

国内外头颈部鳞癌指南循证评价(鼻咽癌除外)

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Evidence-based Evaluation of Global Guidelines for Head and Neck Squamous Cell Carcinoma (Excepting Nasopharynx Cancer)

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Abstract:Objective To review and evaluate the basic contents and development of the current global clinical guidelines for head and neck squamous cell carcinoma. **Methods** Seven databases, PubMed, Embase, NGC(U.S. National Guideline Clearing-house), CMA infobase(the Canadian Medical Association Infobase), GIN(the Guidelines International Network), SIGN(the Scottish Intercollegiate Guidelines Network) and the CMAdisc, were screened according to the predefined inclusion and exclusion criteria. The number of clinical guidelines was counted and the quality of guidelines was also assessed by AGREE(Appraisal of Guideline for REsearch and Evaluation) II. **Results** A total of 514 articles were found to be clinical guideline-related and 49 articles were finally included. The guidelines were issued by 15 countries/regions, mainly by American, Canada and UK. Mean scores of six domains were 71.63%, 43.37%, 45.63%, 68.08%, 32.41% and 42.55%, respectively. **Conclusion** The quality of otorhinolaryngology guidelines in China is not high. China can be drawn lessons from the AGREE system and combined with domestic actual condition to making high level clinical guidelines.

Key words: Head and neck cancer; Squamous carcinoma; Clinical guideline; Evidence-based evaluation

摘 要: 目的 了解国内外头颈部鳞癌指南的发布状况、评价其质量, 为我国制定头颈部鳞癌指南提供借鉴。**方法** 计算机检索PubMed、Embase、NGC(U.S. National Guideline Clearing-house), CMA Infobase(the Canadian Medical Association Infobase), GIN(the Guidelines International Network), SIGN(the Scottish Intercollegiate Guidelines Network), the CMAdisc等中英文数据库和指南网站, 按既定的纳入与排除标准, 筛选文献, 纳入符合标准的指南, 用指南评价工具AGREE(Appraisal of Guideline for REsearch and Evaluation) II 对其进行质量评价。**结果** 共检索出514篇相关文献, 最终纳入49篇头颈部鳞癌指南, 共覆盖15个国家、地区。现有指南主要由美国、加拿大、英国发布。49篇指南6个领域的得分分别为: 71.63%、43.37%、45.63%、68.08%、32.41%、42.55%。**结论** 国内外头颈部鳞癌指南的质量中等, 国内可借鉴AGREE的评价体系结合国内实际制定高水平的临床指南。

关键词: 头颈部肿瘤; 鳞癌; 指南; 评价

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0 引言

头颈部肿瘤以鳞癌为其主要的病理类型。头颈部肿瘤患者的管理主要集中于经验丰富的多学科团队及相关组织、机构。基于大量的原始研究证据, 一些机构发布了自己的临床指南。但是, 并不是所有的指南都是高质量的。本文采用临床指南研究与评价系统(Appraisal of Guideline for

REsearch and Evaluation, AGREE) 评价国内外头颈部鳞癌相关指南的质量, 为我国头颈部鳞癌临床指南的编制工作提供借鉴。

1 资料与方法

1.1 研究资料

计算机检索PubMed、Embase、U.S. National Guideline Clearing-house, the Canadian Medical Association Infobase, the Guidelines International Network, the Scottish Intercollegiate Guidelines Network, CMAdisc数据库文献资料, 截止2012年10月。

英文检索词: head and neck cancer; squamous

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cell of head and neck; guidelines。中文检索词：头颈部肿瘤；指南；规范。

1.2 纳入与排除标准

纳入公开发表的头颈部鳞癌指南，指南针对的主题、研究方法和分期限，语种仅为中文、英文。排除关于临床指南的介绍、评析、应用指导、应用效果评价、勘误表和不同语种版本及重复收录的指南。

1.3 评价与分析方法

纳入的指南采用AGREE II^[1]工具评价其质量。评价前培训评价者并分析评价结果的一致性，一致性达到可接受的最低水平后开始评价。

1.4 评价工具及方法

AGREE工具评价指南由6个领域组成：（1）范围和目的；（2）制定指南的参与人员；（3）制定的严谨性；（4）清晰性与可读性；（5）适用性；（6）编撰的独立性。

每个条目根据评价标准按7级划分等级：从1分（非常不同意）到7分（非常同意）进行评分。每个领域最终得分由每个评分人员通过以下计算方法得到：（实际得分-最低可能得分）/（最高可能得分-最低可能得分）×100%。

