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### Quality indicators in head and neck oncology

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# CHAPTER 2

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## Volume criteria for the treatment of head and neck cancer: Are they evidence based?

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Rising health care costs and increasing incidence of cancer prioritize the improvement of the effectiveness of cancer care<sup>1</sup>. This induces a progressing interest in quality indicators measuring the quality and effectiveness of health care in a standardized way. These indicators comprise 3 categories focused on structural, process, and outcome aspects<sup>2</sup>. They are developed to measure health care performance and compare health care providers, for example, on postoperative complication rates, reinterventions, blood transfusions, length of hospital stay, and mortality. In colorectal cancer, measuring the hospitals' performance on these indicators have played decisive roles at several levels of health care management and economics<sup>3</sup>.

#### PROCEDURAL VOLUME

One of the quality indicators frequently mentioned in literature is procedural volume, hospital, or surgeon based<sup>4</sup>. The rationale lying behind this indicator is the notion that the experience of a surgeon with a certain, often complex surgical procedure is related to the outcome<sup>5</sup>. However, experienced surgeons do not treat patients on their own, a multi-disciplinary team of medical specialists and nurses is involved in the care for individual patients. Therefore, hospital volume can act as a surrogate for surgeon volume, although it also adds additional information on the quality of care provided.

Generally, high-volume hospitals have more specialized (diagnostic) facilities, well-organized multidisciplinary meetings, and shorter diagnosis–treatment interval. Thereby, high-volume centers tend to adhere more to national guidelines; the volume effect may also partly represent the institutional organization.

#### PROCEDURAL VOLUME AND OUTCOME FOR OTHER CANCER PROCEDURES

Over the past decade, a strong relation between hospital volume and survival has been reported, suggesting that procedural volume is an important determinant of outcome in surgery and patient care<sup>4–13</sup>. Birkmeyer et al<sup>7</sup> studied the impact of volume of surgical cancer treatment in general and reported a statistically significant inverse relation (adjusted mortality decreased in high-volume centers ranging from 20.3% to 8.4% after esophagectomy and from 2.6% to 2.1% after nephrectomy). This publication was followed by many confirmatory reports, next to esophagectomy, also focusing on other specific high-risk low-volume procedures, like radical prostatectomy and pancreatectomy<sup>8–10</sup>. Wouters et al<sup>8</sup> performed a systematic review of 43 studies (>70,000 patients), studying the relation between volume and outcome in esophagectomies.

They concluded that outcome of esophageal cancer surgery is significantly better when performed at a high-volume hospital. Next to esophagectomies, this correlation has also been established in a systematic review for pancreatectomy by van Heek et al<sup>9</sup>. They included 12 studies with >19,000 patients and found that pancreatic resections performed at high-volume hospitals had lower mortality rates than low-volume hospitals (0% to 3.5% vs 13.8% to 16.5%;  $p < .001$ ). In a recently published systematic review covering >30 (n532) systematic reviews for different surgical procedures (oncology and non-oncology), it was concluded that, especially for cancer procedures, there is a tendency to support a hospital-volume-outcome relationship<sup>14</sup>. Although they were able to summarize evidence, they did not attempt to calculate the minimum volumes (cutoff values) required to provide high-quality cancer care.

#### HEAD AND NECK CANCER

For head and neck cancer, surgery is still the mainstay of primary treatment and its role as salvage treatment after (chemo-)radiation is increasing. As stated before, in general, head and neck surgical procedures are of a high-risk nature and are often performed in a low-volume setting. The risk of functional sequelae is high by the impact of surgery on swallowing, speech, self-image, and shoulder function with a major influence on the patient's quality of life. The essence of high-risk surgical care in this patient group is always balancing between complete resection and preservation of function<sup>15</sup>. In contrast to the plethora of studies on the volume aspects of other high-risk cancer surgeries, a literature search of volume aspects in head and neck surgery did reveal only 8 suitable articles published in the English language<sup>16-23</sup>. An overview of these studies is available in Table 1. These studies did not exceed a total number of 19,000 patients. It remains disappointing that head and neck cancer, which can be characterized as a relatively rare disease with a typical low-volume high-risk profile, contrasts so significantly with the analysis of volume aspects of other surgical procedures. The main reason could be that in contrast to esophagectomies, for example, the studies performed in head and neck cancer evaluate a group of various disease entities, whereas other volume-outcome studies assess single procedures. Therefore, more focused studies on the volume-outcome relationship for specific head and neck procedures, such as neck dissection, laryngectomy, parotidectomy, and transoral resection, are required.

TABLE 1. Studies about the relation between volume and outcome of head and neck cancer surgery

Study	Country	Tumor site	Patients	Hospitals	Surgeons	Case mix adjustment
Gourin 2011 <sup>17</sup>	US	Larynx	1,981	37	284	C, D, U
Cheung 2009 <sup>18</sup>	US	Oral cavity, larynx, pharynx/salivary glands	4,160	333	N.R.	C, D, S, T
Gourin 2011 <sup>19</sup>	US	Oropharynx	1,534	36	233	C, D, U
Morton 2009 <sup>20</sup>	NZ	Neck	289	1	10	N.R.
Lin 2008 <sup>21</sup>	Taiwan	Oral cavity	6,666	89	427	C, D, V
Lee 2010 <sup>22</sup>	Taiwan	Oral cavity	1,256	N.R.	215	C, D, V
Chen 2009 <sup>23</sup>	US	Larynx	11,000	1,427	N.R.	C, D, E, V, S

  

