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·专家共识·

局部晚期口腔鳞状细胞癌PD-1抑制剂新辅助治疗专家共识(2026年版)

李劲松[1]，廖贵清[2]，李龙江[3]，张陈平[4]，尚政军[5]，张杰[6]，钟来平[7]，刘冰[5]，陈刚[5]，魏建华[8]，季彤[9]，李春洁[3]，林李嵩[10]，任国欣[11]，李一[12]，尚伟[13]，韩冰[14]，蒋灿华[15]，张胜[16]，宋明[17]，刘学奎[17]，王安训[18]，刘曙光[19]，陈展洪[20]，王友元[1]，林钊宇[1]，李海刚[21]，段小慧[22]，叶玲[23]，郑军[24]，王军[25]，吕晓智[26]，朱李军[27]，曹昊天[1]

1.中山大学孙逸仙纪念医院口腔颌面外科,广东 广州(510123)；2.中山大学附属口腔医院口腔颌面外科,广东 广州(510055)；3.四川大学华西口腔医院头颈肿瘤外科,四川 成都(610041)；4.上海交通大学附属第九人民医院口腔颌面外科,上海(200011)；5.武汉大学口腔医院口腔颌面头颈肿瘤外科,湖北 武汉(430070)；6.北京大学口腔医院口腔颌面外科,北京(100082)；7.复旦大学附属华山医院口腔颌面头颈外科,上海(200031)；8.空军军医大学口腔医院颌面肿瘤科,陕西 西安(710032)；9.复旦大学附属中山医院口腔颌面外科,上海(200032)；10.福建医科大学附属第一医院口腔颌面外科,福建 福州(350004)；11.上海交通大学附属第九人民医院口腔颌面头颈肿瘤科,上海(200011)；12.重庆医科大学附属口腔医院口腔颌面外科,重庆(401147)；13.青岛大学附属医院口腔颌面外科,山东 青岛(266071)；14.吉林大学口腔医院口腔颌面外科,吉林 长春(130021)；15.中南大学湘雅医院口腔颌面外科,湖南 长沙(410008)；16.中南大学湘雅二医院口腔颌面外科,湖南 长沙(410011)；17.中山大学肿瘤防治中心头颈科,广东 广州(510060)；18.中山大学附属第一医院口腔颌面外科,广东 广州(510080)；19.南方医科大学口腔医院口腔颌面外科,广东 广州(510280)；20.中山大学附属第三医院肿瘤内科,广东 广州(510630)；21.中山大学孙逸仙纪念医院病理科,广东 广州(510123)；22.中山大学孙逸仙纪念医院放射科,广东 广州(510123)；23.中山大学孙逸仙纪念医院放疗科,广东 广州(510123)；24.江门市中心医院口腔颌面外科,广东 江门(529070)；25.南昌大学第二附属医院口腔颌面-头颈外科,江西 南昌(330006)；26.南方医科大学珠江医院口腔颌面外科,广东 广州(510282)；27.广东省人民医院口腔颌面外科,广东 广州(510080)

【摘要】 口腔鳞状细胞癌(oral squamous cell carcinoma,OSCC)是头颈部常见恶性肿瘤,约50%~60%的OSCC患者确诊时已处于局部晚期(临床分期Ⅲ~Ⅳa期),以手术为主的综合序列治疗模式下其5年总生存期(overall survival,OS)率仍低于50%,且术后常伴随语言、吞咽等功能障碍。程序性死亡受体-1(programmed death receptor-1,PD-1)抑制剂在局部晚期OSCC新辅助治疗中逐步推广,并取得了较好的疗效,但临床实践中仍面临适应证界定、联合治疗方案优化、疗效评估标准等诸多关键问题。基于国内外最新研究进展,本专家共识系统评估PD-1抑制剂在局部晚期OSCC新辅助治疗中的应用、联合治疗策略、治疗疗程与手术时机、疗效评估、生物标志物的应用、特殊人群与免疫相关不良反应的管理、免疫治疗再挑战原则、功能保留等关键问题,经专家组多轮讨论,采用Delphi法匿名投票形成以下共识:1)对局部晚期OSCC患者术前可采用PD-1抑制剂进行新辅助治疗;新辅助治疗首选PD-1抑制剂联合含铂药物化疗方案,疗程为2~3个周期;2)在新辅助治疗疗效评估阶段,影像学评估需参照实体瘤疗效评价标准1.1版(response evaluation criteria in solid tumors 1.1,RECIST 1.1)与实体瘤免疫治疗疗效评价标准(immune response evaluation criteria in solid tumors,iRE-

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【通信作者】李劲松,二级教授/一级主任医师,博士,Email:lijins@mail.sysu.edu.cn;廖贵清,二级教授/一级主任医师,博士,Email:liaogq@mail.sysu.edu.cn;李龙江,二级教授/一级主任医师,博士,Email:muzili63@163.com;张陈平,二级教授/一级主任医师,博士,Email:zhang.chenping@hotmail.com;尚政军,二级教授/一级主任医师,博士,Email:shangzhengjun@hotmail.com

CIST）双重标准；术后需对原发灶和区域淋巴结分别进行系统病理评估；联合化疗方案则可不将PD-L1表达及联合阳性评分（combined positive score，CPS）作为入组或排除标准；3）特殊人群如高龄（≥70岁）、病毒载量稳定的HIV感染者及慢性HBV/HCV携带者，可在多学科团队（multidisciplinary team，MDT）指导下慎重用药并加强不良反应监测；4）对于新辅助治疗后疗效不佳的，不建议继续维持原治疗方案，应及时进行MDT评估，调整后续治疗方案；对于器官移植受者与活动性自身免疫疾病患者，因存在免疫异常激活相关高风险，不推荐使用PD-1抑制剂新辅助治疗；对于已发生了高风险免疫相关不良事件（如免疫性心肌炎、神经毒性、肺炎等）的患者，一般不建议再挑战；5）病理缓解良好的患者可探索个体化降级手术与功能保存策略。本共识旨在推动PD-1抑制剂新辅助治疗策略在局部晚期OSCC患者中的规范、安全与精准应用。