1.5 统计学方法

在进行评价前，随机抽取6篇文献，两名评价员独立评价^[2]。结果采用组内相关系数（Interclass Correlation Coefficient, ICC)及其95%可信区间（95%CI)描述评价标准的符合程度或一致性^[3]。一致性超过最低水平0.75后方可开始独立纳入研究质量。各领域得分采用平均值±标准误($\bar{x}\pm s$)表示。独立样本t检验用于比较两组的差异，单因素方差分析用于比较多组间的差异， $P<0.05$ 为差异有统计学意义。采用SPSS18.0软件进行统计分析。

2 结果

2.1 指南纳入的一般特征

共检索出514篇相关文献，最终纳入49篇头颈部鳞癌指南，见表1。最早发布于2001年，最近发布于2012年。指南覆盖15个国家和地区。39篇指南由专业的指南机构、组织发布，10篇以个人名义发表。29篇指南基于循证方法学制定，其余的指南制定基于专家意见、临床经验、回顾性研究等方法。指南关注的问题集中于放疗、化疗、手术、肿瘤筛查等领域。22.4%的指南有过更新。

2.2 指南质量评价

正式评价前，两名评价者采用AGREE II对随机抽取的6篇指南进行独立评价，两位评价员的评价结果的ICC为0.96(95%CI: 0.93~0.98)。评价员对评价条目的理解、判断及评价结果的一致性较高。

2.3 纳入指南的整体质量

49篇指南的整体质量中等。六个领域得分分别为：(71.63±2.80)%、(43.37±2.96)%、(45.63±3.84)%、(68.08±2.53)%、(32.41±3.03)%、(42.55±4.57)%，见表2。

2.4 临床指南质量亚组分析

根据发表年限（2001-2005,2006-2010,>2010)、指南制定机构类型（专业机构与非专业机构）、更新与否、制定的方法学（基于循证医学、未基于循证医学）对纳入的指南的各领域得分进行亚组分析，见表3。

3 讨论

本研究是首次采用专业的评价工具系统进行的国内外头颈部鳞癌指南的质量评价，纳入指南的整体质量中等。所纳入的指南各领域得分较好的为“范围和目的”及“清晰性”。大多数的指南详细描述了他们的特定目标人群和集中关注的临床问题。近几年来，“范围和目的”这一领域的得分交前有所上升。

“制定的严谨性”这一领域得分较低。可能存在以下原因：首先,大部分的指南没有报道其系统的检索、筛选证据的方法；其次，只有极少数的指南在发布之间进行了外审工作；再者，极少数的指南对证据进行了测试验证；最后，只有22.4%的指南进行了更新或拟定了更新时间。

“参与人员”这一领域的得分也较低，这与缺乏多学科指南制定小组有关。所纳入指南中，79.6%由专业的指南制定小组、机构、组织制定，然而，几乎没有指南在制定过程中考虑目标人群对卫生服务的体验和期望，也没有让目标人群参与指南制定小组。

得分最低的两个领域是“应用性”及“编撰的独立性”。这可能与较差的表达有关，指南制定人员应能提供用于实践的推荐建议和工具，例如：简介、快速参考手册、教具等。几乎所有的医学文献中都要求作者详细说明是否存在利益冲突，这已成为共识，然而，在指南制定中，对于是否存在利益冲突及赞助商等却未能引起足够的重视。

