Theme 11 Respiratory and Nutritional Management

P323 USING LUNG VOLUME RECRUITMENT THERAPY IN MOTOR NEURONE DISEASE (MND): A COMMUNITY SERVICE EVALUATION

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Keywords: lung volume recruitment, patient feedback, service evaluation

Background: The lung volume recruitment (LVR) bag is a device used by physiotherapists to support patients with decreased inspiratory effort and associated symptoms. It enables patients to “breath stack”. This is where inspiratory lung volume is increased by stacking several inspiratory breaths together without any exhalation between (the device has a one way valve). The larger inspiratory volume can, in turn, help patients cough, clear secretions, maintain lung and chest wall compliance, and reduce the risk of respiratory infections. The technique can be used in neuromuscular disorders such as MND, and has been introduced locally.

Objectives: To establish whether MND patients report benefits from using the LVR bag; to identify patient reported problems with its use; to determine whether therapy is being commenced at an appropriate time.

Methods: A semi-structured postal questionnaire was sent to all eligible patients under the Coventry Integrated MND MDT, i.e. patients with a confirmed MND diagnosis, Coventry GP and clinical or patient reported respiratory symptoms, who used the device over a 4-month study period in 2015.

Results: Twelve MND patients were known to the team; eight were suitable for LVR therapy. The response rate was 50% (n=4). Of the non-responders, three died during the study period. The length of time using the LVR bag ranged from 1 to 8 months with frequency of use several times a day (n=3), once a day (n=1) or less than once a day (n=1). Benefit from using the device was reported by three patients, including anticipated benefits of help with cough, breathing and nose blowing. One patient was a non-regular user and unsure of benefit. There was a reported psychological benefit from using a self-help technique. No significant problems were reported, although a need for dexterity, perseverance and establishing a routine were highlighted. The patients indicated introducing the device earlier would have been helpful (n=2).

Discussion and conclusions: Positive physical benefits were reported, in addition to an unanticipated psychological benefit. Patient feedback supports use of the LVR bag earlier in the disease trajectory. No adverse effects or significant problems with use were reported. It can offer an interim solution prior to the need for noninvasive ventilation. It is a cost-effective patient-led device (approximately £16.50 + p&p per bag).

DOI: 10.1080/21678421.2016.1232066/001

P324 BREATHE STACK USING A LUNG RECRUITMENT BAG WITH ALS PATIENTS IN NORTH SCOTLAND

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Keywords: breath stacking, lung recruitment bag, treatment medium

Background: In April 2012 the author completed a literature review to investigate the use of adapted lung recruitment bags (LRB) with ALS patients. This was to examine whether this straightforward method could be introduced as a therapeutic medium for patients and facilitated the introduction of Breath Stacking (BS) as a treatment option in the north of Scotland.

Objective: To explore the practicalities with provision, training, patient compliance and uptake in a largely rural population. Patient and carer feedback was also sought on BS as treatment option.

Sample: It was offered to the patients in the early stages of their diagnosis. Patients without upper arm function or with dementia were excluded.

Methods: A BS Patient Leaflet and video was produced. An initial assessment, including a symptom based respiratory review and regular 3 monthly reviews thereafter, were completed. Training was undertaken with the patients’ local physiotherapist.

Results: Patients found the LRB helpful to increase voice volume and the feeling of having more air in their lungs for around 20–30 minutes after completion of BS. They also found it helped expectorate lung secretions. Early introduction, regular monitoring of patient technique and completion of a respiratory assessment became standard practice. Patients who felt the most benefit complied with the prescribed treatment. Patients who felt less benefit would complete the BS less frequently, but would still use the LRB or complete BS without the LRB. Once the patients’ upper limb function stopped them from completing the BS independently, compliance deteriorated.
Conclusion: Positive patient feedback has led to a practical package being developed for the clinical specialists and physiotherapists in this area. It will be introduced nationally later this year and at that time the package will be available for use/adaptation for anyone who would like to introduce the therapeutic technique with their patients.

DOI: 10.1080/21678421.2016.1232066/002

P325 IMPACT OF COMBINED INSPIRATORY- EXPIRATORY EXERCISE ON RESPIRATORY AND BULBAR FUNCTION IN AN INDIVIDUAL WITH ALS

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Keywords: bulbar, exercise, respiration

Background: The role of exercise in individuals with ALS is controversial. We have recently reported that expiratory muscle strength training (EMST) is feasible, safe and leads to improvements in expiratory force generating pressures immediately following a five-week treatment program in a pilot study of 25 ALS patients. Here we examined the impact of a combined inspiratory and expiratory respiratory exercise program on an individual with ALS.

Methods: This case study was on a 59-year-old male with ALS (Revised El-Escorial Criteria) who participated in a respiratory exercise training that was 5 days per week at 30% of individualized maximum inspiratory (MIP) and expiratory (MEP) pressure. At time of abstract submission, the patient had completed 12 weeks of training. Outcome measures included: MIPs, MEPs, peak cough flow, forced vital capacity (% predicted), FEV1, speech intelligibility, speaking rate (words per minute, WPM) and communication efficiency index (CEI).

Results: Following twelve weeks of RST, and at the time of abstract submission, this individual demonstrated a 62% improvement in MIPS (71cm H2O vs. 115cm H2O), a 40% improvement in MEPS (108 vs. 148cm H2O), a 24% improvement in peak cough flow rate (331 vs. 410L/min), a 16% improvement in speaking rate (108 WPM vs. 128 WPM) and a 14% improvement in his CEI.

