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Prevalence, nature and trajectory of dysphagia postoesophageal cancer surgery: a prospective longitudinal study protocol

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ABSTRACT

Introduction Dysphagia is a common problem following oesophagectomy, and is associated with aspiration pneumonia, malnutrition, weight loss, prolonged enteral feeding tube dependence, in addition to an extended in-hospital stay and compromised quality of life (QOL). To date, the prevalence, nature and trajectory of post-oesophagectomy dysphagia has not been systematically studied in a prospective longitudinal design. The study aims (1) to evaluate the prevalence, nature and trajectory of dysphagia for participants undergoing an oesophagectomy as part of curative treatment, (2) to determine the risk factors for, and post-operative complications of dysphagia in this population and (3) to examine the impact of oropharyngeal dysphagia on health-related QOL across time points.

Methods and analysis A videofluoroscopy will be completed and analysed on both post-operative day (POD) 4 or 5 and at 6-months post-surgery. Other swallow evaluations will be completed preoperatively, POD 4 or 5, 1-month and 6-month time points will include a swallowing screening test, tongue pressure measurement, cough reflex testing and an oral hygiene evaluation. Nutritional measurements will include the Functional Oral Intake Scale to measure feeding tube reliance, Malnutrition Screening Tool and the Strength, Assistance With Walking, Rise From a Chair, Climb Stairs and Falls questionnaire. The Reflux Symptom Index will be administered to investigate aerodigestive symptoms commonly experienced by adults post-oesophagectomy. Swallowing-related QOL outcome measures will be determined using the European Organisation for Research and Treatment of Cancer QLQ-18, MD Anderson Dysphagia Inventory and the Swallowing Quality of Life Questionnaire.

Ethics and dissemination Ethical approval has been granted by the Tallaght University Hospital/St. James' Hospital Research Ethics Committee (JREC), Dublin, Ireland (Ref. No. 2021-Jul-310). The study results will be published in peer-reviewed journals and presented at national and international scientific conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first prospective longitudinal study to evaluate the presence, nature and trajectory of dysphagia following oesophagectomy and the impact of dysphagia on quality of life over a 6-month timeframe.
⇒ Public and patient representatives have contributed to the study design including the selection of meaningful outcome measures across time points.
⇒ This study will take place in a national specialist centre for oesophageal cancer, involving multidisciplinary experts in oesophageal cancer and two patient and public representatives as co-researchers.
⇒ This prospective longitudinal study will evaluate dysphagia post-oesophagectomy, across all open surgical approaches (including transthoracic and transhiatal).
⇒ Limitations include the single-centre study design, excludes patients who undergo a complex post-operative course (eg, post-operative pulmonary complications) who may present with an oropharyngeal dysphagia, and the long-term time point is limited to 6-months post surgery.

INTRODUCTION

The incidence of oesophageal cancer has increased markedly in the western world over the last 50 years, with the rates of the pathological subtype of adenocarcinoma linked to an increased prevalence of obesity, gastro-oesophageal reflux disease and Barrett's oesophagus.[1] The mainstay of curative treatment is surgery, often combined with preoperative combination chemoradiotherapy, or perioperative chemotherapy as per the MAGIC/FLOT or CROSS regimens.[2] Surgery for oesophageal cancer is major, with up to 5% risk of mortality and over 50% risk of morbidity, irrespective of whether surgery is via open, minimally invasive or robotic-assisted approaches.[3–7] Post-operative complications include pulmonary dysfunction, atrial fibrillation and anastomotic leak.[8] Post-operative pulmonary complications (PPCs) are among the most serious postoperative challenges occurring between 15% and 40%

of patients post-oesophagectomy, impacting length of stay in critical care units, increasing overall hospital stay with significant cost implications.[9 10] Malnutrition, weight loss and sarcopaenia are common after surgery or combination therapies.[11 12]

Due to centralisation of services and enhanced recovery programmes, operative mortality has decreased.[13] Furthermore, the 5-year survival rates among survivors of oesophageal cancer have improved in high-income countries.[14] This has led to a shift in focus to improving survivorship in adults who have undergone curative treatment for oesophageal cancer.[15] The health-related quality of life (HR-QOL) among oesophageal cancer survivors varies considerably. Symptoms known to impact long-term survivors and HR-QOL include coughing, reflux and deterioration in swallowing function.[16]

Dysphagia is the most common presenting symptom for the majority of patients with oesophageal cancer.[17] Following oesophageal resection, dysphagia continues to present post-operatively alongside other complications, which may be a result of, or further exacerbated by PPCs, recurrent laryngeal nerve (RLN) damage, neo-oesophageal strictures and gastrointestinal reflux.[18–20] Interventions for oesophageal dysphagia include oesophageal dilation, stenting and thermal and chemical ablation therapy.[21] Dysphagia may be associated with aspiration pneumonia, malnutrition, prolonged feeding tube dependence and an extended inpatient hospital stay.[22]

Dysphagia is highly associated with compromised quality of life (QOL) among oesophageal cancer survivors.[16] One-year post-oesophagectomy, almost half of survivors' report eating restrictions and other symptoms include dry mouth, taste problems, difficulty swallowing saliva and choking.[15] At two years post-oesophagectomy, eating difficulties and reluctance to eat in front of others has been associated with psychological distress.[23] In a recent cross-sectional cohort study on patient-reported outcomes post-oesophagectomy, long-term symptom burden is common in this patient group, with swallowing/conduit problems being one of the six main problems reported.[24] Ten years post-operatively, swallowing difficulties persist for half of survivors.[25]

Despite the prevalence of dysphagia post-oesophagectomy as well as its impact on QOL, the prevalence, nature and trajectory of dysphagia has been poorly studied in oesophageal cancer. Some small studies have identified impairment of oropharyngeal structures post-operatively during videofluoroscopy (VFS). Swallowing impairment following resection have been reported to include a reduction in tongue pressure, delayed initiation of the pharyngeal swallow, impaired biomechanics, RLN palsy and increased pharyngeal residue, which may increase the patients' risk of aspirating, silently aspirating and developing pneumonia.[26–28] To date there has been no systematic research using a prospective longitudinal study design in this patient group. By determining the prevalence, nature and trajectory of dysphagia post-oesophagectomy the researchers anticipate that this would inform future research and guidelines in prevention and management of dysphagia, including exercise-based dysphagia interventions, which may optimise clinical and QOL outcomes.

Study objectives

The primary objectives of this study are:

1. To establish the prevalence, nature, severity and trajectory of dysphagia post-oesophagectomy among adults who have undergone a transthoracic (2-stage or 3-stage) or a transhiatal oesophagectomy (THO).
2. To determine the impact of oropharyngeal dysphagia on HR-QOL in this population across short and long-term time points.

The secondary objectives of this study are:

1. To determine the risk factors for post-operative dysphagia among adults post-oesophagectomy.
2. To identify the post-operative complications of dysphagia within this clinical population.

METHODS AND ANALYSIS

Study design

This is a proposed prospective longitudinal study which will be reported according to the Strengthening the Reporting of Observational Studies in Epidemiology checklist (see online supplemental appendix A).[29]

Study setting

The study will take place in a National Oesophageal Centre (NOC) where patients with a diagnosis of oesophageal cancer who are scheduled for oesophagectomy will be identified from the upper gastrointestinal (UGI) clinic. Recruitment will be completed in this clinic over a 2-year period using consecutive sampling. Adults with a diagnosis of oesophageal cancer who are due to have curative oesophageal cancer surgery within the study setting will be invited to participate in this study by an independent gatekeeper. This prospective research study will assess patients across four time points: (1) A preoperative assessment of swallow will be recorded using the Functional Oral Intake Scale (FOIS) at time of consent for this study prior to their surgery,[30] (2) on day 4 or 5 post-oesophageal resection, (3) 1-month post-surgery and (4) 6-months post-surgery. The research team will evaluate swallowing-related outcome measures across these four time points. Risk factors and post-operative complications have been selected based on research in this clinical population to date. This will create a large resource of original data, which will inform further studies targeting prevention, early detection and intervention in dysphagia.

