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· 专题研究 ·

扩大肝切除与局限肝切除治疗Ⅲ、Ⅳ型肝门部胆管癌有效性和安全性的Meta分析

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摘要

背景与目的: 肝门部胆管癌(HC)是临床上最常见的肝外胆管癌,其恶性程度高,预后较差,根治性切除仍是HC患者获得长期生存的最有效手段。Ⅲ、Ⅳ型(Bismuth-Corlette分型)HC病变复杂,手术难度大,危险程度高。通过局限肝切除手术风险相对低,但可能导致更高的切缘阳性率,从而影响预后,而扩大肝切除可以提高根治性切除率和生存率,但也增加了手术风险,因此,目前Ⅲ、Ⅳ型HC的肝切除范围尚无统一意见。本研究通过使用Meta分析的方法评价扩大肝切除和局限肝切除治疗Ⅲ、Ⅳ型HC的疗效和安全性,以期获得循证医学证据为临床提供参考。

方法: 检索多个国内外文献数据库,收集研究对象为比较扩大肝切除和局限肝切除治疗Ⅲ、Ⅳ型HC的临床对照研究文献,检索时间为各数据库自建库截至2022年11月30日。由两名研究者按照纳入和排除标准,独立筛选文献并提取数据,运用RevMan 5.2软件进行Meta分析。

结果: 共纳入11篇文献,844例Ⅲ、Ⅳ型HC患者;其中扩大肝切除组423例,局限肝切除组421例。Meta分析结果显示,与局限肝切除组比较,扩大肝切除组根治性切除率明显提高($OR=4.44$, $95\% CI=2.65\sim7.45$, $P<0.000\ 01$),临床预后更好($HR=0.53$, $95\% CI=0.41\sim0.68$, $P<0.000\ 01$);扩大肝切除组术后肝功能衰竭发生率升高($OR=3.00$, $95\% CI=1.07\sim8.40$, $P=0.04$),但术后死亡发生率($OR=1.12$, $95\% CI=0.25\sim4.99$, $P=0.88$)、术后总并发症发生率($OR=1.44$, $95\% CI=0.95\sim2.18$, $P=0.09$)及术后其他单个并发症发生率差异均无统计学意义(胆汁漏: $OR=1.44$, $95\% CI=0.68\sim3.04$, $P=0.34$;腹腔出血: $OR=0.77$, $95\% CI=0.29\sim2.05$, $P=0.60$;腹腔感染: $OR=1.36$, $95\% CI=0.50\sim3.71$, $P=0.55$)。此外,与局限肝切除组比较,扩大肝切除组术中出血量、手术时间、住院时间均明显增加($MD=153.48$, $95\% CI=32.63\sim274.33$, $P=0.01$; $MD=78.19$, $95\% CI=54.56\sim101.82$, $P<0.000\ 01$; $MD=2.55$, $95\% CI=1.61\sim3.50$, $P<0.000\ 01$)。

结论: 扩大肝切除术可以提高Ⅲ、Ⅳ型HC的根治性切除率,明显改善预后,并未增加术后死亡和总体并发症发生率,但术后肝功能衰竭发生率升高。鉴于研究的局限性,仍需更多前瞻性随机对照研究进一步证实。

关键词

Klatskin肿瘤;肝切除术;Meta分析

中图分类号:R735.8

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Efficacy and safety of extended hepatectomy versus limited hepatectomy for type III and IV hilar cholangiocarcinoma: a Meta-analysis

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Abstract

Background and aims: Hilar cholangiocarcinoma (HC) is the most common form of extrahepatic cholangiocarcinoma in clinical practice. It is highly malignant and associated with a poor prognosis. Radical resection remains the most effective approach for achieving long-term survival in HC patients. Type III and IV (Bismuth-Corlette classification) HC lesions are complex, with serious surgical difficulty and risk. Surgery by limited hepatectomy carries relatively low risk but may result in a higher rate of positive margins, which may affect prognosis. Conversely, extended hepatectomy may improve radical rates and survival and increase surgical risks. There is yet to be a consensus on the appropriate scope of hepatectomy for type III and IV HC. This study evaluated the efficacy and safety of extended hepatectomy and limited hepatectomy for type III and IV HC by a Meta-analysis to provide evidence-based guidance for clinical decision-making.

Methods: The clinical control studies comparing extended hepatectomy and limited hepatectomy for type III and IV HC were collected by searching several domestic and foreign literature databases, with a time restriction from inception to November 30, 2022. Two researchers independently screened the literature and extracted data according to inclusion and exclusion criteria, and Meta-analysis was performed using RevMan 5.2 software.