Discussion: This individual demonstrated clinically significant gains in his ability to generate both maximal inspiratory and expiratory pressures. The noted improvements in subglottic air pressure generation led to improved peak cough and expiratory flow rates. An intriguing and unexpected finding was the noted improvement in speaking rate and communication efficiency. We speculate that the central motor programing and coordination required to perform respiratory training may have primed the speech system made up of the respiratory, laryngeal, phonatory, resonatory and articulatory sub-systems. These preliminary findings are currently being studied as part of a larger clinical trial.

DOI: 10.1080/21678421.2016.1232066/003

P326 RESPIRATORY MUSCLE UNLOADING (RMU) TO TREAT EXERTIONAL RELATED DYSPNEA (ERD) IN AMBULATORY PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS (AMBALS)

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Keywords: exertion, dyspnea, ventilation

Background: Physical exercise has neuroplastic and neuroprotective benefits on motor function. An adequate amount of physical activity is needed to improve, maintain, or reduce the progression of motor deficits. Due to dyspnea, ambALS may have difficulties increasing their minute ventilation to meet the metabolic demands of physical exertion leading to exercise intolerance. Non-invasive ventilation (NIV) therapy delivered by a pressure (P-NIV) or volume (V-NIV) mode is the current standard treatment to improve breathing by unloading the respiratory muscles during sleep and at rest. The use of V-NIV to improve exercise tolerance and functional work capacity of ambALS has not been carefully studied.

Objectives: To determine the feasibility, tolerability, safety, and treatment effect size of respiratory muscle unloading by V-NIV to treat exertional related dyspnea during exercise.

Methods: AmbALS who use V-NIV for their respiratory care perform two maximum exertion six-minute walk test (6MWT) on a treadmill, one test with and one without V-NIV at random with a 1 hour rest in between. Feasibility was evaluated by the percentage of patients who consented to those who completed the intervention. Tolerability was evaluated by rate of perceived exertion (RPE) and perceived dyspnea (RPD). Safety was evaluated by the change in heart rate (HR) and arterial blood saturation (SpO2) during the 6MW. Treatment effect size was evaluated by the changes in the 6MW distance. Wilcoxon signed-ranks test was used to compare RPD and RPE, and T-test for two dependent means for 6MW distance. Differences in performance between the two tests were considered statistically significant if one-way p-value was ≤0.05.

Results: Ten out of 11 consented patients completed the 6MW with and without V-NIV. RPE and RPD were 12% and 28% (p ≤0.05), respectively less with V-NIV. 6MW distance increased by 6% (429 to 456 m) (p ≤0.05) with V-NIV. Changes in HR and SpO2 were within the normal exercise intensity response and no adverse events during or after testing indicating no safety concern.
Discussion and conclusions: RMU by V-NIV to treat ERD is feasible, tolerated, safe, and is effective to improve exercise tolerance in ambALS. These results are similar to limb muscle unloading during treadmill ambulation.

DOI: 10.1080/21678421.2016.1232066/004

P327 FALSE NEGATIVE, NEGATIVE INSPIRATORY TESTS IN AN ALS PATIENT

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Introduction: The forced vital capacity (FVC) with supine challenge and the maximal inspiratory pressure (MIP) tests are commonly used to evaluate the diaphragm function in ALS patients. The sniff nasal inspiratory pressure (SNIP) is another negative inspiratory test that can be helpful for patients with bulbar disease. Generally, these values decline together as the diaphragm becomes weak.

Objective: To report an ALS patient who maintained high values on MIP and SNIP at a time when the diaphragm became severely weak.

Case report: A 67 year old man had limb onset ALS for 7 months before starting non-invasive ventilation (NIV) for nocturnal obstructive apnea. Pulmonary function tests (PFTs) at the time NIV was started, showed conflicting results regarding diaphragm strength. The patient reported no dyspnea at rest, but orthopnea was present.

Results: Serial PFTs showed decreasing FVC, from 70% to 43% predicted with corresponding supine challenge decline of additional 16% and 33% over a 4-month period. Corresponding negative inspiratory values at these same visits were –116, –130 for MIP and –115 and –116 for SNIP. To further evaluate this discrepancy, phrenic nerve conduction studies showed no responses and a fluoroscopic SNIFF test showed no diaphragm movement.

Conclusion: Some ALS patients can generate excellent negative inspiratory pressures at a time when the diaphragm is severely weak. We speculate that enhanced function of accessory breathing muscles likely accounts for this discrepancy. This finding suggests caution must be used when interpreting PFTs in ALS patients and a single measurement of inspiratory function cannot be relied on to accurately estimate diaphragm function.

DOI: 10.1080/21678421.2016.1232066/005

P328 EVALUATION OF THE RESPIRATORY FUNCTION IN ALS PATIENTS BY DIAPHRAGM ECHOMYOGRAPHY

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Keywords: echomyography, diaphragm, ventilation

Background: Respiratory failure is an almost constant evolutionary stage of amyotrophic lateral sclerosis (ALS). Respiratory function is usually assessed by means of spirometry and arterial blood gas analysis. Spirometry can be performed only by patients whose respiratory function is not too impaired. On the other hand, diaphragm electromyography and phrenic nerve electroneurography are more invasive options to investigate diaphragmatic function. Diaphragm echomography, on the contrary, is a quick and non-invasive exam that can represent an alternative or a complementary approach to evaluate ventilatory impairment in ALS patients (1).

Objectives: Our goal was to demonstrate the usefulness of diaphragm echomography over time along the disease progression in the evaluation of the respiratory function, in particular, in predicting the respiratory failure, as compared to diachronic data from spirometry and blood gas analysis.

