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## **Title**

### **Prevention of Pulmonary Complications using High flow with tracheostomy interface vs Conventional Oxygen Therapy in Patients after Major Head and Neck Surgery: Randomized Clinical Trial**

## **Investigators**

Primary Investigators

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## **Abstract**

Patients undergoing major head and neck surgery, especially those receiving a tracheostomy, are at risk for postoperative pulmonary complications. This is attributed to high prevalence of preexisting comorbidities in this population due to smoking, as well as the prolonged anesthesia time for these complex surgeries followed by prolonged periods of immobilization during recovery. Current oxygen therapy relies on cool mist delivered via a tracheostomy collar, which has been shown to be suboptimal as the airway functions best at physiological temperatures with a higher relative humidity than the aerosol mask can deliver. High flow humidified air is a safe and effective way to provide respiratory support, but has not been widely utilized after major head and neck surgery to prevent pulmonary complications. The goal of this randomized clinical trial is to evaluate the effectiveness of high flow oxygen at preventing postoperative pulmonary complications after major head and neck surgery, when compared to conventional oxygen therapy.

## **Background:**

Major head and neck surgery can come with considerable postoperative risk due to prolonged surgical procedures and time under anesthesia, that often directly involve the airway. Postoperative pulmonary complications are quite common after major head and neck surgery, estimated to be around 18.8-47%, and are increased in those requiring tracheostomy [1-5]. Head and neck oncology surgical patients are at high risk due to the high prevalence of preexisting cardiopulmonary disease, further complicated by a higher proportion of smokers [6]. The patients then undergo long surgeries with general anesthesia, often followed by prolonged immobilization during their recovery. The majority of these patients also undergo elective tracheostomy for airway protection. The tracheostomy can further increase risk for pulmonary complications, because it naturally bypasses the airways natural physiologic warming and humidification system. This causes pathological changes in the lower airways, including damage to the ciliated tracheal mucosa, thickening of airway secretions, and loss or reduction of mucociliary transport [7]. All of

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these pathological changes can lead to pneumonia. While not often fatal in this population, pneumonia can still result in prolonged length of stay, need for intensive critical care, increased use of broad-spectrum antibiotics, and lengthen the time to tracheostomy decannulation [4].

The current standard for oxygen and humidification postoperatively is delivered via cool mist from an aerosol tracheostomy collar. Studies have shown this system is inadequate, as humidification delivered at room air causes mucociliary damage, resulting in increased airway secretion production and retention. Ultimately, this can cause serious complications like mucous plugging and pneumonia [8].

High flow oxygen therapy (HFOT) delivers heated and humidified oxygen, which has been shown to have multiple benefits, the first being able to delivery physiologically optimal heated humidification, as well as the ability to deliver positive airway pressure. By mimicking the optimal airway temperature and humidification, patients have less respiratory secretions and have improved clearance, preventing infection [9,10]. Positive airway pressure has been shown to improve oxygenation via increased end-expiratory lung volumes, and is important postoperatively as it can reduce lower airway collapse and atelectasis [11]. Meta-analysis of clinical trials, examining prophylactic use of HFOT during the immediate postoperative course for other major operations (cardiac, intrathoracic, abdominal), and showed a reduction in reintubation and the need to escalate respiratory support, when compared to conventional oxygen therapy [13].

Use of high flow after major head and neck surgery is generally unexplored. To date, only one study evaluates use of prophylactic HFOT tracheostomy collar after major head and neck surgery. In this small controlled trial (n=20), they concluded that HFOT was safe and feasible for this patient population [2].

### **Research Question**

Among subjects undergoing major head and neck surgery with tracheostomy, does perioperative use of HFOT tracheostomy collar, when compared to conventional oxygen therapy, result in fewer postoperative pulmonary complications?