Chen等^[4]对国内115部临床指南采用AGREE II进行评价，国内指南在“范围和目的”“清晰性”两个

表1 49篇指南的基线资料

Table1 The basic information of 49 guidelines

No	Time	Country	Organization	Guidelines	Update	Topic
1	2012	America	American College of Radiology	ACR appropriateness criteria: ipsilateral radiation for squamous cell carcinoma of the tonsil ^[8]	No	Radiotherapy
2	2010	America	American dental association	Evidence-based clinical recommendations regarding screening for oral squamous cell carcinomas ^[9]	No	Screen
3	2011	Switzerland	NA*	Management of radiation dermatitis in patients receiving cetuximab and radiotherapy for locally advanced squamous cell carcinoma of the head and neck: proposals for a revised grading system and consensus management guidelines ^[10] SEOM clinical guidelines for the treatment of head and neck cancer ^[11]	1 time	Management
4	2010	Spain	Spanish Society for Medical Oncology	Squamous cell carcinoma of the head and neck: EHNES-ESMO-ESTRO Clinical Practice Guidelines for diagnosis, treatment and follow-up ^[12]	No	Multiple
5	2010	Europe	European Society for Medical Oncology	ACR Appropriateness Criteria: local-regional therapy for resectable oropharyngeal squamous cell carcinomas ^[13]	5 times	Multiple
6	2010	America	American College of Radiology	Management of squamous cell carcinoma of the head and neck: updated European treatment recommendations ^[14]	No	Treatment
7	2010	Spain	NA	Management of the neck after chemoradiotherapy for head and neck cancers in Asia: consensus statement from the Asian Oncology Summit 2009 ^[15]	No	Multiple
8	2009	Asian	Asian Oncology Summit	Joint practice guidelines for radionuclide lymphoscintigraphy for sentinel node localization in oral/oropharyngeal squamous cell carcinoma ^[16]	No	Anatomy
9	2009	Europe	European Association of Nuclear Medicine	Predicting regional control based on pretreatment nodal size in squamous cell carcinoma of the head and neck treated with chemoradiotherapy: a clinician's guide ^[17]	No	Prognosis
10	2008	Australia	NA	Re-irradiation in the management of isolated neck recurrences: current status and recommendations ^[18]	No	Radiotherapy
11	2006	India	NA	The Danish national guidelines for treatment of oral squamous cell carcinoma ^[19]	No	Multiple
12	2006	Danish	Danish Society for Head and Neck Oncology	Proposal for the delineation of the nodal CTV in the node-positive and the post-operative neck ^[20]	No	Radiotherapy
13	2006	Belgium	NA	Initial work-up in head and neck squamous cell carcinoma ^[21]	No	Multiple
14	2005	Brazil	NA	GEC-ESTRO recommendations for brachytherapy for head and neck squamous cell carcinomas ^[22]	No	Radiotherapy
15	2009	Europe	European Society for Therapeutic Radiology and Oncology	A new guide to mandibular resection for oral squamous cell carcinoma based on the Ca-wood and Howell classification of the mandible ^[23]	No	Surgery
16	2005	UK	NA	The Role of amifostine as a radioprotectant in the management of patients with squamous cell head and neck ^[24]	1 time	Drug
17	2011	Canada	Cancer Care Ontario	Hyperfractionated radiotherapy for locally advanced squamous cell carcinoma of the head and neck ^[25]	1 time	Radiotherapy
18	2003	Canada	Cancer Care Ontario	The role of endolaryngeal surgery (with or without laser) versus radiotherapy in the management of early (T1) glottic cancer ^[26]	No	Surgery
19	2012	Canada	Cancer Care Ontario	ACR Appropriateness Criteria [®] adjuvant therapy for resected squamous cell carcinoma of the head and neck ^[27]	No	Multiple
20	2011	America	Association for Research in Otolaryngology	Prophylactic feeding tubes for patients with locally advanced head-and-neck cancer undergoing combined chemotherapy and radiotherapy-systematic review and recommendations for clinical practice ^[28]	No	Nutrition
21	2011	Canada	Canadian Oncology Nutrition Clinical Practice Guideline	The role of IMRT in head & neck cancer ^[29]	No	Radiotherapy
22	2011	Canada	Cancer Care Ontario	ACR Appropriateness Criteria [®] retreatment of recurrent head and neck cancer after prior definitive radiotherapy ^[30]	No	Multiple
23	2010	America	American College of Radiology	Hypopharyngeal cancer ^[31]	No	Multiple
24	2007	Netherlands	Dutch Association of Comprehensive Cancer Centers		No	Multiple

表1 49部指南的基线资料 (续表)
Table 1 The basic information of 49 guidelines(Continued)

