存率分别为33.3%、33.7%。虽然两组中大部分患者出现了复发, 但是仍有近一半的患者可以再次接受外科处理⁽⁵³⁾。相比之下, 虽然CRLM患者的全身化疗方案得到改善, 但增加的生存获益有限, 在没有手术的情况下, 3年OS为20~30%^(57,58)。K. Imai等⁽⁵⁹⁾通过对553例接受HR的CRLM患者资料进行倾向性匹配分析认为, RFA联合HR治疗CRLM后的短期和长期预后与单独HR术后相似。HR+RFA组患者的OS和DFS率与单独HR组患者的OS和DFS率均无差异。Saxena等⁽⁶⁰⁾分析了701例接受HR和/或MWA的CRLM患者的结果, 在151例≥5个病灶的CRLM的患者中, HR联合MWA不仅获得了与单独HR相当的生存获益, 而且有效地扩大了可切除性的标准。Oba等⁽⁶¹⁾同时认为: MWA不仅能保留更多残肝体积, 还能保存肝脏中

的重要血管, 为复发后的再次外科治疗提供机会。Mima等⁽⁶²⁾学者认为, HR联合TA后肝内复发率高于单纯HR, 可能与HR联合TA治疗患者中高度恶性因素占比高相关, 这些高度恶性因素包括肿瘤多发、位于两个或多个肝叶、同时性肝转移等。Masuda等⁽⁶³⁾分析指出, 对于≥4个病灶的CRLM患者, 接受HR+RFA或单纯HR的预后是相似的, 认为肝脏中广泛转移性肿瘤数量可能中和RFA相关的负面预后影响。Viganò等⁽⁶⁴⁾统计分析也认为, ≥4个病灶是CRLM患者HR术后早期复发的独立危险因素。

5. 总结

综上所述, 考虑到CRLM的浸润性生长方式, 或靠近大血管、主要肝蒂的热沉效应等导致不理想的完全消融率和比较高的LR, 以及伴随的胆道损伤风险, 笔者亦认同日本学者的意见, HR是可切除CRLM的首选治疗方式。但笔者中心同时认为, 针对部分外科学不可切除或解剖位置深在而<3cm的CRLM患者, 在能达到NED的前提下, 单独TA或TA联合HR是一个可供选择方案, NCCN、ESMO、中国结直肠癌肝转移指南均有推荐。在实施TA时, 安全的消融边缘(>5mm)是达到完全消融的重要保障。在同等基线条件下, 谨慎挑选的亚组如<3cm可切除CRLM, 开展TA对比HR的安全性和有效性的前瞻性随机对照研究的意义值得进一步探讨。

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