【关键词】 口腔鳞状细胞癌；　局部晚期；　新辅助治疗；　PD-1抑制剂；　免疫治疗；　疗效评估；　免疫相关不良反应；　联合阳性评分；　功能性外科；　化疗

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Expert consensus on neoadjuvant PD-1 inhibitors for locally advanced oral squamous cell carcinoma (2026 edition)

LI Jinsong[1], LIAO Guiqing[2], LI Longjiang[3], ZHANG Chenping[4], SHANG Zhengjun[5], ZHANG Jie[6], ZHONG Laiping[7], LIU Bing[5], CHEN Gang[5], WEI Jianhua[8], JI Tong[9], LI Chunjie[3], LIN Lisong[10], REN Guoxin[11], LI Yi[12], SHANG Wei[13], HAN Bing[14], JIANG Canhua[15], ZHANG Sheng[16], SONG Ming[17], LIU Xuekui[17], WANG Anxun[18], LIU Shuguang[19], CHEN Zhanhong[20], WANG Youyuan[1], LIN Zhaoyu[1], LI Haigang[21], DUAN Xiaohui[22], YE Ling[23], ZHENG Jun[24], WANG Jun[25], LV Xiaozhi[26], ZHU Lijun[27], CAO Haotian[1]. 1. Department of Oral and Maxillofacial Surgery, Sun Yat-sen Memorial Hospital, Sun Yat-sen University, Guangzhou 510123, China; 2. Department of Oral and Maxillofacial Surgery, Hospital of Stomatology, Sun Yat-sen University, Guangzhou 510055, China; 3. Department of Head and Neck Oncology Surgery, West China Hospital of Stomatology, Sichuan University, Chengdu 610041, China; 4. Department of Oral and Maxillofacial Surgery, Shanghai Ninth People′s Hospital, Shanghai Jiao Tong University, Shanghai 200011, China; 5. Department of Oral and Maxillofacial Head and Neck Oncology Surgery, Hospital of Stomatology, Wuhan University, Wuhan 430070, China; 6. Department of Oral and Maxillofacial Surgery, Peking University Hospital of Stomatology, Beijing 100082, China; 7. Department of Oral and Maxillofacial Head and Neck Surgery, Huashan Hospital, Fudan University, Shanghai 200031, China; 8. Department of Maxillofacial Oncology, School of Stomatology, Air Force Medical University, Xi′an 710032, China; 9. Department of Oral and Maxillofacial Surgery, Zhongshan Hospital, Fudan University, Shanghai 200032, China; 10. Department of Oral and Maxillofacial Surgery, The First Affiliated Hospital of Fujian Medical University, Fuzhou 350004, China; 11. Department of Oral and Maxillofacial Head and Neck Oncology, Shanghai Ninth People′s Hospital, Shanghai Jiao Tong University, Shanghai 200011, China; 12. Department of Oral and Maxillofacial Surgery, Hospital of Stomatology, Chongqing Medical University, Chongqing 401147, China; 13. Department of Oral and Maxillofacial Surgery, The Affiliated Hospital of Qingdao University, Qingdao 266071, China; 14. Department of Oral and Maxillofacial Surgery, Hospital of Stomatology, Jilin University, Changchun 130021, China; 15. Department of Oral and Maxillofacial Surgery, Xiangya Hospital, Central South University, Changsha 410008, China; 16. Department of Oral and Maxillofacial Surgery, The Second Xiangya Hospital, Central South University, Changsha 410011, China; 17. Department of Head and Neck Surgery, Sun Yat-sen University Cancer Center, Guangzhou 510060, China; 18. Department of Oral and Maxillofacial Surgery, The First Affiliated Hospital, Sun Yat-sen University, Guangzhou 510080, China; 19. Department of Oral and Maxillofacial Surgery, Hospital of Stomatology, Southern Medical University, Guangzhou 510280, China; 20. Department of Medical Oncology, The Third Affiliated Hospital, Sun Yat-sen University, Guangzhou 510630, China; 21. Department of Pathology, Sun Yat-sen Memorial Hospital, Sun Yat-sen University, Guangzhou 510123, China; 22. Department of Radiology, Sun Yat-sen Memorial Hospital, Sun Yat-sen University, Guangzhou 510123, China; 23. Department of Radiation Oncology, Sun Yat-sen Memorial Hospital, Sun Yat-sen University, Guangzhou 510123, China; 24. Department of Oral and Maxillofacial Surgery, Jiangmen Central Hospital, Jiangmen 529070, China; 25. Department of Oral and Maxillofacial Head and Neck Surgery, The Second Affiliated Hospital of Nanchang University, Nanchang 330006, China; 26. Department of Oral and Maxillofacial Surgery, Zhujiang Hospital, Southern Medical University, Guangzhou 510282, China; 27. Depart-

ment of Oral and Maxillofacial Surgery, Guangdong Provincial People's Hospital, Guangzhou 510080, China
Corresponding author: LI Jinsong, Email: lijins@mail.sysu.edu.cn; LIAO Guiqing, Email: liaogq@mail.sysu.edu.cn; LI Longjiang, Email: muzili63@163.com; ZHANG Chenping, Email: zhang.chenping@hotmail.com; SHANG Zhengjun, Email: shangzhengjun@hotmail.com

