



SESSION 2 - Advances in technology and innovation treatment in Head and Neck

1. REACTIVE VERSUS PROPHYLACTIC FEEDING DURING ADJUVANT RADIOTHERAPY: RESULTS FROM A PROSPECTIVE STUDY

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2. SENTINEL LYMPH NODE BIOPSY FOR EARLY STAGE ORAL CANCER; EXPERIENCE OF 3 DUTCH HEAD AND NECK CENTERS

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3. A COMPARATIVE STUDY OF UK CENTRAL AND PERIPHERAL UNIT HISTOPATHOLOGY REPORTING OF MAJOR HEAD AND NECK RESECTION SPECIMENS; DATA FROM THE CRUK LIHNCS RANDOMISED CONTROLLED TRIAL OF 419 PATIENTS

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Pantziarka Pan

Anticancer Fund

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5. NOVEL INSIGHTS IN TONGUE CANCER: THE ROLE OF T-N TRACT

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Gorphe Philippe

Gustave Roussy, Villejuif, France

9. MICROVASCULAR MEDIAL FEMUR CONDYLE FOR NASAL RECONSTRUCTION: AN INNOVATIVE TECHNIQUE

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10. FIBRIN SEALANTS IN HEAD AND NECK SURGERY: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMISED CONTROLLED TRIALS

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11. DETECTING OROPHARYNGEAL CARCINOMA USING MULTISPECTRAL, NARROW-BAND IMAGING AND MACHINE-LEARNING: A FEASIBILITY STUDY

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1. Reactive versus prophylactic feeding during adjuvant radiotherapy: Results from a prospective study

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Rationale: Radical or adjuvant Radiotherapy (RT) is an integral component in the treatment of head neck cancer (HNC). RT causes alteration or loss of taste, mucositis, and xerostomia, which may cause decreased intake, consequential malnutrition and interruptions in therapy. Prophylactic tube feeding to prevent weight loss and avoid treatment breaks is common. This study aimed to compare the impact of different enteral interventions on weight dynamics in HNC patients undergoing adjuvant RT and their effect on disease outcomes.

Materials and methods: Patients from a prospective, randomized trial comparing methods of adjuvant treatment in locally advanced, stage III and IV, resectable squamous carcinoma of oral cavity were analyzed. Serial body weight was regularly recorded up to 2 years post radiotherapy. Prophylactic (PEG or NGT – Group A) enteral tube feeding was compared to reactive (including oral – Group B) feeding. Weight loss between the 2 groups was compared using t-test and proportion of patients with $\geq 10\%$ weight loss was compared using chi-square test. Impact of different feeding strategies and weight loss on disease control was calculated using log-rank test. Any p value < 0.05 was considered significant.

Results: 757 patients were eligible for this analysis. 489 composed Group A [375 (76%) PEG]. Of the 268 patients in Group B, 69 (26%) required reactive tube placement for \geq grade 3 dysphagia, severe mucositis, etc. on RT. Baseline KPS, nutritional status, disease stage, and treatment type were similar across both groups. Patients in Group A had significantly worse median weight loss at RT conclusion & until 18 months post RT (At conclusion- 4 vs 3kg; $p= 0.00$, 6 months- 4 vs 2kg; $p=0.01$). Median weight loss recovered by 9 months in Group B compared to 24 months in Group A. Proportion of patients with weight loss $\geq 10\%$ was greater in Group A at all time points (At conclusion- 39 vs 25.7%; $p=0.00$, 9 months- 29 vs 19.6%; $p=0.01$). Median duration of enteral feeding was significantly longer in PEG patients (64 vs 4 days; $p=0.00$). On univariate analysis, timing of tube insertion, or type of enteral tube feeding did not impact disease outcomes.

Conclusions: Prophylactic feeding is not superior to reactive feeding for nutritional support in HNC patients on adjuvant RT. Oral feeding and dietary counselling must be encouraged in all patients, unless contraindicated.

