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·短篇论著·

乳腺癌患者新辅助化疗后行前哨淋巴结活检可行性的系统评价

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[摘要] **目的** 评价乳腺癌患者在新辅助化疗(NCT)后行前哨淋巴结活检术(SLNB)可行性。**方法** 以"乳腺癌"、"新辅助化疗"及"前哨淋巴结活检"为自由词和主题词于中国生物医学文摘数据库(CBM)和PubMed、Medline及Embase数据库进行文献检索。按照严格的纳入、排除标准对所获得文献进行筛选。根据NCT前腋窝淋巴结状况分为腋窝淋巴结阴性组和腋窝淋巴结阳性组。对纳入文献记录提取必要数据后,使用STATA软件将各项研究结果合并后计算前哨淋巴结检出率及假阴性率。**结果** 共纳入41项原创性研究,共计5 848例患者。腋窝淋巴结阴性组患者2 050例,其中1 891例成功检出前哨淋巴结,检出率为0.94(95%CI 0.92～0.96),假阴性率为0.07(95%CI 0.04～0.10)。腋窝淋巴结阳性组患者3 798例,3 059例成功检出前哨淋巴结,检出率为0.87(95%CI 0.84～0.90),假阴性率为0.13(95%CI 0.11～0.16)。**结论** NCT前腋窝淋巴结阴性的乳腺癌患者可在NCT后行SLNB,NCT前腋窝淋巴结阳性患者则不建议NCT后行SLNB。

[关键词] 乳腺癌;新辅助化疗;前哨淋巴结活组织检查;检出率;假阴性率
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Feasibility of sentinel lymph node biopsy in breast cancer patients following neoadjuvant chemotherapy: a systematic analysis

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[**Abstract**] **Objective** To evaluate whether sentinel lymph node biopsy (SLNB) can be used in breast cancer patients following neoadjuvant chemotherapy (NCT) by systematically reviewing the published literatures. **Methods** The databases CBM, PubMed, Medline and Embase were searched using "breast cancer", "neoadjuvant chemotherapy" and "sentinel lymph node biopsy" as free words and MeSH terms for related literatures. The papers were selected strictly in accordance with the inclusion and exclusion criteria. The studies were divided into axillary lymph node-negative group and axillary lymph node-positive group according to the status of axillary lymph node before NCT. The data of the included researches were extracted and were then merged using STATA to estimate the identification rate and false-negative rate of SLNB in this setting. **Results** Forty-one studies were identified which involving a total of 5 848 patients. Lymph node-negative group contained 2 050 patients, and 1 891 of them were successfully detected in more than one sentinel lymph node, with the detecting rate and the false-negative rate being 0.94 (95% CI = 0.92-0.96) and 0.07 (95% CI = 0.04-0.10), respectively. Lymph node-positive group contained 3 798 patients, and 3 059 of them were successfully detected in more than one sentinel lymph node, with the detecting rate and false-negative rate being 0.87 (95% CI = 0.84-0.90) and 0.13 (95% CI = 0.11-0.16), respectively. **Conclusion** SLNB is reliable for women with lymph node-negative breast cancer receiving neoadjuvant chemotherapy. But it is not recommended for those with lymph node-positive breast cancer.

[**Key words**] breast neoplasms; neoadjuvant chemotherapy; sentinel lymph node biopsy; identification rate; false-negative rate

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腋窝淋巴结(axillary lymph node,ALN)状况是预测乳腺癌患者预后的主要影响因素。2015 年美国国家综合癌症网络(NCCN)指南提倡使用前哨淋巴结活检术(sentinel lymph node biopsy,SLNB)替代腋窝淋巴结清扫术成为腋窝淋巴结预测的手段[1]。对于 SLNB 结果阳性的患者需要进一步行腋窝淋巴结清扫术,而结果阴性的患者则不需要。对于 SLNB 明确前哨淋巴结肿瘤转移而未行腋窝淋巴结清扫术的部分患者,腋窝的局部复发风险仍然低于 1%[2]。ACOSOG Z0011 的研究结果也同样证实了这一点[3]。