Methods: Placing the probe of a Telemed Echo-wave II ultrasound in the right intercostal place between the antero- and the medium-auxiliary lines, with the patient in the supine position (2), morphological (thickness and echogenicity) and functional (changes during the respiratory dynamics) assessment of diaphragm was diachronically carried out in 15 ALS patients and 15 age- and sex-matched healthy subjects. Expiratory and inspiratory thicknesses were correlated to vital capacity, forced vital capacity, FEV, ALS-Functional Rating Scale (ALS-FRS) scores, in particular, respiratory ones, and to blood gas analysis values.

Results: Expiratory and inspiratory thicknesses and the difference between them were found significantly (p<0.01) reduced in the ALS patients compared with the control group. Their decrease over time across disease progression was proportional to the worsening of the respiratory function as detected by spirometry, blood gas analysis or respiratory ALS-FRS scores.

Conclusion: Diaphragm echomography has been proven to be a fast and easy method, painless and risk-free, and able to provide useful functional and structural insights for a better monitoring of the disease progression in ALS patients. Furthermore, it may predict the incoming respiratory failure allowing appropriate therapeutic measures to be promptly undertaken.
Acknowledgements: I would like to acknowledge the help of Anthony Hanratty, MND specialty nurse (JCUH), in helping to pull case data and analyze results. I also thank Dr Janine Evans, consultant neurologist (MND specialist, JCUH) and Dr Neil Archibald, consultant neurologist (JCUH), in reviewing and guiding the audit.

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excessive uncontrolled secretions were involved. Ninety-six patients used >4 h of NIV daily and their NIV would be during the immediate post-operative period. Post-operatively, all patients received either airway clearance therapy, positive airway pressure therapy or both along with appropriate pain management. Pacing began within first 24 h of implant. Routine analysis of diaphragm electromyography is performed (1). When dEMG is suppressed with NIV use or if instability of respiratory control is identified, DP usage is tailored to manage it. Long-term DP management includes: progressive utilization to 24 h a day including sleep, increasing DP setting and respiratory rate, and utilizing DP in conjunction with NIV.

Conclusion: DP can be safely implanted with a low peri-operative morbidity with a median survival of 18.6 months for all patients implanted which is similar to the pilot results (2). Identifying the appropriate ALS/MND patient with stimulable diaphragm motor units may involve laparoscopic evaluation. DP is never warranted when there is no stimulation at surgery. Excessive secretions with aspiration is a relative contra-indication. Appropriate pre-operative testing, intra-operative assessment and active DP management will provide the optimum care for ALS/MND patients.

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DOI: 10.1080/21678421.2016.1232066/008

P331 NOVEL TRIAL DESIGN IN A CLINICAL STUDY OF DIAPHRAGM PACING (DPS) FOR ALS

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Keywords: clinical trials, trial design, diaphragm pacing

Background: NeuRx DPS was FDA approved in 2011 for persons with ALS (PALS). Enrollment for the open label post approval study was completed ahead of schedule. However, enrollment in a US randomized controlled trial of DPS was substantially slower. To quickly learn more about the value of DPS, we developed a protocol (PARADIGM study) with novel design and control groups.

Objectives: To further examine the impact of DPS upon survival of PALS already stabilized on non-invasive ventilation (NIV). Survival of those who elect to receive DPS will be compared to that for concurrent controls, historical controls, and virtual controls.

Methods: Enroll 106 PALS who are using NIV and meet FDA-approved DPS indications of chronic hypventilation and stimulatable diaphragm. PALS who decline DPS will be monitored as concurrent controls. All PALS will be followed until death, tracheostomy or 2-year follow-up. Other measures of ALS progression and adverse events will also be monitored.

Analytic plan: For the primary outcome of death or tracheostomy, a log-rank test will be used to compare survival post enrollment among those who elected versus refused DPS. We will also test whether DPS treatment or refusal predicts survival in a Cox Proportional Hazards model that includes other covariates suspected to influence survival. Secondary tests will compare DPS treated survival with that for a matched group of historical controls assembled from the PRO-ACT database; and compare observed survival with survival predicted for a virtual set of patients whose baseline characteristics match those who selected DPS. Survival predictions for the virtual controls will be based on baseline values and 3-month slopes for FVC and ALSFRS-R. The prediction model will first be validated using the outcomes of the patients who refused DPS, the null hypothesis being that the patients who refused DPS will not differ significantly from their predictions. Once validated, the model will be applied to the DPS implanted cohort to determine whether the DPS implanted patients differed significantly from their predicted survival and ALSFRS-R outcomes. Results from the three control populations will be compared to determine which is the most efficient in terms of sample size and power.

Comment: This is the first study to enroll only PALS who are already on NIV. In this way, the impact of DPS can be more clearly examined in the presence of NIV. Moreover, this design will speed recruitment by empowering patient choice to obtain concurrent controls and thereby increase participation of PALS in clinical research. The use of virtual controls is also innovative and shows great promise for ALS trials.

DOI: 10.1080/21678421.2016.1232066/009

P332 CLINICAL RESULTS OF DIAPHRAGM PACING IN JAPANESE PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS

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Keywords: diaphragm pacing, clinical course, adverse events

Background: Respiratory insufficiency is a critical problem in amyotrophic lateral sclerosis (ALS) patients. Diaphragm pacing (DP) is used to augment respiration when patients have intact diaphragm motor units and have been applied to several neurological disorders.

