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REVIEW ARTICLE

Standardization for oncologic head and neck surgery

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Abstract
The inherent variability in performing specific surgical procedures for head and neck cancer remains a barrier for accurately assessing treatment outcomes, particularly in clinical trials. While non-surgical modalities for cancer therapeutics have evolved to become far more uniform, there remains the challenge to standardize surgery. The purpose of this review is to identify the barriers in achieving uniformity and to highlight efforts by surgical groups to standardize selected operations and nomenclature. While further improvements in standardization will remain a challenge, we must encourage surgical groups to focus on strategies that provide such a level.

Keywords Standardization · Quality assurance · Head and neck cancer · Surgical oncology

Abbreviations

RT	Radiotherapy
CT	Chemotherapy
MDT	Multidisciplinary team
HNSCC	Head and neck squamous cell carcinoma

This article was written by members of the International Head and Neck Scientific Group (www.IHNSG.com).

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Introduction

Comparisons of treatment outcomes for oncologic surgery are challenging because of the lack of uniformity among specific procedures. In contrast, modern radiotherapy (RT) techniques are more standardized with less variation among centers [1–6]. Both RT and chemotherapy (CT) have a long history in the development of guidelines for uniformity. In contrast, the sequence of steps and extent of surgical procedures vary greatly in head neck surgery, as do the expertise and preferences of individual surgeons. This variability presents a barrier in clinical trials research and in measuring the therapeutic efficacy of selected surgical interventions.

Distinct from achieving standardization of treatment modalities, quality assurance measurements involve assessment of adherence to standardized guidelines. Such initiatives have been implemented to achieve safe and affordable health care, reduced surgical complications, improved hygiene standards, improved patient satisfaction, and lowered health care costs [7–12]. Measuring patient satisfaction, producing cost-analysis comparisons, and reducing complications are all important parts of improving quality; according to the American Society for Quality Control, quality assurance or quality control includes all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality [13]. However, in the absence of standards for surgical technique, the validity of such measures may be unreliable. The purpose of this manuscript is to analyze the challenges that compromise standardization of surgical procedures, highlight some successful projects, and to offer strategies for further progress toward improving standardization. The challenges with suggested solutions are summarized in Table 1.

Challenges for achieving standardization

Surgical training

Operative techniques are primarily learned over time, through hands-on experience with the master modeling behavior and supervising the apprentice. As an analogy, one cannot learn how to drive a car from a book. Courses provided by surgical societies such as the European Head and Neck Society and the American Head and Neck Society (EHNS and AHNS) aim to organize training sessions based on surgical approaches that are generally accepted and evidence-based. Surgeons are exposed to hands-on learning during residency and fellowship training. While techniques among experienced surgeons have common threads, it is not unusual to find variations among different institutions and countries. Moreover, in the absence of formal guidelines, surgical practices vary greatly, complicating efforts to compare outcomes or to perform quality assurance studies.

Host factors

There are various unavoidable obstacles that potentially may interfere with surgical outcomes such as abnormal body habitus, patient comorbidity, and even advanced stage of disease. Dysmorphia may present challenges with surgical exposure of target organs and structures and may interfere with postoperative wound healing. While obesity is detrimental to the general health of patients, a recent meta-analysis found that patients with higher body mass indices had increased overall survival and decreased disease-related mortality and recurrence rate [14]. Such considerations are less prominent when delivering radiotherapy or chemotherapy in a standardized fashion [14]. On the other hand, low skeletal muscle mass, often referred to as sarcopenia, is associated with an increased risk of wound complications and decreased survival [15]. The negative impact of various

Table 1 Recommended actions for achieving standardization

Issue	Suggested solution
Surgical training	Courses and training sessions conducted by surgical societies
	Broader exposure to multiple surgeons with varying philosophies and skills
	Use of simulation and technical skills laboratories
Host factors	Inclusion of patients associated factors in clinical trials
Experience	Inclusion of minimal case load and measurable surgery-related measures in clinical trials
Multidisciplinary treatment planning	Promotion of impartial, data-driven, patient-centered recommendations and discussions
Emerging technologies	Formal teaching and mentoring during learning curve period
Heterogeneous surgical procedures	Develop standardized terminology
	Develop consensus among surgeons from multiple institutions
Quality assurance	Application of surrogate markers and use of measurable outcomes

co-morbidities has been included in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP). The availability of its universal surgical risk calculator allows an online risk calculation derived from a real-world database [16].

