European Archives of Oto-Rhino-Laryngology
https://doi.org/10.1007/s00405-018-5046-9

HEAD & NECK

Quality assurance in head and neck surgery: special considerations to catch up

Guy Andry[1,3] · Marc Hamoir[2,3] · C. René Leemans[1,2,3]

Received: 29 March 2018 / Accepted: 20 June 2018

Abstract

Purpose Quality assurance is much more difficult to achieve in surgical oncology than in medical oncology and radiotherapy where doses are standardized and toxicities are well-classified. To better define what is required in surgery, we analyzed recent articles addressing the point in head and neck surgery.

Results The surgical report should match with the pathological description of the resected specimen with accurate delineation of the margins, number and level(s) of lymph nodes (capsular rupture if any). Complications (minor and major) should be standardized and meticulously recorded; as well as comorbidities and patient status. The acuity of the procedure should be defined by metrics collected in check-lists. Age > 60 years, male gender, tumor site and T_4 stage, neck dissection(s), flap reconstruction, alcohol and tobacco consumption, are acknowledged risk factors for more complications and longer hospital stay (or readmission).

Needs Randomized controlled trials should be designed adopting the consolidated standards of reporting trials (CONSORT). Training young head and neck surgeons should encompass formation in designing, conducting and interpreting clinical trials.

Keywords Quality assurance · Head and neck surgery · Risk factors

Introduction

In surgical oncology, quality assurance is more difficult to achieve than in the other two oncological treatment modalities, medical oncology and radiotherapy, where treatments can be compared in terms of chemotherapy or radiation doses based on often digital data. In medical oncology, systematic check-lists are used insuring a standardized report on timing and doses of chemotherapy as well as toxicities induced with a grading system. The radiotherapy group of EORTC has likewise defined measures insuring report of the doses delivered to each patient and verifies that the protocol requirements are met (or not) [1].

✉ Guy Andry
Guy.andry@bordet.be

Marc Hamoir
Marc.Hamoir@uclouvain.be

C. René Leemans
Cr.leemans@vumc.nl

1 Surgery Department, Centre des Tumeurs ULB, Institut Jules Bordet, Brussels, Belgium

2 Department of Head and Neck Surgery, Institut Roi Albert II, UCL, Cliniques Universitaires Saint-Luc, Brussels, Belgium

3 Department of Otolaryngology-Head and Neck Surgery, VU University Medical Center/Cancer Center Amsterdam, 1007 MB Amsterdam, The Netherlands

QA in surgery includes pathology

In oncologic surgery, one needs to define in each surgical report the type of procedure performed with a detailed description of the resection and the reconstruction when the latter was needed. Close co-operation with surgical pathologists is essential to ensure an accurate delineation of the margins of resection and a correct orientation of the surgical specimen with respect to the anatomy of the region where the tumor is resected. A same collaboration is needed for the neck lymph nodes resected, according to the level system as proposed by Robbins [2]. In fact, in this respect, measuring surgical quality includes measuring the quality of the pathology.

Published online: 29 June 2018

Complications

Recording complications after a procedure uniformly may equally be regarded difficult, as it should take into account postdischarge events, as emphasized by Schwam and co-authors in their recent overview of 408 patients operated for oral cavity cancer [3]. They observed an overall complication and mortality rates of 20.3 and 1%, respectively. Reoperation was needed in 9.6%, flap failure occurred in 2.2%. Infections ranked third with 6.6% just before respiratory complications (5.1%). After a median length of stay of 3 days (mean: 4.8 days) postdischarge complications occurred in 4.9%, among which a significant proportion of surgical site complications (42.1%), severe sepsis (20%), flap failure (22.2%), deep venous thrombosis (33.3%) and death (25%). Neck dissection emerged as an independent risk factor for several complications. A 33% rate of adverse events was observed when neck dissection was performed; this high rate may be explained by larger incisions, prolonged operative time and more advanced disease.

A recent significant weight loss (usually correlated with a low albumin level), a recent history of stroke or transient ischemic attack were also associated with higher postoperative morbidity, as was current smoking, which factor is well-known in this kind of disease, not only as a causal factor of the cancer, but also as an indicator of respiratory and cardiovascular poor conditions.

