University Hospitals of Leicester NHS Trust

FULL/LONG TITLE OF THE STUDY

Functional Outcome following Ivor-Lewis Oesophagectomy

SHORT STUDY TITLE / ACRONYM

- Functional Outcome Ivor Lewis

PROTOCOL VERSION NUMBER AND DATE

- Version 2
- Date 02/06/2018

RESEARCH REFERENCE NUMBERS

IRAS Number: 240683

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:
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Name:

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Position:
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Chief Investigator:

Signature: Date:
..../...../.....

Name: KUMARESAN SUPRAMANIAM

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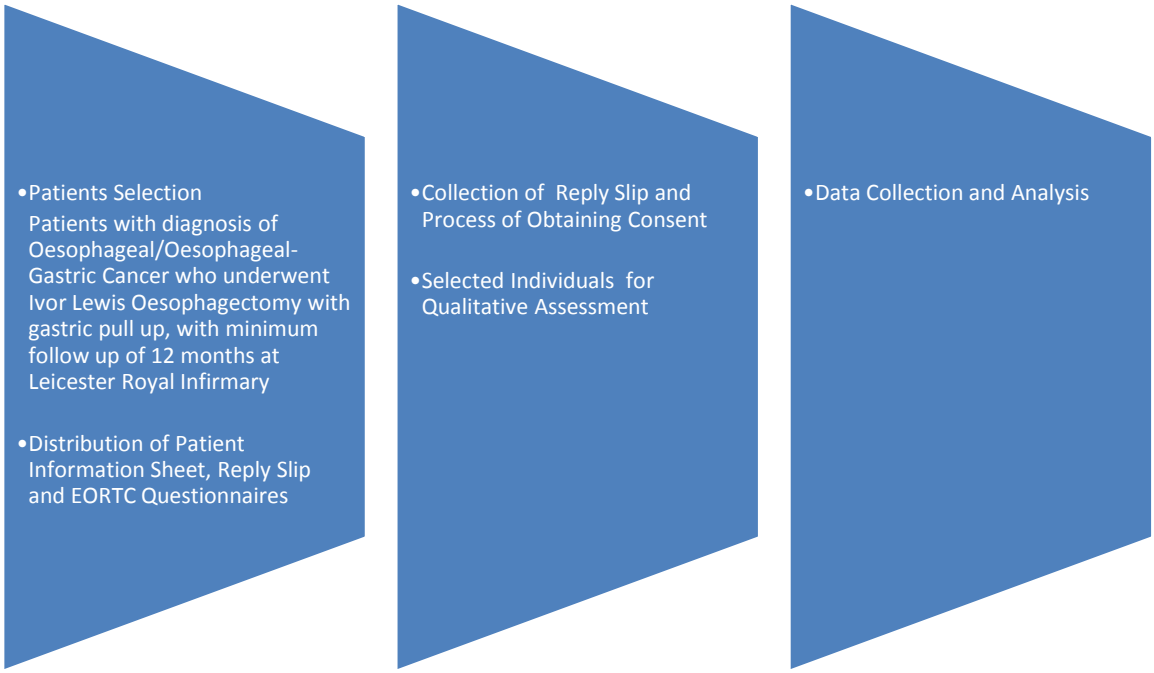
STUDY SUMMARY

Study Title	Functional Outcome Following Ivor Lewis Oesophagectomy
Internal ref. no. (or short title)	Functional Outcome Ivor Lewis
Study Design	A. Quality of life Questionnaires B. Qualitative Semi-structured Interviews
Study Participants	Patients who underwent Ivor Lewis Oesophagectomy with minimum follow up of 12 months at Leicester Royal Infirmary
Planned Size of Sample (if applicable)	Part A: 100 patients Part B: 15 patients
Follow up duration (if applicable)	NA
Planned Study Period	Study Recruitment Period – 12 months
Research Question/Aim(s)	To -Evaluate midterm Quality of Life in patients that underwent Ivor Lewis Oesophagectomy with gastric pull-up -Identify clinical factors influencing quality of life post operatively -Explore patients' experiences of their quality of life and how they handle their new life situation from a long-term perspective after oesophagectomy