Objectives: The aim of our open study was to investigate the efficacy and safety of DP for ALS patients in Japan. We started DP with NeuRx Diaphragm Pacing SystemR (NeuRx DPS, Synapse Biomedical, Oberlin, OH, USA) for five Japanese ALS patients without positive-pressure
mechanical ventilation (three men and two women, aged 59.6 ± 9.6 years). We implanted DP electrodes into the diaphragm close to the phrenic motor point laparoscopically under general anesthesia according to a previous report (1) and initiated DP for 24 hours a day. We evaluated the clinical course, especially in respiratory function, and adverse events in 2 years of follow-up.

**Results:** Patient 1 died of pneumonia after 232 days (28 months from the onset). Patient 2 died of chronic respiratory failure after 338 days (43 months from the onset). Autopsy findings of Patient 2 revealed a marked loss of motor neurons in the anterior horn and primary motor cortex with Bunina bodies and TDP-43 positive cytoplasmic inclusions. The diaphragm showed severe atrophy and several adhesions between the DP electrodes and diaphragm were observed adjacent to the tip of the DP electrodes. Mild hyalinization and a few multinucleated giant cells were present around the electrode tracks in the diaphragm. However, the infiltration of mononuclear cells around the tracks was not observed (2). Patient 3 withdrew the pacing due to aspiration pneumonia after 151 days. Both Patient 4 and Patient 5 continue DP as of 1 May 2016 (Patient 4: 674 days, Patient 5: 609 days). There were no serious adverse events.

**Discussion and conclusion:** The size of our study is small; however, NeuRx DPS could be one of the useful respiratory assistances for ALS patients and might have no safety issues regarding the adjacent diaphragm tissue.

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DOI: 10.1080/21678421.2016.1232066/0010

### P333 THE USE OF A HAND HELD VENTILATOR TO SUPPLEMENT NIV FOR PATIENTS WITH RESPIRATORY INSUFFICIENCY

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Keywords: hand held ventilator, NIV, breathlessness

**Background:** Non-invasive ventilation (NIV) is widely used in the support of respiratory muscle weakness in ALS/MND. Within the Medway area patients are reviewed in a multi-disciplinary clinic, including a palliative medicine consultant, respiratory consultant and a specialist ventilation nurse. The aim of therapy is to maximize activities of daily living, quality of life and ease symptoms. This includes AVAPS-AE (Average volume-assured pressure support - auto end positive airway pressure). The use of monitoring of NIV using a modem attached to the ventilator has allowed the use of NIV to be considered longitudinally

**Objective:** To identify any trends in pressure support and hours of use of AVAPS ventilation in patients commencing NIV.

**Methods:** The data of the five patients receiving NIV using AVAPS-AE over a period of 6 months were reviewed and analyzed, looking at average pressure support (PS) and usage over 3 month periods. The short form-36 questionnaire and a satisfaction survey were also sent to these patients.

**Results:** Patients felt satisfied with their NIV, feeling their machine matched their everyday needs. Patients used different devices including hand-held, mouthpiece and facemask breathing devices. Despite using NIV they felt...
their health had worsened and bodily pain was an issue. The use of NIV was analyzed for six patients – 5 male, 1 female, median age 46 years (range 38–68). There was no change in Inspiratory Positive Airway Pressure (IPAP) (Mean 15.34 at 1 month, 14.98 at 3 months) or Expiratory Positive Airway Pressure (EPAP) (6.3 at 1 month, 6.28 at 3 months). The average use – 7h 28 min at one month rising to 9h 1 min at three months – and compliance – percentage greater than 4 h 75% at 1 month to 87% at 3 months; did show a positive trend, however, this did not reach significance. Of the four patients on prolonged use of AVAPS-AE, three saw an increase in PS requirements over time (range 0.7–7.4cmH2O).

**Conclusions:** This initial study shows an increase in average hours of use and compliance in the first 3 months of use and pressure support appears to increase over time. A larger prospective study looking at disease progression and ventilation usage in MND is planned.

**DOI:** 10.1080/21678421.2016.1232066/0012

**P335 PROLONGED SURVIVAL OF NON-INVASIVE VENTILATION IN JAPANESE PATIENTS WITH ALS**

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**Keywords:** tracheostomy/invasive ventilation, non-invasive ventilation, prognosis

**Objective:** Non-invasive (NIV) and tracheostomy/invasive ventilation (TIV) in patients with ALS were common therapeutic options in Japan. NIV is considered a first-line treatment at respiratory distress in ALS since 2000. We evaluated the prognostic factors to survive in concern to NIV, in addition to factor relating to shift to TIV.

**Methods:** A survival data until tracheostomy or death could be obtained from 200 Japanese patients including 115 patients after 2000.

**Results:** Fifty-nine patients (51%) underwent NIV after 2000 and 20 patients out of 59 patients underwent NIV followed by TIV. NIV prolonged median survivals as compared to natural course (43 months vs. 32 months p<0.01). Survival during the post-NIV period: patients with bulbar palsy at the time of initiation of NIV showed significantly shorter survival than those without it, not related to nutrition state; but patients with bulbar palsy who could adopt NIV showed longer survival as compared with those on a natural course. At any time of pulmonary function state, even under 30% of %FVC, NIV showed longer survival in patients with ALS. Progression rate at diagnosis calculated by ALSFRS-R was related to post-NIV period. Patients who had prolonged survival over 6 months by NIV tended to refuse the acceptance for TIV. No relation between prognosis after NIV and blood gas analysis was found. **Conclusions:** NIV offered advantages of being non-invasive, having no risk and being easy to introduce or discontinue.