### **Specific Aims**

1. Determine if HFOT tracheostomy is superior to conventional oxygen therapy at preventing postoperative complications
  - a. Determine the association between HFOT tracheostomy collar and postoperative pulmonary complications
  - b. Determine the association between HFOT tracheostomy collar and time to tracheostomy decannulation
  - c. Determine the association between HFOT tracheostomy collar and total length of stay after surgery

### **Research Plan**

#### **Study Design**

- Single center, non-blinded, prospective randomized clinical trial

Population:

- Inclusion
  - Patients undergoing major head and neck surgery that includes any neck dissection
    - Major head and neck surgery is defined as having a mean length of stay of three or more days, based on the diagnosis [14]
  - Surgery requires an elective tracheostomy for airway protection or laryngectomy tube in the case of total laryngectomy
- Exclusion
  - <18 years of age

## **Study Protocol**

### Screening

- Potential participants will be screened for enrollment at their preoperative surgery clinic appointments by their surgeon according to established inclusion/exclusion criteria. If the patient meets inclusion criteria, they will be referred to research coordinator to determine if patients wishes to participate and to consent the patient in person or via phone (see phone script for informed consent).
  - The following procedures will be performed during pre-operative consultation by one of the study team physicians.
  - Patient screening using predefined inclusion and exclusion criteria
  - Demographics, medical and medication history
  - Physical exam
  - Vital signs
  - Preoperative imaging is standard of care and ordered on all subjects prior to surgery
  - Subjects will be sent for pre-anesthesia testing for evaluation prior to surgery
    - At this appointment everyone will undergo EKG, chest radiograph, basic metabolic panel, complete blood count
    - This appointment must occur within 1 week from surgery
  - All patients are routinely presented at the University of Florida Jacksonville Head and Neck Tumor Board for discussion of diagnosis and ideal treatment
- Consent
  - Once subjects are determined eligible by the physician, they will be referred to the study coordinator. The study coordinator will meet the patient in person at the clinic or over the phone to discuss the full study details, and details of the study consent, including risks and benefits (see recruitment and consent scripts).

- This is so the patients will have time to adequately decide if they would like to participate in the study.
- If the patient chooses to not participate in the study, they will still receive conventional oxygen therapy.
- If the patient requests to speak to the treating surgeons about the study, they will be contacted separately to discuss the study as well as risks vs benefits.
- Informed consent will be obtained from the patient in person at a pre-operative clinic appointment, by phone/electronically via REDcap or on the day of surgery by the surgeon/resident or trained research coordinator, explaining risks and benefits of the study.
  - A written consent form will be presented to the patient with oral explanation from the research staff trained for formal study consent.
  - Patients will have opportunity to ask questions regarding the study and any risks that may be involved.

#### Randomization

- Randomization will be assigned by the study coordinator once the patient completes the consent process.
- Patients will be divided into three subgroups after enrollment: no free flap, free flap, and laryngo-pharyngectomy
- Randomization into COT vs HFOT will be performed based on a block randomization scheme, stratified by subgroup- no free flap, free flap, or laryngo-pharyngectomy.
- This system will be used to ensure well-balanced distribution into these three subgroups and in the two arms.
- The goal will be to always keep enrollment balanced accordingly to the usual volume of no free flap, free flap, or laryngo-pharyngectomy among the two treatment groups.
- The block randomization scheme will be generated by the analyst with the Center for Data Solutions at the UF College of Medicine Jacksonville, FL and it will be uploaded into REDCap before the data collection.

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### Day of Surgery

- If patients missed their preoperative labs and x-rays, the chest x-ray and labs can be drawn in the preoperative area the day of surgery
- The consents for surgery and the study will be completed
  - Subjects are allowed to drop from the study at any time. If they do, they will be treated with COT, which is our current standard of care

### Operating Room

- In the operating room, patients will undergo their surgery per normal operating protocol. No patients will be treated differently because of the study.
- At the end of the procedure all patients requiring tracheostomy will have a size 8-0 cuffed Portex trach placed, the cuff will be deflated within 3 hours of leaving the operating room. Total laryngectomy patients will have a laryngectomy tube placed at end of procedure.
- The Anesthesia team will be instructed to treat the patients according to their normal standard of care for head and neck surgery
- All patients must be extubated prior to leaving the operating room, or else they will be dropped from the study
- Subjects will leave the operating room and be transported to the post anesthesia care unit for appropriate monitoring prior to being transferred to a progressive floor
- Starting at the PACU, tracheostomy patients will be started on COT or HFOT via tracheostomy adapter , until occlusive capping of the tracheostomy is tolerated. Once the trach is capped, patients can be placed on oxygen via nasal cannula if it is required to maintain O2 saturation levels as stated below.. Total laryngectomy patients will remain on COT or HFOT via trach mask adapter from the time they are in PACU until the time they can tolerate HME (heat moisture exchange) use or are discharged from the hospital, whichever comes first.