KEY WORDS: Functional Outcome, Ivor Lewis Oesophagectomy, Quantitative, Qualitative

STUDY FLOW CHART



STUDY PROTOCOL

Functional Outcome Following Ivor Lewis Oesophagectomy

1 BACKGROUND

Oesophago-gastric (OG) cancer is the fifth most common malignancy in the United Kingdom, affecting approximately 16,000 people each year. The prognosis for most patients with these cancers is poor as they typically experience symptoms when the disease has become fairly advanced. Five-year survival rates for oesophageal and gastric cancer are 15 percent and 19 percent respectively. (1,2)

The figures from Office of National Statistics (ONS) pertaining to net survival estimates for oesophageal cancer in England are 42.3 percent for one year and 14.2 percent for five years, which compares unfavourably too many other types of cancer. (3)

Surgery is the mainstay of curative treatment for patients with localized disease, and is often combined with neoadjuvant chemotherapy and/or radiotherapy. Curative surgery for OG cancer is a major undertaking, even in a high volume centres, and is only suitable for patients who are relatively fit. Only, approximately 30 percent of patients are candidates for a treatment with curative intent with the remainder either presenting with advanced disease or being judged unfit for the radical treatments required for cure. (1)

Although surgery offers the best prospect for potential cure of OG cancers, radical treatment may result in increased treatment related mortality, high treatment-induced morbidity, and reduced quality of life. Traditionally, many centres managing OG cancers focused on mortality and morbidity as their key outcome measures. However, a growing body of opinion considers that a measure of broader effects of ill health and treatment on the patient's quality of life (QOL) is necessary. (4,5). Such considerations are important, as it is questionable if patients are subjected to treatment merely to offer them a few extra months of life, particularly if this is at the expense of quality of life. These include physical, functional, social and physiological aspects of life.

More than half of the operated patients will develop significant functional disorder after surgery affecting QOL. The most common problems observed are dysphagia, dumping syndrome, delayed gastric emptying, and reflux. (6) These functional disorders are not always detected immediately post operatively, but may become more troublesome as time goes by. (7)

A frequent gastrointestinal symptom following surgery for oesophageal cancer is dysphagia which has an estimated incidence of between 21 to 56%, and interestingly is similar following definitive chemoradiation therapy. (26, 27) Several studies have identified risk factors for developing post-surgical, non-malignant, strictures which could lead to significant dysphagia including tension on the anastomosis, insufficient blood supply, radiotherapy, chemotherapy, anastomotic leak and fistula, reflux and intra or post operative hypotension. Systemic disorders such as diabetes mellitus and cardiovascular disease also been identified as risk factors. (6,8,9)

Delayed gastric emptying is also a significant problem following oesophagectomy. This occurs because of the gastric tubulisation, which reduces the function as a reservoir, and compounded by alteration in hormonal reflexes and vagotomy. Stasis of gastric acid could potentially lead to anastomotic stricture. Early satiety and postprandial discomfort are the two most common symptoms of delayed gastric emptying. Patients are generally advised to consume small frequent meals, up to five or six times a day, followed by fluid intake. To date, no surgical procedure has been clearly demonstrated to be effective for the prevention of delayed gastric emptying. Nine randomised trials were analysed in a meta-analysis regarding pyloroplasty, which found a lower rate of early post operative gastric obstruction after pyloroplasty but no difference for the quality of gastric emptying at mid and long term. It also could lead to biliary reflux and dumping syndrome. Contradictary results have been reported concerning the influence of the size of gastroplasty and the use of vagal-sparing oesophagectomy. (6)

Another common functional problem is reflux. Up to 80% of patients present with symptoms related with acid or bilio-pancreatic reflux. (21,22) Oesophagitis has been reported in 38 to 76% of patients (23) and supra-anastomotic Barrett's metaplasia in 8 to 50%. (24,25) Loss of the anti-reflux mechanism and the exposure of gastric tube to the negative intra thoracic pressure increase chances of developing significant reflux post operatively. Patients would usually present with burning sensations in upper chest and neck worsened by lying in prone position especially at night. This subsequently leads to poor sleep and nocturnal cough. (6) Multiple variation in creating the anastomosis has been studied in an attempt to reduce incidence of post operative reflux, including; formation of a neck anastomosis rather than thoracic anastomosis; retrosternal gastroplasty; pyloroplasty; and creation of peri-anastomotic valve. Nevertheless, these different techniques are not used in routine surgical practice with most surgeons preferring to avoid a more complex surgery.