【Abstract】 Oral squamous cell carcinoma (OSCC) is a common head and neck malignancy. Approximately 50% to 60% of patients with OSCC are diagnosed at a locally advanced stage (clinical staging III-IVa). Even with systemic and sequential treatment primarily based on surgery, the 5-year overall survival rate remains below 50%, and patients often suffer from postoperative functional impairments such as difficulties with speaking and swallowing. Programmed death receptor-1 (PD-1) inhibitors are increasingly used in the neoadjuvant treatment of locally advanced OSCC and have shown encouraging efficacy. However, clinical practice still faces key challenges, including the definition of indications, optimization of combination regimens, and standards for efficacy evaluation. Based on the latest research advances worldwide and the clinical experience of the expert group, this expert consensus systematically evaluates the application of PD-1 inhibitors in the neoadjuvant treatment of locally advanced OSCC, covering combination strategies, treatment cycles and surgical timing, efficacy assessment, use of biomarkers, management of special populations and immune related adverse events, principles for immunotherapy rechallenge, and function preservation strategies. After multiple rounds of panel discussion and through anonymous voting using the Delphi method, the following consensus statements have been formulated: 1) Neoadjuvant therapy with PD-1 inhibitors can be used preoperatively in patients with locally advanced OSCC. The preferred regimen is a PD-1 inhibitor combined with platinum based chemotherapy, administered for 2-3 cycles. 2) During the efficacy evaluation of neoadjuvant therapy, radiographic assessment should follow the dual criteria of Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 and immune RECIST (iRECIST). After surgery, systematic pathological evaluation of both the primary lesion and regional lymph nodes is required. For combination chemotherapy regimens, PD-L1 expression and combined positive score need not be used as mandatory inclusion or exclusion criteria. 3) For special populations such as the elderly (≥ 70 years), individuals with stable HIV viral load, and carriers of chronic HBV/HCV, PD-1 inhibitors may be used cautiously under the guidance of a multidisciplinary team (MDT), with close monitoring for adverse events. 4) For patients with a poor response to neoadjuvant therapy, continuation of the original treatment regimen is not recommended; the subsequent treatment plan should be adjusted promptly after MDT assessment. Organ transplant recipients and patients with active autoimmune diseases are not recommended to receive neoadjuvant PD-1 inhibitor therapy due to the high risk of immune related activation. Rechallenge is generally not advised for patients who have experienced high risk immune related adverse events such as immune mediated myocarditis, neurotoxicity, or pneumonitis. 5) For patients with a good pathological response, individualized de-escalation surgery and function preservation strategies can be explored. This consensus aims to promote the standardized, safe, and precise application of neoadjuvant PD-1 inhibitor strategies in the management of locally advanced OSCC patients.

【Key words】 oral squamous cell carcinoma; locally advanced stage; neoadjuvant treatment; PD-1 inhibitor; immunotherapy; efficacy evaluation; immune-related adverse reactions; combined positive score; functional surgery; chemotherapy
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口腔鳞状细胞癌(oral squamous cell carcinoma,OSCC)是头颈部最常见的恶性肿瘤之一,约占所有头颈部恶性肿瘤的25%~30%[1-2]。在确诊时,约50%~60%的患者已处于局部晚期(临床分期Ⅲ~Ⅳa期),表现为肿瘤侵犯邻近结构或区域性淋巴结转移[3-4]。目前局部晚期OSCC标准治疗模式仍是以根治性手术为主,辅以放化疗的综合序列治疗。然而,其5年总生存期(overall survival,OS)率低于50%,且术后存在功能障碍与生活质量下降[5-7]。近年来,免疫检查点抑制剂(immune checkpoint inhibitors,ICIs),尤其是程序性死亡受体-1(programmed death receptor-1,PD-1)抑制剂,在多种实体瘤的治疗中展现出持久的抗肿瘤作用,已成为晚期肿瘤治疗的重要组成部分。针对复发/转移

性头颈部鳞状细胞癌(head and neck squamous cell carcinoma, HNSCC)的随机对照Ⅲ期临床研究KEYNOTE-048证实,帕博利珠单抗无论单药或联合化疗均可显著延长患者OS[8];CHECKMATE-141研究证实纳武利尤单抗在铂类化疗失败的复发/转移HNSCC患者中显著改善OS[9-10]。

临床医生近年来尝试将免疫治疗引入新辅助治疗阶段。新辅助治疗是指在恶性肿瘤患者接受手术前,先采用化疗、免疫治疗或靶向治疗等手段,以达到缩小肿瘤病灶、降低肿瘤分期、减少远处转移、提高手术根治效果和延长生存的一种综合治疗策略[11]。在针对可切除局部晚期HNSCC的KEYNOTE-689研究的结果显示主要终点无事件生存期(event free survival,EFS)显著延长(中位EFS:帕博利珠单抗组51.8个月 *vs.* 标准治疗组30.4个月,*HR*=0.73,95%*CI*:0.58~0.92,*P*=0.004 1)[12]。

值得注意的是,HNSCC虽然病理学上均表现为鳞状细胞癌特征,但各部位临床表现、生物特征及免疫敏感性具有显著异质性[12-15]。其中OSCC在病因(烟草、酒精、槟榔)[16-18]、HPV阴性率[19-20]、肿瘤微环境的免疫抑制程度[21]、PD-L1表达异质性[22]、肿瘤浸润及复发模式等方面,均显著不同于口咽癌、下咽癌及喉癌[23-24]。尽管PD-1抑制剂在局部晚期HNSCC新辅助治疗中已显示出良好的安全性和初步疗效,由于OSCC与头颈部其他亚型肿瘤在免疫应答方面的差异,使得OSCC新辅助免疫治疗策略具有其特殊性。目前,在适应证的明确、联合治疗方案的优化、手术时机的确定、疗效评价的标准化、生物标志物的选择等关键环节,临床实践中仍面临诸多挑战,缺乏统一的指导原则。为此,专家组汇集国内外最新循证研究证据和临床实践经验,对临床实践中的关键问题进行多轮讨论,采用Delphi法匿名投票,对80%以上专家达成一致的条目形成专家共识,以期为我国局部晚期OSCC患者的PD-1抑制剂新辅助免疫治疗提供一套科学、规范且可操作的初步临床指导方案,后续随着循证医学证据的积累将不断更新。

本共识已在国际实践指南注册与透明化平台(Practice guideline REgistration for transPAREncy, PREPARE)注册,注册号为PREPARE-2026CN172。

1　共识制定方法

本专家共识由来自口腔颌面外科、头颈外科、肿瘤内科、放疗科、影像学及病理学等多学科领域的专家组成工作小组共同制定,旨在结合现有循证医学证据与中国专家临床实践经验,提出适用于局部晚期OSCC患者接受PD-1抑制剂新辅助治疗的临床指导建议。