### Oxygen Protocols- COT v HFOT

- The experimental group will receive HFOT at a flow rate of 60 liters per minute, maximum concentration of 40%, which will be titrated by bedside nurse to maintain

an oxygen saturation of 92% or greater (unless there is a history of COPD and then the clinician can recommend >88%)

- The control group will be placed on aerosolized trach mask with humidification, and titrated to keep oxygen saturation >92% (unless there is a history of COPD and then the clinician can recommend >88%)
- Patients can be temporarily disconnected from the HFOT or COT for short periods (no greater than 1 hour three times a day) to allow for toileting, mobilization
- Patients will all be positioned with head of bed at 30 degrees, undergo PRN tracheal suctioning, which will be recorded, and encouraged to take deep breaths.
- A tracheostomto nasal cannula oxygen if required to maintain oxygen saturations as specified above.
- Patient will receive a 1 view chest radiograph at the beginning of postoperative day 4
- Physicians can order chest radiographs more frequently if deemed clinically necessary- must document reasons

#### Hospital Care

- Care of patients will follow the University of Florida Jacksonville's standardized head and neck protocol (**Figure 1**)
- Analgesia management will be standardized:
  - Scheduled
    - Ibuprofen 600 mg q6 hours scheduled for 72 hours
    - Acetaminophen 650 mg q6 hours scheduled
    - Methocarbamol (Robaxin): 500 mg q 8 hours scheduled
    - Gabapentin 300 mg TID--can scale up if needed to 600 TID after 2 days
  - PRN
    - Oxycodone 5-10 mg q4-6 hours PRN
  - Breakthrough/PRN:
    - Morphine 1-4 mg IV q 2-4 hours PRN
    - Hydromorphone 0.5-1 mg IV q 2-4 hours PRN

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- Fluids will be standardized to prevent fluid overload/pulmonary edema, and ordered based on body weight, and ideal body weight for obese patients. Fluids will be discontinued once the patient is taking adequate intake by mouth or via tube feeds
- Weaning of the tracheostomy will be standardized
  - If patient is deemed clinically acceptable by team (no sign of pulmonary complication as defined above), the tracheostomy will be downsized on postoperative day 4, to a 6-0 fenestrated uncuffed Shiley, and will undergo occlusive capping as soon as tolerated after the downsize
  - Once the patient tolerates 24-hour capping, and deemed clinically acceptable for decannulation, the tracheostomy will be removed
  - Tracheostomy may be determined necessary if capping not tolerated, or needed for aggressive pulmonary toileting
- Consultation for specialty management of subject comorbidities will be permitted

#### Clinic Follow Up Appointments

- Subjects will follow up in clinic between 1-2 weeks postoperatively from their discharge date
- Vitals and physical exam will be performed, and all subjects will be monitored for adverse events
- Subjects will be closely followed every 1-3 weeks for the first 2 months after surgery
- At 12 days postoperatively all subjects will be called or evaluated in clinic for the final screening for adverse events or pulmonary complications

#### **Potential adverse events that could result in subject withdrawal from the trial:**

- Subjects unable to be extubated in the operating room after surgery
- Subjects who cannot tolerate COT or HFOT for the specified amount of time each day
- Subjects with surgical complications requiring significant alteration of the treatment plan
  - Subjects requiring a return to the operating room during their admission will be excluded, unless it is for a procedure not related to the original surgery

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occurring after post op day 3, such as a gastrostomy tube or long-term IV access.