25	2003	Netherlands	Dutch Association of Comprehensive Cancer Centers	Carcinoma of the larynx: the Dutch national guideline for diagnostics, treatment, supportive care and rehabilitation ^[32]	No	Multiple
26	2009	Canada	Cancer Care Ontario	The management of head and neck cancer in Ontario ^[33]	No	Multiple
27	2011	Canada	Cancer Care Ontario	Epidermal growth factor receptor (EGFR) targeted therapy in stage III and IV head and neck cancer ^[34]	1 time	Drug
28	2009	America	National Health Service	Cetuximab for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck ^[35]	No	Drug
29	2012	Canada	Cancer Care Ontario	PET imaging in head and neck cancer ^[36]	1 time	Image
30	2007	America	Health Partners Dental Group	HealthPartners Dental Group and Clinics oral cancer guideline ^[37]	No	Multiple
31	2006	Scottish	Scottish Intercollegiate Guidelines Network	Diagnosis and management of head and neck cancer: A national clinical guideline ^[38]	No	Multiple
32	2006	America	American Society of Clinical Oncology	American Society of Clinical Oncology: Clinical Practice Guideline for the Use of Larynx-Preservation Strategies in the Treatment of Laryngeal Cancer ^[39]	No	Multiple
33	2004	UK	National Health Service	Improving outcomes in head and neck cancers ^[40]	No	Multiple
34	2001	UK	British Association of Head and Neck Oncologists	Practice care guidance for clinicians participating in the management of head and neck cancer patients in the UK: Drawn up by a Consensus Group of Practising Clinicians. ^[41]	No	Multiple
35	2006	America	American Society of Clinical Oncology	The use of larynx-preservation strategies in the treatment of laryngeal cancer ^[39]	No	Surgery
36	2009	India	NA	making sense of post-treatment surveillance in head and neck cancer:when and what of follow-up ^[42]	No	Follow-up
37	2004	Canada	Cancer Care Ontario	The Role of Post-operative Chemoradiotherapy for Squamous Cell Carcinoma of the Head and Neck ^[43]	No	Chemoradiot herapy Treatment
38	2004	Canada	Cancer Care Ontario	Symptomatic Treatment of Radiation-Induced Xerostomia in Head and Neck Cancer Patients ^[44]	1 time	
39	2011	Brazil	Brazilian Oral Care Working Group	Oral adverse effects of head and neck radiotherapy: literature review and suggestion of a clinical oral care guideline for irradiated patients ^[45]	No	Nurse
40	2011	UK	British Association of Otolaryngology	Head and Neck Cancer ^[46]	3 times	Multiple
41	2012	America	National Comprehensive Cancer Network	Head and Neck Cancer ^[47]	8 times	Multiple
42	2003	Canada	Cancer Care Ontario	The Role of Neoadjuvant Chemotherapy in the Treatment of Locally Advanced Squamous Cell Carcinoma of the Head and Neck (Excluding Nasopharynx) ^[48]	No	Chemotherapy
43	2003	UK	British Columbia Cancer Agency	Head and Neck Cancer management guideline ^[49]	No	Multiple
44	2011	Australia	Clinical Oncological Society of Australia	Evidence Based Guidelines for the Nutritional Management of Patients with Head and Neck Cancer ^[50]	No	Nutrition
45	2012	UK	NA	Guideline for prophylactic feeding tube insertion in patients undergoing resection of head and neck cancers ^[51]	No	Nutrition
46	2009	America	NA	Clinical practice guidance for radiotherapy planning after induction chemotherapy in loco-regionally advanced head-and-neck cancer ^[52]	No	Radiotherapy
47	2008	America	American Head and Neck Society	Consensus statement on the classification and terminology of neck dissection ^[53]	2 times	Anatomy
48	2008	UK	British Columbia Cancer Agency	Guideline for the early detection of oral cancer in British Columbia 2008 ^[54]	No	Screen
49	2001	France	French National Federation of Cancer	Epidermoid cancers of the oropharynx ^[55]	1 time	Multiple

*NA: not applicable

表2 指南得分及各领域得分分布情况

Table2 Guideline score ($\bar{x}\pm s$) and Guideline distribution (%) according to scores in each domain assessed by the AGREE II instrument

Domain	$\bar{x}\pm s$	Guideline distribution (%)		
		<30	30-60	>60
Scope & Purpose	71.63±2.80	6.1	18.4	75.5
Stakeholders	43.37±2.96	24.5	51.0	24.5
Rigor	45.63±3.84	36.7	28.6	34.7
Clarity	68.08±2.53	4.1	24.5	71.4
Applicability	32.41±3.03	53.1	30.6	16.3
Editorial independence	42.55±4.57	36.7	34.7	28.6

领域得分较高，仅分别为19%、26%，而“参与人员”、“制定的严谨性”及“应用性”“编撰的独立性”的得分分别为8%、7%、6%、2%。Zhang等^[5]对国内21部耳鼻喉指南进行评价的结果较Chen等^[4]的稍好，六个领域的得分分别为：45.4%、30.4%、20.9%、48.8%、12.6%、6.2%。然而，相较于国际指南的平均值仍相差甚远。Alonso-Coello等^[6]对1980至2010年期间全球各领域指南进行评价，六个领域得分分别为：64%、60%、35%、43%、22%、30%。Burgers等^[7]曾对100部指南进行系统评价，其中包含32部肿瘤学指南，研究显示，肿瘤学指南较非肿瘤学指南得分稍好，六个领域得分分别为：62.5%、37.2%、48.8%、60.0%、19.1%、52.8%。本研究结果与国际平均值较为接近，然而，在所纳入的指南中，未有一部是中国原创。国内对于头颈部肿瘤的诊疗基本依靠国

