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· 专家论坛 ·

早期乳腺癌腋窝手术降阶梯策略的研究进展与思考

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摘要

乳腺癌腋窝管理正经历由“最大耐受治疗”向“最小有效治疗”的降阶梯转变。前哨淋巴结活检(SLNB)的广泛应用显著减少了腋窝手术创伤,而近年来多项高质量前瞻性研究进一步推动了在特定早期乳腺癌人群中豁免腋窝手术的探索。SOUND和INSEMA试验证实,在严格影像学评估为cN0的T1~2期乳腺癌患者中,豁免SLNB在侵袭性无病生存方面不劣于SLNB,并可显著降低淋巴水肿等并发症的发生风险。导管原位癌、小体积低危肿瘤及≥70岁HR+/HER2-老年患者中,豁免腋窝手术对区域控制及生存率影响有限。随着影像学、正电子发射断层成像和人工智能技术的发展,基于多模态评估筛选cN0患者的准确率不断提高,部分新辅助治疗后达到乳腺病理完全缓解的HER2+/三阴性亚型患者亦显示出豁免腋窝手术的潜力。总体来看,精准患者选择是实施腋窝降阶梯策略的关键;但需关注分期信息缺失对后续系统治疗与放疗决策的影响。未来,在更成熟的循证证据和影像/病理评估技术支持下,腋窝手术将迈向更加个体化、精准化的管理模式。

关键词

乳腺肿瘤; 前哨淋巴结活组织检查; 肿瘤辅助疗法; 精准医学

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Advances and reflections on de-escalation strategies for axillary surgery in early-stage breast cancer

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Abstract

Axillary management for early-stage breast cancer is shifting from maximal tolerated treatment to minimal effective intervention. The introduction of sentinel lymph node biopsy (SLNB) markedly reduced surgical morbidity, and growing evidence now supports omitting axillary surgery in selected patients. The SOUND and INSEMA trials demonstrated that, among strictly defined cN0 patients assessed by high-quality imaging, omission of SLNB is non-inferior to SLNB in terms of invasive disease-free survival while significantly reducing complications such as lymphedema. In ductal

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carcinoma in situ, low-burden tumors, and elderly patients aged ≥ 70 years with HR+/HER2- disease, omission of axillary staging has minimal impact on regional control and survival outcomes. Advances in imaging technologies, dedicated lymph node PET, and artificial intelligence have improved the accuracy of identifying true node-negative patients. Furthermore, highly selected HER2+/triple-negative patients who achieve breast pathologic complete response after neoadjuvant therapy may also be candidates for axillary surgery omission. Accurate patient selection remains central to safe de-escalation, although the loss of pathological staging information may influence subsequent systemic and radiation therapy decisions. With accumulating evidence and more refined assessment tools, axillary surgery is expected to evolve toward increasingly individualized and precise management.

Key words

Breast Neoplasms; Sentinel Lymph Node Biopsy; Neoadjuvant Therapy; Precision Medicine

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乳腺癌是全球女性中发病率最高的恶性肿瘤^[1],其外科治疗策略不断向“精准降阶”转型。20世纪90年代,乳腺癌前哨淋巴结活检技术(sentinel lymph node biopsy, SLNB)成为乳腺外科领域的里程碑式进展,推动乳腺癌的腋窝诊疗开始迈向微创时代。乳腺癌外科治疗的理念从最大的、可耐受的局部区域治疗转向最小的、有效的局部区域治疗。随着循证医学证据的不断积累,SLNB的适应人群不断扩展,有效保留了腋窝的功能^[2-6]。与腋窝淋巴结清扫术(axillary lymph node dissection, ALND)相比,SLNB创伤较小,但仍存在一定的创伤性,以及发生淋巴水肿和感觉异常等并发症发生的可能性^[7]。因此,越来越多研究者开始关注并探索豁免SLNB的可行性和安全性,尤其是针对低危且高龄的乳腺癌患者。2019年St. Gallen乳腺癌会议专家共识^[8]提出,年龄 >70 岁的cT1N0期激素受体(hormone receptor, HR)阳性、HER2阴性且拟接受内分泌治疗的乳腺癌患者,可考虑选择性的豁免SLNB。近期的SOUND研究^[9]和INSEMA研究^[10]再次将乳腺癌腋窝淋巴结的外科处理推向“无手术”时代。然而,如何合理选择豁免手术的人群、解剖学分期缺失对后续治疗的影响等问题仍需进一步探讨。本文将基于现有研究证据和临床指南,探讨豁免腋窝手术的理论基础、适应人群、潜在风险及未来发展方向,旨在为腋窝淋巴结个体化精准治疗提供参考,推动乳腺癌腋窝手术策略的进一步优化。