1.1　专家组构成与职责分工

共识起草小组由34位来自全国各区域的口腔颌面-头颈肿瘤多学科诊疗专家组成,涵盖三甲综合医院与专科医院。根据学科背景划分若干工作组,分别负责证据检索与汇总、推荐条目拟定、争议问题论证与共识撰写。本共识于2025年2月11日启动。专家构成强调跨学科协作与地区平衡代表性,以确保共识兼具科学性与可推广性。

1.2　文献检索与证据收集

工作组系统检索了PubMed、Embase、Cochrane Library及中国知网等主要数据库,检索关键词包括“oral squamous cell carcinoma”、“head and neck cancer”、“PD-1 inhibitors”、“neoadjuvant immunotherapy”等。

纳入文献类型包括随机对照试验(randomized controlled trial,RCT)、系统评价与Meta分析、真实世界研究(real world data,RWD)、国内外临床实践指南与其他相关专家共识等。为提升实用性与代表性,特别参考了中国多个中心真实临床数据。

1.3　共识形成流程

本共识严格遵循结构化、多轮论证流程,依次包括:

1)初稿拟定:基于文献回顾与临床调研,完成共识初稿;2)专家会议与专题讨论:组织多轮线上线下专题研讨,围绕关键条目展开深入讨论;3)Delphi法匿名投票:对存在争议的条目采用两轮及以上Delphi法匿名投票,80%以上达成一致方可纳入共识[25];4)广泛征求意见:向相关专业学会、临床一线医生及科研机构发放征求意见稿,提升内容兼容性;5)正式发布与动态优化:经专家组审议修订后由中国科技核心期刊口腔医学类学术期刊发布。

1.4　证据级别与推荐等级

本共识采用国际主流的欧洲肿瘤内科学会临床实践指南标准作业程序(European Society for Medical Oncology Clinical Practice Guideline SOP)(2023年2.3版)体系对证据质量与推荐强度进行分级(表1和表2)[26-27]。所有推荐条目在正文中均标注相应证据级别与推荐等级,便于临床参考与推广使用。

表1　证据级别[26-27]

Table 1　Levels of evidence[26-27]

Level of evidence	Description
Ⅰ	Evidence from at least one large randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted randomised trials without heterogeneity
Ⅱ	Small randomised trials or large randomised trials with suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
Ⅲ	Prospective cohort studies
Ⅳ	Retrospective cohort studies or case-control studies
Ⅴ	Studies without control group, case reports, expert opinions

RCT: randomized control trial

表2　推荐等级[26-27]

Table 2　Grades of recommendation[26-27]

Grades of recommendation	Description
A	Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
B	Strong or moderate evidence for efficacy but with limited clinical benefit, is generally recommended
C	Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs, etc.), optional
D	Moderate evidence against efficacy or for adverse outcome, generally not recommended
E	Strong evidence against efficacy or for adverse outcome, never recommended

1.5　共识动态更新机制

鉴于免疫治疗领域新技术、新药物和新证据不断涌现，为保持共识的科学性与时效性，本共识设立动态更新机制。原则上每2年更新1次，由原工作组或其授权单位定期梳理最新证据，并组织专家会议更新内容，若出现重大研究突破或影响临床实践的关键数据则随时更新，最终目标是制定符合中国国情的局部晚期OSCC PD-1抑制剂新辅助治疗的临床诊治指南。

2　共识推荐

2.1　PD-1抑制剂在局部晚期OSCC患者新辅助治疗适应证的共识推荐

PD-1抑制剂已在复发/转移HNSCC中确立了其一线标准治疗地位。KEYNOTE-048、KEYNOTE-040、CHECKMATE-141等Ⅲ期随机对照研究均证实帕博利珠单抗在复发转移HNSCC的一线治疗中、帕博利珠单抗和纳武利尤单抗在铂类药物耐药患者中的疗效和安全性[8-10, 28-29]。

在此基础上，研究者探索了PD-1抑制剂在可切除局部晚期HNSCC中的新辅助阶段应用。如前所述，随机对照Ⅲ期KEYNOTE-689研究结果显示帕博利珠单抗提高了局晚期HNSCC患者EFS[12]。之后被写入美国国立综合癌症网络（National Comprehensive Cancer Network，NCCN）指南（2025 V5）[30]。在KEYNOTE-689研究中，入组病例中约60.5%为局部晚期OSCC患者[12]。

因此，PD-1抑制剂在局部晚期OSCC新辅助治疗中的应用具有坚实的循证基础，已逐步成为综合治疗的新范式。

专家共识1：对局部晚期OSCC患者术前可采用PD-1抑制剂进行新辅助治疗（证据级别：Ⅰ级，推荐等级：A级）。

2.2　PD-1抑制剂新辅助联合治疗策略共识推荐

KEYNOTE-689研究方案中的新辅助治疗方案为单药帕博利珠单抗，但病理缓解率不高，联合阳性评分（combined positive score，CPS）≥10人群组主要病理缓解（major pathological response，MPR）率为13.7%，病理完全缓解（pathological complete response，pCR）率仅为4.3%，甚至低于化疗新辅助治疗的病理缓解率[12]；CHECKMATE-358也表明，纳武利尤单抗用于可切除HPV阳性的HNSCC新辅助治疗的pCR率仅为5.9%[31]。提示需要联合用药，以提高免疫新辅助治疗疗效。

为提升PD-1抑制剂在OSCC新辅助治疗中的疗效，近年来多个研究探索了其与化疗、放疗或靶向治疗的联合应用方案。其中，化疗药物可诱导免疫原性细胞死亡（immunogenic cell death，ICD），促进抗原释放与免疫应答激活，与PD-1抑制剂在