Patient and public involvement (PPI)

PPI in research has evolved over the past decade demonstrating a positive impact on health-related research.[31] Early collaboration is known to enhance the quality and relevance of research when setting research priorities important to both the researcher and PPI, while also guiding further research.[32] This prospective longitudinal

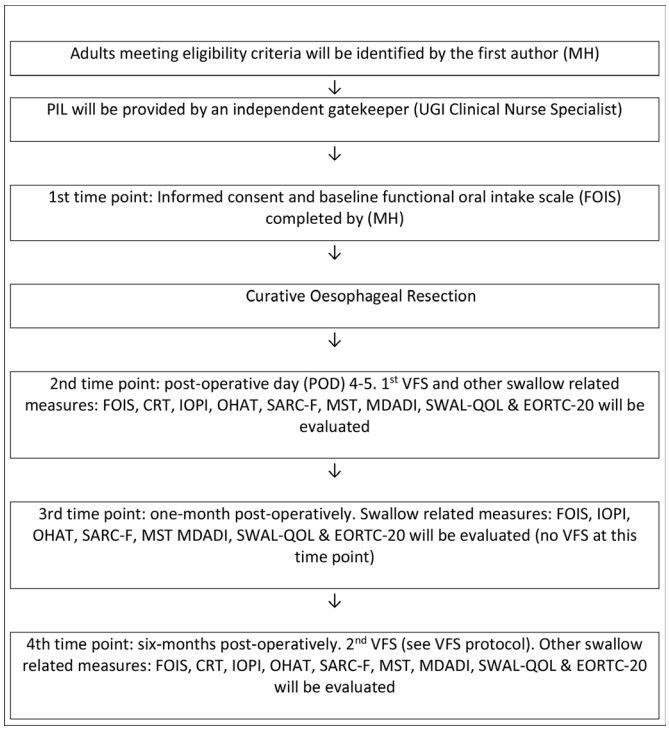

Figure 1 Study flowchart. CRT, cough reflex testing; EORTC-20, EORTC Quality of Life Questionnaire-18; FOIS, Functional Oral Intake Scale; IOPI, Iowa Oral Performance Instrument; MDADI, MD Anderson Dysphagia Inventory; MST, malnutrition screening tool; OHAT, oral health assessment tool; PIL, patient information leaflet; SARC-F, Strength, Assistance with Walking, Rise from a Chair, Climb Stairs, and Falls; SWAL-QOL, The Quality of Life in Swallowing Disorders; UGI, upper gastrointestinal; VFS, videofluoroscopy.

study has two PPI representatives (one male (SD); one female (BW)) involved on the research team, both of whom have undergone curative oesophageal cancer treatment. The PPI representatives are participating throughout the research study from the research design to dissemination. The PPI committee initially reviewed resource materials including the consent forms, patient information leaflet and rated patient-reported outcome measures (PROMs) for their relevance and ease of use. PPI involvement will be recorded using the Guidance for Reporting Involvement of Patients and the Public 2 form,[33] ensuring quality and consistency throughout the research. The PPI will be an integral part of the Knowledge Exchange and Dissemination scheme plan.[34]

Study participants

Eligibility criteria are listed below.

Inclusion criteria

- A diagnosis of oesophageal cancer as confirmed by biopsy.
- Treated with curative intent involving surgery, which may be either open or minimally invasive.
- +/− neoadjuvant/adjuvant therapy.
- Scheduled for either a transthoracic (2-stage or 3-stage) or THO.
- Adults (>18 years).
- Ability to provide informed consent as per ethical approval obtained.

Exclusion criteria

- Known metastatic disease.
- Unable to complete VFS due to post-operative complications on POD 4 or 5.
- Patients who experience prolonged intubation beyond enhanced recovery after surgery (ERAS) protocol (>2 days).
- Patients who have a tracheostomy inserted due to failed extubation, secondary to prolonged intubation or reintubated post-operatively.
- Premorbid conditions potentially causing oropharyngeal dysphagia such as an acute or progressive neurological disease, history of head and neck cancer.
- 2-stage oesophagectomy with a confirmed anastomotic leak based on failed water-soluble swallow study at POD 5.

Patient recruitment

The proposed study will recruit 60 adults with oesophageal cancer undergoing oesophagectomy for curative intent. Participants will be recruited from the NOC, at St. James's Hospital (SJH). Details on recruitment and data collection can be viewed in figure 1.

ERAS protocol

All participants will be treated according to standardised ERAS care pathway (see online supplemental appendix B),[35] involving either multimodal therapy (pre-operative chemotherapy alone or combined with radiation therapy), as per the MAGIC/FLOT or CROSS regimens, respectively, or surgery only. Surgical resection is typically performed at least 6 weeks post neoadjuvant therapy. Date of expected discharge from hospital is POD 9 as per the local oesophagectomy integrated care pathway.

Study protocol

Videofluoroscopy

The prevalence, nature and trajectory of oropharyngeal dysphagia post-oesophageal resection will be examined using VFS, a reference standard instrumental evaluation of oropharyngeal dysphagia and the evaluation of aspiration risk. Two VFS examinations will be completed on patients undergoing transthoracic (2-stage or 3-stage) and THO across two time points, immediately post-operatively (POD 4 or 5) and at 6-months post-oesophagectomy. Where a water-soluble contrast swallow study is required for inpatients post 2-stage oesophagectomy, the VFS will be completed immediately after this study, once the radiologist has ruled out an anastomotic leak. If an anastomotic leak is determined in this test, the participant will be withdrawn from the research study and the UGI clinical team informed.

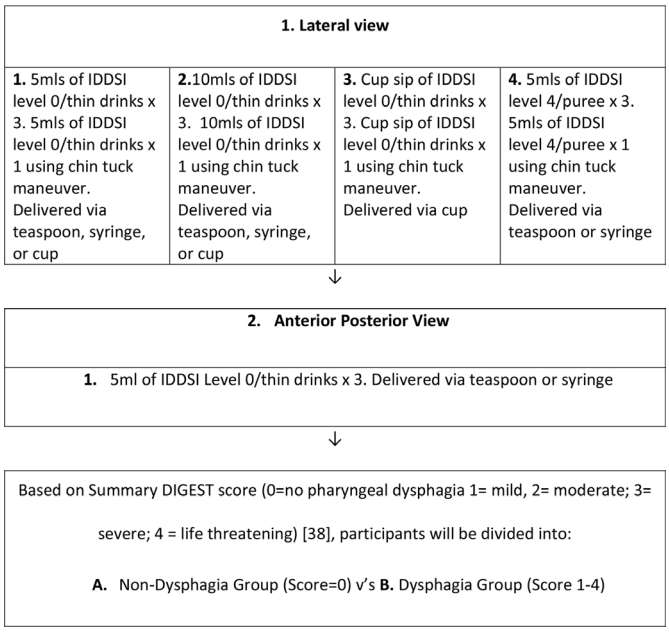

Figure 2 Videofluoroscopy protocol. DIGEST, Dynamic Imaging Grade of Swallowing Toxicity; IDDSI, International Dysphagia Diet Standardisation Initiative.

The VFS will be completed by one researcher (MH) using Siemen Axiom Luminos TF flouroscopy in the study setting: (1) post-resection on POD 4 or 5 and (2) at 6 months postoesophagectomy. The VFS pulse and frame rates will be 25 frames per second as per international recommendations.[36] Maxibar (98.45% w/w powder for oral suspension) is the contrast medium that will be used for VFS studies. This will be mixed with food and fluids to be radiopaque, assisting in determining anatomical and physiological deficits, rating the severity of oropharyngeal dysphagia and identifying aspiration risk during the study. The VFS will take approximately 20 minutes to complete. A standardised VFS protocol will be completed with participants in a seated position in lateral view followed by an anterior–posterior (AP) view as depicted in figure 2. Standardised bolus volumes and consistencies will be administered as per the International Dysphagia Diet Standardisation Initiative (IDDSI).[37]

Tongue pressure evaluation

To investigate the nature of oropharyngeal dysphagia within this population, tongue pressure will be measured at three study time points. The Iowa Oral Performance Instrument (IOPI) is a handheld device frequently employed in clinical dysphagia research which will be used to measure tongue pressure.[38] This evaluation will be conducted at the bedside (POD 4 or 5) and in outpatient clinics (1-month and 6-month time points) before the VFS examination, where relevant. Participants will be instructed to insert an air-filled bulb into the oral cavity and to use their tongue to press this bulb against their hard palate. Measures of anterior peak tongue pressure (kPa) and tongue endurance (s) will be obtained.