SLNB 最初应用于早期乳腺癌患者。近年来聚焦于新辅助化疗(neoadjuvant chemotherapy,NCT)实施前后 SLNB 的研究越来越多,但 SLNB 在行 NCT 的乳腺癌患者中如何应用仍然存在争议。NCT 后行 SLNB 是否能准确反映腋窝淋巴结的状况是我们关注的焦点。本研究汇总了对 NCT 后乳腺癌患者实施 SLNB 的文献,以整合计算 NCT 后 SLNB 的检出率及假阴性率,判断其否可应用于临床。

1　材料和方法

1.1　*文献检索*　中文文献以“乳腺癌”、“新辅助化疗”及“前哨淋巴结活检”为自由词在中国生物医学文摘数据库(CBM)上进行检索;非中文文献以“breast cancer”、“neoadjuvant chemotherapy”和“sentinel lymph node biopsy”为自由词和主题词在 PubMed、Medline 及 Embase 上进行检索。检索文献日期由 1990 年 1 月 1 日至 2014 年 4 月 1 日。

1.2　*文献纳入标准*　(1)研究对象均为经组织学证实的浸润性乳腺癌患者;(2)NCT 后腋窝淋巴结阴性;(3)NCT 后行 SLNB,无论前哨淋巴结状况如何,均随后实施腋窝淋巴结清扫术;(4)明确记录 NCT 前腋窝淋巴结状况;(5)根据石蜡切片进行腋窝淋巴结的肿瘤转移诊断;(6)能够提取明确的研究例数、检出率、假阴性例数、假阴性率;(7)同一研究机构或研究者发表的多项研究,选择最近更新的研究。将临床查体、影像学检查(B 超、钼靶、MRI)及细针穿刺细胞学检查提示腋窝淋巴结存在肿瘤转移定义为腋窝淋巴结阳性。

1.3　*文献排除标准*　(1)仅接受新辅助内分泌治疗者;(2)摘要中无法获得所需数据的非中英文文献;(3)研究对象为炎性乳癌者。

1.4　*数据提取*　根据 NCT 前腋窝淋巴结状况分为腋窝淋巴结阴性组和阳性组,分别对文献数据进行整理归纳。记录纳入文献的发表时间、病例总数、检出前哨淋巴结例数和检出率、假阴性例数、腋窝淋巴结阳性例数及假阴性率。检出率=(前哨淋巴结检出例数/实施 SLNB 的所有例数)×100%;假阴性率=(前哨淋巴结假阴性例数/腋窝淋巴结转移阳性例数)×100%。前哨淋巴结为阴性而腋窝淋巴结为阳性的病例定义为前哨淋巴结假阴性。

1.5　*统计学处理*　采用 STATA 11.0 软件进行统计学分析。使用随机效应模型计算前哨淋巴结检出率、假阴性率及 95%可信区间(CI)。检验水准(α)为 0.05。

2　结　果

2.1　*纳入文献基本情况*　文献筛选流程图如图 1 所示。本研究共纳入 41 篇原创性研究文献,发表时间自 2003 年至 2014 年,共计 5 848 例患者,分为 NCT 前腋窝淋巴结阴性组和阳性组 2 组,各组例数分别为 2 050、3 798 例。