机制上具有协同作用[32-33]。

虽然新辅助化疗在OSCC中应用已久，但单纯化疗在临床实践中存在疗效不一致、毒性累积明显、生存获益有限等问题。单纯化疗虽可缩小部分原发灶，但并不能显著改善无病生存期（disease-free survival，DFS）与OS[34-36]。当前实践中，化疗更常作为免疫治疗的基础平台，借助其免疫调节作用增强免疫治疗反应[37-38]。一项Ⅱ期临床研究表明：特瑞普利单抗联合化疗在HNSCC新辅助治疗中显示pCR率50%，安全性良好[39]。一项单中心回顾性队列研究表明，新辅助化学免疫治疗（neo-adjuvant chemo-immunotherapy，NACI）用于可切除局部晚期OSCC安全有效，其pCR率达47.1%、MPR率达65.4%，3年DFS率和OS率分别为89.0%、91.3%，均显著高于单纯手术组的DFS率60.8%和OS率64.0%[40]。另一项回顾性研究显示，79例可切除HNSCC患者接受新辅助PD-1抑制剂特瑞普利单抗联合化疗治疗后，取得了较高病理缓解率（MPR率53.1%）和良好生存结局（1年OS率97.4%）[41]。一项Ⅱ期前瞻性、单臂临床研究表明，82例可切除局部晚期OSCC或口咽鳞状细胞癌患者接受替雷利珠单抗联合化疗新辅助治疗，MPR率为60.3%，pCR率为34.2%。中位随访24个月，2年OS率为84.4%，2年无事件生存期（EFS）率为76.7%[11]。一项针对HNSCC患者新辅助治疗的meta分析，纳入24项研究共1 092例患者，结果显示新辅助PD-1/PD-L1抑制剂联合化疗的客观缓解率（objective response rate，ORR）61%显著高于单药免疫治疗（22%），HNSCC患者可从新辅助免疫治疗联合化疗中临床获益[42]。

同时也有研究表明，对于不耐受化疗的患者，应用表皮生长因子受体（epidermal growth factor receptor，EGFR）单抗联合免疫治疗同样可获得近期缓解，因此靶向治疗与免疫治疗联合以其低毒高效的特点，在局部晚期OSCC的新辅助治疗中也显示出良好的前景[43-45]。同时，新辅助免疫治疗联合放疗也有一定疗效[46]。一项Ⅱ期单臂多中心试验表明，低剂量放疗联合替雷利珠单抗、白蛋白结合紫杉醇和顺铂新辅助治疗可切除局部晚期HNSCC，pCR率达到60.9%，疗效良好且毒性可控[47]。

专家共识2：PD-1抑制剂联合含铂药物化疗可作为局部晚期OSCC患者新辅助治疗的首选方案，以提升新辅助治疗疗效（证据级别：Ⅱ～Ⅲ级，推荐等级：A级）。

专家共识3：免疫治疗联合放疗或联合靶向治疗在局部晚期OSCC患者新辅助治疗中仍处于早期探索阶段，缺乏高质量循证医学证据支持其常规应用（证据级别：Ⅲ级，推荐等级：C级）。

2.3　新辅助免疫治疗疗程与手术时机的共识推荐

在局部晚期OSCC患者采用PD-1抑制剂新辅助治疗策略中，手术时机的精准掌控对于治疗效果最大化和术后并发症控制至关重要。新辅助治疗的目标包括缩小肿瘤体积、清除潜在微转移灶及诱导免疫记忆反应，从而提高手术切除率和长期生存率，但前提是不应延误“可切除窗口期”[48]。

根据现有临床研究与专家共识，多数推荐在新辅助免疫治疗中给予2～3个周期PD-1抑制剂治疗（包括单药或联合含铂药物化疗），每周期约21 d，总疗程控制在6～9周以内，随后尽早手术。该时间框架兼顾了初期免疫应答的激发、肿瘤降期的可评估性、治疗毒性的缓解及术前体能储备的窗口[49]。

真实世界数据表明，若新辅助治疗完成后延迟超过6周进行手术，可能出现肿瘤进展、切除范围扩大及术后并发症风险增高，从而影响整体治疗效果与预后[48，50]。

此外，在免疫治疗联合化疗策略中，部分患者在1～2个周期即出现明显缩瘤反应，此时应积极评估肿瘤切除可行性，必要时可提前择期手术，而不应固守既定周期数。同时，若在治疗过程中出现免疫相关不良事件（immune-related adverse events，irAEs）≥3级、体能下降或营养恶化等情况，也应及时终止免疫治疗并调整后续治疗方案[51]。

专家共识4：局部晚期OSCC患者PD-1抑制剂新辅助治疗疗程推荐2～3个周期，总时长控制在6～9周内；新辅助治疗结束后，建议在2～4周内实施手术（证据级别：Ⅱ～Ⅲ级，推荐等级：A级）。

2.4　新辅助免疫治疗疗效不佳时的手术介入与方案调整共识推荐

新辅助免疫治疗作为围手术期干预策略之一，其核心目标在于术前激活抗肿瘤免疫反应、缩小肿瘤体积、清除潜在微转移灶，并尽可能提高MPR率或pCR率。然而在临床实践中，部分患者在接受PD-1抑制剂联合化疗后，影像学或临床评估提示疗效欠佳，甚至出现肿瘤持续进展[52-54]。这类疗效不佳的患者临床路径面临两难：一方面延

长免疫治疗周期可能失去手术机会；另一方面提前手术则可能面临切除难度大、功能损伤等严重挑战。此外，与传统化疗相比，免疫治疗的疗效呈现出“延迟应答窗口”，部分患者可能在治疗后期才出现显著反应[55]，这一现象增加了手术切缘评估与肿瘤退缩判断的难度[49]。

约15%～25% HNSCC患者在新辅助免疫治疗后未能获得有效缩瘤，其中更需警惕免疫治疗特有的两类非典型反应——“免疫相关超进展（hyperprogression）”与“假进展（pseudoprogression）”。超进展表现为治疗后短期内（通常2个月内）病灶急剧增大、淋巴结快速肿大或新发转移，肿瘤生长速率较治疗前增加2倍以上，本质是对免疫治疗的恶性耐受；假进展则是影像学提示病灶增大或出现新病灶，但实际是免疫细胞大量浸润肿瘤微环境引发的炎症反应与组织水肿，后续多在治疗8～12周内自行退缩，属于治疗有效的早期表现[56]。二者与普通治疗无效的临床意义和处理策略截然不同，需要准确鉴别。