The authors also revealed that 14 days after discharge was the cut-off delay for complications to occur, emphasizing that early clinical follow-up was mandatory for reducing unintended postdischarge events and readmissions (see Table 1).

Improving surgical quality

In a review of the quality of randomized controlled trials in head and neck surgical oncology, Carlton and co-authors scrutinized the difference of reporting items of the check-list between surgeons and non-surgeons. Out of 38 publications, they pointed out that there was a trend towards lower quality for studies in which surgeons were either first, last or both first and last authors compared to studies where the first and/or the last author was a non-surgeon [4]. They also suggested that training of head and neck surgeons should encompass formation in designing, conducting and interpreting clinical trials with dedicated statisticians for their education. Also needed is to adopt the CONSORT guidelines (CONsolidated Standards Of Reporting Trials) as a standard for publication [5].

Table 1 Complications after surgery for head and neck cancer

Author	n PTS	P.op days	% Complications	% Death	Risk factors
Schwam [3]	408 O.C	30	20.3	1	
			Reoperation: 9.6		Current smoke
			Infections: 6.6		Recent weight loss
			Respiratory: 5.1		Neck dissection (33% complic.)
			Postdischarge: 4.9		Current smoke
Santoro [7]	(1) 320 (2003–2006)	30	43.4	NA	$T_4 > T_{1-3}$
			Syst: 15		Neck dissection
	(2) 307 (2007–2010) O.C.; OP		Loc: 17.5		OP worse than OC (58.6% v.s. 40.1%)
			Loc + Syst: 10.9		Male, alcohol
Awad [8]	355 O.C	45	62[a]	0.8	Readmission rate 5%
			Minor: 90 Loc 56, Syst 44		Neck dissection (n = 247): 34% complic. (2% major)
			Major: 10 Loc 33, Syst:67		Reconstruction: 30% complic. (3% major)
Patel [10]	796[b] 1999–2007 O.C., OP, CUT, SAL, A.S	30 (for discharge)	30 major	1.4	
			Medical: 22.2		Age > 60 years
			Surgical: 22.2		BMI, ASA, KFI scores, pre-op Hb level
			Tot. flap fail: 4.6		Tracheostomy
			Partial: 2.1		

Complic. complications, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *KFI* Kaplan–Feinstein Index, *OC* oral cavity cancer, *OP* oropharynx cancer, *CUT* cutaneous, salivary, *A.S.* all sites, *Hb* hemoglobin

[a]Use of Clavien–Dindo classification of surgical complications

[b]All with free flap reconstruction

In an attempt to improve the quality of surgery, the team of the department of head and neck surgery at M.D. Anderson Cancer Center has established an audit and feedback system [6]. The authors have defined metrics that were significantly associated with the acuity of the procedure, patient's comorbidities and the operative surgeon. The collected metrics included the length of stay, the perioperative blood product utilization (24 h), the need to return to the operating room within 7 days from the initial operation, the occurrence of infection in the operative site, the event of hospital readmission and the 30-day rate of mortality. Low acuity procedures (LAPs) included outpatient or those normally requiring less than 2 days of observation whereas high acuity procedure (HAPs) were tumor resections requiring pedicled- or free-flap reconstruction (with a mean hospital stay of 11 days).

When the initial and post-feedback cohorts were compared, they observed a significant reduction in the length of stay both for LAPs and HAPs. For HAPs, there was a significant reduction of 30-day surgical site infections and of 30-day readmission rate.

Looking at surgeon-specific improvement, they found that 6/10 surgeons improved for LAPs and half of surgeons improved for HAPs. The authors acknowledge the fact that their observations could have been biased by a growing national awareness about the importance of the performance indicators and by changes in institutional processes as time goes on.

Comparing the results of the surgical performance evaluated for two consecutive cohorts of patients, 2618 patients operated from 2004 to 2008 and 1389 patients operated from 2009 to 2010, respectively, before and after providing feedback to each surgeon, the authors, in a detailed and adjusted statistical method, demonstrated that the individual surgeon, patient comorbidities and procedure acuity significantly affected the prevalence of negative performance indicators in both cohorts.(see Table 2).