Cough reflex testing

To evaluate laryngeal sensation, a dose–response method of cough reflex testing (CRT) will be measured across two of the study time points (prior to VFS POD 4 or 5 and at the 6-month clinic). CRT involves inhalation of a single concentration of a tussive agent (citric acid) via a face-mask nebuliser for a fixed period (within 15 s of starting the nebuliser).[39] For best sensitivity and specificity to detect silent aspiration risk and impaired laryngeal sensation, a dosage of 0.4–0.8 mol/L of citric acid in 0.9% saline solution is recommended.[40] In this study, various increments of citric acid in conjunction with a placebo 0.9 normal saline will be administered. A cough response will be considered positive if two (C_2) or more consecutive strong coughs are triggered within the time period where citric acid is induced. A weak cough will be determined as a cough that does not appear strong to clear material from the airway and is deemed substantially weaker than their own volitional cough.[41] Patients who do not cough may indicate a greater silent aspiration risk and will be documented as a negative result. The findings of the test will be marked as a pass or fail result.

Aerodigestive symptoms

Based on feedback from the patient representatives, aerodigestive symptoms including cough and reflux are commonly experienced post-oesophagectomy and, given their strong association with swallowing, will be captured alongside swallow status in this study. The Reflux Symptom Index[42] has been selected to address this and will be administered to participants across three time points (POD 4 or 5, 1-month and at 6-months) within the research study.

Patient-reported outcome measures

Based on feedback from PPI representatives, the PROMs selected for this study include the MDADI,[43] SWAL-QOL[44] and the EORTC-18.[45] The MDADI and the SWAL-QOL are validated dysphagia-specific QOL measure which is commonly used in dysphagia research. The EORTC-18 is another PROMs developed specifically for oesophageal cancer which is frequently used to evaluate HR-QOL in oesophageal cancer research[46] (see table 1).

Primary outcome measures

VFS analysis

The primary researcher, an experienced SLT, will complete the VFS analysis. Modified Barium Swallow Impairment Profile (MBS-Imp) ratings will be used to rate the presence, severity and trajectory of any swallow pathophysiology.[47] Fifteen randomly selected VFS studies (25%) will be rerated by blinded researchers to minimise bias (AG and JR).

The following validated VFS analysis measures will be obtained:

1. MBS-Imp ratings to identify the presence, severity and nature of any swallow pathophysiology.[47] The VFS images will be analysed frame by frame and graded using

Table 1 Swallowing, nutritional and QOL measurements across all time points

Instrument	Time point 1: baseline function and consent	Time point 2: POD 4/5	Time point 3: 1 month	Time point 4: 6 months
1. Swallow screening tool (TOR-BSST)[60]		x	x	x
2. Cough reflex testing (CRT)[39–41]		x	x	x
3. Tongue pressure measurement (IOPI)[38]		x	x	x
4. Aerodigestive symptoms: Symptom Reflux Index[42]		x	x	x
5. FOIS, IDDSI, SARC-F, MST, weight and BMI[30 37 50 51]		x	x	x
6. QOL measures: ► MDADI[43] ► SWAL-QOL[44] ► EORTC-18 [45]		x	x	x

EORTC, Quality of Life Questionnaire-18; FOIS, Functional Oral Intake Scale; IDDSI, International Dysphagia Diet Standardisation Initiative; IDDSI, International Dysphagia Diet Standardisation Initiative; IOPI, Iowa Oral Performance Instrument; MDADI, MD Anderson Dysphagia Inventory; MST, malnutrition screening tool; POD, post-operative day; QOL, quality of life; SARC-F, Strength, Assistance with Walking, Rise from a Chair, Climb Stairs, and Falls; SWAL-QOL, Swallowing Quality of Life questionnaire.

the standardised MBS-Imp to identify the presence, severity and nature of swallow pathophysiology across 17 components. The components closely examine physiological components including the oral, pharyngeal and oesophageal phases of swallowing via lateral and AP radiological positioning during VFS. Please see table 2.

2. Penetration-Aspiration Scale (PAS) ratings to measure swallow safety and cough response to aspiration across all swallows.[48] The validated PAS will be used to evaluate aspiration and cough response to penetration and aspiration. This is an 8-point ordinal scale, which characterises the depth and response to airway penetration/aspiration during a VFS study.
3. Dynamic Imaging Grade of Swallowing Toxicity (DIGEST) score[49] will be used to stratify participants into dysphagia and non-dysphagia subgroups.

Table 2 Modified Barium Swallow Impairment Profile analysis components[47]

Number	Physiological component
1	Lip closure
2	Tongue control during bolus hold
3	Bolus preparation/mastication
4	Bolus transport/lingual motion
5	Oral residue
6	Initiation of pharyngeal swallow
7	Soft palate elevation
8	Laryngeal elevation
9	Anterior hyoid excursion
10	Epiglottic movement
11	Laryngeal vestibular closure
12	Pharyngeal stripping wave
13	Pharyngeal contraction (AP view)
14	Pharyngoesophageal segment opening
15	Tongue base retraction
16	Pharyngeal residue
17	Oesophageal clearance (AP view)

AP, anterior–posterior.

Secondary outcomes

Risk factors

The data on risk factors and post-operative complications will be obtained from participants' medical charts and from a local research database. Potential predictor variables will include: (1) age, (2) gender, (3) pre-surgical chemo/radiation, (4) tumour staging, (5) tumour type (squamous cell carcinoma/adenocarcinoma), (6) surgery type, (7) surgery duration (measured in hours), (8) RLN damage, (9) presence/degree of sarcopaenia using the Strength, Assistance With Walking, Rise From a Chair, Climb Stairs, and Falls,[50] (10) malnutrition (weight, body mass index (BMI), >10% wt loss and malnutrition screening tool,[51] (11) oral health assessment tool and (12) number of co-morbidities.

Post-operative complications

Post-operative complications data will be collected from medical records and post-oesophagectomy database at outpatient appointments (1-month and 6-month clinic). Data will be obtained on (1) length of stay in the Intensive Care Unit (ICU) (days >3 days); (2) time to oral intake (days >5 POD); (3) tube feeding duration (days> 30 days post discharge); (4) presence of pneumonia as per American Thoracic Society (ATS) post-operative pneumonia score[52] (as per local UGI database) (yes/no); (5) oesophageal strictures±dilatation/stenting; (6) mortality/survival rates; and (7) other complications as per the Esophageal Complications Consensus Group definitions.[10]

Pneumonia

PPCs, primarily pneumonia, is a common post-operative complication, which may be infection associated or complicated by respiratory failure or acute respiratory distress syndrome (ARDS).[53] The risk is greater in patients with existing chronic obstructive pulmonary disease or in current smokers.[53] Other risk factors include age, gender, total number of lymph nodes resected and operation approach (transthoracic extended).[54] The ATS post-operative pneumonia score will be used to determine pneumonia in post-oesophagectomy patients. The ATS define hospital-acquired pneumonia as a pneumonia not incubating at the time of hospital admission, occurring >48 hours or more after admission whereas ventilated-acquired pneumonia is determined >48 hours post endotracheal intubation.[55] Pneumonia is suspected if the patient has radiographic infiltrates that is new or progressive in association with the following clinical findings suggestive of a pneumonia include: (1) new onset of fever, (2) purulent sputum, (3) leukocyosis and (4) a decline in oxygenation.[55] As pneumonia is the most prevalent complication post-oesophageal resection, research supports assessing patients for any swallowing dysfunction or predisposition to aspiration prior to commencing oral intake to reduce risk of post-operative complications and mortality.[56] As the prevalence, nature and trajectory of oropharyngeal dysphagia has not been determined in a prospective longitudinal study, its link and impact on pneumonia rates postoesophageal cancer surgery are relatively unknown.