因此，需在新辅助治疗阶段建立明确的疗效判断标准与无应答干预路径。影像学应答标准建议采用实体瘤疗效评价标准1.1版（response evaluation criteria in solid tumors 1.1，RECIST 1.1）联合实体瘤免疫治疗疗效评价标准（immune response evaluation criteria in solid tumors，iRECIST）判定；对于稳定病变（stable disease，SD）或进展性病变（progressive disease，PD）患者，应由多学科团队（multidisciplinary team，MDT）尽快评估并制定后续治疗方案，避免因盲目等待造成不可逆手术窗口丧失。

专家共识5：对于新辅助治疗后疗效不佳（SD或PD）的患者，不建议继续维持原治疗方案，应及时MDT评估，调整后续治疗方案（证据级别：Ⅲ级，推荐等级：A级）。

2.5　新辅助免疫治疗影像学疗效评估的共识推荐

在PD-1抑制剂新辅助治疗应用于局部晚期OSCC的治疗中，如何准确评估疗效成为围手术期管理的核心环节之一。影像学作为疗效评估的重要手段，直接影响何时实施手术及手术方式选择。

传统的RECIST 1.1主要依据肿瘤最长径变化进行评价，但在免疫治疗中存在一定局限。部分患者在接受免疫治疗早期可能出现影像学“假进展”和“免疫相关超进展”。因此，传统RECIST 1.1标准易造成误判[57-59]。

为应对这一问题，iRECIST（immune RECIST）被提出，其在传统RECIST基础上引入“免疫确认性进展”的概念，强调对初始进展需进行再评估确认后判定“免疫真实进展”，避免过早中止治疗。在新辅助治疗时，采用iRECIST可提高疗效判断的敏感性与特异性[60-61]。

此外，功能影像技术在免疫治疗疗效预测中日益受到重视。PET-CT或PET-MR能够检测代谢活性变化，有助于识别早期响应与微小病灶[62-65]；扩散加权成像-磁共振成像（diffusion weighted imaging-magnetic resonance imaging，DWI-MRI）对肿瘤细胞密度与组织结构变化敏感，可作为治疗反应的重要补充指标[66]。

人工智能（artificial intelligence，AI）辅助放射组学技术迅速发展，通过对CT/MRI/PET图像特征进行深度挖掘，构建多维预测模型，有望在术前非侵入性预测MPR/pCR、分子分型、免疫微环境状态等方面提供支持[67-68]。已有初步研究将影像纹理、血管特征等参数与免疫应答建立相关模型，显示出良好的区分能力[69]。

专家共识6：建议局部晚期OSCC患者在新辅助免疫治疗前后常规行影像学对比检查，并参照RECIST 1.1与iRECIST双重标准评估疗效（证据级别：Ⅰ～Ⅲ级，推荐等级：A级）。

2.6　新辅助免疫治疗病理疗效评估的共识推荐

病理评估是判断新辅助治疗疗效的“金标准”。不同于传统术后病理评估，新辅助免疫治疗后肿瘤组织常表现为非典型组织学反应，包括坏死、纤维化、淋巴细胞浸润等特征，这些变化虽提示已诱导免疫应答，但并不等同于肿瘤细胞的完全清除[70]。因此，建立针对免疫治疗反应特征的专属病理评估体系，对于术后综合治疗决策和预后判断具有关键价值。

目前国际共识推荐采用MPR及pCR作为标准化评估终点。MPR通常定义为残余活肿瘤细胞占原发灶组织面积≤10%；pCR则表示原发灶与区域淋巴结中均未检出可识别的活肿瘤细胞[71]。已有研究表明，达到MPR或pCR的患者DFS显著提高，具有良好预后价值[54, 72]。

为进一步提升评估精度，部分学者提出引入肿瘤残存评分系统（tumor regression score，TRS），结合坏死、炎性反应与残瘤比例进行多维度评分[70]；也有研究提出使用免疫特异性病理模式（如

“免疫清扫带”、“纤维化边缘”等）进行半定量评价，以更精准反映免疫应答相关反应[73]。

但是区域淋巴结的病理反应常与原发灶不完全一致。有研究表明，即使原发灶达到MPR或pCR，部分患者仍在淋巴结中检出残余活肿瘤细胞。因此，淋巴结应作为独立病理评估终点，建议术后病理报告中分别明确原发灶与淋巴结的MPR/pCR状态，并标注活肿瘤细胞比例、肿瘤浸润淋巴细胞（tumor infiltrating lymphocytes，TILs）分布、坏死区/纤维化带等关键指标[74]。也有研究强调应该重点评估明确的病理缓解定义、肿瘤退缩模式、免疫相关病理特征、以及PD-L1 CPS、三级淋巴结构（tertiary lymphoid structures，TLS）密度、$CD4^+$T细胞浸润等与疗效相关的标志物[45, 75]。

专家共识7：建议在新辅助免疫治疗术后对原发灶和区域淋巴结分别进行系统病理学疗效评估，以指导术后辅助治疗（证据级别：Ⅰ～Ⅲ级，推荐等级：A级）。

2.7　新辅助免疫治疗的生物标志物PD-L1表达与CPS评分的共识推荐

PD-L1是目前最常被应用于预测免疫检查点抑制剂（ICIs）疗效的肿瘤生物标志物。在HNSCC中，PD-L1表达水平已被纳入KEYNOTE-048等多项Ⅲ期研究作为患者分层的重要指标。其表达与PD-1抑制剂治疗的ORR、无进展生存期（progress free survival，PFS）和OS均存在一定相关性[76-77]。

目前，国际临床实践中主流的检测方式是基于免疫组化的CPS，即PD-L1阳性细胞（肿瘤细胞+免疫细胞）数量占肿瘤总细胞数量的百分比。CPS可分为3个临床常用阈值：<1（阴性）、1~19（中表达）、≥20（高表达）。多项研究提示，CPS≥20患者的免疫治疗反应率、病理缓解率明显优于低表达人群[8, 12]。

其他多项研究也显示，CPS ≥20的患者在接受PD-1抑制剂治疗时的ORR、MPR及pCR率更高，而且预后更好[12, 42, 78-79]。在新辅助免疫治疗时，PD-L1表达虽然不是决定治疗是否实施的绝对标准，但作为风险因素和疗效预测的参考指标仍具临床价值。