Significant gastrointestinal symptoms are associated with dumping syndrome which is relatively common consequence of oesophagectomy with a reported prevalence of between 10 to 50%. The pathophysiology of dumping syndrome is complex but includes rapid transit of a hypersomolar bolus into the jejunum leading to splanchic vasodilatation and systemic hypotension due to relative hypovolemia. The hyperosmolarity also triggers excessive secretion of various peptides which leads to diarrhoea and inhibition of water and sodium absorption. Symptoms include palpitations, nausea, diaphoresis, flushes, diarrhoea and abdominal cramps. Late dumping can also occur with symptoms of trembling, somnolence and concentration disorder. Small group of patients can present with both accelerated and delayed dumping syndrome. (6)

It is recognised that only a small number of patients are asymptomatic in the long term (10,11) and that the occurrence of functional disorders and postoperative complications has an influence on QOL. Previous studies have shown that the lowest level of QOL occurs at approximately four to six weeks postoperatively. (12,13) Almost 50 percent of the patients have at least one functional disorder within the first month following surgery. (14) Most functional recovery takes place during the first two years after surgery with concurrent improvement in QOL.

2 RATIONALE

Much of the focus for the treatment of oesophageal cancer is based on cancer clearance, peri-operative morbidity and mortality. Treatment frequently consists of chemotherapy and or radiotherapy followed by a complex major operation consisting of surgery performed both in the abdomen and thorax. Cancer registries have rightly focused on measuring mortality and morbidity for these patients and considerable improvements in these outcomes has been evident of the years. With improvements in oesophagectomy outcomes patients may be left with long-term consequences of their treatment, experiencing unpleasant gastrointestinal symptoms that may have a prolonged deleterious effect on their QOL. Much of the qualitative research to date has focused on recovery in the first two years post-op.

3 THEORETICAL FRAMEWORK

This study focuses on the prevalence of functional complications and their impact on QOL in patients who underwent an Ivor Lewis Oesophagectomy.

This study will assess the prevalence of gastrointestinal symptoms and QOL from beyond the first year following surgery. The aim is to determine whether gastrointestinal side effects and QOL are compromised in the long-term.

This study will also explore in details, the impact of surgery on their quality of life and gastro intestinal symptoms that patients has experienced post operatively.

4 RESEARCH QUESTION/AIM(S)

To assess quality of life following Ivor Lewis Oesophagectomy with a minimum of 1 year follow up
To explore patient's personal experience of their quality of life and how they handle their new life situation from a long-term perspective after oesophagectomy

4.1 Objectives

The purpose of this study is

-To evaluate mid to long term HRQL in patients that underwent Ivor Lewis Oesophagectomy with gastric pull-up

-To identify clinical factors influencing quality of life post operatively.

-To explore patients perspective on changes that they have experienced post operatively focusing on quality of life and gastro intestinal symptoms.

4.2 Outcome

Quality of life based on EORTC questionnaires

Qualitative semi-structured interviews

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

PART A: QUALITY OF LIFE QUESTIONNAIRES

Subjects will be recruited through existing Upper GI Cancer Database following which identified patients will receive invitation letter, patient information leaflet and reply slip. Interested cohort of patients will be approached for obtaining consent and distribution of stamped addressed envelope containing questionnaires. This process will be done from 1st Sept 2018 up to 31st Aug 2019.

Quality of life will be evaluated using the validated EORTC core questionnaire (QLC C-30, OES-18). The combination of QLQ-C30 and QLQ-OES18 is considered to precisely reflect the changes in the quality of life of oesophageal cancer patients and is recommended by EORTC to evaluate the quality of life of such patients.