- Subjects who do not stay in the hospital for at least 4 days after surgery

## **Outcome Measures**

- Primary
  - **Incidence of post-operative pulmonary complication within 14 days after surgery**
    - Postoperative pulmonary complication will be defined as
      - Atelectasis or infiltrate diagnosed by radiologist on any postoperative chest radiograph within first 14 days or discharge (whichever occurs first)
      - Pneumonia
        - *Diagnosis is suggested by a history of cough, dyspnea, pleuritic pain, or acute functional or cognitive decline, with abnormal vital signs (e.g., fever, tachycardia) and lung examination findings. Diagnosis should be confirmed by chest radiography or ultrasonography.* [15]
    - Chronic pulmonary obstructive disease exacerbation
      - *An event in the natural course of the disease characterized by a change in the patient's baseline dyspnea, cough, and/or sputum and beyond normal day-to-day variations, that is acute in onset and may warrant a change in regular medication in a patient with underlying COPD* [16]
    - Adult respiratory distress syndrome (Berlin definition)
    - Need for reintubation/mechanical ventilation
    - Need for non-invasive mechanical ventilation
  - Secondary
    - **Time to tracheostomy decannulation** (half days)

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- **Hospital length of stay after surgery** (half days)
- **Need for antibiotics for pulmonary complication** (escalation to broad spectrum, addition of a second antibiotic, antibiotics past post-operative day 7)
- **Need for pulmonary physiotherapy** (acapella, flutter, etc.)
- **Discharge destination:** Home vs nursing facility vs rehabilitation

### **Data Collection**

- Data will be recorded in the subject's medical record list and in their medication administration record. These entries are time stamped at administration. Research data will be collected in REDcap database.

### **Patient Privacy and Protection**

- Identifiable information will be used to monitor clinical records and identify subjects for the study.
- Each participant enrolled in the study will be assigned a participant ID number. The participant ID number will be used on all forms containing data and information from the study.
- Identifiable information (name, date of birth, or MRN) will only be used for data acquisition of a master list and all other PHI used of the participants' names and participant ID numbers will be kept on an institutional server and on the dedicated UF research drive provided by the research department. The master list will be retained in a password protected institutional server for 3 years and will then be

destroyed per institutional guidelines. The de-identified data will be retained indefinitely in a password protected institutional server.

- Data using the participant ID number will be kept on an institutional server and on the dedicated UF research drive
- All data will be stored in REDCap and will later be used for data analysis.
- Consents will be a hard copy and kept in the designated regulatory binder located in the study coordinator's office in a locked cabinet.
- It is possible that your research information, with all personally identifiable information removed, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

## **Statistical Analysis**

### Sample Size Rationale

A sample size of 164 patients, 82 in each arm, is sufficient to detect a clinically important difference of 20% in the proportion of postoperative pulmonary complications between arms using a two-tailed z-test of proportions with 90% power and a 5% level of significance. This 20% difference represents 10% of postoperative pulmonary complications using HFOT and 30% of postoperative pulmonary complications in the control arm. Assuming a 10% rate of withdrawal, we will need to recruit 91 patients per arm to be adequately powered to detect the difference.

An interim analysis of the proportion of postoperative pulmonary complications is planned after 100 subjects (50:50) are enrolled to assess whether there will be overwhelming evidence of a benefit from HFOT, as compared with conventional oxygen therapy, or of harm in any study group. As a consequence, the p-value for the primary comparison between the two arms will be adjusted to conserve an overall significance level of 0.05[17]. Descriptive summaries will be frequencies and percentages for categorical variables and means, standard deviations, medians, and quartiles for continuous variables. The primary analysis will compare the difference in the proportion of postoperative pulmonary complications

between the intervention group and the control group. This difference is assessed using univariate analyses and ANCOVA (Analysis of Covariance) models. Demographic and baseline characteristics between groups are assessed using the non-parametric Wilcoxon Rank-Sum test for continuous data, and Pearson Chi-squared test or Fisher's Exact test (when expected frequencies are small) for categorical data. The secondary outcomes will be analyses using the same statistical methods, based upon the data distributions. Data analyses will be performed by a statistician with the Center for Data Solutions.

### **Possible Discomfort and Risks**

- Participants may be in some discomfort due to their planned head and neck surgery. Patients in this study will be receiving our current standard of care (COT) or HFOT therapy, which is also an established standard of care modality. Thus, risks to patients are low, and have not been observed in similar studies.

There is the minimal risk of a participant's privacy being compromised. Several measures to ensure the privacy protection of those enrolled in the study will be in place as described in the Patient Privacy and Protection section on page 11.

### **Possible Benefits**

- There may be a benefit to those randomized to HFOT oxygen versus COT or there may not be any difference between the two in reducing postoperative pulmonary complications. The results of this study will help guide best practices in the postoperative care of head and neck cancer surgical patients.