然而，需要强调的是，新辅助免疫治疗联合化疗与单免疫治疗应该分开讨论。联合治疗中PD-L1阴性（CPS<1）患者中亦存在一定应答比例，在联合化疗的治疗中，CPS可不作为入组或排除标准[12, 40]。

专家共识8：建议在PD-1抑制剂单药新辅助治疗前，对OSCC肿瘤组织进行PD-L1检测和CPS评分（证据级别：Ⅰ级，推荐等级：A级）。

专家共识9：在PD-1抑制剂联合化疗的新辅助治疗中，CPS可不作为新辅助免疫治疗的绝对入组或排除标准（证据级别：Ⅱ～Ⅲ级，推荐等级：B级）。

2.8　特殊人群新辅助免疫治疗应用与免疫相关不良反应管理的共识推荐

随着PD-1抑制剂在局部晚期OSCC患者新辅助治疗中的广泛应用，部分存在合并疾病或生理状态特殊的患者逐渐被纳入临床实践。如何识别并安全管理特殊人群的免疫治疗适用性与风险，成为新辅助免疫治疗策略全面推广的重要环节。

常见特殊人群包括高龄患者（≥70岁）[80]、HIV感染者[81]、慢性病毒携带者（如HBV/HCV）[82]、器官移植术后人群[83]、活动期自身免疫疾病患者（如系统性红斑狼疮、类风湿关节炎等）[84]。这些人群在既往免疫治疗大型研究中多被排除，缺乏系统性安全数据，真实世界数据成为参考依据[85-86]。

多项观察性研究表明，高龄患者只要基本脏器功能良好，免疫治疗的耐受性与疗效并不劣于年轻人。中国人群研究也提示：PD-1抑制剂在≥70岁患者中不良反应整体可控，尤其在短周期新辅助治疗中风险较低[80]。对于HIV感染者，若病毒载量稳定、$CD4^+$T细胞计数＞200/μL，免疫治疗未观察到明显加重感染风险，亦可在多学科协作下尝试谨慎使用[39]。

而对于活动期自身免疫疾病、实体器官移植受者，因免疫治疗可能诱发疾病激活或排异反应，建议谨慎使用，原则上不推荐列为常规适应证，必要时应在充分评估及严密监控下个体化处理。

另一方面，免疫相关不良事件（irAEs）虽在新辅助阶段多数表现为1、2级皮疹、疲乏、轻度甲状腺功能紊乱等，但部分患者亦可能出现肺炎、肠炎、肝炎等3、4级毒性。其管理原则为：及时识别、早期干预、严重者停药并系统治疗[85]。

专家共识10：对于高龄患者（≥70岁）、病毒载量稳定的HIV感染者及慢性HBV/HCV携带者，可在MDT指导下慎重给予PD-1抑制剂新辅助治疗，需加强不良反应监测和管理（证据级别：Ⅰ～Ⅲ级，推荐等级：A级）。

专家共识11：对于器官移植受者与活动性自身免疫疾病患者，因存在免疫异常激活相关高风险，不推荐使用PD-1抑制剂新辅助治疗（证据级别：Ⅳ级，推荐等级：B级）。

2.9　免疫治疗再挑战策略的共识推荐

再挑战（rechallenge）指患者在接受初始免疫治疗后因特定原因停药（如不良反应或疾病进展），后续重新启用同类或不同类免疫检查点抑制剂（ICIs）的治疗策略。其核心在于：通过调整治疗方案，重新激活患者自身免疫系统对肿瘤的杀伤作用[87]。

对于因irAE中断治疗者，是否可进行免疫治疗再挑战，需根据既往irAE类型、严重程度及恢复情况综合判断。一般认为，1～2级irAE完全缓解后，可在严密随访下尝试重新引入免疫治疗；既往发生过3级或4级irAE的患者进行免疫检查点抑制剂（ICIs）治疗再挑战时有再次发生严重不良事件的风险。再挑战取决于多种因素，需要进行MDT讨论，权衡每例患者的临床获益和治疗相关毒性[88]。3级以上irAE特别是涉及肺、神经、心肌等的患者，不建议再挑战[89]。

专家共识12：对于已发生了高风险irAE（如免疫性心肌炎、神经毒性、肺炎等）的患者，一般不建议再挑战（证据级别：Ⅲ级，推荐等级：B级）。

2.10　新辅助免疫治疗后功能保存与降级治疗探索的共识推荐

局部晚期OSCC患者的根治性治疗长期以来依赖广泛手术切除和术后放疗或同步放化疗的模式，虽有助于控制肿瘤进展，但常造成严重的语言、吞咽、咀嚼以及容貌等功能损害，影响患者生存质量。

随着新辅助免疫治疗在头颈部肿瘤中的应用拓展，越来越多患者在术前实现了肿瘤降期，这为降级治疗[90]提供了新的可能。免疫诱导的快速缩瘤和长期抗肿瘤记忆反应可能部分替代术后放疗的系统控制作用，尤其在pCR或低残余肿瘤负荷人群中，保功能治疗策略成为研究热点[91-92]。一项单臂Ⅱ期临床试验表明，替雷利珠单抗联合化疗新辅助治疗用于局部晚期OSCC和口咽鳞状细胞癌患者，取得了主要病理缓解（MPR）和良好的生存指标，安全性可接受，且部分患者得以避免激进手术[11]。

既往多瘤种研究正在探讨术后放疗的“选择性省略”，即在达到MPR或影像-病理双缓解后，依据风险分层豁免或减弱辅助放疗[93-94]；也有研究尝试基于冰冻切缘术中评估进行功能区保存切除[52]。

此外，“免疫驱动的个体化减量”概念逐渐成型，即以新辅助治疗的疗效与生物标志物（如TILs、高CPS、$CD103^+CD8^+$、pCR）为基础，对后续治疗强度进行生物学调节，以最大程度实现肿瘤控制与功能保存的双重目标[95]。

专家共识13：对于新辅助免疫治疗后获得显著疗效的患者，可在MDT指导下，探索个体化降级治疗方案，同时鼓励开展相关临床研究以获得更高级别循证医学证据（证据级别：Ⅳ级，推荐等级：B级）。