EORTC QLQ-C30 (version 3.0) is a self-assessment questionnaire describing 5 functional indices, including physical, role, cognitive, emotional and social functions, 3 symptom indices, including fatigue, pain and nausea or vomiting and 1 general score. EORTC QLQ-OES18 includes 18 indices, namely specific symptoms, such as dysphagia and oesophageal reflux. (15,16)

Descriptive analysis of all the demographic, clinical and outcome variables will be performed. Results of the continuous variables will be described in mean and standard deviation for normally distributed data and median and inter-quartile range for non-normally distributed data. Results of categorical variables will be described in frequency and percentage. Test of Normality will be used to determine the distribution of the outcome variables.

Correlation between the subscales will be determined using Pearson (for normally distributed) or Spearman (for non-normally distributed) Correlation, with the corresponding Correlation Coefficient and p values reported. To identify demographic and clinical factors associated with functional, symptom and global health status outcome, univariate and multivariate linear regression analysis will be used.

PART B: QUALITATIVE EXPLORATORY STUDY

Potential participants for part B will be those recruited into EORTC QOL assessment study. At the initial recruitment stage, participants will be asked to indicate on the consent form if they agree to be interviewed. Purposeful sampling will be adopted to ensure appropriate selection of cases. On agreement, consent will be taken prior to interview taking place. It is anticipated that no more than 15 patients will be included.

The interviews will all follow the same semi-structured format. The interview schedule (APPENDIX 3) has been developed and encourages exploration and discussion of the following areas:

- evaluate changes over time, and factors that may impact patients' quality of life the first year after oesophagectomy for cancer

- illuminate patients' experiences of their quality of life and how they handle their new life situation from a long-term perspective after oesophagectomy for cancer

Interviews will be conducted in a private room with estimated duration approximately 90 minutes. Following each interview, the researcher will make field notes including any observations. This will help to inform reflexive reflection. The interview will be digitally recorded and then transcribed verbatim. Each participant will be assigned a false name when the interview transcribed, and the recording will be destroyed when no longer needed for study purposes. Data organisation and retrieval will be managed using the qualitative software package NVivo.

6 STUDY SETTING

PART A: QUALITY OF LIFE QUESTIONNAIRES

Patient who underwent Ivor Lewis oesophagectomy with lymphadenectomy for oesophageal cancer will be selected from our database at the Department of Surgery, Leicester Royal Infirmary. These include patients from Leicestershire and Northamptonshire treated at the Leicester Royal Infirmary. Mid to long term survivors operated in our institution with a follow up of at least 12 months will be identified from our database to be included in our study. Personalised invitation letter together with patient information leaflet and reply slip will be posted to all eligible patients. Group of patients who express their interest in participating in the study by submitting reply slip will be approached individually during their routine clinic follow up or cancer support group meeting. They will be consented for both participation and access to their medical records from the disease registers ensuring confidentiality. Each patient will be provided with both sets of questionnaires (QLC C-30, OES-18) to be completed. Patients will have a choice of returning the completed questionnaires during the meeting itself or they could choose to post it back on a later date. Complete demographic data, staging of disease, type of treatment received and postoperative complications will be recorded on a structured proforma.

In creating the database with the participant's scores from the questionnaires, each individual will be assigned a number to anonymise their data. Hard copies of questionnaires will be kept in a locked cabinet at the University Hospitals of Leicester. These questionnaires will be kept securely for five years post study and all information held electronically will be password protected. Only the Chief Investigator will have access to the electronic database. Participants are free to withdraw consent and terminate the study at any point.

If participants are lost to follow-up / non-compliant, every attempt will be made to contact them, and these will be documented. Any reason for withdrawal will be documented on the appropriate CRF form.

Confidentiality and record keeping will be explained to participants within the participant information sheet.

PART B: QUALITATIVE EXPLORATORY STUDY

Qualitative approach of thematic analysis will be used for this study. The conceptual framework of the thematic analysis was mainly built upon the theoretical positions of Braun and Clarke (28). According to them, thematic analysis can be used for 'identifying, analysing, and reporting patterns (themes) within the data and can produce an insightful analysis that answers particular research questions.
A theme is something that captures the key idea about the data in relation to the research question and which represents some level of patterned response or meaning within the data set.
Six phase guide provided by Braun and Clarke will be used as a framework in conducting and analysing this part of the study
Step 1: Become familiar with the data
Step 2: Generate initial codes
Step 3: Search for themes
Step 4: Review themes
Step 5: Define themes
Step 6: Write-up
Questions will be semi-structured and adapted on individual basis to cover themes that might emerge out of discussions.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Patients who underwent Ivor Lewis Oesophagectomy in Leicester Royal Infirmary with minimum follow up of 12 months.