2. Sentinel lymph node biopsy for early stage oral cancer; experience of 3 Dutch Head and Neck centers

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Rationale: To evaluate the results of sentinel lymph node biopsy (SLNB) in patients diagnosed with a cT1-T2 oral squamous cell carcinoma and clinically negative (cN0) neck in three Dutch Head and Neck centers.

Materials and methods: Retrospective analysis of 328 previously untreated patients, who underwent SLNB between 2007 and 2016. The SLNB procedure consisted of preoperative lymphoscintigraphy, intraoperative detection using gamma probe guidance and postoperative histopathological examination including step-serial sectioning and additional keratin immunohistochemical staining. A positive SLNB was followed by a neck dissection, while patients with a negative SLNB underwent regular follow-up with ultrasound guided fine-needle aspiration cytology on indication.

Results: The SLN identification rate was 98% (322/328). At least one histopathologically positive SLN was found in 77 of 322 patients (24%). In 15 patients (19%) SLNs contained only isolated tumor cells as largest tumor deposit, in 28 patients (36%) micrometastases and in 34 patients (44%) macrometastases. Median follow-up was 26 months (range 1-104). During follow-up 16 patients developed isolated regional recurrence after a negative SLNB. Therefore, sensitivity of SLNB was 81% and the negative predictive value was 93%. The SLNB sensitivity of patients with a floor of mouth tumor was lower compared with tumors on other locations (67% vs. 84%, $P=0.11$), although the negative predictive value was comparable (92% vs. 93%). SLN-negative patients showed a longer overall survival (78% vs. 73%, $P<0.001$) and disease specific survival (99% vs. 85%, $P<0.001$) compared to SLN-positive patients. Isolated regional disease free survival did not differ significantly (90% vs 87%, $P=0.13$).

Conclusions: SLNB is a safe and reliable diagnostic staging technique for detection of occult lymph node metastasis in patients with early stage (cT1-T2N0) oral cavity cancer, but needs improvement in patients with floor of mouth tumors.

3. A Comparative study of UK central and peripheral unit histopathology reporting of major head and neck resection specimens; Data from the CRUK LIHNCS Randomised Controlled Trial of 419 patients

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Rationale: UK Head and Neck Cancer histopathology reporting is mandated to follow the Royal College of Pathologists (RCPATH) Minimum Dataset guideline¹. This study reports disparities in comparative data reported in the Lugol's Iodine in Head and Neck Cancer Surgery Trial.

Materials and methods: Data from 419 patients in 24 centres was analysed in two arms randomised 1:1 (Lugol's iodine used for margin dysplasia assessment in the intervention groups and control arm). Slide sets were retrieved from all centres. Where slides were missing new sections were cut. We performed a comparison of datasets independently reported by local histopathologists and by the central trial pathology team.

Results: While central pathologist histopathology reporting was concordant, there were significant disparities between local and central pathology data. This included both the completeness and content of the dataset. All central re-reporting followed the RCPATH dataset closely. Some cases were significantly upstaged by the central team examining the same slides.

Conclusions: Although the UK national dataset is widely recognised, disparities exist in reporting, even when the pathology team is aware of data scrutiny. Under reporting of pathological stage could have significant implications for therapy and indeed survival.

Ref 1. Pathological aspects of the assessment of head and neck cancers: United Kingdom National Multidisciplinary Guidelines T R Helliwell¹ and T E Giles 2016.

4. Drug Repurposing as a Source of Innovative Therapies in Head and Neck Cancer

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Rationale: Head and neck cancer (HNC) continues to pose a significant global health burden, with high levels of morbidity and mortality in both high and low/middle income countries (LMICs). While new treatment modalities, for example targeted immunotherapies, may offer promise for the future, it is likely that these interventions will impose severe financial strains on health systems in high income countries and remain inaccessible and unaffordable for many LMICs. Drug repurposing is an alternative development pathway that seeks to reuse existing non-cancer medications as the source of new treatment options. Repurposing benefits from existing data on safety, tolerability, dosing and from the clinical experience gained in the primary medical indications of these drugs.