Study size

This is an exploratory longitudinal study in an area with limited previous research or group comparisons and no reporting of effect size. Based on previous literature in this cancer cohort to estimate an effect size 0.5 at a significance level of 0.05 and a power of 0.8, a sample size of 60 is calculated for repeated measures. This sample estimate is consistent with other publications in this area.[57 58]

Data analysis

SPSS V.22.0 will be used for statistical analyses.[59] Variables will be tested for normality using the Shapiro-Wilks test. Normally distributed variables will be summarised as mean and SD. Non-normally distributed data will be summarised as median and IQR. Categorical variables are presented as frequency (percentage). To establish changes in participant swallow outcomes across time points, repeated measures will be performed using repeated measures analysis of variance or Friedman tests.

To identify independent risk factors, multiple logistic regression will be performed. To identify complications of dysphagia, mean/median (depending on distribution of data) differences in length of hospital stay, pneumonia, sarcopaenia, tube-feeding reliance, mortality and QOL will be compared across dysphagia and non-dysphagia subgroups. The VFS protocol outlined includes a robust system of validated measures to detect oropharyngeal dysphagia in this patient group. A strict data management plan includes data being stored securely, anonymously and processed in adherence to the general data protection regulator best practice guidelines in line with ethical approval.

Ethics and dissemination

Ethical approval has been obtained from the SJH-Tallaght University Hospital (TUH) Joint Research Ethics Committee (J-REC) (2021-Jul-310), alongside the SJH Research and Innovation (R&I) committee. The patient will be formally enrolled into the research study if meets the research criteria and informed consent has been obtained. The primary researcher (MH) involved will eliminate any potential risks to the participant. During the procedure, the patient may be at risk of aspiration if oropharyngeal dysphagia post-oesophagectomy is present. The researcher will inform the patient, refer to inpatient Speech and Language Therapy and Physiotherapy team and notify the UGI Surgeons. The Radiology department where the VFS will take place is located within SJH and is covered by the hospital response team. All adverse events will be documented, and any serious adverse incidences will be immediately reported to the patients' surgical team and to the research ethics committee.

Findings of the prospective longitudinal study will be disseminated via conference presentations including the World Dysphagia Summit, Dysphagia Research Society, The European Society of Swallowing Disorders and the International Society of Diseases of the Esophagus conference. The findings will be published in peer-reviewed academic journals. Study participants will be informed of study results.

DISCUSSION

Data collection and analysis will be completed at a NOC, where approximately 55–60 curative oesophageal resections are completed annually. This research study has not received any specific grants from funding agencies, and no known competing financial interests or personal conflict that could appear to influence the nature of this research has been declared.

As survival rates are improving among adults with oesophageal cancer, there has been a shift in research and clinical focus to optimise HR-QOL among survivors. Dysphagia is strongly associated with HR-QOL in this population, but relatively understudied in terms of prevalence and modifiable intervention target, and the studies proposed will provide comprehensive data on this cohort and inform further research and clinical advances in this context. Physiological changes impacting the oropharyngeal swallow across four separate time points will be determined using rigorous reference standard and validated swallowing assessment tools. A robust study design will be implemented, using a broad range of clinical swallowing outcomes. This will be examining the prevalence, nature

and trajectory of oropharyngeal dysphagia following oesophagectomy.

PPI will be a key strength in this research study. Patients' previous experience of the oesophageal cancer journey will provide invaluable insight and guidance across different time points in the study. Furthermore, the collaboration between the researcher and committee members will strengthen research priorities set out and aim to meet at different intervals throughout the research cycle within this study.

This study has some limitations that we acknowledge. Firstly, the risk of post-operative complications including ARDS,pneumothorax, risk of re-intubation, delirium, anastomotic leak who require medical interventions, will prevent recruitment into this study. Failure to collect data on patients with complex post-operative needs who may potentially present with an oropharyngeal dysphagia is recognised as a limitation. Patient retention may be challenging due to the increased risk of cancer recurrence in this population, ultimately impacting their ability to participate during the different time points. For this reason, it was decided to recruit patients up to 6-months post-resection rather than 1-year following oesophagectomy. The author acknowledges that the 6-month timeframe may not fully capture swallowing impairment and QOL measures following surgery, however this research group is also conducting another major study, examining the prevalence, nature and impact of dysphagia 1-year post-oesophagectomy and into survivorship.

This longitudinal study will create a large database encompassing detailed information about the presence, nature and trajectory of dysphagia in the post-oesophagectomy setting, its link to other complications and its impact on recovery of QOL. The database will inform the development of intervention programmes tailored to the unique needs of people with oesophageal cancer. The results will provide a large resource of original data and inform further studies targeting prevention and early intervention. Furthermore, the findings may target development of swallowing compensatory strategies and rehabilitation therapy to optimise swallow function and safety. The results may further inform current clinical practice and provide direction for future research.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

St. James's Hospital

SACC Directorate Service Title

Critical Care Units

Oesophagectomy care following *Enhanced Recovery after Surgery (ERAS) Pathway No.*

Protocol Number SACC 036

Owner: CNM2 ICU/HDU Ann-Marie Duff	**Approved by:** Professor John V. Reynolds
Reviewed by: CNM 2 Bennetts ward. B Waterhouse CNM 3 Theatre S Budoiu Practice Development ICU/HDU: D Doyle Physiotherapist: N Keohane	**Effective from:** April 2022 **Revised:** March 2022 **Revision due**: April 2025 **Document History:** Version 1: January 2010 Version 2: April 2022

This protocol replaces all existing protocols/guidelines from April 2022 onwards and is due for review in April 2025. It will be reviewed during this time as necessary to reflect any changes in best practice, law, and organisational, professional or academic change.

Distributed to:

Clinical Lead Critical Care: Dr JD Coakley

Assistant Director of Nursing (ADON) Critical Care: Ms R Gilligan

Assistant Director of Nursing (ADON) Theatre: Ms M O'Brien

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Disseminated on the intranet: Insert Link

1.0 Introduction

St. James's Hospital is committed and acknowledges its responsibility to provide evidence based, quality, safe and effective healthcare to all of its patients/clients, staff and site visitors. Oesophagectomy is the surgical resection of oesophageal neoplasm through an abdominal incision and right thoracotomy. The anastomosis is located in the upper chest.

The surgical management of oesophageal cancer represents a complex and challenging problem. **Enhanced Recovery after Surgery (ERAS)** is a paradigm shift away from the more traditional surgical vision to that of one that encompasses the multidisciplinary approach. ERAS attempts to standardise care that reflects International best practice. This multimodal approach is thought to improve perioperative care, reduce complications and ultimately mortality and accelerates patient recovery. In doing so it decreases the economic burden associated with longer hospital stays and a quicker return to a functional baseline for the patient. Academic experts in each discipline of surgery grade the available evidence and provide recommendations for future practice.

The ERAS components discussed here encompass a Preoperative, Intraoperative and Postoperative approach to oesophagectomy surgery with the intention for seamless integration a priority.

The ideal ERAS protocol has seamless integration of all three components. ***Table 1***

- Preoperatively patient optimisation is key.
- The surgical approach and anaesthetic management in the intraoperative section are integral to minimise surgical insult and reduce the impact on physiology.
- Postoperatively early removal of drains/lines, early mobilisation, early enteral nutrition and adequate analgesia are important.

Table 1

Preoperative	**Intraoperative**	**Postoperative**
Multidisciplinary team discussion with appropriate workup	Surgical approach	Adequate analgesia with opiate limitation to lowest effective dose.
Prehabilitation	Anaesthetic management	Early mobilisation
Cardiorespiratory assessment at Pre- Assessment clinic	Lung protective ventilation	Early removal of drains/invasive lines
Patient counselling & education	Perioperative fluid management	Postoperative nausea & vomiting management
Smoking & alcohol cessation	Hypothermia management	Tight glycaemic control
Venous thromboprophylaxis	Limitation of blood products	Early enteral feeding
Suitable fasting time and carbohydrate loading.		