Results: A total of 11 articles involving 844 patients with type III or IV HC were included in the study, with 423 patients in the extended hepatectomy group and 421 patients in the limited hepatectomy group. The Meta-analysis results showed that compared to the limited hepatectomy group, the extended hepatectomy group had significantly higher radical rates ($OR=4.44$, 95% $CI=2.65-7.45$, $P<0.000\ 01$) and better clinical prognosis ($HR=0.53$, 95% $CI=0.41-0.68$, $P<0.000\ 01$). The extended hepatectomy group had a higher incidence of postoperative liver dysfunction ($OR=3.00$, 95% $CI=1.07-8.40$, $P=0.04$), but there were no statistically significant differences in postoperative mortality rate ($OR=1.12$, 95% $CI=0.25-4.99$, $P=0.88$), and incidence rates of overall complications ($OR=1.44$, 95% $CI=0.95-2.18$, $P=0.09$) and other individual complications (bile leakage: $OR=1.44$, 95% $CI=0.68-3.04$, $P=0.34$; abdominal bleeding: $OR=0.77$, 95% $CI=0.29-2.05$, $P=0.60$; abdominal infection: $OR=1.36$, 95% $CI=0.50-3.71$, $P=0.55$). Additionally, the extended hepatectomy group had significantly increased intraoperative blood loss, operative time, and hospitalization duration compared to the limited hepatectomy group ($MD=153.48$, 95% $CI=32.63-274.33$, $P=0.01$; $MD=78.19$, 95% $CI=54.56-101.82$, $P<0.000\ 01$; $MD=2.55$, 95% $CI=1.61-3.50$, $P<0.000\ 01$).

Conclusion: Extended hepatectomy can improve the radical resection rate and significantly enhance the prognosis for stage III and IV HC. Moreover, it does not increase postoperative mortality or overall complication rates. However, an elevated risk of postoperative liver failure is associated with extended hepatectomy. Given the limitations of this study, further prospective randomized controlled trials are still needed to provide additional verification.

Key words Klatskin Tumor; Hepatectomy; Meta-Analysis

CLC number: R735.8

肝门部胆管癌 (hilar cholangiocarcinoma, HC) 也被称为 Klatskin 肿瘤, 是发生于左、右肝管及其汇合部和肝总管之间的常见胆管恶性肿瘤^[1]。HC 解剖部位特殊, 容易侵犯邻近的肝实质和血管, 并且容易从胆管周围的淋巴管以及神经周围间隙向肝内外扩散转移, 预后较差, 根治性切除是 HC 患者获得长期生存的最有效手段^[2-3]。

目前临床多采用 Bismuth-Corlette 标准进行 HC 分型: I型肿瘤位于肝总管, 未侵犯汇合部; II型肿瘤侵犯左右肝管汇合部, 但未侵犯左右肝管; III型肿瘤侵犯右肝管 (IIIa) 或左肝管 (IIIb); IV型肿瘤同时侵犯左右肝内胆管^[4]。目前对于 HC 的治疗方案已基本达成共识, 根据 Bismuth-Corlette 临床分型, 结合术前影像学检查结果了解肝脏、血管及淋巴结受侵情况, 对 HC 实施肝外胆管切除联合肝叶切除、淋巴结清扫以及必要时血管切除重建^[5]。对 I、II型 HC 采用单纯肝外胆管切除或联合小范围肝切除治疗也已基本达成一致意见^[6-7]。但由于 III、IV型 HC 病变复杂, 手术难度大, 危险程度高, 其肝切除范围目前尚无统一意见^[8]。扩大肝切除可以将 HC 直接浸润的肝组织、肿瘤周围的血管神经组织以及可能存在的转移病灶整块切除, 从而提高根治性切除率, 延长 HC 患者生存期^[9-10]。但另有研究^[11-12]表明, 扩大肝切除并未提高患者术后生存率, 反而造成术后并发症发生率升高、病死率升高。因此, 对于 III、IV型 HC 患者实施扩大肝切除术治疗的疗效和安全性尚存在争议。本文目的是通过 Meta 分析以往发表过的有关文献, 以为扩大肝切除治疗 III、IV型 HC 的临床应用提供证据。

1 资料和方法

1.1 文献检索

在线检索 Cochrane Library、PubMed、Web of Science、中国生物医学文献数据库、维普、万方数据库和中国知网。检索期限为各数据库自建库