Materials and methods: The Repurposing Drugs in Oncology (ReDO) project, an international collaboration, has identified over 230 licensed non-cancer medications with potential utility in oncology. These repurposing candidates come from multiple drug classes and diverse disease areas. In contrast to the high costs of newly developed medicines, many repurposing candidates are very low cost, including some generics, and are affordable globally.

Results: Of the ReDO repurposing candidates 42% have in vitro, in vivo or human evidence of anticancer effects in one or more head and neck cancers. Examples include aspirin, metformin, sulindac, niclosamide, propranolol and tadalafil. 35 are included in the WHO List of Essential Medicines. In the HNC context repurposed medicines are of particular interest in two distinct areas. Firstly as perioperative therapies to improve long-term surgical outcomes through reduction in locoregional and distant recurrence rates. Secondly, as adjuncts to chemoradiation in order to improve the tolerability or efficacy of current treatments. A range of such interventions are outlined in this paper – including a number of examples supported with data from small clinical trials. Furthermore, it is proposed that international multi-arm, multi-stage clinical trial designs present an ideal platform for developing such novel HNC interventions.

Conclusions: Drug repurposing is a clinical development strategy that offers clinical researchers a palette of existing licensed medications for use in innovative, independent trials to address the high unmet needs of patients with HNC.

5. Novel insights in Tongue Cancer: The role of T-N tract

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Rationale: The tongue is a very important organ involved in functional and relational life. The incidence of squamous cell carcinoma of the oral tongue (OTSCC) has increased in the last decades and its prognosis is still poor. We have analyzed a large series of patients with OTSCC, at homogeneous stage, treated in a single center with an identical surgical procedure: a compartmental tongue surgery (CTS) where the tumor is resected together with the lymph node tract in an “en bloc” resection. We investigated the prognostic factors responsible of local relapse and, in particular, the role of soft tissue tract between the primary tumor and the neck lymph nodes called T-N tract.

Materials and methods: We collected data on 322 patients with OTSCC, who underwent a CTS at the European Institute of Oncology, Italy. Chi-squared or Fisher's exact tests were used, crude cumulative incidence curves of local or distant reappearance, whichever occurred first, were computed in a competing risk framework. Overall Survival (OS) curves were estimated by the Kaplan-Meier method. The log-rank test was used to compare survival time between groups. A Cox proportional hazards model was used to identify independent predictors of survival, with adjustment for relevant covariates.

Results: In our data T-N tract involvement was significantly associated with distant recurrence and death. At 4 years, patients with T-N tract involved by disease have significantly more distant recurrence (40%) than patients without T-N tract involvement (22%, $p=0.02$). Patients with T-N tract involved are significantly more likely to die (76% versus 57%, $p<0.0001$). Among patients with positive neck lymph-node metastasis, T-N tract status was also significantly and negatively associated with OS ($p=0.002$). The competing risk Cox regression models indicate a significant triple risk of distant metastases with ‘T-N tract involvement’ (HR=3.13, with 95%CI: 1.15 to 8.33, $p=0.03$, adjusting for age) and a significant double risk of death (HR=2.38, with 95%CI: 1.32 to 4.35, $p=0.004$).

Conclusions: This study highlights the negative impact of involvement of the T-N tract on patient survival. Further studies should confirm these results in order to include the T-N tract in the standard surgical treatment of OTSCC and to evaluate whether patients with disease in the T-N tract should have a different adjuvant therapy or follow-up scheme.

6. Lymphatic drainage pattern assessment and staging using sentinel lymph node biopsy in oral and oropharyngeal cancer patients with a previously treated neck

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Rationale: Second primary tumors and local recurrences are relatively common in oral and oropharyngeal squamous cell carcinoma (OSCC). Lymphatic drainage patterns could be aberrant due to disruption of lymphatic channels by previous treatment of the neck and neck levels at risk for metastasis may be changed. The aim of this study was to evaluate the lymphatic drainage patterns and determine the accuracy of sentinel lymph node biopsy (SLNB) in patients diagnosed with a cT1-2N0 OSCC and a history of neck surgery or radiotherapy in three Dutch Head and Neck Centers.