### **Conflict of Interest**

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- This study is funded by Fisher and Paykel, Inc., manufacturers of the Airvo 2 high flow device
- However, the sponsor company cannot interfere with the study, data collection, or statistical analysis

### **Data Safety Monitoring Board**

- No experimental interventions are taking place, as HFOT tracheostomy delivery and conventional oxygen therapy are both well established and widely used modalities.
- The PI will monitor for any adverse events. If any adverse events are identified, they will be reported to the IRB in the required time frames.

**Anticipated study duration:** 14-24 months

### **References**

1. McMahon JD, MacIver C, Smith M, Stathopoulos P, Wales C, McNulty R, Handley TP, Devine JC. Postoperative complications after major head and neck surgery with free flap repair--prevalence, patterns, and determinants: a prospective cohort study. *Br J Oral Maxillofac Surg*. 2013 Dec;51(8):689-95. doi: 10.1016/j.bjoms.2013.04.015. Epub 2013 May 31. PMID: 23727043.

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IRB202102700  
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2. Twose P, Thomas C, Morgan M, Broad MA. Comparison of high-flow oxygen therapy with standard oxygen therapy for prevention of postoperative pulmonary complications after major head and neck surgery involving insertion of a tracheostomy: a feasibility study. *Br J Oral Maxillofac Surg.* 2019 Dec;57(10):1014-1018. doi: 10.1016/j.bjoms.2019.08.021. Epub 2019 Sep 9. PMID: 31515152.
3. Loeffelbein DJ, Julinek A, Wolff KD, Kochs E, Haller B, Haseneder R. Perioperative risk factors for postoperative pulmonary complications after major oral and maxillofacial surgery with microvascular reconstruction: A retrospective analysis of 648 cases. *J Craniomaxillofac Surg.* 2016 Aug;44(8):952-7. doi: 10.1016/j.jcms.2016.05.007. Epub 2016 May 14. PMID: 27259678.
4. Petrar S, Bartlett C, Hart RD, MacDougall P. Pulmonary complications after major head and neck surgery: A retrospective cohort study. *Laryngoscope.* 2012 May;122(5):1057-61. doi: 10.1002/lary.23228. Epub 2012 Mar 23. PMID: 22447296.
5. Ong S, Morton RP, Kolbe J, Whitlock RML, McIvor NP. Pulmonary Complications Following Major Head and Neck Surgery With Tracheostomy: A Prospective, Randomized, Controlled Trial of Prophylactic Antibiotics. *Arch Otolaryngol Head Neck Surg.* 2004;130(9):1084-1087. doi:10.1001/archotol.130.9.1084
6. Paleri V, Wight RG, Silver CE, Haigentz M Jr, Takes RP, Bradley PJ, Rinaldo A, Sanabria A, Bień S, Ferlito A. Comorbidity in head and neck cancer: a critical appraisal and recommendations for practice. *Oral Oncol.* 2010 Oct;46(10):712-9. doi: 10.1016/j.oraloncology.2010.07.008. Epub 2010 Sep 17. PMID: 20850371.
7. Heffner JE, Hess D. Tracheostomy management in the chronically ventilated patient. *Clin Chest Med.* 2001 Mar;22(1):55-69. doi: 10.1016/s0272-5231(05)70025-3. PMID: 11315459.
8. Doyle, A. et al. A change in humidification system can eliminate endotracheal tube occlusions. *Journal of Critical Care* 26, 637. e1-637.e4 (2011)
9. Burton, J.D.K. Effects of dry anesthetic gases on the respiratory mucous membrane. *Lancet* 279, 235-238 (1962).
10. Branson, R.D. Secretion management in the mechanically ventilated patient. *Respiratory Care* 52, 1327-1328 (2007)