2.0 Scope

This protocol is applicable to all members of the multidisciplinary team caring for patients undergoing oesophagectomy surgery on the St. James's Hospital site.

3.0 Definitions/Abbreviations:

- **ABG:** Arterial blood gas
- **APTT:** Activated Partial Thromboplastin time.
- **ASA stage:** American Society of Anaesthesiologist's physical classification stage. Used pre-operatively/ pre anaesthesia to communicate a patient's pre-morbid state or if co-morbidities are present.
- **BMI:** body mass index
- **Cardiac ejection fraction:** ejection fraction is a percentage of blood ejected in each cardiac cycle and is a representation of left ventricular performance. It is calculated by the end diastolic and end systolic volumes of the left ventricle.
- **CXR:** chest x-ray

- **DLCO:** diffusion capacity for carbon monoxide. Also known as the transfer factor. It is the extent to which oxygen passes from the alveoli in the lungs into the blood stream.
- **EPR:** Electronic Patient Record (Cerner) used in ward areas
- **EUS:** Endoscopic ultrasound
- **FEV1:** Forced expiratory volume of air in 1 second of maximal expiration after a maximal inspiration. FEV1/FVC: FVC is forced vital capacity. FEV1/FVC is expressed as a ratio. It is useful to analyse airflow limitation/obstruction.
- **FiO2:** Fraction of inspired oxygen
- **ICCA** Intellivue Critical care & Anaesthesia**:** The electronic patient record used in Critical Care.
- **NSAID's** Non-Steroidal Anti Inflammatory Medications
- **Oesophagectomy Three–Stage:** The technique is the same as a two-stage oesophagectomy with the addition of a neck incision. This is performed to facilitate mobilisation of higher tumours: choice of operation depending on the location of the tumour.
- **Oesophagectomy Transhiatal:** If a patient's pulmonary function does not allow for a thoracotomy, and in some patients with an early tumour, a transhiatal approach is the preferred technique as this avoids a thoracotomy. This involves both an abdominal and neck incision. The intra-thoracic part of the oesophagus is bluntly dissected away from the adjacent thoracic structures. The stomach is refashioned and passed up through the chest where it is anastomosed in the neck.
- **Oesophagectomy Two–Stage:** This involves an abdominal incision and a right thoracotomy incision. The mid and lower parts of the oesophagus are removed along with the upper part of the stomach. The stomach is refashioned into a tube to replace the oesophagus. A thoracotomy follows and the oesophagus is divided in the chest. The stomach is anastomosed to the oesophagus in the chest cavity. One chest tube with underwater sealed drain is placed and will remain in situ post-operatively.
- **OLV:** One lung ventilation.
- **PET:** Positron emissions scan.
- **PF Ratio:** The P/F ratio is an objective tool to identify acute hypoxemic respiratory failure at any time while the patient is receiving supplemental oxygen. The P/F ratio equals the arterial pO2 ("P") from the ABG divided by the FiO2 ("F") – the fraction (percent) of inspired

oxygen that the patient is receiving expressed as a decimal (e.g., 40% oxygen = FiO2 of 0.40).

- **PFT:** Pulmonary function test.
- **POD:** Post-operative day
- **PT:** Prothrombin time.
- **SLT:** Speech and language therapy/therapist
- **TIVA:** Total intravenous anaesthesia. A technique of anaesthesia which uses a combination of agents given exclusively by intravenous route without the use of inhalational agents.
- **UGI team:** Upper Gastrointestinal Team.

4.0 Standards

4.1. Pre-operation assessment completed by Pre-Op Assessment Nurse, UGI team and Anaesthetist. Record if the following are applicable or not.

- Full work-up as per multidisciplinary team i.e. pathology, oncology, radiation oncology and surgical input staging/EUS/PET as indicated
- Known drug allergies documented
- Pre-op patient information provided in clinic (word/written format)
- Chemotherapy or Radiotherapy and chemotherapy combined treatment prior to surgery
- Clinical Trial patient
- Prehabilitation
- Pre-operative Assessment Clinic
- If on anticoagulation, ensure appropriate bridge to surgery is prescribed.
- **Thromboprophlaxis:** As per European Guideline recommendations ensure all patients receive intermittent Pneumatic device (IPC) intra op and that anticoagulation is stratified in low risk and high risk patients. Administration of low molecular weight heparin (LMWH) 3000 to 4000 anti-xa international units (IU) administered subcutaneously 12 hourly in patients with a BMI of over 40 kgm^2 is advised. This decision is made prior to theatre.

- PFTs: FEV 1 (L); FEV1/FVC (%; DLCO (%)

- Cardiac ejection fraction
- APTT, PT and platelet count.
- ASA stage.
- Pre-op weight and BMI - document in notes
- Bloods to include: Hb, Albumin, Creatinine
- SpO2 on room air
- ABG on room air/pre surgery in patients with respiratory co-morbidity.

4.2. Pre-operative Oral Fluids and Fasting: Care administered by ward nurse's unless otherwise stated.

4.2.1. Avoid Oral fluids in dysphasic patients unless enteral route is available.

4.2.2. Clear fluids allowed up to 2 hrs pre-surgery if no dysphagia.

4.2.3. **No food for 6 hours** pre induction of anaesthesia

4.2.4. Administer **Chlorhexidine 0.12% mouthwash** e.g. KIN™ the night before & morning of surgery.

4.2.5. Carbohydrate loading drink e.g. 'Preload' provided the night before and morning of surgery. The Carbohydrate drink is prescribed by UGI team on EPR per ***Table 2.*** These sachets will be kept on Bennett's ward and/or Private ward.

Oral Carbohydrate drink administered by nursing staff		
Preload Sachet(s)	**Evening/Night before surgery**	2 x Preload sachets in 400mls
	Morning of surgery	1 x Preload sachet in 400mls up to 2 hours prior to induction of anaesthesia

Table 1

4.3. Induction: The Anaesthetist is responsible for recording the interventions below on the Anaesthetic Record Sheet (Form no WMN00041).

4.3.1. **Airway**

- Grade of intubation:
- Time spent with Double Lumen tube.

4.3.2. **Ventilation** intraoperatively to include the following:

- Mode of ventilation recorded throughout procedure:
- Was a lung protective strategy used
- Tidal volume and level of peep (mean) used during procedure
- Driving pressures used
- Time spent in OLV
- Highest level of FiO2 used:
- Lowest SpO2 recorded.
- Detail any episode of hypoxaemia including duration in minutes.

4.3.3. **Circulation:**

- Was Advanced haemodynamic monitoring used e.g. Flotrac™
- Volume of IV Fluids administered including bolus.
- Blood products administered including Type and Volume
- Vasopressor or inotrope include Drug administered, maximum in dose and duration of therapy.
- If high risk for cardiac arrhythmia record the treatment and/or medication prophylaxis used.

4.4. Intraoperative Anaesthesia: The Anaesthetist is responsible for recording the interventions below on the Anaesthetic Record Sheet (Form no WMN00041).

- Pre-op medication
- Volatile agent
- T.I.V.A used
- Spinal Morphine State time and dose.
- Magnesium
- Nitrous oxide
- Remifentanil
- Ketamine infusion (If required use low dose, may be beneficial if history of chronic pain)
- **Epidural** Content and rate. Ease of placement of epidural: 1st pass, 2nd pass?

- Where an **Epidural is NOT used**; state adjunct analgesia administered.
- State if **Paravertebral block** or **Rectus sheath catheters** were considered if epidural is not used.

4.5. Post Op Theatre Recovery Area:

The Recovery area nurse administers and records the interventions below until handover to Critical Care nursing staff (see 4.6).