Materials and methods: Retrospective analysis of 53 cT1-2N0 OSCC patients, who underwent neck staging using SLNB between 2007 and 2016, after a history of neck surgery or radiotherapy. SLNB consisted of preoperative lymphoscintigraphy, peroperative gamma-probe detection and step-serial sectioning with additional keratin immunohistochemical staining of the sentinel lymph nodes. A positive SLNB was followed by a neck dissection and patients with a negative SLNB underwent regular follow-up. Ten patients had previous treatment of the neck only contralateral from the current tumor. Forty-three patients had previous treatment of the ipsilateral or bilateral neck and were used for the analysis of lymphatic drainage patterns. Those 43 patients had a history of ipsilaterally SLN extirpation (n=9, 21%), neck dissection (n=16, 37%), radiotherapy (n=10, 23%), or combined neck dissection and radiotherapy (n=8, 19%).

Results: SLNs were detected in 45 patients, resulting in an identification rate of 85% (45/53). Three patients (7%) had at least one positive SLN. One patient (1/45, 2%) was diagnosed with isolated regional recurrence during follow-up, resulting in a sensitivity of 75% and a negative predictive value of 98%. With respect to the lymphatic drainage patterns in ipsilaterally treated patients, the first SLN was detected in level I-III in 58% of the patients, unexpected drainage patterns were observed in 30% (first SLN: 9% level IV, 5% level V, 16% contralateral neck) and in 12% no lymphatic drainage patterns were seen.

Conclusions: SLNB seems to be a safe and reliable procedure for neck staging of cT1-2N0 OSCC patients with a previously treated neck. SLNB renders an assessment of the individual lymphatic drainage pattern, compensating for a potential variability after previous treatment of the neck in 30% of these patients.

7. Pharyngoesophageal Reconstruction and Neck Resurfacing after salvage ablative surgery in prior radiation treatment patients. Personal experience with single or multiple simultaneous perforator flaps

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Rationale: Malignancies of the larynx and hypopharynx after prior organ-preservation chemoradiotherapy present challenges in oncologic ablative surgery and reconstruction. The primary objective is creation of neoconduit for digestive continuity, swallowing function and speech. A multitude of flap options have been used for reconstruction. Salvage laryngopharyngectomy for cancer recurrence or laryngeal dysfunction from prior chemoradiotherapy introduces additional complexity, compromising the quality of the remaining soft tissue and neck skin for primary closure and tracheal-stoma creation, as well as the quality of vessels for microanastomosis. Consequently, additional vascularized tissue is required to resurface the anterior neck skin in addition to the digestive neoconduit reconstruction. Many techniques can be implemented to provide resurfacing, including a second skin paddle from the same vascular pedicle used to create the neoconduit or a chimeric muscular component of the same pedicle followed by skin grafting.

Materials and methods: In the present study, we evaluated a series of 36 cases of pharyngoesophageal reconstruction.

Results: The ALT remains our flap of choice for hypopharyngeal reconstruction because of minimal donor-site morbidity and versatility in designing multiple skin paddles or chimeric flaps. Furthermore, neck coverage with vascularized tissue is recommended in patients with prior radiation therapy or neck surgery, for neck vessels without adequate coverage, if conduit reconstruction has created a resurfacing deficit and if the neck skin doesn't approximate with gentle apposition. Both thighs should be prepared in case local ALT flap anatomy does not allow for a chimeric solution and a second flap with separate anastomosis is needed. However, if the carotid system may have been previously used, encased in scar, or otherwise compromised a pedicled flap should be required. In turn of well known pectoralis flap or supraclavicular flap, an internal mammary artery perforator (IMAP) propeller flap prepared in anticipation was performed in our patients for neck resurfacing.

Conclusions: Prior radiation treatment are strong predictors for pharyngoesophageal reconstruction and for resurfacing needs. Careful surgical planning and proper flap selection and design can help manage even the most complex scenarios and improve patient outcomes.