至 2022 年 11 月 30 日。中文检索词为: “肝门部胆管癌” “Bismuth-Corlette III、IV型” “扩大肝切除” “局限肝切除” “局部肝切除”; 英文检索词为: “Hilar Cholangiocarcinoma” “Bismuth-Corlette type III and IV” “Extended Hepatectomy” “Limited Hepatectomy” “Local Hepatectomy”。

1.2 纳入和排除标准

研究对象纳入标准: (1) HC 临床对照研究; (2) 确诊为 III、IV型 HC 患者, 并接受扩大肝切除或局限肝切除术; (3) 结局观察指标包括总生存率、根治性切除率、术后并发症发生率、手术时间、术中出血量、住院时间。排除标准: (1) 二次手术或胆囊癌侵犯肝门部; (2) 单组病例数 < 10 例的研究; (3) 病例报道、摘要、综述等。

1.3 文献筛选和资料提取

根据纳入标准、排除标准确定文献后, 两名研究者独立提取数据, 如有分歧, 双方讨论或请第三者判定。生存数据如果文献未直接描述, 则从提供的 Kaplan-Meier 生存曲线图进行估算。

1.4 质量评价

使用 Newcastle-Ottawa Scale (NOS) 评分系统对非随机对照试验进行质量评价。涉及三个方面, 即人群选择、可比性及暴露评价或结果评价, 总分 0~9 分, >6 分及以上认为高质量文献。采用改良 Jadad 评分标准对随机对照试验 (randomized controlled trial, RCT) 进行质量评价, 主要包括四个方面, 即随机序列的产生、分配隐藏、盲法和退出, 总分 0~7 分, >3 分为高质量文献。

1.5 统计学处理

采用 RevMan 5.2 软件进行 Meta 分析。计量资料采用均数差 (MD), 计数资料采用比值比 (OR), 均计算其 95% 可信区间 (CI), $P < 0.05$ 为两组间有统计学差异。异质性评估采用 I^2 检验, 如异质性小 $I^2 \leq 50\%$, 采用固定效应模型 (F 模型); 如异质性大 $I^2 > 50\%$, 采用随机效应模型 (R 模型)。通过漏斗图评估发表偏倚。

2 结果

2.1 纳入研究的文献特点

最初检索到可能符合的文献 1 103 篇，根据纳入和排除标准，最终 11 篇文献^[13-23]纳入分析，其中 10 篇为回顾性队列研究^[13,15-23]，1 篇为 RCT^[14]，共 844 例患者，其中扩大肝切除组 423 例，局限肝切除组 421 例。文献筛选流程及结果见图 1。纳入研究的基本特征及质量评分见表 1。