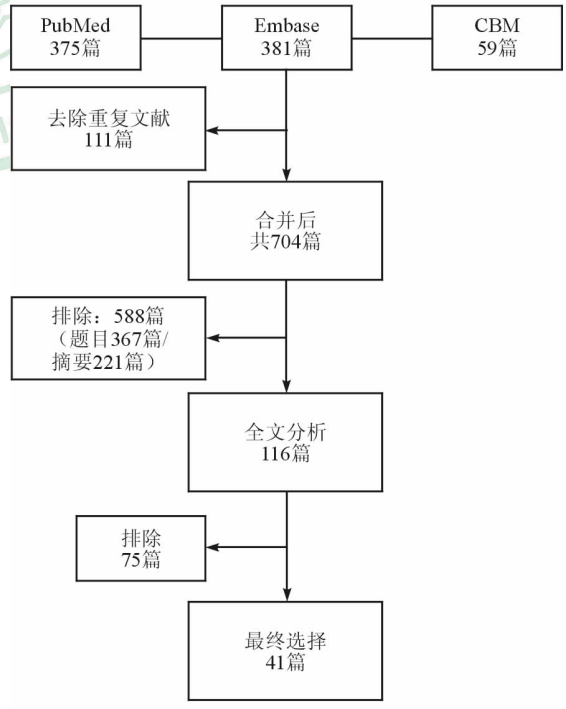

图 1　文献筛选流程图

2.2　*NCT 后行 SLNB 检出结果*　NCT 前腋窝淋巴结阴性组共纳入 24 项原创性研究[4-27],纳入研究的发表时间自 2003 年至 2014 年,共计 2 050

例患者，其中 1 891 例患者成功检出前哨淋巴结（文献[24]无检出前哨淋巴结例数，予以排除）。将上述研究结果进行单个样本率的 meta 分析后得到阴性组患者 NCT 后行 SLNB 的检出率为 0.94(95%CI 0.92～0.96)，见图 2。假阴性例数 64 例，腋窝淋巴结阳性病例 606 例，假阴性率为 0.07(95%CI 0.04～0.10)，见图 3(文献[7]、[16]和[19]无假阴性例数，予以排除)。为排除因纳入病例数较少而造成的统计偏移，研究又分为病例数≥50 例和病例数＜50 例 2 个亚组，两组的前哨淋巴结检出率分别为 0.93(95%CI 0.89～0.97)和 0.97(95%CI 0.95～0.99)，假阴性率分别为 0.09(95%CI 0.04～0.13)和 0.06(95%CI 0.01～0.10)，差异无统计学意义。