4.5.1. Administer high flow humidified oxygen via nasal prongs e.g. *AIRVO®*.

4.5.2. Perform ABG within 15 minutes of extubation recording FiO2

4.5.3. Epidural Drug (s) & Rate; Aim for rate of 10 ml/hour.

4.5.4. PCA Fentanyl is the drug of choice unless otherwise indicated. State rate and lockout period.

4.5.5. Administer Shoulder tip pain care as a bundle as described below as proposed standard of care.

4.5.6. Paracetamol 1g IV, Ondansetron 4mg IV & Clonidine*, discuss appropriate Clonidine low dose with anaesthetist.

4.5.7. Be vigilant for hypotension with co-administration of opioid and clonidine.

4.5.8. **Anti-emetics:** Commence Post-Operative Nausea and Vomiting (PONV) pathway with Cyclizine 50mg; then escalate to Ondansetron 4mg as standard. NB: Ondansetron 4mg is given in the shoulder tip pain bundle. If total of 8mg is given, escalate only as per anaesthetic advice.

4.5.9. Avoid additional Dexamethasone unless clinically indicated as directed by anaesthesia.

4.6. Immediate Post Op Transfer and Recovery Handover to Critical Care Team

Anaesthetic and theatre recovery nursing staff hand over care of patient together to the critical care team to include the following:

4.6.1. Surgical approach

4.6.2. Extubation time

4.6.3. Humidified High Flow Oxygen/Flow settings and start time i.e. *AIRVO®*

4.6.4. IF CXR is completed and/or reviewed. If reviewed, by whom.

4.6.5. Total fluids administered intraoperatively and prior to transfer:

4.6.5.1. Blood products administered & number of units

4.6.5.2. Estimated blood loss.

4.6.5.3. Fluid balance at the end of case.

4.6.6. Circulation and/or Renal issues or concerns.

4.6.7. Chest drains, pleural drains and Jejunostomy and all invasive devices.

4.6.8. ICU medical team to document if difficult airway during anaesthesia on ICU admission. Reintubation for standard indications. If the patient develops respiratory failure, then high flow oxygen may be used. Non-Invasive ventilation **is not** to be used in 3 stage oesophagectomy. Please discuss with surgical team prior to commencing non-invasive ventilation.

5.0 Standards for Postoperative care: Overview of specific care targets for the multidisciplinary team.

5.1. Complete patient admission assessment and 12 hourly assessments thereafter or if condition changes.

5.2. Implement continuous patient monitoring as per ICU standards. Frequency of vital Signs monitoring in ward areas is directed by the Early Warning Score and/or the UGI team.

5.3. Pain Management:

5.3.1. Target pain score less than 4 on moving, deep breathing and coughing.

5.3.2. If standard post-operative analgesia is insufficient consider consulting pain team for advice/consult.

5.3.3. If an epidural is in situ, perform pain assessment on admission and complete all care in accordance with **Epidural Analgesia - Nursing Management Protocol No. SJH: ORIAN(Pt)022**
https://www.stjames.ie/intranet/ppgs/clinicaldirectorates2/ORIANPt022.pdf

5.3.4. Epidural pain relief may be inadequate for a 3-stage oesophagostomy; Levobupivicaine Epidural combined with a PCA opioid intravenously may be

required. In general, the Epidural must not contain an opioid in this instance unless specified by Consultant Anaesthetist/Pain Team. Refer to

5.3.5. **Patient Controlled Analgesia (PCA) - Nursing Management Protocol SJH: SACC-021** https://www.stjames.ie/intranet/ppgs/clinicaldirectorates2/SACC021.pdf

5.3.6. If TEA is not used, please record adjunct modality used (e.g. Rectus sheath catheter, spinal morphine) on ICCA and/or EPR.

5.3.7. Administer Intravenous Paracetamol as prescribed. Advise 6 hourly unless contraindicated.

5.3.8. Monitor Renal Function: If Creatinine has increased with no background renal history avoid the use of NSAID's

5.3.9. Implement non-pharmacological methods to relieve pain as indicated e.g. patient positioning, pillow for splinting abdominal wound when coughing and deep breathing.

5.3.10. If the patient is ventilated, please record CPOT in ICCA.

5.4. Respiratory Management:

5.4.1. The risk of respiratory complications is substantial after any oesophageal surgical procedure.

5.4.2. Maintain adequate oxygenation via humidified high flow Oxygen to Target oxygen saturations of >94% and/or PaO2> 10kPa unless otherwise specified.

5.4.3. Maintain patient in an upright position ≥45°and encourage deep breathing and coughing exercises hourly.

5.4.4. Portable chest X-ray to be performed on admission unless completed in recovery. Repeat Chest X-ray for first three days only. Subsequent CXR's should only be ordered dependant on clinical scenario.

5.4.5. Administer nebulised bronchodilators as prescribed if sputum retention is a problem.

5.4.6. Suction only as indicated by patient assessment. Avoid suctioning patient orally or via nasal airway, especially if neck anastomosis is in place.

5.4.7. Mobilise the patient with physiotherapy input the morning after surgery provided the patient is haemodynamically stable and pain is controlled.

5.4.8. Liaise with the respiratory physiotherapists who must review the patient twice daily for 1st 5 days then once daily.

5.4.9. Provide care as per **Chest Drain - Nursing Management Protocol SJH:N:016** including chest clamps (metal) at the bedside) https://www.stjames.ie/intranet/ppgs/clinicalsupport/SJHN016.pdf

5.4.10. **Observe closely for clinical signs of respiratory distress, respiratory rate, work of breathing and/or increasing oxygen requirements**: If noted

5.4.10.1. Consult with ICU team and/or UGI immediately.

5.4.10.2. Inform CNM /Senior Nurse in charge.

5.4.10.3. Urgent referral to Physiotherapist/ On-Call Physio if necessary.

5.4.10.4. Record and highlight increasing Oxygen requirements.

5.4.10.5. Perform ABG analysis. Ensure P/F ratio is recorded.

5.4.10.6. If clinically indicated a repeat CXR is ordered.

5.4.10.7. If suspicion of pulmonary complications e.g. purulent secretions and/or temperature; send a full set of cultures to Microbiology (unless cultures were sent in the previous 24 hours.)

5.4.11. Ensure anticoagulation is administered (unless contraindicated).

5.4.12. If >300ml fresh blood loss into chest drain per hour contact UGI team.

5.4.13. Please ensure pleural drain Is secured. If for any reason bag needs to be unattached clamp drain and make sure to unclamp drain once bag is securely re-attached.

5.4.14. Monitor the patient for subcutaneous emphysema. If subcutaneous emphysema is present, check chest drain for patency and for air leak.

5.4.15. Thoracic suction is rarely needed but use at 3.5 –5kPa if pneumothorax, subcutaneous emphysema, or air leak (bubbling) is present. ICU Anaesthetic team or Surgical team orders thoracic suction.

5.4.16. Non-invasive Ventilation (NIV) if necessary is used with caution after consultation with ICU consultant and UGI team. To be avoided in high anastomosis i.e. 3-stage. Can be used in 2 stage but please consult with surgical team. General safe principle is to re-intubate early rather than persist with NIV if patient clearly tiring and deteriorating.

5.5. Cardiac Management:

5.5.1. Maintain continuous invasive haemodynamic monitoring and observation. Report any deviation/changes in vitals to ICU team in Critical Care. Increase frequency to half hourly if haemodynamically unstable.

5.5.2. Monitor & report cardiac arrhythmias. Perform 12 Lead ECG

5.5.3. Report Temperature >38.5º C.

5.5.4. Daily Blood Tests: ICU admission set to include FBC, Coagulation, ICU profile and liver function tests. Monitor results and report abnormalities.

5.5.5. Monitor electrolytes in particular monitor potassium and magnesium levels and replace as necessary.

5.5.6. Ensure prophylactic pharmacological DVT therapy has been ordered. If pharmacological prophylaxis is contraindicated use intermittent pneumatic compression device.

5.6. Fluid Optimisation:

5.6.1. IV fluid maintenance prescribed on admission.

5.6.2. Ensure strict fluid intake/output is recorded hourly including nasogastric aspirate and chest tube drainage.

5.6.3. If patient requires fluid boluses; monitor closely for signs of fluid overload and bring to the early attention of the ICU Medical or UGI teams.

5.6.4. Observe fluid balance. If trending into a positive balance bring to the early attention of the ICU Medical or UGI teams.

5.6.5. Record Daily weights. The ICU bed scale is zeroed pre admission (where available). Alternatively weigh using SECA seated scales or Hoist.