Age more than 18

7.1.2 Exclusion criteria

Disease recurrence within the follow up period

Age less than 18

7.2 Sampling

7.2.1 Size of sample

PART A: QUALITY OF LIFE QUESTIONNAIRES

Based on literature reviews, most functional recovery takes place during the first two years after surgery along with improvement in QOL. Study is designed to include every patient with minimum follow up of 12months, estimated to be approximately 100 patients.

PART B: QUALITATIVE EXPLORATORY STUDY

It is anticipated that no more than 15 patients will be included

7.2.2 Sampling technique

Subjects will be recruited through existing Upper GI Cancer Database following which identified patients will receive invitation letter, patient information leaflet and reply slip. Interested cohort of patients will be approached for obtaining consent and distribution of stamped addressed envelope containing questionnaires.

7.3 Recruitment

7.3.1 Sample identification

PART A: QUALITY OF LIFE QUESTIONNAIRES

All eligible patients will be identified through our pre-existing Upper GI Cancer Database at Leicester Royal Infirmary. This process will be done by chief investigator and collaborator.

Agreeable patients will be approached during upcoming clinic follow up or support group meeting.

PART B: QUALITATIVE EXPLORATORY STUDY

Potential participants will be those recruited into the Part A of the study. At the initial recruitment stage participants will be asked to indicate on the consent form if they agree to be interviewed. Purposeful sampling will be adopted to ensure an appropriate selection of cases.

7.3.2 Consent

The nature and objectives of the study and possible risks associated with their participation will be discussed between chief investigator/supervisor and potential participant. Patient information leaflet and written consent forms will be provided to each potential participant. Patients also will be provided time and opportunity to consider decision and to ask further questions. Only when written informed consent has been obtained including access to their medical records from the patient can they be considered a trial participant.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Whilst it is not anticipated that any harm should come to those participating in the study, it is acknowledged that there is a possibility that individuals may become upset whilst completing the questionnaires. This will be taken into consideration when explaining the research and debriefing. Participants will be made aware verbally and via the participant information sheet that the questionnaires may ask upsetting questions.

Taking into consideration the potential risks, it was felt that the benefits justified the potential burden to the participants.

Due to the sensitive nature of the all participants, they will be made aware that their decision to take part in this research will not affect the care they receive or will receive in future. When suitable individuals have been identified for recruitment to the study, the Chief Investigator will obtain full informed consent in writing. Records detailing the date, time and by whom consent was obtained from will be kept. Furthermore, emphasis will be placed on the anonymity of the questionnaire responses highlighting that only the Chief Investigator will have access to identifiable information and this won't be accessible to the medical team on site.

Information sheets detailing the research aims and rationale will be given to each potential participant. Participants will be made aware of their right to withdraw from the study at any time and emphasis will be placed that this will not affect their future care. The Chief Investigator will comply with any requests of withdrawal by removing individuals' data from the database and destroying the questionnaires in an appropriate manner that complies with data protection legislation.

Person-identifiable information of the data set will be integral to the research as it will form the basis of comparison across groups for demographic features. It will however be kept in a separate password protected document only accessible to the Chief Investigator. On inputting of the data, participants' data will be anonymised by the use of identification numbers.

Electronic databases containing the information will have restricted access and be password protected.

Participants will be given the chance to ask questions following the data collection and offered the opportunity to receive a lay summary of the key research findings.

8.2 Research Ethics Committee (REC) and other Regulatory review& reports

Before the start of the study, a favourable opinion will be sought from UK Health Departments Research Ethics Service NHSREC for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

Regulatory Review & Compliance

Before any enrolment into the study takes place, the Chief Investigator/Principal Investigator will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

8.3 Peer review

This study protocol has been reviewed by 2 Upper Gastrointestinal Consultant who is not involved directly in this project.