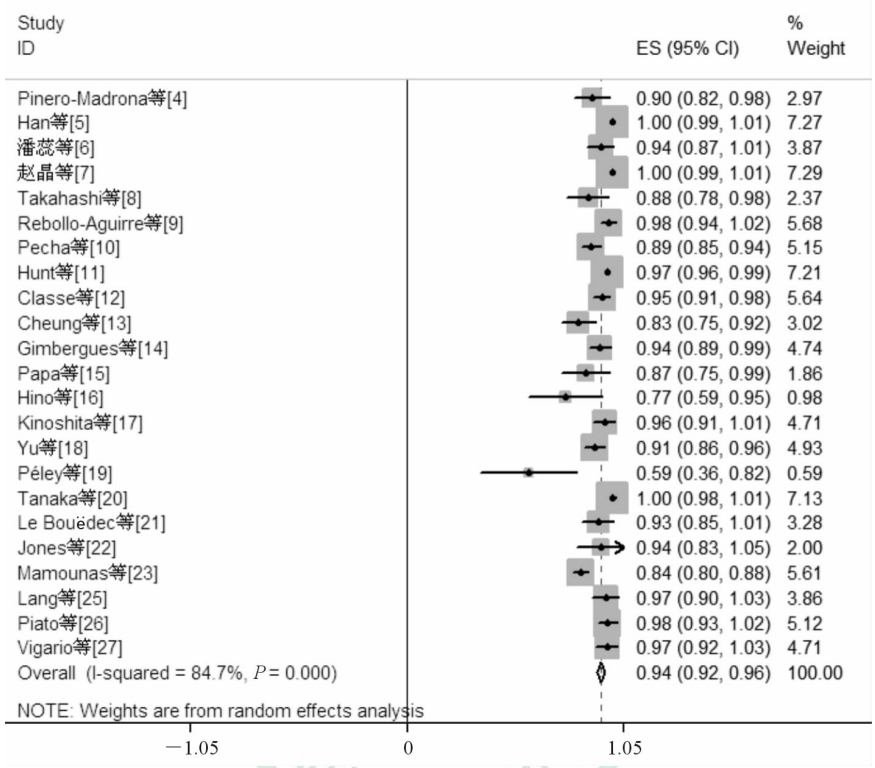

图 2　新辅助化疗(NCT)前腋窝淋巴结阴性组前哨淋巴结检出率

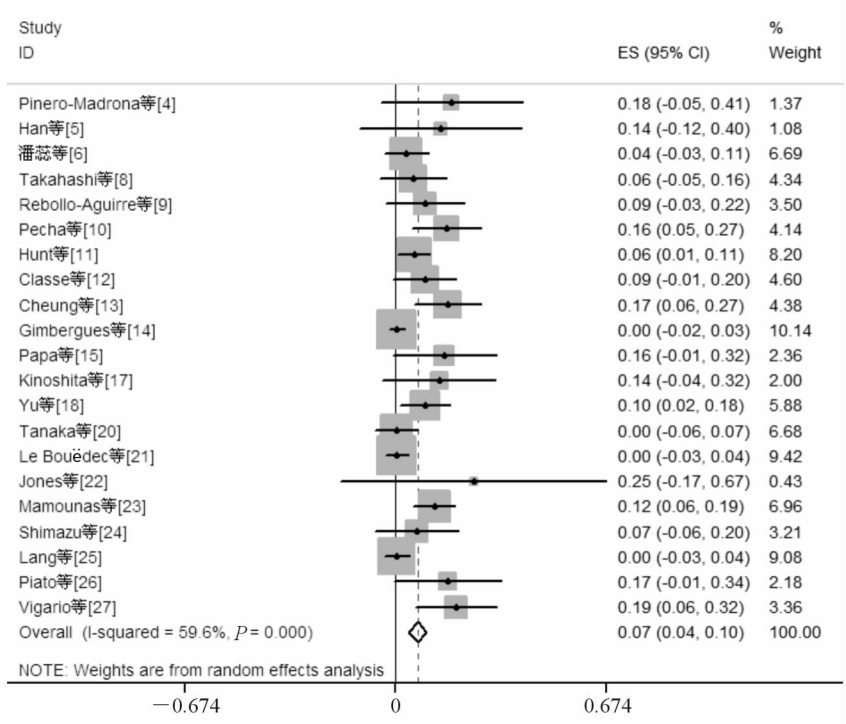

图 3　新辅助化疗(NCT)前腋窝淋巴结阴性组假阴性率

NCT 前腋窝淋巴结阳性组共纳入 32 项原创性研究[4-10,12,14,16,20-23,25,28-44]，纳入研究的发表时间自 2004 年至 2014 年，共计 3 798 例患者，其中 3 313 例患者成功检出前哨淋巴结。将上述研究结果进行单个样本率的 meta 分析后得到阳性组患者 NCT 后行 SLNB 的检出率为 0.87(95%CI 0.84～0.90)，见图 4(文献[44]无检出前哨淋巴结例数，予以排除)。假阴性例数 266 例，腋窝淋巴结阳性病例 1 843 例，假阴性率为 0.13(95%CI 0.11～0.16)，见图 5(文献[7]和[16]无假阴性例数，予以排除)。为排除因纳入病例数较少的研究造成的统计偏移，研究分为病例数≥50 例和病例数<50 例 2 个亚组，两组的前哨淋巴结检出率分别为 0.87(95%CI 0.84～0.90)和 0.89(95%CI 0.83～0.95)，假阴性率分别为0.13(95% CI 0.10～0.16)及 0.16(95% CI 0.07～0.23)，差异无统计学意义。

