Outcomes following neck surgery in oral cancer: Understanding the contribution of sentinel node biopsy.

12 Month Progress Report to BAOMS

Synopsis

The aim of this study is to compare post-operative functional outcomes in patients following sentinel lymph node biopsy (SLNB) and selective neck dissection for treatment of T1-2 oral squamous cell carcinoma (OSCC). The study will be observational, collecting data using mixed methods research.

Introduction & Rationale for Study

Occult neck metastases are found in approximately 20% of patients with early (cT1/2N0) oral cancer and the management of the neck remains controversial. NICE have recently mandated that patients with T1 and T2 N0 oral cancers are offered surgical management of the neck and should be offered SLNB (NICE guideline 36 Cancer of the upper aerodigestive tract <u>www.nice.org.uk/guidance/NG36</u>). While it seems likely that Sentinel lymph node biopsy (SLNB) will cause fewer side effects than elective neck dissection (END) and be associated with less shoulder dysfunction, better health related quality of life and a better qualitative experience of treatment, the evidence for this is poor (Govers, Clin. Otolaryngol (2016) 41;228–233). If minimal differences in the above measures were found, the role of SLNB would be highly questionable.

Study design

A retrospective, cross-sectional study using mixed methods research to compare outcomes of SLNB and END.

Inclusion Criteria:

- Early stage T1-2 clinically node negative OSCC
- Treated by SLNB, SND or W&W, or following a positive SLNB
- Patients must be at least 6 months post operation at the time of the research observations

Exclusion Criteria:

- Unrelated shoulder or neck morbidity at the time of surgery.
- Previous unrelated head, neck or shoulder surgery.
- Previous irradiation of head, neck or shoulder region (prior to index surgery).

Primary outcome measure

- Functional shoulder outcomes as measured by range of movement.
 - As described in Scott B, Lowe D, Rogers SN. The impact of selective neck dissection on shoulder and cervical spine movements. Physiotherapy. 2007 Jun;93(2):102–9.

Secondary Outcome measures

- Objective outcome measures
 - o Scar length
 - o Patient and Observer Scar Assessment Scale
 - Facial nerve function

- as described in Batstone MD, Scott B, Lowe D, Rogers SN. MARGINAL MANDIBULAR NERVE INJURY DURING NECK DISSECTION AND ITS IMPACT ON PATIENT PERCEPTION OF APPEARANCE. Head Neck. 2009 Apr 13;31(5):673–8.)
- Electromyography of accessory nerve function
 - A described in Parikh S, Tedman BM, Scott B, Lowe D, Rogers SN. A double blind randomised trial of IIb or not IIb neck dissections on electromyography, clinical examination, and questionnaire-based outcomes: a feasibility study. British Journal of Oral & Maxillofacial Surgery. British Association of Oral and Maxillofacial Surgeons; 2012 Jul 1;50(5):394–403.
- Health related quality of life outcomes
 - Measured by University of Washington quality of life questionnaire, neck dissection impairment index, MD Anderson dysphagia index, shoulder disability questionnaire, EORTC-H&N43.
- Qualitative experience of patients undergoing SLNB and END
 - o Structured interviews to investigate patient experience of SLNB and END.
 - To explore the decision making process of SLNB vs END
 - To explore long term satisfaction with the chosen modality

Progress to date

The project is now registered as an MD with the University of Liverpool. MD student – Mr C McDonald Supervisors – Mr R Shaw, Mr A Schache, Mr S Rogers, Dr L Frith.

The study protocol is in the final stages of development.

Links have been made with Queen Elizabeth Hospital Glasgow, and Guys Hospital London, who have expressed an interest in contributing patients to the study.

Literature review, IRAS application and study protocol are expected to be finalised by April 2018.

Data collection is expected to commence May 2019 and be complete by September 2019.

Publication of initial findings is expected by January 2020.

Thesis writing is expected to be complete by November 2021.

Expenditure

Grant awarded £5,100 Expenditure to date £0.