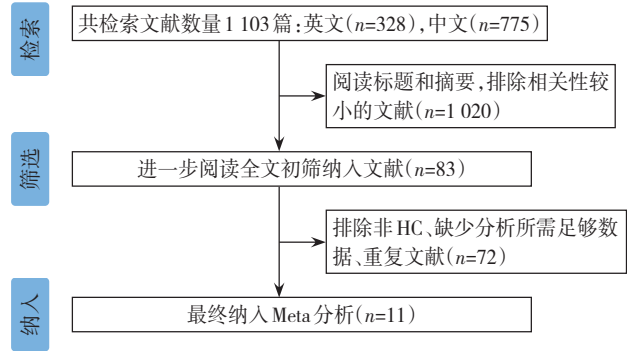


图 1 文献筛选流程及结果

Figure 1 Literature screening process and results

表 1 纳入研究的基本特征

Table 1 General characteristics of the included studies

作者	发表时间	国家	病例数(n)		III型/IV型(n)		年龄(岁)		研究类型	质量评分 (NOS/Jadad)
			扩大组	局限组	扩大组	局限组	扩大组	局限组		
陈孝平, 等 ^[13]	2009	中国	31	60	31/0	60/0	未提及	未提及	回顾性	7
葛金年, 等 ^[14]	2017	中国	36	36	未提及	未提及	53.3±10.4	53.5±10.5	RCT	3
刘文师, 等 ^[15]	2018	中国	38	32	未提及	未提及	52.08±11.07	51.16±12.24	回顾性	6
王晓庆, 等 ^[16]	2018	中国	37	13	27/10	6/4	未提及	未提及	回顾性	8
王冬冬, 等 ^[17]	2018	中国	29	44	17/12	28/16	56.2±10.6	58.8±10.6	回顾性	7
张大伟, 等 ^[18]	2019	中国	41	32	31/10	24/8	54±6	55±6	回顾性	8
戴伟, 等 ^[19]	2019	中国	20	17	20/0	17/0	63±8.9	58±9.2	回顾性	8
李恩山, 等 ^[20]	2019	中国	38	70	未提及	未提及	57.5±5.3	56.9±5.3	回顾性	7
董巍, 等 ^[21]	2019	中国	50	48	32/18	29/19	55.4±9.6	56.7±10.0	回顾性	6
丁建龙, 等 ^[22]	2021	中国	46	40	31/15	26/14	56.3±9.5	56.8±9.7	回顾性	8
卢灿亮, 等 ^[23]	2022	中国	57	29	45/12	17/12	58.0±10.1	62.5±10.9	回顾性	8

2.2 Meta分析结果

2.2.1 术后死亡 4 个研究^[13,16-17,23]报告了术后死亡情况，研究间无明显异质性 ($P=0.50$, $I^2=0\%$)，采

用固定效应模型进行 Meta 分析显示，两组术后死亡发生率差异无统计学意义 ($OR=1.12$, $95\% CI=0.25\sim 4.99$, $P=0.88$) (图 2)。

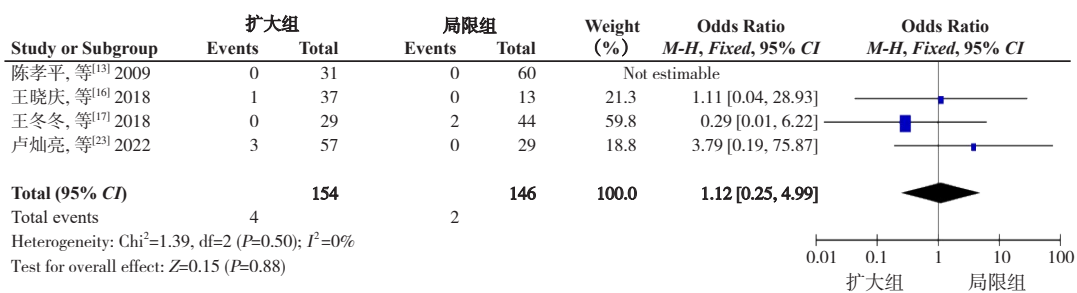


图 2 两组术后死亡发生率的比较

Figure 2 Comparison of postoperative mortality between the two groups

2.2.2 术后并发症 7 个研究^[14-15,17,20-23]报告了术后总并发症发生率，研究间无明显异质性 ($P=0.26$, $I^2=22\%$)，采用固定效应模型进行 Meta 分析显示，两组术后总并发症发生率差异无统计学意义 ($OR=1.44$, $95\% CI=0.95\sim 2.18$, $P=0.09$) (图 3A)。进一步对术后单个并发症进行 Meta 分析显示，扩大肝切除组术后肝功能衰竭发生率明显高于局限肝切

除组 ($OR=3.00$, $95\% CI=1.07\sim 8.40$, $P=0.04$) (图 3B)；两组术后胆汁漏、腹腔出血、腹腔感染等并发症发生率差异均无统计学意义 ($OR=1.44$, $95\% CI=0.68\sim 3.04$, $P=0.34$; $OR=0.77$, $95\% CI=0.29\sim 2.05$, $P=0.60$; $OR=1.36$, $95\% CI=0.50\sim 3.71$, $P=0.55$) (图 3C-E)。

