

# Protocol

## **Title:**

- Using narrow-band imaging (NBI) technique to detect post-radiotherapy mucosal residual nasopharyngeal carcinoma (NPC)

## **Investigator**

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## **Background**

- NPC has a uniquely high prevalence in Southern China. According to the Hong Kong Cancer Registry in 2012, NPC was the sixth commonest cancer in men and thirteenth in women. It accounted for 2.9% of all new cancer cases. In 2012, there were 819 new cases of NPC.
- NPC is highly radiosensitive. Radiotherapy and chemotherapy are the mainstay of treatment. Despite the chemo-irradiation, disease control failure still occurred in NPC patients presenting as persistent tumor. Early detection of those post-radiotherapy residual NPC is essential for early arrangement of salvage therapy. Detection methods include imaging, plasma Epstein-Barr virus DNA, endoscopy examinations and nasopharynx biopsy.
- Narrow Band Imaging (NBI) is an optical image enhancement technology that improves the visibility of blood vessels. White light is composed of an equal mixture of wavelengths. The shorter wavelengths only penetrate the top layer of the mucosa, while the longer wavelengths penetrate deep into the mucosa. NBI light is composed of just two specific wavelengths that are strongly absorbed by hemoglobin: blue light (415 nm) and green light (540 nm). This wavelength allows a better understanding of the vasculature of suspect lesions.
- NBI system has been well proven as a tool to detect early digestive tract cancer and head and neck cancer. However, there were only few studies targeting the detection of post-radiotherapy mucosal residual of NPC using NBI system

## **Objective**

1. To identify the vessel pattern of those confirmed NPC case using NBI system
2. To identify the endoscopy features of post-radiotherapy mucosal residual nasopharyngeal carcinoma using NBI system
3. To establish the positive predicted value, negative predicted value, sensitivity and specificity of using both normal white light (WL) endoscopy and NBI system for detecting mucosal residual NPC

## **Design**

- Prospective cross sectional study

## **Study Period:**

- 12/2015 – 12/2016 for case recruitment
- Every patient follow up time around 4 months ( till 4/2017)
- Present at College Annual Scientific Meeting in 11/2017

### **Inclusion Criteria**

- New NPC patient

### **Exclusion Criteria**

- History of radiotherapy to head and neck region
- Poor premorbid status/ non-communicable patients
- <18 years old
- Pregnancy

### **Method**

- 1 A New ENT NBI clinic **is established and held** on every Friday pm (preferably) and Wednesday am (in case the patient is not available on Friday pm session or Friday is a public holiday)
- 2 Newly biopsy confirmed NPC patient
  - 2.1 Department of ENT: All biopsy confirmed NPC patients will be called back to the NBI clinic. They will be assessed by Dr. Fergus Wong and a complete ENT examination would be performed. Patient will undergo endoscopy examination (both WL + NBI), endoscopy image will be stored in the ePR system, consent forms will be signed and, baseline pure tone audiogram will be arranged. Patients will also be referred to oncology department.
  - 2.2 Department of Oncology: All new biopsy confirmed NPC patients **will be referred to ENT NBI clinic**. They will be assessed by Dr. Fergus Wong and a complete ENT examination would be performed. Patient will undergo endoscopy examination (both WL + NBI), endoscopy image will be stored in the ePR system, consent forms will be signed and, baseline pure tone audiogram will be arranged.
- 3 All patients will be followed up by both oncology and ENT department (**in ENT general clinic**) together regularly and look for chemo-radiation complication and hearing impairment.
- 4 At post-radiotherapy (2nd weeks) follow up in oncology department
  - 4.1 An appointment at post-radiotherapy 8th weeks will be arranged for the ENT NBI clinic (preferably on Friday pm) to perform nasopharynx biopsy
  - 4.2 An appointment at post-radiotherapy 10th weeks will be arranged for the oncology clinic to review biopsy result
- 5 At post-radiotherapy 8th weeks NBI clinic: The patient will undergo endoscopy examination (both WL and NBI) and nasopharyngeal biopsy will be taken. All the images will be saved in ePR. The consultation note template will be as same as the oncology endoscopy session template.
- 6 Biopsy results will be reviewed by oncology colleagues at the post-radiotherapy 10th weeks clinic

### **Analysis**

- Results will be process and analyzed as mean +/- standard deviation for continuous variables, and percentage for categorical variable.
- Positive predicted value, negative predicted value, sensitivity, specificity of both white light and NBI system will be calculated

- Statistical difference will be compared by chi-square test. P<0.05 was set as statistically significant
- Statistical analysis will be carried out with SPSS version 13

**Ethic issue/ Major point in consent form**

- Prolonged the endoscopy examination time

**Target Patient number:**

- New case: 50-70

**Reference**

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- 5 Lin YC, Watanabe A, Chen WC, Lee KF, Lee IL, Wang WH. Narrowband imaging for early detection of malignant tumors and radiation effect after treatment of head and neck cancer. *Arch Otolaryngol Head Neck Surg.* 2010 Mar;136(3):234-9.
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