Recently, Santoro et al. (European Institute of Oncology, Milan) proposed a sophisticated statistical analysis leading to establish a user-friendly nomogram to predict the risk of postoperative complications in patients with oral cavity or oropharyngeal cancer with the goal of adapting the treatment to the individualized patient [7].

In a first cohort of 320 patients with oropharyngeal and oral cavity squamous cell carcinomas operated between 2003 and 2006, they developed an algorithm predicting postoperative complications, based on a multivariate analysis of preoperative characteristics retrospectively assessed. Subsequently, they tested this algorithm on a second cohort of 307 patients operated on for similar tumors from 2007 to 2010 and produced a nomogram accurately predicting the presurgical risk of postoperative local and systemic complications.

The following factors emerged as indicators of worse outcome: T_4, male patient, alcohol consumption, oropharynx site (58% complications vs 40% for oral cavity) and neck dissection. It is needless to say that the probability of complications predicted by the model was correlated to the length of the hospital stay. The patients were grouped in quintiles according to the predicted complication rate probability. Those gathered in the lowest risk quintile (i.e., $\leq$ 20% of postoperative complications) had a median stay of 4 days whereas those belonging to the highest risk quintiles ($>$ 80% of postoperative complications) had a median stay of 14 days.

Interestingly, the authors suggested that alcohol consumption was a pre-eminent risk factor as compared to age and global comorbidity. This also may explain why male gender, for a given cT, had a greater probability of complications than women, the latter consuming less alcohol (see Table 1).

The only concern about these data is that the reported rate of current alcohol consumers was only 17.2% whether rates of 4.7% of former consumers and 77.5% of never consumers were reported, respectively, which are far from what we would have expected in this kind of population.

The importance of collecting accurately data in a registry of postoperative complications after surgery of oral cavity cancer was stressed by the team of the Head and Neck Service at Memorial Sloan-Kettering Cancer Center, New

Table 2 Improvements of quality in surgical procedures

Author	n PTS	P.op days	Objectives by feedback from (1) to (2) successive cohorts
Lewis [2]	(1) 2168 (2004–2008) (2) 1389 (2009–2010)	30	To reduce Hospital stay: LAPS 2.1–1.5 ($p=0.005$) (days): HAPS 10.5–7.0 ($p=0.03$) Infection site: HAPS 14.1–8.4% ($p=0.046$) Readmission rate: HAPS 14.2–7.4% ($p=0.015$) To improve surgeon-specific performance LAPS: 6/10 surgeons HAPS: 5/10 surgeons To reduce one or more negative performance indicators LAPS: 39–28.6% (p < 0.001) HAPS: 60.9–53.5% (p = 0.081)

LAPS low acuity procedures, *HAPS* high acuity procedures

York USA, based on a retrospective study of 355 previously untreated patients [8].

They used the Clavien–Dindo classification subdividing the severity of complications in five grades. Complications graded I and II were considered as minor while complications graded III–V were defined as major (see Table 1). In an attempt to standardize surgical complications Dindo et al. proposed a straightforward classification of surgical complications in 2004 that has unfortunately not yet found widespread adoption [9].

The team of Milan observed a 62% overall complication rate with 90% of those identified as minor while the remaining 10% were considered as major complications [7].

Among the minor complications, 56% were local whereas major complications were systemic in 67% (36 patients experiencing 55 major complications), with an average rate of 2.5 complication per patient. Readmission rate was 5% and the overall mortality rate was 0.8%. Neck dissections were associated with complications in 34% of the patients (247 patients), but the rate of major complication was 2% and all of which were grade IIIb.

Reconstruction was performed in 141 patients (39.7%). Among them, 30% experienced complications of which 3% were major with 6% of flap failure.

Of interest, the authors compared their results with the yield of the International Classification of Disease-9th revision (ICD-9)codes. Only 36% of the complications recorded from the chart review (cf supra) were identified by ICD-9 diagnosis code (claims data). Thereafter, comparing to the National Surgical Quality Improvement Program (NSQIP) data available for 27 patients of the 355 in the study cohort (8%), the NSQIP identified 27% (3/11) of patients with complications and 33% (5/15) of complications (NSQIP Data).