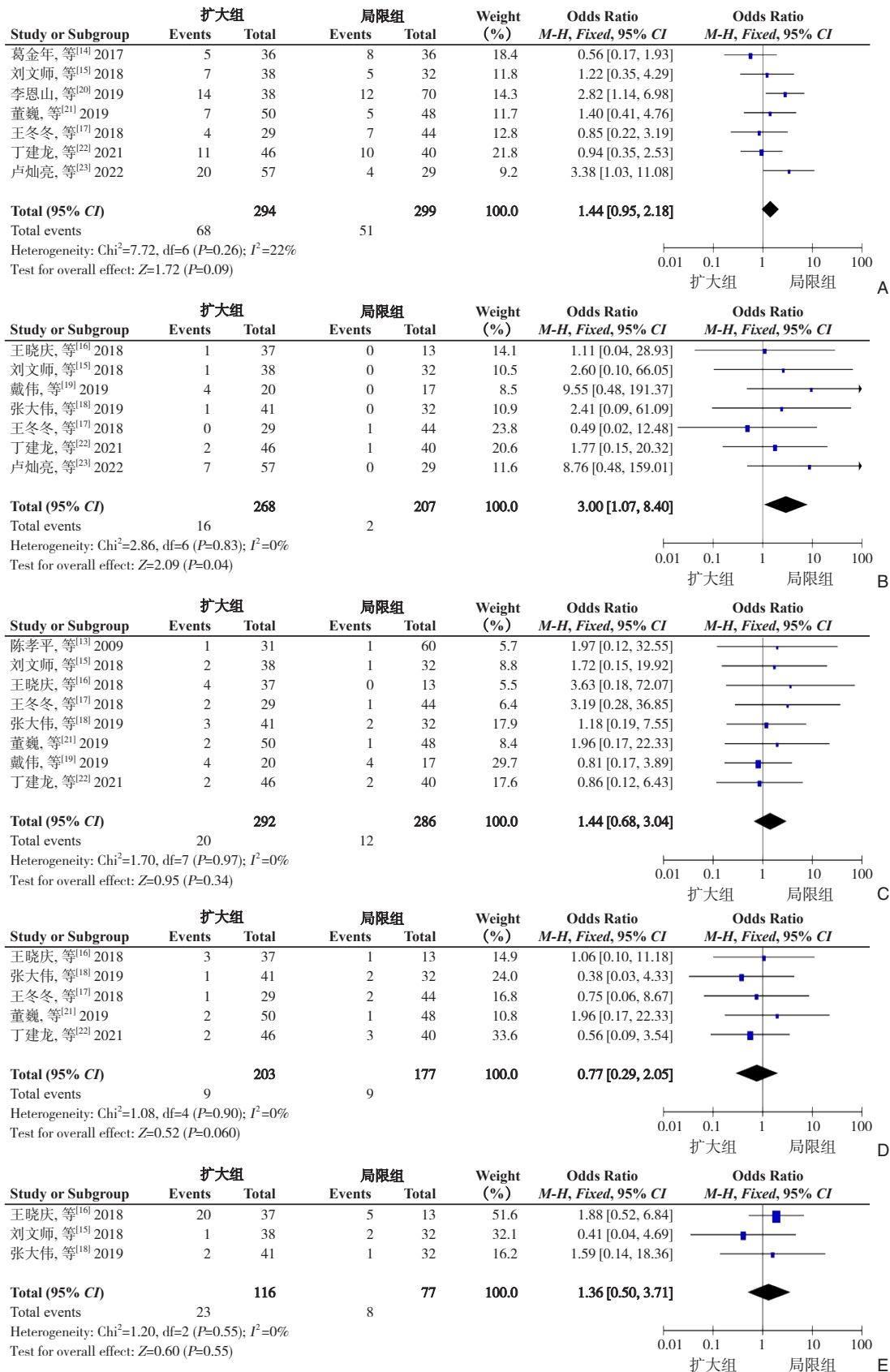


图 3 两组术后并发症比较 A: 术后总并发症发生率; B: 术后肝功能衰竭发生率; C: 术后胆汁漏发生率; D: 术后腹腔出血发生率; E: 术后腹腔感染发生率

Figure 3 Comparison of postoperative complications between the two groups A: Overall postoperative complication rate; B: Postoperative liver failure rate; C: Postoperative biliary leakage rate; D: Postoperative abdominal bleeding rate; E: Postoperative abdominal infection rate

2.2.3 肿瘤学结果 5个研究^[15-17,21,23]报告了根治性切除率，研究间无明显异质性 ($P=0.26$, $I^2=24%$)，采用固定效应模型进行Meta分析结果显示扩大肝切除组根治性切除率高于局限性肝切除组 ($OR=4.44$, $95\% CI=2.65\sim7.45$, $P<0.000\ 01$) (图4A)；

7个研究^[15-19,22-23]报告了总生存率，研究间无明显异质性 ($P=0.61$, $I^2=0%$)，采用固定效应模型进行Meta分析结果显示，扩大肝切除组预后优于局限性肝切除组 ($HR=0.53$, $95\% CI=0.41\sim0.68$, $P<0.000\ 01$) (图4B)。