Experience

One major factor that correlates with surgical expertise is the number of patients managed and the experience in treating rare or complex cases. This varies greatly across training programs. There is general agreement that treatment of rare cancers such as HNC should be concentrated in high volume, specialized and performed in multidisciplinary centers [17]. A recent paper showed that high volume academic centers had significantly better oncological results than smaller institutions. When compared with high-accruing centers, patients at low-accruing centers had worse overall survival (5 years: 51.0% v 69.1%; P = 0.002). Treatment at low-accruing centers was associated with an increased death risk of 91% (hazard ratio [HR], 1.91; 95% CI, 1.37–2.65) [18]. In a retrospective study, authors from medical centers in North Carolina managed to show that HNSCC patients treated at academic hospitals, community cancer centers, and hospitals that were in the top third by case volume had more favorable outcomes [19]. From a surgical point of view, the influence of surgeon and/or hospital case volume on head and neck surgery outcomes [20] is lacking. An example of validating surgical quality in the setting of a prospective multicenter randomized trial was recently published by Ferris et al. [21] In this study, a credentials committee composed of ten experienced head and neck surgeons assessed the eligibility of applicant surgeons based on specific minimal case-loads, the maximal number of positive and close margins, the rate of surgery-related bleeding, and the nodal yield from lymphadenectomy. Surgeons were re-evaluated during the study and could be placed on hold based on predetermined criteria.

Multidisciplinary treatment planning

The process of multidisciplinary treatment planning is considered to be an important aspect of cancer treatment that may influence the outcome. Furthermore, it could be argued that such treatment planning may help to compensate for variations in surgical technique as well as for quality assurance [22]. Given the complexity of treating HNSCC patients and the involvement of many disciplines, MDT improves communication among many healthcare professionals who are involved in decision-making processes by bringing together the essential expertise to deliver high-quality cancer care [23, 24]. MDT offers the opportunity for optimal oncological outcomes with less adverse effects of treatment using coordinated professional efforts. Indeed, a balance between cure and complications remains a central goal, requiring optimization of the therapeutic effect with prudent and individualized application of the various treatment modalities in appropriately selected patients [25]. However, reviews that examined the effect that multidisciplinary teams are mixed with some showing no improvement on survival while others did [26–30]. One possible explanation for this contradiction is the inherent issue of patient compliance for recommended treatment plans [31]. Another possible reason is the personality dynamics within the MDT. The team should be patient-centered and members should express recommendations that are impartial and data-driven.

Emerging technologies

The development of novel surgical techniques that employ advanced technology such a robotic manipulation present added pitfalls for standardization. Most senior surgeons did not receive formal training in the field of minimal access surgery which often involve either lasers or robots. In such situations, the technical expertise of the surgeon may have an influence on outcomes. For example, in trans-oral laser surgery, the experience of the operator has been shown to be inversely correlated with tumor recurrence [32]. Accompanying the challenges of minimal access surgery is the issue of piecemeal resections. Although cutting through tumor is less frequently considered a taboo, [33] its negative effect on clinical outcomes compared to 'en bloc' resection remains to be proven. Relevant to piecemeal resection, the advent of minimal access surgical techniques often precludes the removal of tumors as a mono bloc specimen. However, the evidence indicates that mono bloc procedures are not always essential and that tumors can be fragmented as long as radical removal of the tumor is accomplished at the end of the procedure [34, 35].

Progress toward standardization

Several efforts by surgical groups have engaged in projects intended to overcome the heterogeneity associated with surgical procedures. Some of these have focused on terminology and classifications while others have actually analyzed specific techniques to reduce variability and thereby improve accuracy for measuring outcomes in clinical trials.

One example of standardizing terminology was a project on neck dissection types enacted by the American Academy of Otolaryngology – Head and Neck Surgery [36–38]. The exact definitions of the various neck levels and sub-levels were defined in the clinical, [39] radiologic [4] and surgical settings [40]. While this was an important step toward standardization, surgeons still used their own discretion as to the extent of the surgery as well as the sequence of steps during surgery. A second example of efforts to improve terminology is the work done by the European Laryngological Society [41, 42] in developing a classification for endoscopic cordectomies and supraglottic laryngectomies. The proposal included eight different types according to the surgical approach used and the degree of resection. The intent of this proposal was to reach a better consensus among clinicians and uniformity in reports of the extent and depth of resection in cordectomy procedures. Development of a common language in the head and neck surgical community could allow relevant comparisons of results of surgery within the literature and facilitate standardization of practice [41]. A 2007 revision of this classification, which added endoscopic cordectomy type VI, [43] is currently used in many centers. In 2017, The ELS Working Committee for Nomenclature proposed a clarification of classification, emphasizing the type of laser used and the route this laser is transmitted [44]. The ELS also proposed a systematic nomenclature for endoscopic and open partial horizontal laryngectomies [44, 45].