5.6.6. Notify ICU Medical Team/UGI team if urine output is <0.5ml/kg/hr for two consecutive hours.

5.7. Gastro-Intestinal Tract (G.I.T)

5.7.1. Patients are nursed with head up 45º.

5.7.2. Where possible the patient should not be laid flat. Patients are at risk of gastric reflux and aspiration post-surgery due to sphincter incompetence and because the stomach now lies in the thorax. Risk of aspiration is greater in 3-stage resection or transhiatal techniques: i.e. neck anastomosis.

5.7.3. Assess abdomen for distention, rigidity, pain and tenderness & auscultate for bowel sounds on admission and every shift.

5.7.4. Keep patient nil by mouth until otherwise directed by the UGI team. The stomach must be kept empty as patients are at high risk of gastric reflux and aspiration.

5.7.5. Patients will have a Nasogastric tube and a Jejunostomy tube inserted at the time of surgery.

5.7.6. The **Nasogastric tube** will be sutured in place;

5.7.6.1. Do not manipulate. **If it becomes dislodged inform UGI team; do not reinsert.**

5.7.6.2. Naso-gastric tube is maintained on free drainage and gentle aspiration 6 hourly.

5.7.6.3. Monitor for amount and colour of drainage and patency of Naso-gastric tube. Report large amounts of drainage, presence of blood and changes in colour to surgical team.

5.7.6.4. Do not flush unless surgically advised (not as standard of care).

5.7.6.5. No medications are to be administered via the Naso-gastric tube.

5.7.7. The Jejunostomy tube will be sutured in place.

5.7.7.1. If it becomes dislodged inform UGI team; do not reinsert.

5.7.7.2. Maintain patency of Jejunostomy tube; Flush prior to use and once a shift or as directed by the surgeons. Keep clamped when not in use.

5.7.7.3. Avoid administering medication via Jejunostomy unless approved by the UGI team.

5.7.7.4. If enteral medications are required they are administered via the jejunostomy tube i.e. not via nasogastric tube.

5.7.7.5. STRICTLY NO PPIs via Jejunostomy tube. Administration of Proton Pump Inhibitors or H2 antagonists is not required. The patient has had a vagotomy and therefore will not be at risk of increased gastric acidity.

5.7.7.6. Do not administer Magnesium Verla™. If Magnesium replacement is required, administer via IV route.

5.7.7.7. If any a medication is administered flush Jejunostomy tube with Sterile Water 50mls pre and 50mls post administration.

5.7.7.8. See **Information for Ward Staff on the 8Fr Argyle Surgical Jejunostomy Feeding Tube on the ICU intranet – Clinical reference.** **https://www.stjames.ie/intranet/oncampus/departments/intensivecareunit/clinicalreferencecribcards/ICUHDU,Information,on,the,8Fr,Surgical,Jejunostomy,Feeding,Tube,2018.pdf**

5.7.8. Ensure strict oral care as per patient assessment to promote patient comfort and reduces risk of oral mucosa breakdown, colonisation by hospital bacteria and infection. Chlorhexidine 0.12% Mouth wash is administered TDS for 3 days.

5.7.9. Enteral feeding commences via Jejunostomy at 08:00hrs the morning after surgery.

5.7.9.1. Commence feeds at 30ml/hr and increase as ordered by the clinical nutritionist.

5.7.9.2. Reduce IV fluids by the same increment as the increase in enteral feeds.

5.7.9.3. Aim to have 100% of fluid and caloric intake within 1st 48hrs post-surgery.

5.7.9.4. If intolerance to jejunostomy feeding occurs; stop feed and inform the UGI team.

5.7.10. Monitor blood sugar levels on admission and 12 hourly thereafter. Monitor 6 hourly if known diabetes mellitus or on TPN.

5.7.11. If Blood sugar elevated above 7.1 – 9 mmols/L in Critical Care, inform ICU Medical team. Insulin administration is provided as per **Intravenous Insulin Therapy Management in Critical Care Patients Protocol SJH:SACC013** https://www.stjames.ie/intranet/ppgs/clinicaldirectorates2/SJHSACC013.pdf

5.7.12. Wound Care: Initial dressing change after 48 hrs then every 7 days PRN.

5.7.12.1. Advise transparent dressing e.g. Opsite™ Grid to ensure visualisation of wound.

5.7.12.2. Send a swab to microbiology if suspicion of infection.

5.8. Psychological Care

5.8.1. Provide Psychological support and reassurance to the patient.

5.8.2. Assess level of family support and involvement. Ensure the patient and their relatives are informed and involved as much as possible.

5.8.3. Ensure visits from Cancer Co-ordinator are facilitated.

5.8.4. Refer to the Social Work Department if required.

6.0 **POD 0:**

Nursing staff complete interventions unless stated otherwise. **Refer to Section 5.0.** If any deviations from baseline refer to the ICU Medical Team without delay.

6.1. Administer high flow humidified oxygen e.g. *via Airvo®*. Titrate to target saturations.

6.2. If for any reason CXR was not performed in recovery after surgery please order.

6.3. Elevate the Head of the bed to 45 degrees as much as tolerated.

6.4. Monitor and record output from underwater seal & pleural drains.

6.5. Suction only as indicated by patient assessment.

6.6. Perform ABG recorded with P/F ratio.

6.7. Order & send bloods & admission screens as standard to include Albumin, Hb, CRP and LFTs.

6.8. Assess effectiveness of epidural therapy. If ineffective contact the ICU Medical team immediately for review

6.9. If pain relief remains ineffective 2 hours following an epidural top-up i.e. Pain Score ≥ 4, request a further review by ICU medical team.

6.10. Ensure patency of Nasogastric & Jejunostomy tubes.

6.11. Perform oral assessment & care as prescribed e.g. Chlorhexidine 0.12% TDS.

6.12. Administer Enoxaparin as prescribed unless clinically indicated otherwise. If withheld record in ICCA.

6.13. Pressure relieving mattress as per Braden Scale.

7.0 POD 1:

Nursing staff complete interventions unless stated otherwise. **Refer to Section 5.0.** If any deviations from baseline refer to the ICU Medical Team without delay.

7.1. Administer high flow humidified oxygen titrate to effect e.g. *via Airvo®*.

7.2. Start enteral feeding regime at 08:00 as documented by dietician notes.

7.3. CXR ordered and reviewed by the ICU Medical Team.

7.4. Order & send routine ICU bloods to include albumin, Hb, CRP and LFTs and Creatinine.

7.5. Record Daily weight.

7.6. Strict Intake Output Monitoring. Avoid positive fluid balance.

7.7. Assess effectiveness of the epidural/paravertebral block/rectus sheath catheter to provide analgesia prior to physiotherapy session i.e. ideal self-reported pain score of less than < 4/10.

7.8. Early Mobilisation: Sit patient out of bed **by 11am** unless clinically indicated otherwise (Nursing staff ± Physiotherapist). Target:

7.8.1. Standing & Marching on the spot.

7.8.2. Goal; walking 60-100 metres twice a day.

7.8.3. Sitting out in the chair as tolerated

7.8.4. If targets are not achieved document reason why in ICCA.

7.9. Perform oral assessment & care as prescribed (e.g. Chlorhexidine 0.12% TDS)

7.10. Discuss the following with the ICU Medical Team:

7.10.1. Reducing Epidural infusion rate by 25% of current dose.

7.10.2. Reducing or discontinuing IV fluids

7.11. Administer Enoxaparin as prescribed unless clinically indicated otherwise. If withheld record in ICCA.

7.12. Initial antibiotic dose given intra-op followed by two doses in the post-operative period. Please ensure prescription is discontinued after three doses unless clinically indicated otherwise.

7.13. Assess devices for removal daily.

8.0 **POD 2:**

Nursing staff complete interventions unless stated otherwise. **Refer to Section 5.0.** If any deviations from baseline refer to the ICU Medical Team without delay.