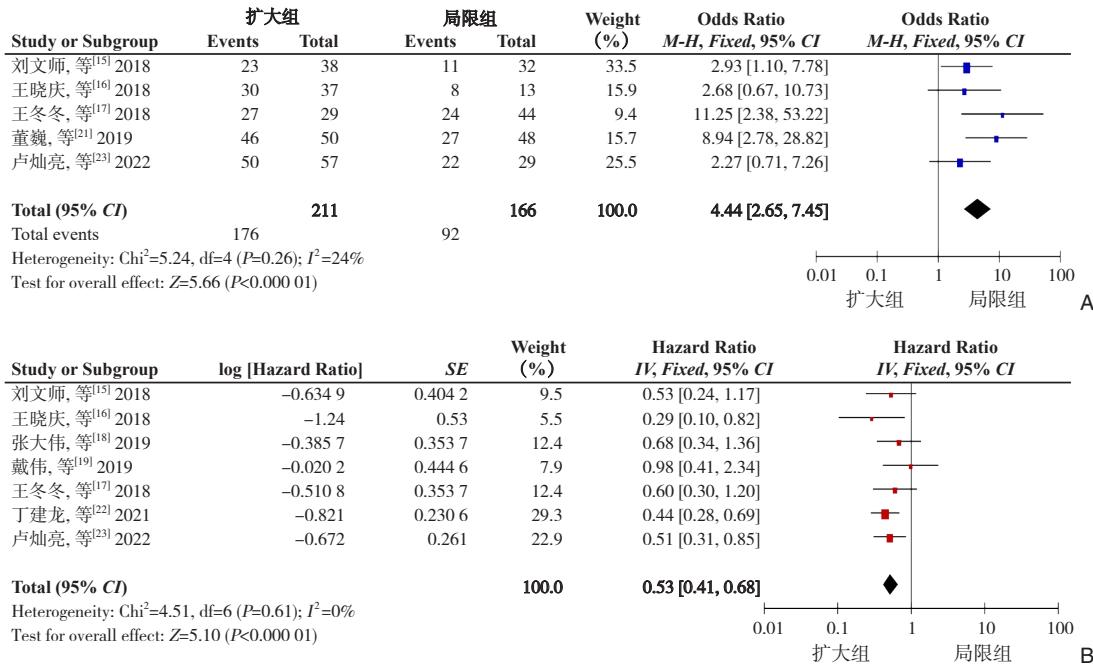


图4 两组肿瘤学结果比较 A: 根治性切除率; B: 术后总体生存率

Figure 4 Comparison of oncological outcomes between the two groups A: Radical resection rate; B: Overall postoperative survival rate

2.2.4 其他围手术期指标 9个研究^[14-22]报告了术中出血量情况，研究间存在异质性 ($P<0.01$, $I^2=98%$)，采用随机效应模型进行Meta分析显示，扩大肝切除组术中出血量增多 ($MD=153.48$, $95\% CI=32.63\sim274.33$, $P=0.01$) (图5A)。9个研究^[14-22]报告了手术时间情况，研究间发现异质性 ($P<0.01$, $I^2=87%$)，采用随机效应模型进行Meta分析显示，扩大肝切除组手术时间延长 ($MD=78.19$, $95\% CI=54.56\sim101.82$, $P<0.000\ 01$) (图5B)。7个研

究^[15-18,20-22]报告了住院时间情况，研究间发现异质性 ($P=0.01$, $I^2=63%$)，采用随机效应模型进行Meta分析显示，扩大肝切除组住院时间延长 ($MD=2.55$, $95\% CI=1.61\sim3.50$, $P<0.000\ 01$) (图5C)。