8.4 Patient & Public Involvement

Patients will be actively involved as they will provide current status of their function and quality of life guided by the questionnaires provided. Following data analysis and completion of final report, participants as well as the public will be able to access the outcome of the study.

8.5 Protocol compliance

The current study has been reviewed through the internal peer review process within the Department of Surgery of University Hospitals of Leicester.

The Chief Investigator will receive ongoing supervision from the Academic Supervisor.
The University Hospitals of Leicester NHS Trust, as Sponsor, operates a risk based monitoring and audit programme, to which this study will be subject.

8.6 Data protection and patient confidentiality

Demographic information will be stored securely and anonymised on an electronic database. All data will be identifiable using a unique participant number allocated to each participant and only the Chief Investigator will have access to the demographic information.
Hard copies of the questionnaires will be kept in a secure storage cabinet at the Department of Surgery of University Hospitals of Leicester.

Electronic databases will have restricted access, be password protected and contain no personal information. A participant information sheet will outline details of confidentiality employed in the research process.
Participants will be given the chance to ask questions on completion of the questionnaires and will be offered the opportunity to receive a lay summary of the key research findings.

8.7 Indemnity

NHS indemnity will apply as the study sponsor

8.8 Access to the final study dataset

After analysis, data will be securely stored at the University Hospitals of Leicester for five years after the date of submission and will be accessible by chief investigator and study supervisor. After this period, data will be appropriately destroyed.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Upon completion of the data collection and data analysis, a Final Study Report will be prepared and will be considered for presentation/publications. Information will be given to the patients on how to ask for a copy of the results. A patient friendly lay summary of the research will be produced and made available to participants if they wish.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship on the final study report will be granted to chief investigator and study supervisor

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11. APPENDICIES

11.1 Appendix 1- QLQ-C30

11.2 Appendix 2 - QLQ-OES18

11.3 Appendix 3 – Semi-structured interview schedule

APPENDIX 1

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:
Your birthdate (Day, Month, Year):
Today's date (Day, Month, Year): 31

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:		Not at All	A Little	Quite a Bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need to rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4
16.	Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

APPENDIX 2

ENGLISH

EORTC QLQ – OES18

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:		Not at all	A little	Quite a bit	Very much
31.	Could you eat solid food?	1	2	3	4
32.	Could you eat liquidised or soft food?	1	2	3	4
33.	Could you drink liquids?	1	2	3	4
34.	Have you had trouble with swallowing your saliva?	1	2	3	4
35.	Have you choked when swallowing?	1	2	3	4
36.	Have you had trouble enjoying your meals?	1	2	3	4
37.	Have you felt full up too quickly?	1	2	3	4
38.	Have you had trouble with eating?	1	2	3	4
39.	Have you had trouble with eating in front of other people?	1	2	3	4
40.	Have you had a dry mouth?	1	2	3	4
41.	Have you had problems with your sense of taste?	1	2	3	4
42	Have you had trouble with coughing?	1	2	3	4
43.	Have you had trouble with talking?	1	2	3	4
44.	Have you had acid indigestion or heartburn?	1	2	3	4
45.	Have you had trouble with acid or bile coming into your mouth?	1	2	3	4
46.	Have you had pain when you eat?	1	2	3	4
47.	Have you had pain in your chest?	1	2	3	4
48.	Have you had pain in your stomach?	1	2	3	4

APPENDIX 3

SEMI STRUCTURED INTERVIEW SCHEDULE

Introduction, explanation about proceedings and consent

In general, tell me about how your life has been since your operation.

Can you tell me how you feel about oesophageal cancer and the impact on your life so far?

Post operatively, have your symptoms changed with time? Have they got worse, more frequent? Have new symptoms come on, that weren't there to start with? Would you mind telling me more about them?

What is the main changes/adaptation in your daily activity that you have had to make following surgery?

Can you describe any changes to your life that have happened as a consequence of having the surgery E.g. daily routine, social activities, relationships, quality of life.

How is your appetite, eating and drinking compared to before the operation?

Is there anything else that you would like to discuss, relating to your experience of the JEJ feeding tube, your appetite and food intake that you feel is important?

To facilitate open discussion,

Can you tell me more?

Can you expand on that?

Can you explain what you mean?