1 豁免腋窝手术的理论基础与早期探索

有关乳腺癌外科治疗的持续探索中,腋窝手术的必要性始终是临床研究关注的热点与争议焦点。早期研究表明,在缺乏有效系统治疗的条件下,腋窝局部区域处理并未对乳腺癌患者的总生存(overall survival, OS)率产生显著的影响。NSABP B-04研究^[11]的数据显示,与Halsted根治术组相比,全乳切除加放疗(total mastectomy+radiation, TM+RT)组($P=0.49$)和单纯全乳切除(TM)组($P=0.39$)在无病生存率(disease-free survival, DFS)方面均无统计学差异,即腋窝手术与否对DFS影响有限;然而,在局部区域复发方面,三组之间存在显著差异($P=0.002$),其中TM+RT组发生率最低,其次是Halsted根治术组优于单纯TM组。该发现与法国居里所的早期研究^[12-13]一致,后者也指出腋窝区域放疗在OS结局上不亚于ALND,从而为腋窝手术豁免的理论基础提供了支持。随后的多项临床研究逐渐印证了这一点,国际乳腺癌研究组(International Breast Cancer Study Group, IBCSG)10-93试验^[14]纳入了473例 ≥ 60 岁,临床腋窝淋巴结阴性(cN0)可手术的乳腺癌患者,结果显示接受ALND组与单纯腋窝观察组在中位随访6.6年内的DFS率无显著差异(67% vs. 66%, $P=0.69$)。此外, Martelli等^[15]与 Agresti等^[16]的长期随访研究亦表明,是否行ALND对OS无显著影响。这些研究初步表明,在特定的低负荷肿瘤人群中,豁免腋窝手术具有可接受的安全性,手术的意义更多体现在分期和预后评估方面。然而,在早期以解剖学分期为主要决策依据的背景下,这一观

点并未被广泛采纳。即便在当前,乳腺癌系统治疗策略仍高度依赖淋巴结病理状态。因此,在推动腋窝手术降阶梯的过程中,仍需审慎评估其可能对系统治疗方案选择带来的影响。

2 特殊情况中豁免腋窝手术

近年来,导管原位癌(ductal carcinoma in situ, DCIS)和老年乳腺癌患者在特定条件下豁免腋窝手术的建议首先写入指南^[17-18]推荐。NSABP B-17试验,共纳入813例接受保乳手术的DCIS患者,中位随访15.3年的结果显示,在253例(31.1%)同期接受了ALND的患者中,同侧淋巴结复发(ipsilateral nodal recurrence, INR)发生率为0.83‰,而未接受ALND患者INR发生率则为0.26‰;NSABP B-24研究中,11.5年的随访数据显示,接受ALND的162例(占比9%)患者中INR发生率为0.36‰,未接受ALND者为0.52‰,即DCIS患者INR的绝对风险极低^[19-20]。然而,对于肿块较大或病变范围广泛的DCIS,由于病理取材及切片的局限性,存在漏诊微浸润病灶的可能。随着肿块大小的增加,DCIS发生微浸润的概率增加^[21]。Maffuz等^[22]报道肿块大小对浸润及淋巴结转移均有提示作用:DCIS肿块>2.5 cm者易发生浸润,其中2.5~3.5 cm者发生浸润的概率为10%,3.6~4.5 cm者为57%,4.5~6.0 cm者为71%。因此,对于肿块较小或病变范围较局限,经过充分的病理取材及评估诊断为DCIS者,可考虑豁免腋窝手术^[23-24];但对于肿块较大或多中心性病变的患者,豁免腋窝手术则需谨慎考虑。

在老年乳腺癌患者中,Martelli等^[25]开展的一项为期15年的随机对照试验结果显示,腋窝手术对老年患者的OS、无远处转移生存率(distant metastasis-free survival, DMFS)及乳腺癌相关死亡率(breast cancer mortality, BCM)无显著影响。Liang等^[26]通过Meta分析也指出,尽管豁免ALND会增加区域复发风险($P=0.04$),但对于年龄 ≥ 70 岁、cN0的患者,其OS率($P=0.92$)和乳腺癌特异性死亡率($P=0.75$)未受显著影响。2021年美国临床肿瘤学会(American Society of Clinical Oncology, ASCO)指南推荐:对于年龄 ≥ 70 岁、T1N0、HR+/HER2-的早期浸润性乳腺癌患者,可考虑免除SLNB^[17]。不过需要注意的是,尽管免除SLNB对生存结局没有显著影响,但与复发风险增加相关^[27-28]。因此,在