2.3 研究发表的结果偏倚分析

术后总体生存率以及术后总并发症发生率的漏斗图显示左右基本匀称，说明无明显发表性偏倚 (图6)。

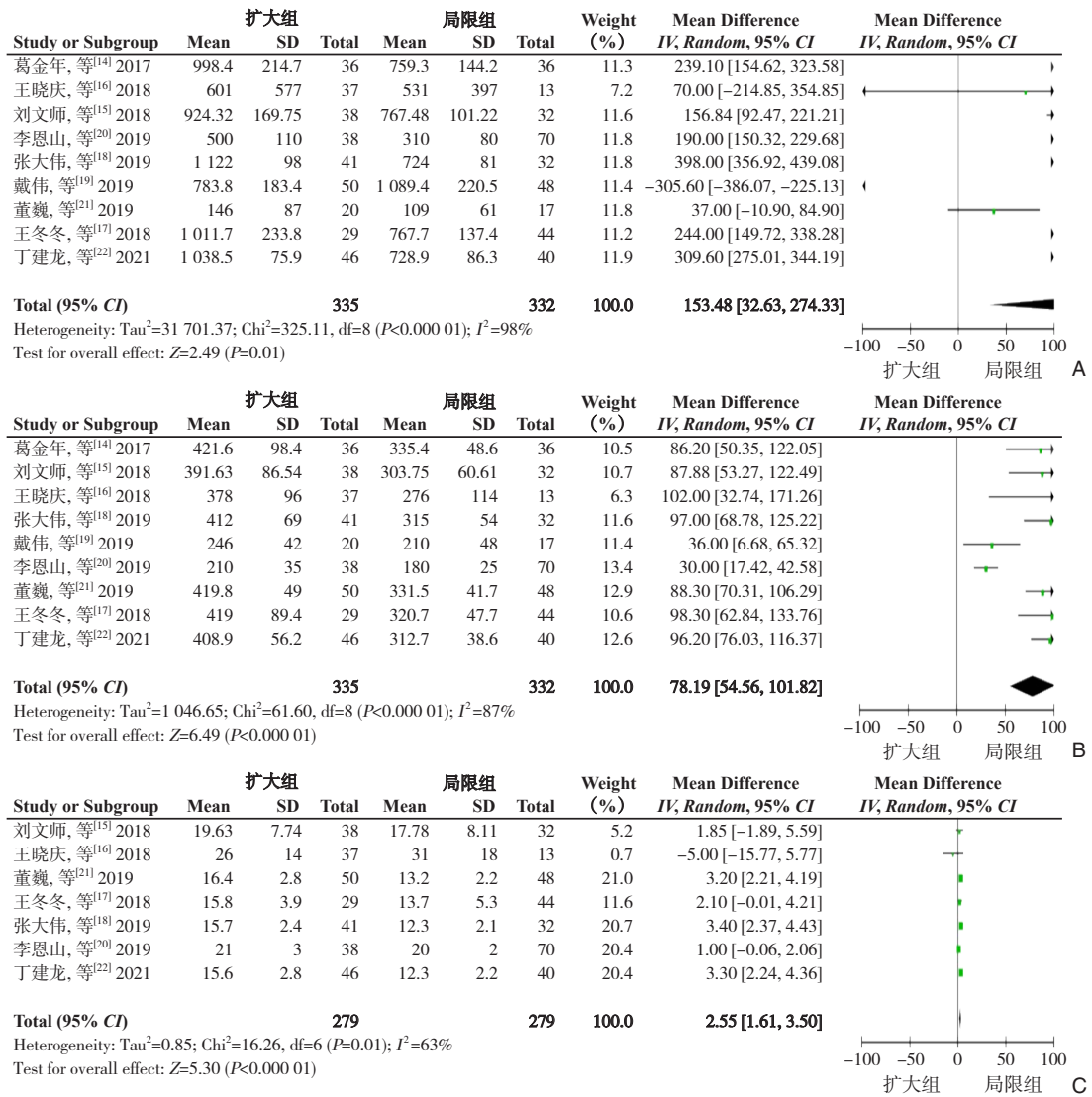


图 5 其他围手术期指标 A: 术中出血量; B: 手术时间; C: 住院时间

Figure 5 Comparison of other perioperative indicators between the two groups A: Intraoperative blood loss; B: Operative time; C: Hospitalization duration

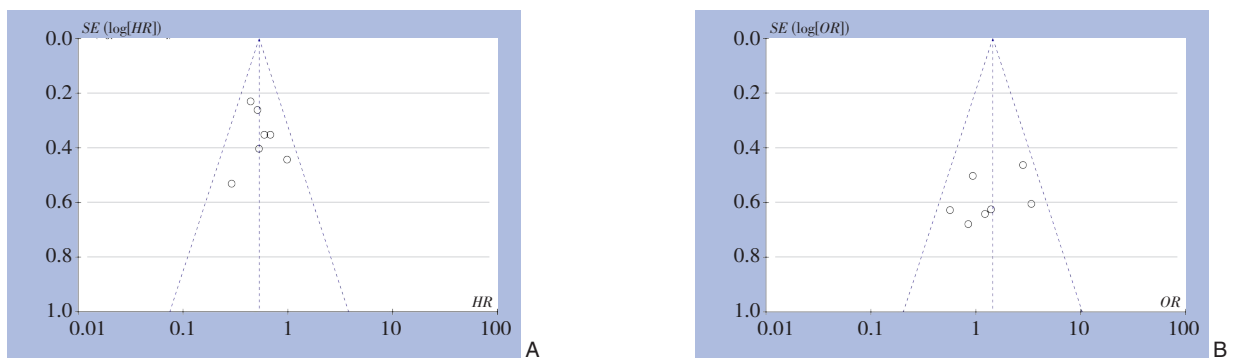


图 6 发表偏倚漏斗图分析 A: 术后总体生存率; B: 术后总并发症发生率

Figure 6 Publication bias funnel plot analysis A: Postoperative overall survival rate; B: Overall postoperative complication rate