The frequency of use of NIV significantly increased after 2000 and tended to reduce the shift to TIV in Japan. Various factors impact the survival of patients after NIV (bulbar symptom preservation, progression rate at diagnosis and %FVC).

**DOI:** 10.1080/21678421.2016.1232066/0013

**P336 SPONTANEOUS BREATH CYCLING IS IMPAIRED IN PATIENTS WITH ALS USING NON-INVASIVE VENTILATION**

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**Keywords:** non-invasive ventilation, spontaneous triggering, pulmonary function

**Background:** Amyotrophic lateral sclerosis is a progressive neuromuscular disease resulting in respiratory failure and death. Of all muscle groups involved, respiratory muscle function deteriorates more rapidly (1). Diaphragmatic and inspiratory intercostal muscle weakness develops (2,3), and patients are at increased risk of hypoventilation and hypercapnia (4). However, use of non-invasive ventilation (NIV) improves survival.

**Objectives:** To explore the clinical utility of a detailed evaluation of device-recorded NIV data in the management of chronic respiratory failure in ALS.

**Methods:** Retrospective chart review of 271 patients with ALS using NIV. An evaluation of device-recorded data, specifically triggering and cycling ability. Triggering and cycling sensitivities were set to “very high” and “very low”, respectively. **Results:** Two hundred and seventy-one patients were included. Percent spontaneous triggering (% SpT) was preserved at 86.7% [95% CI: 83.9-88.8], whereas percent spontaneous cycling (% SpC) was reduced at 43.1% [95% CI: 38.8-47.9] vs. p<0.0001. 52 patients (20.7%) demonstrated decreased % SpT (<80%), whereas 171 patients (63.1%) demonstrated decreased % SpC (<80%). % SpC did not correlate with Forced Vital Capacity (Spearman’s rho = −0.03, p=0.58) or Maximal Inspiratory Pressure (Spearman’s rho = −0.9, p=0.33). Similarly, % SpT did not correlate with FVC (Spearman’s rho = 0.026, p=0.71) or MIP (Spearman’s rho = −0.17, p=0.08).

**Discussion:** For some patients, respiratory muscle weakness leads to failure to trigger the ventilator, whereas for a greater proportion of patients it is the premature cycling-off of respiratory efforts that is more apparent. Importantly, no association was found between spontaneous triggering or cycling, and pulmonary function. While ineffective triggering might be addressed by using a set backup rate, it does not however address rapid shallow breathing associated with reduced spontaneous cycling.

**Conclusions:** Spontaneous cycling is decreased despite preservation of triggering ability. While a set backup rate...
may address decreased triggering, setting a sufficient fixed inspiratory time would address the issue of decreased cycling.

Acknowledgements: The Les Turner ALS Foundation.

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DOI: 10.1080/21678421.2016.1232066/0014

P337 DIFFERENCES IN ACHIEVEMENT OF TIDAL VOLUMES AND RAPID SHALLOW BREATHING BETWEEN PS AND VAPS MODES OF NON-INVASIVE VENTILATION

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Keywords: non-invasive ventilation, volume assured pressure support

Background: Amyotrophic lateral sclerosis is a progressive neuromuscular disease resulting in respiratory failure and death. Of all muscle groups involved, respiratory muscle function deteriorates more rapidly (1). Use of non-invasive ventilation (NIV) improves survival. Volume assured Pressure Support (VAPS) is a pressure-cycled mode of NIV that aims to achieve a “goal” tidal volume (Vt) over time. Despite this, little is known about the efficacy of VAPS in ALS.

Objectives: To evaluate device-recorded NIV data, to gain an improved understanding of a patient’s response to NIV, as well as to evaluate efficacy of treatment.

Methods: Retrospective chart review of 271 patients with ALS using NIV, along with an analysis of device-recorded data to explore achievement of tidal volumes in addition to Respiratory rate/tidal volume (f/VT), indicative of a rapid shallow breathing pattern.

Results: Two hundred and fifteen patients were using PS, while 56 were using VAPS. There were no significant differences in demographic data, symptoms, pulmonary function, or patient compliance between the cohorts. Overall, mean Vt was significantly lower for PS at 356.2 ml vs. 390.4 ml (p=0.01). Expressing this as Vt in ml/kg ideal body weight (IBW), for PS, mean Vt was 5.51 ml/kg, while for VAPS, mean Vt was 5.9 ml/kg (p<0.01). There was a wide range in achieved Vt, for both cohorts, ranging from 2.2 to 14.7 ml/kg for PS, compared with VAPS, where Vt ranged from 2.7 to 8.8 ml/kg. Rapid shallow breathing, as indicated by f/VT was also significantly greater in standard PS users compared to VAPS, with a mean of 51.6 vs. 44.6, respectively (p=0.02).

Discussion: Effective NIV better predicts survival in patients with ALS (2). This study found that VAPS achieves a more reliable Vt than PS, and is associated with significantly less rapid shallow breathing. This may be related to compensation for mask leak as a major advantage of VAPS is the ability to overcome leak, by constantly adjusting the level of PS to achieve the desired Vt (3). Another may be the ability of VAPS to “adapt” to progression of disease, maintaining Vt over time.

Conclusions: Examination of device data for exhaled tidal volumes and f/VT may be of use in evaluating efficacy of NIV in ALS. This study shows that VAPS provides more reliable goal Vt than PS, and is associated with decreased f/VT.

Acknowledgements: The Les Turner ALS Foundation.