8. Transoral robotic oropharyngectomy and free flap reconstruction: a new surgical paradigm

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Rationale: Surgical approaches for resection of oropharyngeal neoplasms are often associated with high rates of morbidity, even more when the resection requires a free flap reconstruction to improve functional outcomes and to decrease the risk of complications because of local extents or previous radiotherapy. However, recent advances in technology and surgical innovations have permitted to propose reducing surgical morbidity while improving functional outcomes by associating transoral robotic surgery and free flap reconstruction in patients with oropharyngeal cancers.

Materials and methods: In the prospective non-randomized phase II trial NCT02517125, recruited patients underwent a cervical-transoral robotic oropharyngectomy with free flap reconstruction. Primary endpoint was feasibility without major complication, secondary endpoints were dysphagia index, quality of life, and oncologic outcomes. We evaluated registered perioperative outcomes, evolution of the MD Anderson Dysphagia Index, evolution of quality of life using standardized EORTC QLQ-C30 and HN35 questionnaires, and oncologic results using pathological review and carcinologic events.

Results: Between september 2015 and septembre 2017, 18 patients underwent transoral robotic oropharyngectomy and free flap reconstruction, 6 for primary surgery, 6 in a previously irradiated field, and 6 for salvage surgery after failure of chemoradiotherapy. 8 lesions originated from the tonsillar fossa, 6 from the tongue base, 4 from the posterior pharyngeal wall. Feasibility was excellent, without peroperative difficulty. 2 minor postoperative complications occurred, and 1 bleeding that required hemostasis. No patient had a fistula, and mean oral feeding was day 17. The 6-month MDADI score showed a global decrease of 11%, with a 6-month rate of complete oral intake of 92%. The QLQ-C30 initial score resumed at 1 year. The rate of locoregional control is 100%, with a median follow-up limited to date at 10 months.

Conclusions: In the preliminary results of our prospective study, TORS and free flap reconstruction in oropharyngeal cancers appears feasible with favorable perioperative outcomes, good 6-month dysphagia index and oral-intake rate, preserved quality of life, and satisfactory locoregional control without recurrence to date.

9. Microvascular medial femur condyle for nasal reconstruction: an innovative technique

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Rationale: Nasal reconstruction after total or subtotal rhinectomy is challenging due to anatomical characteristics of this site. Functional and aesthetics results of conventional technique is often non satisfactory and many operations are needed. We present an innovative reconstructive technique of the nasal pyramid using medial femur condyle microvascular flap (MFC) and forehead flap.

Materials and methods: From January 2015 to July 2017, at the ENT and Maxillofacial Department of the University of Verona and the Plastic and Reconstructive Department of the University of Insubria, Varese, 5 cases of total or subtotal reconstruction of nasal pyramid with MFC and forehead flap has been done. In all patients nasal bone and anterior portion of nasal septum were involved and removed during the resection. MFC was used to reconstruct the bone with periosteal side positioned inside the nose; forehead flap was used to cover the hardware with skin and reconstruct the nostrils.

Results: All patients were satisfied both from an aesthetic and a functional point of view. Morbidity of the donor site in the knee was very low after recovery. We report pictures of pre-operative scan, operation steps and post-operative aesthetic results and scan.

Conclusions: Nasal reconstruction is always challenging. Between many free flaps used for this reason and reported in international literature the most used is probably radial forearm free flap. This flap has the disadvantage that is a soft tissue flap so usually a free bone or cartilage graft is needed, but the risk of resorption or necrosis is high.

In our experience MFC with a forehead flap can be a good option in complex nasal reconstruction.

10. Fibrin sealants in head and neck surgery: a systematic review and meta-analysis of randomised controlled trials

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Rationale: Fibrin sealants (FS) are commercially available products used in surgical wounds as adjuncts to haemostasis and closure of dead space. However their role in soft tissue head and neck surgery has not been established. The aim of this review was to assess whether FS improves wound-related outcomes in patients undergoing soft tissue surgery of the head and neck.