Categorization of transoral lateral oropharyngectomies is a third example where standardized nomenclature has been recommended [46]. The increase in incidence of human papilloma virus (HPV) related oropharyngeal squamous cell carcinoma was followed by a rise in surgical transoral excision of the lateral oropharynx. Similar to Remacle et al. [43] the authors managed to construct a comprehensive yet simple classification system of the depth of lateral pharyngeal resection and the direction of resection for disease extension.

With regard to standardizing operative techniques, the Japan Neck Dissection Study Group launched a collaborative national effort to reach a consensus on a uniform neck dissection procedure [47]. This was prompt by the lack of consensus by the authors in comparing the specific aspects of the various non-radical neck dissections. To unify the understanding of the procedure, a formal protocol was initiated. During the initial observation phase, the group found the technique for neck dissection to be highly variable among the participating institutions. In essence, surgeons used the same terminology to describe slightly different procedures. The group managed to compare and standardize the procedure mainly by requiring surgeons to observe their colleagues perform the technique in different institutions. A construct of 79 items was developed, thus allowing the procedures to be analysed based on general and detailed anatomic data. Through this approach, surgeons could observe subtle differences compared to their own practice and adjust their own techniques accordingly. After a second observation stage, improvements in standardization were documented.

Similarly, the effort to standardize sentinel node biopsy for patients with clinically node-negative oral cavity squamous cell carcinoma represents another example of unifying surgical guidelines based on available evidence and expert opinion. A consensus statement on this issue was developed during the eighth international symposium for sentinel node biopsy in head and neck cancer held in London in 2018 [48]. In this international project, a wide variety of topics ranging from patient selection, surgical technique, to management was debated and agreed upon. Potential areas of development were highlighted for future prospective studies.

Strategies to expand standardization

While there remain a number of obstacles to achieving standardization in oncologic surgery, further improvements are possible. The continued application of indirect measures and surrogate markers, as demonstrated by Ferris et al. [21] represents one approach to assess uniformity and the quality of surgery. Also, there remain opportunities to improve the terminology for selected operations such as glossectomy, maxillectomy and mandibulectomy along with its array of variations [49–51]. For example, currently there are many suggested nomenclatures for mandibulectomy, but none is recognized as the standard [51–57]. Such variations make it difficult to compare reports of different outcomes, particularly with regard to surgical complications that affect not only the quality of life, but essential functions in the head and neck region [58]. Similar to the consensus reached for classifying neck dissection, agreements could be reached for other operative procedures that have numerous variations.

In terms of standardizing the specific components of a surgical procedure, projects like the Japan Neck Dissection Study Group [47] and the European Laryngologic Society represent significant contributions. Such examples lead one

Table 2 Potential surrogate markers and measurable outcomes for quality analysis in head and neck surgery

Quality surrogate markers and measurable outcomes
I *Pre-operative*
Multidisciplinary team meetings
High-volume surgeons
High-volume hospitals
II *Intra-operative*
Negative surgical margins
Nerve monitoring
Nodal yield
III *Immediate post-operative*
Early complications
Functional impairment
Mortality
Days of admission
IV *Late post-operative*
Late complications
Locoregional failure rate
Survival outcomes
Quality of life measurements

to surmise that such coordinated exercises can be extended to other operations. The question becomes what other procedures should be addressed and by whom. Definitely, whenever a specific surgical intervention becomes an influential component of treatment outcomes in a prospective clinical trial, there is an important need to standardize it. Under such circumstances, this can be achieved through the cooperation of the participating surgeons to reach agreements on technique, use of surrogate markers for quality assurance, and acceptable levels for complications and adverse surgical outcomes (Table 2).

Beyond the existing strategies applied to enhance uniformity, recent technologies and approaches offer novel opportunities for future progress. For example, simulation laboratories have become an integral component for teaching surgical techniques [59]. While the emphasis to date has been on training surgical residents, simulation technology could be redirected to improve standardization for selected procedures [60]. Also, simulation provides uniform and objective metrics for use in the assessment of technical skills [61]. One could imagine this approach becoming an important step in developing and activating a treatment protocol in which a surgical intervention is being measured within a multi-institutional setting. An additional strategy that has now moved beyond the realm of novelty is the application of virtual conferencing. In addition to increasing the opportunities to communicate both verbally and visually among participating surgeons, the virtual sharing of sound and imagery to outline selected operative techniques has become a reality. Such advances provide a sense of optimism for advancing a level of standardization within the field.

Author contributions OR: conceived the idea of the paper, OR and KTR: performed literature research, and drafted the manuscript; all authors: provided scientific revision of the manuscript.

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