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11. Nishimura M. High-Flow Nasal Cannula Oxygen Therapy in Adults: Physiological Benefits, Indication, Clinical Benefits, and Adverse Effects. *Respir Care*. 2016 Apr;61(4):529-41. doi: 10.4187/respcare.04577. PMID: 27016353.
12. Kim HJ, Asai T. High-flow nasal oxygenation for anesthetic management. *Korean J Anesthesiol*. 2019 Dec;72(6):527-547. doi: 10.4097/kja.19174. Epub 2019 Jun 5. PMID: 31163107; PMCID: PMC6900423.
13. Chaudhuri D, Granton D, Wang DX, Burns KEA, Helviz Y, Einav S, Trivedi V, Mauri T, Ricard JD, Mancebo J, Frat JP, Jog S, Hernandez G, Maggiore SM, Mbuagbaw L, Hodgson CL, Jaber S, Goligher EC, Brochard L, Rochwerg B. High-Flow Nasal Cannula in the Immediate Postoperative Period: A Systematic Review and Meta-analysis. *Chest*. 2020 Nov;158(5):1934-1946. doi: 10.1016/j.chest.2020.06.038. Epub 2020 Jun 29. PMID: 32615190.
14. Bhattacharyya N, Fried MP. Benchmarks for Mortality, Morbidity, and Length of Stay for Head and Neck Surgical Procedures. *Arch Otolaryngol Head Neck Surg*. 2001;127(2):127-132. doi:10.1001/archotol.127.2.127
15. Kaysin A, Viera AJ. Community-Acquired Pneumonia in Adults: Diagnosis and Management. *Am Fam Physician*. 2016 Nov 1;94(9):698-706. Erratum in: *Am Fam Physician*. 2017 Apr 1;95(7):414. PMID: 27929242.
16. GOLD Executive and Science Committees. Executive summary: global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease; December 2006. Available from: <http://www.goldcopd.org/Guidelineitem.asp?l1=2&l2=1&intId=996> (accessed March 14, 2007).
17. O'Brien PC, Fleming TR. A multiple testing procedure for clinical trials. *Biometrics* 1979; 35:549-56.

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**Figure 1. Oral and Maxillofacial Surgery Free Flap Management Protocol by Postoperative Day**

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Discharge Goals
<b>Trachea/Airway</b>		Trach suction by respiratory every 6 hours  Albuterol/ipratropium nebulized q 6 hours scheduled until decannulated or discharged			Trach changed to 6 cuffless, fenestrated tube CAN CAP IF READY	Decannulate when capped >24 hours			Trach tube out or all at-home supplies and care instruction provided
<b>Flap Donor Site</b>	Dressing kept until discharge								Dressing to be changed at first follow-up
<b>Skin Graft Donor Site</b>	Dressing kept until discharge								Skin graft dressing change at first follow-up
<b>Flap Checks</b>	Every two hours			Every 4 hours after 48 hours					Flap checks discontinued upon discharge
<b>Drains</b>	JP drains to bulb suction with output, recorded		Discontinue drains when <30 ml / 24 hours						
<b>Laboratory</b>		Complete blood count, basic metabolic panel, magnesium, phosphorus, others as indicated each morning		Discontinue labs when IVF discontinued					
<b>IV Fluids, Antibiotics</b>	One dose of abx prior to incision	Continue antibiotics 3 doses post-op	Titrate IV fluids to heplock to accommodate TF rate	D/C IVF when TF at goal		Antibiotics until POD 7			

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<b>Pain Management</b>	IV pain meds	Oral pain medication with IV for BTP		Narcotic pain meds weaned as tolerated					Pain control on oral medication alone
<b>Delirium Tremens Prophylaxis</b>	CIWA protocol as appropriate								
<b>Activity</b>	Bedrest	Bedrest	Bedrest or sitting on edge of bed	To chair	Ambulate	Ambulate	Ambulate	Ambulate	Baseline mobility or independent at home
<b>Nutrition</b>	NPO. Meds only pre NGT	After 24 hours, start tube feeds				P.O. trials or start bolus tube feed	D/C NGT or arrange for TF upon D/C		Tolerate at least full liquids or home with enteral feed teaching machine
<b>Catheter</b>	Maintain Foley catheter			D/C Foley					
<b>Gastrointestinal</b>	PPI to start post-operatively Stool softeners							Discharge with normal bowel function, no GI bleed	
<b>Thromboprophylaxis</b>	Compression stockings, SCDs during and after surgery	Prophylactic lovenox, ASA 325mg/d to start at 24 hours							Discharge with no deep vein thrombosis, or pulmonary embolism
<b>Miscellaneous</b>		Consult PT, nutrition, respiratory, case manager, speech therapy							Smooth and timely discharge with high patient satisfaction

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