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DOI: 10.1080/21678421.2016.1232066/0015

P338 EFFECTIVENESS OF AUTOMATIC INTRATRACHEAL SUCTIONING SYSTEM FOR AMYOTROPHIC LATERAL SCLEROSIS PATIENTS WITH TRACHEOSTOMY-INVASIVE VENTILATION

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Keywords: automatic intratracheal suction system, respiratory care support team

Objectives: We performed retrospective hospital-based study to clarify the clinical effectiveness of automatic intratracheal suctioning system (AISS) for amyotrophic lateral sclerosis (ALS) patients with tracheostomy-invasive ventilation (TIV).

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DOI: 10.1080/21678421.2016.1232066/0015
Background: We provide long-term medical care for neuromuscular disease patients as a neuromuscular-disease center hospital in Hokuriku area of Japan. We have also developed a multidisciplinary care team for ALS and we are supporting their own decision making. Partly as a result of our support, about 25% of our ALS patients choose TIV. So, management of the ALS-TIV respiratory condition is the important part of our care. To reduce respiratory complications, our respiratory care support team (RST) began to apply AISS from 2012.

Methods: To elucidate the clinical effectiveness of AISS, we retrospectively reviewed medical records of ALS-TIV cases and collected vital sign, suction frequency, episode of pneumonia, usage of antibiotics, and reports of RST intervention.

Results: We were able to pick up 3 cases of ALS-TIV using AISS. Duration between the TIV starting and the AISS introduction was 83 months (M), 19M and 97M. Observation periods after AISS introduction were 32M, 36M and 6M. The frequency of manual intratracheal suction decreased by an average of 78%. Change of vital signs were not remarkable.

Conclusion: From this retrospective study, AISS could improve respiratory tract clearance of ALS-TIV patients. Consequently, the frequency of manual intratracheal suction dramatically decreased. So, AISS could have great possibility to improve respiratory conditions of ALS-TIV. Also the systematic RST participation was important for the safe introduction of AISS.

DOI: 10.1080/21678421.2016.1232066/0016

P339 SPUTUM SUBSTANCE P CONCENTRATION AND PEAK COUGH EXPERIMENTAL FLOW IN PATIENTS WITH ALS AFTER ADMINISTRATION OF ENALAPRIL

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Keywords: angiotensin-converting enzyme inhibitor, peak cough experimental flow, substance P

Background: Airway protective mechanisms, such as swallowing and coughing, play an important role in patients with ALS to avoid aspiration pneumonia. The angiotensin-converting enzyme inhibitor (ACE-I) significantly induces dry cough, which is normally accumulation of bradykinins, substance P (SP), and prostaglandins. ACE-I also increases sputum SP concentration in patients with hypertension and reduces the risk of pneumonia in aged individuals.

Objective: We examined the sputum SP concentration and pulmonary function after enalapril (ACE-I) treatment in ALS patients with decreased respiratory function.

Methods: All patients were previously diagnosed with ALS based on the revised El Escorial criteria and recruited from August 1, 2015. Informed consent was obtained from all ALS patients who showed <80% forced vital capacity (%FVC). We randomized patients into two groups, ie ALS group administered enalapril 5 mg/day (ALSWE) and ALS group without enalapril (ALSWOE). The efficacy of enalapril was assessed at baseline and at 3 months. The motor component of cough efficacy was assessed by the voluntary peak cough experimental flow (PCEF) and %FVC with a spirometer (CHSETAC-8900, Tokyo, Japan). PCEF was evaluated 3 times per measurement, and the maximum data [A1] was regarded as PCEF. ALS patients for whom accurate measurement was not possible were excluded from the study. We also measured the sputum SP concentration using enzyme-linked immunosorbent assay (ELISA) [A2] in ALS patients. This prospective, observational, open labelled study was approved by the Ethical Committee of Toho University Omori Medical Center (ref no. 27–66).

Results: Initially 25 patients were diagnosed with ALS, and a total of 19 patients were included in the study. Three patients dropped out of the study due to adverse events (severe dry cough, dizziness, and hypotension), and all patients recovered after cessation of the drug. No differences were observed between the ALSWE (n=8) and ALSWOE (n=8) groups with regard to the mean age, sex ratio, disease onset type, disease duration, ALSFRS-R, sputum SP concentration, PCEF, and %FVC at baseline. At 3 months, sputum SP concentration increased in the ALSWE group; however, other parameters, including PCEF and %FVC, showed no change in both the groups.

Conclusion: Enalapril was effective in increasing sputum SP concentration in ALS patients. However, this drug did not affect the PCEF and %FVC over the 3-month observation period.

DOI: 10.1080/21678421.2016.1232066/0017

P340 USE OF A WATER PROTOCOL IN ALS PATIENTS WITH THIN LIQUID DYSPHAGIA

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Keywords: water protocol, dysphagia, quality of life

Background: Patients with bulbar onset ALS often experience thin liquid dysphagia and are prescribed thickened fluids. Compliance is poor and hydration needs are not met. Water protocols have been in use in the rehabilitation setting since the 1980s. They are a set of rules that if followed are thought to allow for safe water intake in people with thin liquid dysphagia (1). They are based on the premise that water is relatively inert when
absorbed in small amounts by the lungs (2). An interprofessional working group designed tools to guide a pilot implementation of a water protocol in patients admitted for rehabilitation.

**Objectives:** The aim of the pilot study was to develop tools to guide appropriate prescription of a WP as well as determine the effectiveness of a WP on fluid intake, satisfaction, and quality of life (QOL) while minimizing adverse events.