制定豁免腋窝手术的临床决策时,应充分权衡患者的合并基础疾病状况与预期寿命,将复发风险与死亡风险进行综合评估^[29],以实现真正意义上的个体化精准治疗。

3 影像学辅助下豁免腋窝手术

越来越多的循证医学证据表明,在影像学技术不断进步的加持下豁免腋窝手术成为可能。SOUND研究^[9]纳入了1 535例cT1N0、计划接受保乳手术及全乳照射的乳腺癌患者,经超声评估腋窝淋巴结阴性,5年侵袭性无病生存(invasive disease-free survival, iDFS)率在无腋窝手术组和SLNB组分别为91.9%与91.7%, $HR=0.91$ (95% $CI=0.73\sim 1.14$),符合预设的非劣效界值;在SLNB组中,13.1%的患者检出1~3枚阳性前哨淋巴结,而 ≥ 4 枚阳性淋巴结的患者仅占0.6%。INSEMA试验^[10]的结果与上述高度一致,研究纳入cT1~2N0乳腺癌患者(其中T2患者占比9.6%),术前临床和影像学评估均提示腋窝无转移,手术组仅15%的患者检测到阳性前哨淋巴结, ≥ 4 枚阳性淋巴结者仅占0.2%;中位随访73.6个月结果显示,无腋窝手术组并不劣于SLNB组($HR=0.91$, 95% $CI=0.73\sim 1.14$)。此外,复旦大学开展的SOAPET试验^[30],利用¹⁸F-氟代脱氧葡萄糖(¹⁸F-FDG)专用淋巴结正电子发射断层成像结合常规的临床腋窝评估方式,第一阶段结果发现可以有效筛选出80%的cN0患者避免SLNB,其阴性预测值高达91%,进一步验证了影像学辅助下豁免腋窝手术的可行性。正在进行的NAUTILUS试验也致力于探究cT1~2N0患者中豁免SLNB的非劣效性,其结果有望进一步巩固该策略的临床适用范围。

4 新辅助治疗(neoadjuvant treatment, NAT)后豁免腋窝手术

随着NAT策略的应用,乳腺癌患者的腋窝病理完全缓解(axillary nodal pathologic complete response, apCR)率显著提高,部分早期乳腺癌患者在NAT后有望成为豁免SLNB评估的潜在人群,从而实现手术范围的合理降阶。研究显示,不同分子分型乳腺癌apCR率存在显著差异,HER2+及三阴性(triple-negative, TN)亚型患者在NAT后获

得 apCR 的概率较高：HR-/HER2+ 患者 apCR 率可达 60%，TN 亚型约为 48%，而 HR+/HER2- 者则仅为 18%^[31]。Tadros 等^[32]进一步指出，对于 HER2+ 或 TN 亚型的乳腺癌患者，若影像和病理评估均提示乳腺病理完全缓解（breast pathologic complete response, bpCR），其腋窝存在残余病灶的风险极低。美国国家癌症数据库的研究结果亦支持该观点，cT1~2N0、HER2+/TN 亚型且达到 bpCR 的患者，NAT 后 ypN+ 的风险不足 2%^[33]。因此，对此类高度选择的患者群体，豁免腋窝淋巴结手术是一种合理的治疗降阶策略。正在进行的 EUBREAST-01、ASICS 等多项国际前瞻性队列研究^[34-35]系统评估 HER2+/TN 乳腺癌患者豁免手术的可行性与安全性，期待这些研究结果能够为该领域提供更为明确的指导。然而，对于 HR+/HER2- 亚型的患者，bpCR 对 apCR 的相关性较弱，且研究提示该亚型在 NAT 后腋窝残余病灶风险仍然较高，在临床实践中需谨慎考虑豁免腋窝手术的适用性^[36-37]。

近年来，结合智能真空辅助活检与人工智能算法的结合展现出临床转化的潜力，Pfoh 等^[38]通过机器学习模型，综合患者基本特征、影像、肿瘤和真空辅助活检结果，构建了预测 NAT 后残余病灶的算法模型，假阴性率为 0~5.2%。该技术有望在未来临床实践中提高 NAT 后豁免腋窝手术患者的筛选效率和准确率，辅助临床医师作出更为精准的治疗决策。