The authors concluded that while ICD-9 codes and NSQIP accurately recorded major complications (98% and 100%, respectively), but failed to report many minor complications. They stressed the importance of managing minor complications as well because a significant number of those patients could go on to develop major complications if not managed properly.

Patel and colleagues from the Princess Margaret Hospital, Toronto, Canada prospectively evaluated 796 operated patients where reconstruction was achieved with microvascular-free flap after resection of various head and neck cancers from 1999 to 2007 [10]. They used univariate and multivariate analyses to determine predictors of morbidity and prolonged hospital stay. The authors re-emphasized the confounding effect of comorbidities that affect patients: mainly age, smoking and alcohol habits and malnutrition. Perioperative complications were included from the start of the operation until discharge from the hospital and if patients required readmission within 30 days of surgery. Surgical complications were defined as an adverse event at the surgical site and medical complications were systemic events or those distant from the surgical site. Length of hospital stay was the number of days in the hospital, after the day of surgery, they dichotomized into two categories: < 21 versus ≥ 21 days. They retrieved all the patient and treatment variable of interest in addition to the indices: ASA-score (American Society of Anesthesiologists Classification of Physical Status System) and ACE-27 (modified Kaplan-Feinstein Index) to quantify and assess the effect of comorbidities.

The authors reported a rate of 30% of major complications of which 15% were multiple (115/796), Overall, they reported 354 complications subdivided in 50% of medical complications and 50% of surgical complications. The mortality rate was 1.4%.

After multivariate regression model analysis, age: > 60 years, Body Mass Index (BMI), ASA score $3+4$, KFI score $2+3$ and tracheostomy were found to independently predict those major complications, without interaction between any of the variables entered into the model.

Major surgical complications were predicted by ASA score $3+4$ and preoperative hemoglobin level. Length of hospital stay was prolonged by recent weight loss, alcohol excess, mucosal surgery (oral cavity, oropharynx and larynx) duration of anesthesia and volume of crystalloid replacement (see summary in Table 1).

In a retrospective analysis of a cohort of 48,028 adult patients who underwent inpatient otolaryngologic surgery, (data collected from the American College of Surgery-NSQIP 2005–2011). Chen et al. focused on the post-discharged complications (PDCs) and their risk factors [11]. Laryngectomy, lip and buccal mucosa surgery had the highest PDCs rates: 8, 7.4 and 4.1%, respectively. Seventy-three percent of those PDCs occurred within the 2 first weeks. Surgical site infections (53.6%) and other infection (37.4%) were more common events, followed by venous thromboembolism (7.4%). Independent risk factors emerging from multivariate analysis were: increasing age (52 vs 67 years: $p<0001$), prolonged operative time, hospital stay >1 day and ASAs score ≥ 3. Overall, the 30-day mortality rate was 0.1%.

Those discrepancies in reported rates of complications reveal how difficult the task is in assessing the quality of the surgery even in rigorously conducted protocols or in well-documented registration data. In a recently published paper on quality assurance in a RCT on larynx preservation, the subcommittee of surgery of the EORTC Head and Neck Cooperative Group has demonstrated that the main difference between participating centers was the time interval between the first consultation and treatment initiation (mean of 45 days: range 12–124 days) [12]. Another matter of concern was the lack of precision of pathology reports about the level of neck lymph node involvement (only 36% were described) and the presence (or not) of extracapsular spread.

Conclusion

Quality assurance is much more difficult to achieve in surgical oncology than in medical oncology and radiotherapy where doses are standardized and toxicities are well-classified.

To better define what is required in surgery, we analyzed recent articles addressing the point in head and neck surgery.

The surgical report should match with the pathological description of the resected specimen with accurate delineation of the margins, number and level(s) of lymph nodes (capsular rupture if any).

Complications (minor and major) should be standardized and meticulously recorded, as well as comorbidities and patient status.