**Methods:** This study (3) was single-blind, randomized controlled trial with subject cross-over to experimental group. Sixteen rehabilitation inpatients with instrumentally documented thin liquid dysphagia participated in the study. Patients in the control group received standard care (NPO or thick liquids) and patients in the experimental group were prescribed the water protocol. Exclusion criteria included acutely unstable medical condition, excessive coughing during intake, oral infection, active pneumonia or absent swallow reflex. An algorithm was used to guide participants to a supervised or independent access to water and an oral care plan was implemented. The main outcome measures were fluid intake as a percentage of estimated daily requirements, a Quality of life measure using the Swal-QOL tool, as well as the expected outcome of no adverse events.

**Results:** No adverse events occurred in the control or WP phase until discharge (mean duration = 54 days). Fluid intake increased at least 10% of the calculated fluid requirements in 11/15 participants who received oral water access (2 = 6.172, df = 1, 22, p = 0.01). The post WP group reported an improvement of fear of swallowing scale on the Swal-QOL over the control group.

**Discussion and conclusions:** Since the completion this pilot WP study, use of the exclusion criteria, algorithm, oral care plan, and information brochure has become standard practice at GF Strong (GFS) Rehabilitation Centre for many different patient populations including ALS patients.

**Acknowledgements:** Supported by the William G. Fraser Rehabilitation Research Award, BC Rehab Foundation

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DOI: 10.1080/21678421.2016.1232066/0018

**P341 DYSPHAGIA IN AMYOTROPHIC LATERAL SCLEROSIS AND POSSIBLE IMPACT ON RILUZOLE MANAGEMENT**

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**Keywords:** Dysphagia, Riluzole, Swallowing evaluation.

**Background:** Dysphagia is a frequent event in amyotrophic lateral sclerosis (ALS), and a regular evaluation of nutrition status is topical. A clear description of modifying both food consistency and riluzole to be able to swallow in dysphagic ALS patients is not completely defined. Our objective was to investigate clinical features associated with deteriorated swallowing in ALS patients with spinal and bulbar onset, and to assess the impact of dysphagia on the assumption of riluzole and on survival.

**Methods:** In December 2015 we conducted an audit of the registry to collect, retrospectively, dysphagia data in terms of: incidence of dysphagia, according to ALS onset (spinal or bulbar), at the time of diagnosis and at last follow up, modification to diet and way of swallowing riluzole. One-hundred and forty five ALS patients were observed periodically every three-six months. They underwent routinely Fiberoptic Endoscopic Evaluation of Swallowing (FEES) and Spirometry; dysphagia evaluation according to the Penetration Aspiration Scale (PAS) and the Pooling score (P score) integrated with other parameters such as sensation of the pharynx, patient collaboration and age (P-SCA score).

**Results:** In a mean follow-up period of about two years (20.1 ±17.9 months), 85% of ALS patients began dysphagic (from 35% to 73% of spinal patients, from 95% to 98% of bulbar patients). Worsened swallowing was more rapid in male and older patients with bulbar onset of disease. As expected in a progressive disease, a gradual significant worsening in PAS score during the follow-up period was evident (p<0.001). The normal and semi-solid diets reduced, while the pureed diets and PEG prescription increased over time. In our series, 44% of dysphagia patients refused requested thickeners or PEG, also if with the impairment of laryngeal reflex. Concerning riluzole administration, 95 patients were treated with riluzole (66%). Many dysphagic patients (64%) assumed the riluzole as whole tablets (Rilutek®), while 25% used crushed tablet and 11% shifted to the riluzole as an oral suspension (Teglutik®). Incidence of mortality was 48% of patients not treated with riluzole, 41% of patients treated with whole tablets, 35% of those crushing the tablets, and 22% of those assuming riluzole as an oral suspension.

**Discussion:** Dysphagia is a very common symptom in all ALS patients. The disease duration impacted mostly on frequency of dysphagia in spinal patients, appearing very early in patients with bulbar onset. The PAS was the best test to evaluate the worsened swallowing in time. Malnutrition needs an early and periodic nutrition assessment and therapeutical intervention to decide the correct modification of consistency of diets and the proper use of thickening agents or PEG, also because sometimes patients with dysphagia highlighted with FESS did not perceive the objectified disorder.

**Acknowledgements:** We gratefully thank the Italfarmaco SpA for assistance and support.

DOI: 10.1080/21678421.2016.1232066/0019
Discussion and conclusion: The established nutritional protocols in combination with the analysis of the fatty acid distribution in erythrocyte lipids as marker for the intake of fat-rich foods over the last 2–3 months facilitates a comprehensive insight into the nutritional habits of the ALS patients. The first evaluation of the data indicates for an association between higher consumption of foods rich in sFA, in particular C17:0 as well as n-3 LC-PUFA and a lower disease progress. However, the observed differences in fatty acid intake was not reflected by their concentrations in erythrocyte lipids which do not vary between the three groups. As a further step, fatty acid distribution of plasma lipids which reflect dietary intake of fat-rich foods over the last 2–4 days will be analysed to prove the resulting hypothesis of an impaired incorporation of selected fatty acids, e.g. n-3 LC-PUFA in ALS patients.

DOI: 10.1080/21678421.2016.1232066/0020

P343 ANALYSIS OF THE INTERFACE BETWEEN DYSPHAGIA AND NUTRITIONAL IMPLICATIONS IN PATIENTS WITH MOTOR NEURON DISEASE

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Keywords: deglutition, malnutrition, deglutition disorders

Background: Motor neuron disease (MND) can have appendicular onset (Amyotrophic Lateral Sclerosis – ALS) or bulbar onset (Progressive Bulbar Palsy – PBP); both present weakness and this is a common symptom that might lead to dysphagia. Because of difficulty in swallowing, loss of lean body mass and the hypermetabolic characteristics of MND, the patient can develop malnutrition. Understanding the interface between dysphagia and nutritional implications can assist the patient to prevent the clinical presentation of malnutrition.