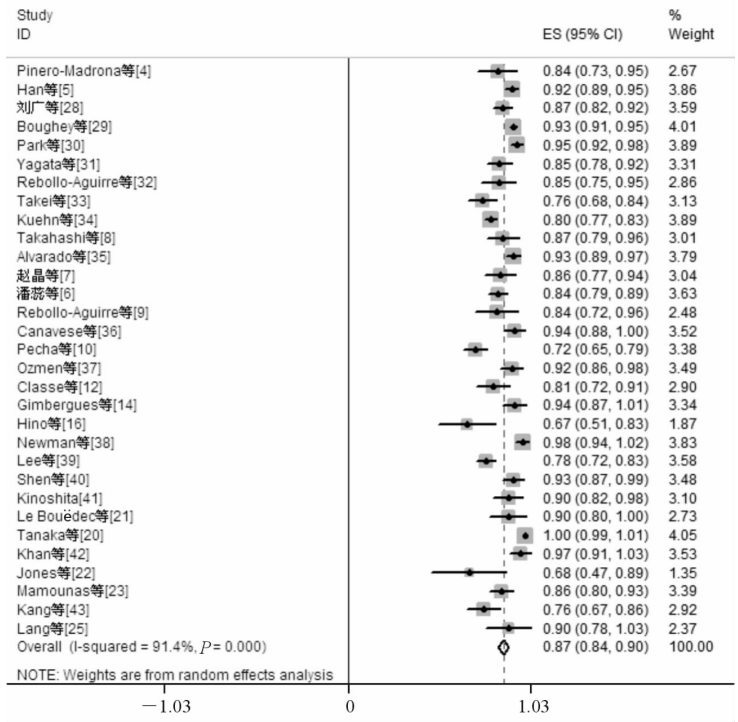

图 4　新辅助化疗(NCT)前腋窝淋巴结阳性组前哨淋巴结检出率

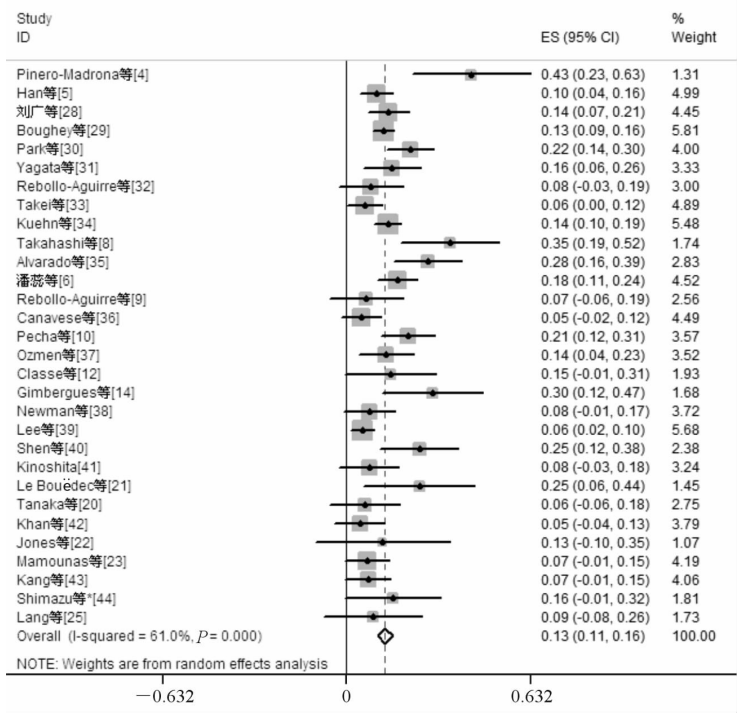

图 5　新辅助化疗(NCT)前腋窝淋巴结阳性组假阴性率

3　讨　论

本研究结果发现 NCT 前腋窝淋巴结阳性的乳腺癌患者在 NCT 后行 SLNB 的前哨淋巴结检出率为 0.87，低于阴性患者(0.94)，原因可能是阳性患者的淋巴管内存在肿瘤细胞，这部分肿瘤细胞被杀死后堵塞淋巴管，导致淋巴管显影剂的回流受阻，从而不能使淋巴管和前哨淋巴结达到理想显影，最终导致了检出率的下降。