表3 纳入指南的各领域亚组分析结果

Table3 The subgroup analysis results of each domain of included guidelines

Subgroups	Domain ($\bar{x}\pm s$)					
	Scope/ Purpose	Stakeholders	Rigor	Clarity	Applicability	Editorial independence
Year of publish						
2011-2012 (<i>n</i> =14)	80.36±3.41	53.29±4.23	53.26±7.53	67.71±3.74	30.21±5.34	56.29±7.94
2006-2010 (<i>n</i> =24)	60.21±4.15	43.58±4.72	37.42±4.70	65.96±3.59	33.04±4.47	36.00±6.53
2001-2005(<i>n</i> =11)	70.18±6.90	48.09±6.14	55.00±9.04	73.18±6.78	33.82±6.90	39.36±9.64
<i>P</i>	0.131	0.383	0.107	0.542	0.900	0.158
Type of development group						
Professional organization (<i>n</i> =39)	73.72±3.09	52.49±2.58	52.21±4.12	71.92±2.49	33.59±3.84	48.13±5.08
Non-professional organization (<i>n</i> =10)	63.50±6.17	27.40±5.15	20.00±3.76	53.10±5.84	27.80±7.29	20.80±7.37
<i>P</i>	0.143	0.000	0.000	0.002	0.447	0.014
Development method						
Evidence-based (<i>n</i> =29)	74.69±3.19	54.34±3.44	60.90±4.18	73.93±3.80	34.38±3.79	51.07±5.85
Nonevidence-based (<i>n</i> =20)	67.20±5.00	37.25±4.44	23.50±3.25	59.60±4.07	29.55±5.04	30.20±6.50
<i>P</i>	0.191	0.003	0.000	0.004	0.439	0.023
Update						
Mentioned (<i>n</i> =11)	70.82±6.41	49.64±5.31	51.64±8.04	74.09±3.23	35.27±3.16	47.36±8.46
Not mentioned (<i>n</i> =38)	71.87±3.14	46.71±3.52	43.89±4.39	66.34±3.09	31.58±3.50	41.16±5.39
<i>P</i>	0.878	0.684	0.406	0.093	0.616	0.576

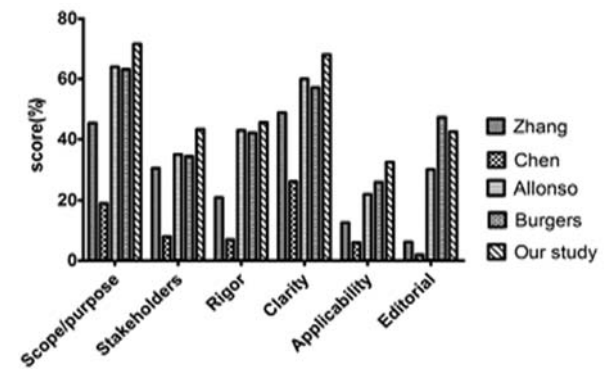


图1 本文与Chen、Alonso-Coello、Zhang、Burgers研究的指南质量的比较

Figure1 Comparison of the quality of the guidelines included in this report with those included by Chen, Alonso-Coello, Zhang and Burgers

外的相关指南及相关权威人士编写的个人指南，如：美国国立癌症综合信息网头颈部肿瘤（中国版）、头颈肿瘤治疗专家共识等。在政府指导下开展头颈部鳞癌防治是我国头颈部鳞癌防治的基本策略。目前，卫生部已颁布我国肺癌、直肠癌等相关诊治规范、指南，但未见头颈鳞癌的诊治规范。

AGREE是评价指南的极为重要的工具，但其只对指南的关键组成部分进行评价，并未涉及指南中具体的临床问题进行评价，且我国目前指南制定的水平较国际平均水平有较大差异，如完全按照AGREE的标准来制定国内头颈鳞癌指南，较为困难。但是，我们可借鉴AGREE的评价体系，促进并提高我国头颈鳞癌指南的制定水平：（1）

提高国内头颈鳞癌临床试验及系统评价的质量；
（2）指南制定可参考临床试验、Cochrane系统评价进行注册，可增加其透明度；（3）指南的制定应是各学科共同作用的结果，各学科间应加强合作；（4）由专业的指南制定组织、机构进行。

本研究也存在不足：（1）评价结果存在一定的主观偏倚；（2）一些以书本、小册子、政府文件等形式发布的指南未能进行评价，且由于语言的限制，一些非英文的指南未能纳入评价；（3）AGREE II评价指南并未涉及对指南推荐建议的评价。

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