	Hospital volume			Surgeon volume				
	Volume categories	Morbidity	Mortality	Survival	Volume categories	Morbidity	Mortality	Survival
Gourin 2011 <sup>17</sup>	18	NS	NS	-	7	NS	NS	-
Cheung 2009 <sup>18</sup>	Tertiles	-	-	Sig	-	-	-	-
Gourin 2011 <sup>19</sup>	30	NS	NS	-	6	NS	NS	-
Morton 2009 <sup>20</sup>	-	-	-	-	1, 2, 3, 4, 7, 35, 98, 182	-	-	-
Lin 2008 <sup>21</sup>	1-342; 343-531; >531	-	-	NS	1-51; 52-141; >141	-	-	Sig
Lee 2010 <sup>22</sup>	Categorical	-	-	NS	<8; -21; >22	-	-	Sig
Chen 2009 <sup>23</sup>	Median	-	-	Sig	-	-	-	-

Abbreviations: US, United States; C, adjusted for comorbidities; D, adjusted for demographic data (eg, patient age, sex, race, income); U, adjusted for urgency of the operation; N.R., not reported; S, adjusted for tumor characteristics (eg, stage, grade, location); T, adjusted for treatment differences; NZ, New Zealand; V, adjusted for other hospital characteristics (eg, teaching or academic status); E, socio-economic area; NS, statistically not significant; Sig, statistically significant.

## CAUSES FOR LATE CENTRALIZATION: METHODOLOGICAL PROBLEMS IN VOLUME–OUTCOME STUDIES

Causes why head and neck surgeons respond late to the trend of evidence-based centralization are philosophical. In most countries, large databases with detailed clinical information, including outcomes of head and neck cancer procedures, are lacking. Most volume–outcome studies evaluate mortality as their main outcome measure, whereas the a priori mortality rate after major head and neck surgery is relatively low. Furthermore, treatment-related effects are multidimensional, complex to investigate, and often lacking administrative and clinical databases. Another methodological problem of “procedural volume studies” is weighing differences in case mix factors between volume-groups. Most positive head and neck volume-outcome relations were found in studies with poor or even without case mix adjustments. Head and neck cancer cohorts are, by definition, heterogeneous, because they consist of many different diseases, with different etiologies, disease stages, and different intrinsic prognoses. For example, half of the studies we found were not corrected for disease stage or treatment (concurrent chemoradiation, primary radiotherapy, or adjuvant radiotherapy after surgery, etc.)<sup>18,20,22,23</sup>. The difficulty in case-mix adjustment is that you do not know whether all possible influencing variables are investigated. Only large detailed clinical databases provide enough variables; although the more variables you include, the more patients are needed to obtain statistically significant results. Another methodological pitfall is the definition of “high” and “low” volume head and neck cancer centers. This remains vague, without any clear evidence-based volume cutoff values. In our systematic literature search, the cutoff points for “high volume” range widely from 22 to 182 procedures annually. Because of differences in subsites and treatment modalities, a firm conclusion on cutoff points based upon the current available literature can therefore not be made. These results are in contrast with volume cutoffs for esophageal cancer, aiming at a minimum of 20 resections annually for high-volume hospitals<sup>8</sup>. Nonetheless, in esophageal cancer, there is also no international consensus reached on the definition of a high-volume hospital.

For head and neck cancer, there is not (yet) an evidence-based volume standard, but the Dutch Head and Neck Society recommends a minimum of 200 new patients with head and neck cancer per year. Another difficulty is the wide variety in biological behavior of all different types of head and neck tumors. For instance, the biological nature of nasopharyngeal carcinomas is completely different from that of hypopharyngeal carcinomas.

Also, surgeries differ significantly from each other; petrosectomy differs in risk and complexity from a transoral excision. It is conceivable that the true effect of hospital volume in head and neck cancer is overshadowed by the above-mentioned case mix differences. Therefore, to represent the true effect of procedural volume in a study, thorough case mix adjustments based on detailed clinical data are crucial<sup>24</sup>. Most volume studies are cross-sectional studies, without exploring changes in volume and performances over time. All of our selected studies belong to this category. Last, volume should be modeled as a continuous variable; by using logistic regression analysis to examine how a set of variables predicts outcome measurements<sup>25</sup>. None of the referenced studies met this criterion

## CONCLUSION

This all makes it problematic to generalize and meta-analyze data regarding volume versus outcome and compare it with well organized studies, like in esophageal surgery<sup>8</sup> and pancreatic surgery<sup>9</sup>. Despite these limitations, volume-criteria studies investigating the relation between volume and outcome are of great importance, because they can move the head and neck field forward. The proposed benefit of high-volume care advocates the foundation of a limited number of comprehensive head and neck cancer centers. Following the example of major head and neck cancers in the world, with annual new patient visits surpassing 4000,<sup>26-29</sup> it should be possible to unravel the process contributing to better head and neck cancer care. With larger patient cohorts and standardized treatment protocols, it might be possible to compare the effect of volume on treatment results. Our comparative survey on volume effects in pancreatic, esophagus, and head and neck surgery makes it definitely clear that more research needs to be done to define the volume–outcome relationship in head and neck cancer. In our opinion, the best study setup would be to start a study comparing international “real” high-volume centers and low-volume centers with thorough case-mix adjustments (stage, treatment, histology, etc.) in specific head and neck procedures (laryngectomy, parotidectomy, and neck dissection). After that, it might be possible to draw evidence-based conclusions and define clear cutoff points for hospital volume in head and neck procedures, as has been done for other types of surgery.

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