SLNB 的假阴性率是一个十分重要的指标，假阴性率的高低决定着 SLNB 的准确程度及其是否能够应用于临床。本研究发现 NCT 前腋窝淋巴结阳性的患者在 NCT 后行 SLNB 的假阴性率为 0.13，未达到 2015 年 NCCN 指南中实施 SLNB 需要满足假阴性率低于 10% 的准入标准[1]；而 NCT 前腋窝淋巴结阴性患者的假阴性率为 0.07，完全达到准入标准，两者几乎相差 1 倍。阳性患者假阴性率的升高可能与腋窝淋巴结在 NCT 后的缓解顺序有关，NCT 前前哨淋巴结与非前哨淋巴结均存在肿瘤转移的患者，在 NCT 结束后，前哨淋巴结已发生病理学完全缓解而非前哨淋巴结尚未发生病理学完全缓解。在这种情况下，SLNB 的结果不能真实的反映腋窝淋巴结状况，从而导致假阴性结果的产生。

王永胜等[45]研究发现，SLNB 完成 40 例以上才有资质应用于临床。考虑到病例数量可能对结果产生影响，本研究对纳入文献以 50 例为标准进行了分组，目的是排除因 SLNB 技术不熟练导致的检出率下降及假阴性率升高。结果显示，无论对于 NCT 前腋窝淋巴结阴性还是阳性的患者，纳入病例数多少对于前哨淋巴结检出率及假阴性率均影响不大，原因可能是纳入文献的研究者在进行研究前均已完成了相当数量的 SLNB 训练，所以样本量的大小不会对手术操作水平产生较大影响。

Boughey 等[29]的研究提示对于检出 3 个以上前哨淋巴结的乳腺癌患者，其假阴性率会较检出 2 个及以下前哨淋巴结的患者显著下降(9.1% vs 21.1%)。Krag 等[46]研究发现，对于化疗前行 SLNB 的乳腺癌患者，随着前哨淋巴结检出数量的增加，假阴性率不断下降：前哨淋巴结检出数量为 1 个的假阴性率为 18%，2 个时假阴性率为 10%，3 个时假阴性率为 7%。与之相同，Hunt 等[11]研究发现，对于临床上腋窝淋巴结阴性的患者，NCT 后行 SLNB，前哨淋巴结检出数量为 2 个及以下的病例组假阴性率更高。本研究中可以根据前哨淋巴结检出个数进行分层的文献数量很少，所以未对此进行进一步研究。

本研究尚存在以下局限性：文献来源主要为中英文文献，其余语言文献仅少量纳入；数据录入存在选择偏移。此外，本研究结果的异质性较高，可能与临床异质性和方法学异质性相关。临床异质性主要有两个方面，一是纳入文献对于腋窝淋巴结阳性的判定标准不尽一致，包括了临床体检、影像学判定及病理性判定(细针穿刺及 B 超引导下细针穿刺)，前两者的判定不一定明确对应腋窝淋巴结存在肿瘤转移，腋窝淋巴结在 NCT 后的缓解顺序假说支持证据不够充分；二是纳入文献中 SLNB 所使用的示踪方法不同，有单用染料、单用核素以及两者合用等方法，示踪方法的异质性可能导致结果的异质性。方法学异质性主要与前哨淋巴结的阳性判定有关，孤立肿瘤细胞阳性是否被定义为前哨淋巴结阳性一直存在争议，纳入文献中约一半未对此问题进行详细说明。

综上所述，NCT 前腋窝淋巴结阴性的乳腺癌患者可以在 NCT 后行 SLNB，但 NCT 前腋窝淋巴结阳性的患者 NCT 后行 SLNB 的检出率较低，而假阴性率较高，所以不建议 NCT 后行 SLNB。

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