3　结　语

随着免疫检查点抑制剂（ICIs）在头颈部肿瘤治疗中的广泛应用，新辅助免疫治疗正在重塑局部晚期OSCC患者的综合治疗格局。本共识在汇集PD-1抑制剂新辅助治疗局部晚期OSCC患者的最新临床研究成果与真实世界数据的基础上，围绕PD-1抑制剂新辅助治疗局部晚期OSCC患者的适应证界定、治疗策略优化、新辅助治疗周期与手术时机、疗效评估体系的建立、生物标志物筛选及应用、特殊人群与免疫相关不良反应的管理、免疫治疗再挑战原则、功能保留路径等关键问题，形成了13项专家共识推荐意见，旨在为临床医生提供科学、规范、可操作的指导框架。

当前循证医学证据表明，PD-1抑制剂联合化疗的新辅助策略已成为局部晚期OSCC患者治疗中最认可的方案，在提高手术切除率、主要病理缓解/病理完全缓解（MPR/pCR）及术后生存质量方面展现出良好潜力。同时，围绕病理疗效分层、功能影像辅助判断、免疫相关毒性监测与术后治疗降级探索等环节的实践也正在临床广泛开展。

未来需依托大型前瞻性临床研究、真实世界注册平台与多中心协作机制，推动免疫新辅助策略的标准化和个性化，实现“长生存、少复发、保功能”的综合目标，最终提高口腔癌患者的生存率和生存质量。

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（编辑　张琳，曾曙光）

官网

【通信作者简介】 李劲松，二级教授/一级主任医师、医学博士、博士生导师。中山大学孙逸仙纪念医院口腔科主任，口腔颌面外科（国家临床重点专科）学科带头人。中华口腔医学会口腔颌面-头颈肿瘤专业委员会副主任委员，中国康复医学会修复重建专业委员会头颈外科学会副主任委员，广东省医学会颌面-头颈外科学分会主任委员，广东省抗癌协会头颈肿瘤分会副主任委员。近年主持国家自然科学基金面上项目8项，以第一作者或通讯作者身份在*Nat Commun*，*Int J of Surg*，*Drug Resist Up*，*Clin Cancer Res*，*Cancer Res*等杂志发表论文100多篇，获得广东省科学技术奖二等奖、广东医学科技奖二等奖。获得发明专利5项，实用新型专利4项。培养博士后、博士研究生、硕士研究生60多人。获评“岭南名医”“羊城好医生”称号。

【通信作者简介】 廖贵清，二级教授/一级主任医师，医学博士，博士生导师，中华口腔医学会口腔颌面－头颈肿瘤外科专业委员会副主任委员、口腔颌面修复专业委员会副主任委员，中国康复医学会吞咽障碍康复专业委员会副主任委员，广东省抗癌协会头颈肿瘤外科专业委员会主任委员，广东省口腔医学会口腔颌面外科专业委员会主任委员，广东省医学会美容与美学分会副主任委员。近年主持国家自然科学基金8项、省部级课题4项，以第一或通讯作者发表学术论文151篇，其中SCI收录82篇，获广东省科技进步二等奖，获国家专利2项、计算机软件著作权3项。主编《口腔癌、口咽癌全生命周期诊疗与康复》《口腔颌面外科学精选模拟习题集》等专著，培养博士后20名、博士研究生39人、硕士研究生65人。获评“岭南名医”“羊城好医生”等称号。

【通信作者简介】 李龙江，二级教授/一级主任医师、博士生导师。四川大学华西口腔医院头颈肿瘤外科学科带头人。中华口腔医学会口腔颌面-头颈肿瘤专业委员会主任委员、口腔颌面外科专业委员会副主任委员，中国抗癌协会口腔颌面肿瘤整合医学专业委员会副主任委员，四川省口腔颌面外科专业委员会主任委员，四川省医学科技创新研究会会长。四川省领军人才。担任*Int J Oral Sci*，*Hum Gene Ther*，《中华口腔医学杂志》《中国肿瘤学杂志》等10余种专业杂志编委。获国家科技进步二等奖1项、省部级科技进步二等奖5项，发表论文300余篇，其中SCI收录100余篇。

【通信作者简介】 张陈平，二级教授/一级主任医师、博士生导师、国务院特殊津贴专家，上海交通大学医学院附属第九人民医院终身教授。现任中华口腔医学会口腔颌面修复专业委员会主任委员、中国中西医结合学会口腔医学专业委员会主任委员。长期致力于口腔颌面-头颈肿瘤的临床及基础工作，累计医治颌面肿瘤病人万余例，在中晚期口腔颌面-头颈肿瘤的治疗方面有很深的造诣，显著提高了中晚期患者的生存率和生活质量。先后承担国家自然、市科委重大课题等27项，获2019年国家科技进步二等奖，国家发明专利24项；发表论文395篇，SCI收录92篇；主持制定口腔颌面-头颈肿瘤外科治疗行业指南；主编专著9部，副主编、参编专著20余部；培养70余名博士、硕士生；创办国家级继续教育学习班等，推动了中国特色的口腔颌面头颈肿瘤学科发展。

【通信作者简介】 尚政军，武汉大学口腔医（学）院院长、二级教授/一级主任医师、博士生导师，兼任中华口腔医学会副会长、国际牙科研究协会（IADR）中国分会执行主席、中华口腔医学会口腔颌面-头颈肿瘤专业委员会主任委员、中华口腔医学会口腔颌面外科专业委员会候任主任委员，担任“十四五”规划教材《口腔颌面外科学》副主编、《口腔颌面外科杂志》副主编。主要从事肿瘤微环境调控的分子基础及临床转化研究、口腔颌面部肿瘤临床诊治工作，尤其擅长口腔颌面部肿瘤诊治、颌面部软组织缺损的显微外科修复及颌骨缺损的功能性重建。2005年入选教育部“新世纪优秀人才支持计划”，2019年入选第二届湖北省医学领军人才，主持国家级、省部级课题14项；先后在*Oncogene*，*Nano Lett*等权威期刊发表SCI论文60余篇；主编专著1部，参编专著5部。