5 总结与展望

近年来，生物学指标逐渐取代腋窝淋巴结状况，成为乳腺癌治疗决策的主要依据，治疗理念的转变推动腋窝手术“降阶梯”趋势的发展。众多研究和国际指南推荐表明，在特定人群中豁免腋窝手术具有一定的可行性，不会影响患者的远期生存。腋窝手术更多地发挥着分期与预后评估的作用，而非治疗本身，且与放疗相比，局部区域控制效果相当，提示在某些人群中腋窝手术的必要性正逐步减弱。

然而，对于 NAT 后腋窝管理，需特别注意的是，NAT 后腋窝残留肿瘤负荷往往提示前序治疗对该病灶不敏感，因此对于腋窝可能的残留病灶应提出更严格的标准以确保局部控制^[39-40]，而不能简单照搬初始手术患者的治疗方案。中国抗癌协

会乳腺癌诊治指南与规范（2024 年版）^[41]目前对豁免 SLNB 的推荐仅在临床试验或高龄/伴随疾病的个案中讨论。在正式的 III 期数据及长期随访结果到来之前，该策略要在个体化场景中充分评估后谨慎尝试。当前证据的适用范围仍主要局限于低风险、老年及特定分子分型的早期乳腺癌患者，对于年轻患者、生物学行为异常或存在高危病理因素的患者，仍缺乏足够的高质量数据支持。此外，影像与病理评估虽日益进步，但在影像判读主观性、标准化流程及微小转移灶检出等方面仍存在实际局限^[42]。在临床决策中，虽然生物学特征、基因评分等逐渐成为治疗决策的核心因素，但腋窝淋巴结状态依然是分期和辅助治疗决策的重要参考。豁免手术后，解剖学分期信息缺失对后续系统治疗决策的影响，是临床医生面临的重要问题^[43]。事实上，目前在一些系统治疗方案中，如 CDK4/6 抑制剂的应用，对腋窝分期的依赖已逐渐减弱。例如，符合豁免 SLNB 条件的患者中，仅 0.6% 最终确诊为 pN2 期疾病，不太可能影响阿贝西利的推荐使用^[24]；瑞波西利的应用主要是基于原发肿瘤特征。在辅助放疗方面，CALGB 9343 研究^[44]显示，对于年龄 ≥70 岁并接受保乳手术的患者，同时豁免放疗和 SLNB，并不会增加远处转移的风险；此外，该研究中 63% 的患者并未接受腋窝手术。PRIME II 试验^[45]10 年随访数据也显示，对于年龄 ≥65 岁、HR+/HER2-、pN0、pT ≤3 cm 的患者，省略放疗也不会影响 OS。依据这些证据推断，对于此类患者，省略 SLNB 不应改变省略放疗的决定。2025 年 ASCO 指南指出，对于符合以下标准的 ≥65 岁乳腺癌患者，可豁免 SLNB，且保乳术后放疗非强制要求：绝经后状态、浸润性癌灶直径 ≤2 cm、Nottingham 分级 1~2 级、HR+/HER2-（患者拟接受辅助内分泌治疗）、腋窝超声未提示可疑淋巴结，或仅有 1 枚可疑淋巴结经活检证实为良性。

从传统的 ALND 过渡到 SLNB 是乳腺外科治疗的重要里程碑^[46]。而 SLNB 本身已属微创手术，其被豁免的临床迫切性相对较低，临床推动远不如 ALND 向 SLNB 转型那般坚定^[47-48]。在此背景下，腋窝手术的需求更多地转向高度选择的人群，强调肿瘤安全性、复发风险和患者的生活质量之间的平衡^[49]。在临床实践中，如何根据患者的具体情况，比如肿瘤特征、年龄、分子分型、影像学评估结果等个性化地决定是否豁免腋窝手术，已成

为制定治疗方案的核心问题。这一决策过程需要严格的风险评估和多学科协作^[50], 确保在降低治疗强度的同时, 最大限度地保证疗效和患者的生存质量。展望未来, 随着影像学、人工智能等新技术的发展, 腋窝状态的评估和豁免手术的选择将日益精准, 推动真正意义上的个体化治疗和风险最小化。如何在局部和全身治疗之间实现最佳平衡, 仍是未来乳腺癌腋窝管理的重要挑战与发展方向。

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