The acuity of the procedure should be defined by metrics collected in check-lists. Age > 60 years, ASA 3–4 score, male gender, tumor site and T4 stage, neck dissection(s), flap reconstruction, alcohol and tobacco consumption, are acknowledged risk factors for more complications and longer hospital stay (or readmission).

The wide variation of reported complications after head and neck surgery (20–67%) witnesses the lack of uniformity in collecting the data.

Randomized controlled trials should be designed adopting the consolidated standards of reporting trials (CONSORT). Training young head and neck surgeons should encompass formation in designing, conducting and interpreting clinical trials.

To enhance performance in surgery we have to improve education and training, therefore, organizing fellowships in cancer centers where several senior surgeons with credentials organize the program of formation. The performance of these centers will increase with case volume and they will foster co-operation with other disciplines, not only radiation oncologists and medical oncologists, but also pathologists specializing in imaging and in basic research to ensure translational research.

Compliance with ethical standards

Conflict of interest Quality Assurance in Head and Neck Surgery: special considerations to catch up. Guy Andry, Marc Hamoir, C. René Leemans. On behalf of all authors, I confirm that this manuscript did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. All authors declare that they have no financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work.

Human and animal rights There is no research involving human participants and/or animals.

Informed consent No informed consent was needed in this review which did not involve patients in a new study.

References

1. Weber DC, Poortmans PM, Hurkmans CW, Aird E, Gulyban A, Fairchild A (2011) Quality assurance for prospective EORTC radiation oncology trials: the challenges of advanced technology in a multicenter international setting. Radiother Oncol 100:150–156
2. Robbins KT, Medina JE, Wolfe GT, Levine PA, Sessions RB (1991) Pruet CW Standardizing neck dissection terminology. Official report of the Academy's Committee for Head and Neck Surgery and Oncology. Arch Otolaryngol Head Neck Surg 117(6):601–605
3. Schwam ZG, Sosa JA, Roman S, Judson BL (2015) Complications and mortality following surgery for oral cavity cancer: analysis of 408 cases. Laryngoscope 125(8):1869–1873
4. Carlton DA, Kocherginsky M, Langerman AJ (2015) A systematic review of the quality of randomized controlled trials in head and neck oncology surgery. Laryngoscope 125(1):146–152
5. Schulz KF, Altman DG, Moher D, Group CONSORT (2011) CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Int J Surg 9(8):672–677
6. Lewis CM, Monroe MM, Roberts DB, Hessel AC, Lai SY, Weber RS (2015) An audit in feedback system for effective quality improvement in head and neck surgery: can we become better surgeons? Cancer 121(10):1581–157
7. Santoro L, Tagliabue M, Massaro MA, Ansarin M, Calabrese L, Giugliano G, Alterio D, Cossu Rocca M, Grosso E, Plànicka M, Benazzo M, Chiesa F (2015) Algorithm to predict postoperative complications in oropharyngeal and oral cavity carcinoma. Head Neck 37(4):548–556
8. Awad MI, Shuman AG, Montero PH, Palmer FL, Shah JP, Patel SG (2015) Accuracy of administrative and clinical registry data in reporting postoperative complications after surgery for oral cavity squamous cell carcinoma. Head and Neck 37:851–861
9. Dindo D, Demartines N, Clavien PA (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 240:205–213
10. Patel RS, McCluskey SA, Goldstein DP, Minkovich L, Irish JC, Brown DH, Gullane PJ, Lipa JE, Gilbert RW (2010) Clinicopathologic and therapeutic risk factors for perioperative complications and prolonged hospital stay in free flap reconstruction of the head and neck. Head Neck 32(10):1345–1353
11. Chen MM, Roman SA, Sosa JA, Judson BL (2013) Postdischarge complications predict reoperation and mortality after otolaryngologic surgery. Otolaryngol Head Neck Surg 149(6):865–872
12. Leemans CR, Tijink BM, Langendijk JA, Andry G, Hamoir M, Lefebvre JL, Subcommittee of Surgery of the EORTC Head and Neck Cooperative Group (2013) Quality assurance in head and neck surgical oncology: EORTC 24954 trial on larynx preservation. Eur J Surg Oncol 39(9):1013–1018