Materials and methods: We conducted a systematic review and meta-analysis of randomised controlled trials (RCTs). The databases used were: MEDLINE (1946-2016); EMBASE (1974-2016); PubMed (2016); CENTRAL (2016); ClinicalTrials.gov (2016); WHO International Clinical Trials Registry and Platform (2016); Research Gate (2016). Two independent reviewers screened and selected studies. Included studies were assessed for risk of bias and data extracted using a predetermined data collection form.

Results: Of the 421 studies that were screened, 11 RCTs met the inclusion criteria. There were two RCTs on thyroidectomy, three on surgery that involved neck dissection (central or lateral), five on rhytidectomy and one on parotidectomy. There was a tendency for FS to reduce total drainage volume (mean difference -26.86 mL, I² =97%, P=0.001). Subgroup analysis of thyroidectomy (mean difference -36.36 mL, I² =79%, P=0.05), surgery that involved neck dissection (mean difference -33.21 mL, I² =94%, P=0.08) and rhytidectomy (mean difference -13.79 mL, I² =0%, P < 0.00001) concurred with the overall analysis. There was a suggestion that FS may reduce retention time of drains by 1.24 days (I² =99%, P=0.25) and length of hospital stay by 2.09 days (I² =97%, P=0.18), but this was not statistically significant. There was also a suggestion that FS may protect against complications (RR 0.69, I²=0%, P=0.29) in particular haematoma/seroma formation (RR 0.49, I² =0%, P=0.07).

Conclusions: There was considerable heterogeneity within the RCTs, thus restricting definitive conclusions. Studies including patients undergoing lateral neck dissection for head and neck cancer were under represented. Also, all studies excluded patients deemed high-risk of surgical complications, leaving the effects of FS in this patient group unstudied. A future pragmatic trial assessing the role of FS in lateral neck dissection that includes 'high-risk' patients is warranted, however there is uncertainty regarding patient centred endpoints. We propose a pilot/feasibility study to optimise trial design.

11. Detecting Oropharyngeal Carcinoma using Multispectral, Narrow-Band Imaging and Machine-Learning: a Feasibility Study

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Rationale: Narrow band imaging has recently been shown to differentially illuminate the intraepithelial papillary capillary loops of superficial tumors of the upper aerodigestive tract in esophageal, hypopharyngeal, and laryngeal carcinoma, but the use of mNBI in oropharyngeal cancer remains understudied. To improve reproducibility and increase sensitivity and specificity, we combined image processing and basic machine learning techniques to automate detection of OPC-associated mucosa.

Materials and methods: Materials/Study Design: Prospective cohort study.

Methods: Multispectral narrow-band imaging (mNBI) and white light endoscopy (WLE) were used to image the tongue base and tonsils of a preliminary cohort of 20 patients (15 with biopsy-proven oropharyngeal carcinoma, 5 healthy). Relevant image features from 5 patients were then extracted and used to train a Naïve Bayesian classifier trained on low-level image features of oropharyngeal mucosa for categorizing healthy or malignant tissue.

Results: Tumors were classified by color features with 66% accuracy, 71.3% sensitivity, and 69.2% specificity under mNBI; in contrast, tumors were classified with 53% accuracy ($p = 0.0456$), 48.7% sensitivity (0.0325), and 57.5% specificity ($p = 0.547$) under WLE. ROC analysis yielded areas under the curve (AUC) of 72.5% and 55.7% for classification under mNBI and WLE, respectively ($p = 0.0201$). For classification using both color and texture features, AUC under mNBI increased significantly (78.6%, $p = 0.0101$) but did not improve under WLE (roughly 50% for both models, $p = 0.618$). Cross validation with 5 folds yielded an AUC above 80% for both mNBI models and below 55% for both WLE models ($p = 0.000531$ and 0.000524).

Conclusions: Compared to white light, multispectral narrow band imaging significantly enhanced the performance of a Naïve Bayesian classifier trained on low-level image features of oropharyngeal mucosa. These findings suggest that automated clinical detection of oropharyngeal carcinoma could be used to provide quantitative assessment of tumor board and thus enhance surgical vision. If validated, such an approach might improve early diagnosis, and allow for high-throughput screening.