8.1. Wean High Flow humidified Oxygen: If feasible switch to low flow oxygen via nasal prongs.

8.2. CXR ordered and reviewed by the ICU Medical Team.

8.3. Order & send daily bloods to include CRP, Albumin, Creatinine & LFTs.

8.4. Strict Intake Output Monitoring. Avoid positive fluid balance.

8.5. Record daily weight.

8.6. Perform oral assessment & care as prescribed i.e. Chlorhexidine 0.12% TDS.

8.7. Assess effectiveness of the epidural/paravertebral block/rectus sheath catheter to provide analgesia i.e. ideal self-reported pain score of less than < 4/10.

8.8. Mobilisation: Sit patient out of bed **by 11am** unless clinically indicated otherwise (Nursing staff ± Physiotherapist). Goal:

8.8.1. Standing & Marching on the spot.

8.8.2. Walking 60-100 metres twice a day.

8.8.3. Sitting out of bed as tolerated

8.8.4. If goals are not achieved document reason why in ICCA.

8.9. Consult with UGI team if UWSD can be removed today. **The UGI team must write a note on EPR to this effect.**

Assess devices for removal daily.

9.0 **POD 3:**

Nursing staff complete interventions unless stated otherwise. **Refer to Section 5.0.** If any deviations from baseline refer to the ICU Medical Team without delay.

9.1. Aim for discharge to the ward on POD 3. If unable to discharge continue to target goals as tolerated.

9.2. Continue weaning oxygen as tolerated.

9.3. Perform oral care. Chlorhexidine 0.12% mouthwash TDS e.g. Kin™ is discontinued this evening.

9.4. Order daily bloods to include CRP and Liver function tests.

9.5. Order CXR. This should be the last day a routine CXR is ordered unless clinically indicated otherwise.

9.6. Assess effectiveness of the epidural/paravertebral block/rectus sheath catheter to provide analgesia i.e. ideal self-reported pain score of less than < 4/10.

9.7. Ensure EPR PCA prescription is entered before transfer to ward. Prescription & pump settings must be checked and co-signed by both nurses at ward handover.

9.8. Mobilisation goal 100 metres x 2 today. If goals are not achieved document reason in ICCA.

9.9. Wound Care. Initial dressing change today.

9.10. Assess devices for removal daily. If UWSD not removed yesterday discuss with **UGI team who must write a note on EPR to this effect.**

10.0 POD 4: Ward level care.

Nursing staff complete interventions unless stated otherwise**. Refer to Section 5.0.** If any deviations from baseline refer to the UGI Team without delay.

10.1. Discontinue Epidural Infusion on POD 4 unless pain control is an issue.

10.2. **NOTE**: Ensure 12 hours have elapsed between administration of anticoagulation and removal of the epidural catheter.

10.3. Remove the indwelling epidural catheter. This should be witnessed by a second registered general nurse. Document in EPR.

10.4. Check with the UGI team if swallow assessment is required. The team must order this on EPR.

10.5. SLT routinely complete bedside swallow exam for those with a neck anastomosis, including both Transhiatal, and Post 3 Stage Oesophagectomy and Thoracotomy. If there are aspiration concerns, a video fluoroscopy is scheduled by the SLT. If swallow assessment is not required as per UGI team: commence 60mls/hr of water initially, and then progress up to half portions of level 7/easy to chew food prior to discharge.

10.6. Mobilisation Goal Walking 200-400 metres twice daily. Physiotherapist documents if goal is not met.

10.7. Wean Oxygen requirements as tolerated.

10.8. Review wound dressing and record findings.

10.9. Assess devices for removal daily.

10.9.1. Remove urinary catheter once epidural is removed (unless clinically required). Monitor urine output post removal as is standard practice.

10.9.2. Remove Central Venous Access Device if no longer required. Ensure Peripheral access is sited prior to removal.

10.10. Document pain assessment and PCA requirements on EPR as standard.

11.0 POD 5:

Nursing staff complete interventions unless stated otherwise**. Refer to Section 5.0.** If any deviations from baseline refer to the UGI Team without delay.

11.1. Wean Oxygen requirements as tolerated.

11.2. Mobilisation target 200-400 metres twice daily. If mobilisation does not take place, Nurse/Physiotherapist records the reason on EPR.

11.3. Assess and record pain score on EPR as standard. Target pain score less than < 4. If not achieved refer to the pain team for further advice.

11.4. If pain is controlled, discontinue the PCA today. If unable record the reason in EPR.

11.5. Barium swallow today; ordered by UGI team - document result.

11.6. Assess devices for removal daily.

11.7. Review wound dressing and record findings.

12.0 POD 6:

Nursing staff complete interventions unless stated otherwise**. Refer to Section 5.0.** If any deviations from baseline refer to the UGI Team without delay.

12.1. Wean Oxygen requirements as tolerated.

12.2. Physiotherapy to continue with mobilisation goals.

12.3. Review wound dressing and record findings.

12.4. Assess devices for removal daily. Discuss with the UGI team if the pleural drain will be removed today. If not, record the reason in EPR.

12.5. Feeding Pump training should be started today by dietician.

12.6. Discharge communication should be started today with all members of multidisciplinary team with a proposed day of discharge given to patients and families.

13.0 POD 7 onwards for remainder of hospital stay:

All members of multidisciplinary team are responsible for providing the following care. **Refer to Section 5.0.** If any deviations from baseline refer to the UGI Team without delay.

13.1. Monitor **Respiratory parameters**.

13.2. Promote daily mobilisation

13.3. **Physiotherapist** provides advice regarding **exercise options post discharge** with links to cancer services accordingly (ARC, Exwell etc.)

13.4. **Dietician** to follow progression of diet e.g. introduce soup, jelly, ice-cream and yogurt. Half portions of easy to chew food. Observe diet tolerance.

13.5. Assess devices for removal daily.

13.6. **Wound:** Remove cervical clips POD 7. Remove remaining clips by POD 9.

13.7. Weekly review jejunostomy site dressing if discharge is delayed.

13.8. Public health nurse referral by nursing staff.

13.9. Less nursing involvement envisaged from POD 7 onwards in patients who have remained on this pathway.

13.10. Aim for discharge on POD 9.

POD1	POD2	POD3	POD4	POD5-9
High flow or AIRVO	Mobilisation goals. Record if not achieved with reason why	Discharge to ward level care.	Discontinue epidural if pain well controlled. Remove indwelling epidural catheter.	If swallow assessment not on POD 4 D/W team if it can be done on POD5.
Start enteral feed at 08:oohrs	Daily weight	ICU bloods and chest x-ray	Remove urinary catheter and CVC	Enteral pump training and education.
ICU bloods, CXR and daily weight.	D/W UGI team if UWSD can be removed today.	Ensure PCA prescribed for transfer to ward.	Assess for swallow assessment as per SLT.	Progress diet to half portions, easy to chew feed as per dieticians.
Chlorhexidine 0.12% mouthwash TDS	Daily CXR	Initial dressing change today.		Remove cervical clips on POD7.

Aim for pain relief to be <4/10. If feasible reduce epidural. Start PCA if applicable. Fentanyl only please.		If UWSD was not removed yesterday can it be removed today – check with UGI.		Public health nurse referral by nursing staff.
Mobilisation goals with physiotherapy. Please record reasons if not achieving set goals.		Chlorhexidine 0.12% can be discontinued today (72hrs duration). Discontinue antibiotics unless otherwise indicated.		Aim for discharge POD9.

14.0 **Audit/Compliance:**

14.1. All members of the Multidisciplinary team must record any deviations to this protocol in the relevant patient chart on EPR or ICCA

14.2. The practices will be audited periodically by the UGI team.

14.3. Adverse Incident Forms will be submitted for any deviations that suggest a near miss or patient harm occurred.

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Document Log			
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Version 2	2	March 2022	Title changed from Oesophagectomy: Post-operative Patient Care Guidelines No. SJH: ORIAN(G)036 to **Oesophagectomy care following *Enhanced Recovery after Surgery (ERAS) Pathway No. Protocol Number SACC 036*** Changed from Guideline to Protocol Introduction expanded to include ERAS pathway Scope expanded to Multidisciplinary team Section 3.0 Definitions & Glossary expanded Section 5 Standards updated Sections 6 -13 Post Op days added