3 讨论

HC, 尤其是Ⅲ、Ⅳ型HC, 既可以纵向沿胆管浸润生长, 也可以垂直向周围组织侵犯。为达到根治性切除, Ⅲ、Ⅳ型HC通常采用半肝或扩大半肝切除。van Gulik等^[24]研究显示, 采取扩大肝切除术后, HC的根治性切除率、5年生存率均较早期明显提高[59% vs. 13%; (33±9)% vs. (20±5)%]。丁建龙等^[22]回顾分析了86例Ⅲ、Ⅳ型HC病例, 结果显示, 扩大肝切除组5年生存率明显高于局限肝切除组(43.5% vs. 20.0%), 5年复发率明显低于局限肝切除组(60.9% vs. 85.0%)。

但扩大肝切除不仅手术技术要求高、手术时间长、术中出血量多、胆道重建复杂, 并且可能导致术后残余肝体积过少, 严重者可发生肝衰竭, 导致患者死亡^[25-26]。早期Ramesh等^[12]研究显示HC扩大肝切除术后住院死亡发生率达25%, 而局限肝切除组无术后死亡病例。Miyazaki等^[27]研究显示, 扩大肝切除组的HC根治性切除率、5年生存率均低于局限肝切除组(71% vs. 93%; 27% vs. 36%); 术后并发症发生率高于局限肝切除组(48% vs. 14%)。因此, 部分学者^[11-13, 27-28]建议采用局限肝切除治疗HC以降低手术风险。值得注意的是, 上述研究中扩大肝切除组中主要是Ⅲ、Ⅳ型HC, 而局限性肝切除组为Ⅱ型和部分Ⅲ型无血管侵犯HC, 扩大切除组HC疾病分期更晚, 可能是导致扩大切除组根治性切除率及生存率更低的原因。

临床实践^[29-31]已证明术前选择性实施胆道引流和门静脉栓塞等措施能够有效降低扩大肝切除术后并发症和病死率。肝静脉剥夺术是近年来二步法肝切除最新开展的手术方式, 以联合应用肝静脉栓塞和门静脉栓塞的方式来达到使残余肝脏快速增生的目的。多个研究^[32-34]显示, 对比传统的门静脉栓塞治疗, 肝静脉剥夺术显著提高了残余肝的功能及体积, 并且两者术后并发症发生率相当, 这也将进一步提高扩大肝切除手术的安全性。

笔者通过Meta分析发现, 扩大肝切除和局限肝切除治疗Ⅲ、Ⅳ型HC, 两组术后死亡和总并发症发生率均无明显差异。戴伟等^[19]研究结果显示, Ⅲ型HC扩大肝切除术后肝衰竭发生率明显高于局限肝切除(20.0% vs. 0)。进一步对术后单个并发症进行Meta分析, 发现两组术后胆汁漏、腹腔出

血、腹腔感染发生率均无明显差异, 扩大肝切除组术后肝衰竭发生率明显高于局限肝切除组。扩大肝切除组术后肝衰竭发生率升高主要与Ⅲ、Ⅳ型HC合并肝硬化、梗阻性黄疸, 行大范围肝切除后残余肝体积不足有关^[23]。

本Meta分析的不足之处主要有:(1)本次纳入文献大部分为回顾性研究, 对结果的可靠性产生一定的影响;(2)不同中心术者的操作水平有所差异, 可能影响试验结果。鉴于本研究的局限性, 仍需更多前瞻性随机对照试验来进一步验证。综上所述, 扩大肝切除提高Ⅲ、Ⅳ型HC根治性切除率, 改善预后, 并未增加术后死亡和总体并发症发生率, 然而术后肝功能衰竭发生率升高。因此应严格把握手术指征, 挑选合适的患者, 对拟行扩大肝切除患者进行充分的术前管理。考虑本研究的局限性, 未来仍需更多前瞻性随机对照试验来进一步验证。

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