Objective: To evaluate the interaction between dysphagia and the nutritional implication on MND patients.

Material and method: Fifty-nine patients were evaluated: 42 (71.18%) ALS patients (47.62% males and 52.38% females) and 17 (28.82%) bulbar patients (41.17% males and 58.83% females). Patients underwent dysphagia and nutritional assessment and other scales e.g.: Functional Oral Intake Scale (FOIS), Functional Rating Scale (ALSFRS-R and ALSSS) and assessment of cough peak flow (CPF).

Results: 100% of patients with PBP showed changes in oral and pharyngeal phases, while ALS patients showed changes in oral phase (66.67%) and pharyngeal phase (73.80%). The nutritional assessment showed malnutrition in 54.8% of the patients with ALS and 58.8% of the patients with PBP. Patients who used other alternative types of feeding: 28% (ALS) and 42% (PBP). Patients who had severe weight loss: 57.14% (ALS) and 76.47% (PBP). On application of FOIS, the appendicular group presented average of 5.1 and the bulbar group, 3.9. The patients with appendicular onset (ALS) had a median score of 8 in the bulbar field ALSFRS-R and a median score of 7 (speech and deglutition fields of ALSSS) and patients with bulbar onset (PBP) had median score 5 in the bulbar field of ALSFRS-R and median score 4 (speech and deglutition fields of ALSSS).
**Discussion and conclusion:** Dysphagia was present in all patients with PBP, in association with malnutrition. Body Mass Index (BMI) and Escore DEP showed correlation to functionality scale ALSFRS-R, in the bulbar group. The highest level of FOIS for the less dysphagic patients indicates that the severity of dysphagia is mandatory in the choice of food consistency. There was correlation between BMI and the FOIS and the CPF. There was no statistical correlation between the CPF, the oral phase of swallowing and the occurrence of cough, in the ALS group. Significant correlations were demonstrated between the CPF and the fields of the ALSFRS-R in patients of the appendicular group. The BMI, FOIS and CPF were correlated with greater intensity in patients with bulbar onset. Knowing the factors that could raise the risk of malnutrition allows the team to establish dietary changes, changes in food consistency, use of swallowing manoeuvres, and indication of the tube feeding. Such measures can be used to prevent the start of malnutrition.

DOI: 10.1080/21678421.2016.1232066/0021

**P344 PERCUTANEOUS ENDOSCOPIC GASTROSTOMY IN PATIENTS WITH ALS AT THE LJUBLJANA ALS CENTRE – A RETROSPECTIVE ANALYSIS**

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*Keywords:* PEG, survival, NIV

**Background:** Percutaneous endoscopic gastrostomy (PEG) is a well-established procedure in patients with ALS with feeding problems. Inadequate nutrition status is an independently negative prognostic marker for survival in ALS. Although recommendations exist on when, in the course of the disease, to perform the PEG tube placement (1), the criteria for optimal timing have not been established.

**Methods:** We performed a retrospective analysis of PEG in patients with ALS at the Ljubljana ALS Centre between January 2003 and June 2016. We analysed patients’ demographic data, clinical features at the onset of the disease and at the time of PEG insertion, respiratory status (including the use of non-invasive ventilation) at the time of PEG insertion, progression of the disease and patient survival. Comparisons were made between two groups of patients: those surviving less than 1 month (<1mo group) and those surviving more than 1 month after the procedure (>1mo group).

**Results:** During the observed period, 419 patients were seen at our ALS center. A PEG tube was inserted in 148 patients (35% of all patients). The procedure was performed at our hospital in 122 out of 148 patients and these patients were further analyzed. 18 patients (15%) died within one month after PEG placement. Comparing the <1mo to >1mo group, the following statistically significant differences were found: 1) in <1mo group, there were more spinal onset patients (72% vs. 41%); 2) ALSFRS-R score at PEG placement was lower (20.4 vs. 26.0); 3) a higher proportion was using NIV at PEG (28% vs. 25%); 4) arterial blood gas analysis showed higher pCO2 (5.97 kPa vs. 5.55 kPa); 5) lower pO2 (9.89 kPa vs. 10.94 kPa); 6) higher base excess (4.62 mEq/l vs. 2.58 mEq/l); 7) survival from disease symptom onset was shorter in <1mo group (24.5 months vs. 38.5 months).

**Discussion and conclusions:** According to our results, PEG tube placement is associated with longer survival in patients with bulbar onset ALS, with less functional impairment and with better respiratory function. Our 1-month mortality rate (15%) is comparable to some of the published data (13% in (2), 12.9% in (3)) but higher than in other studies (3% in (4)). It remains to be answered to what extent can the post-procedural mortality be a consequence of the PEG tube placement or of the natural course of the disease itself.

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DOI: 10.1080/21678421.2016.1232066/0022

**P345 GASTROSTOMY AND SURVIVAL IN ALS PATIENTS**

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*Keywords:* PEG, prognosis, disease progression

**Background:** Percutaneous endoscopic gastrostomy (PEG) placement is often recommended in patients with amyotrophic lateral sclerosis (ALS) who have dysphagia but its effect on functional decline and survival is uncertain. There is some retrospective data to suggest that weight-maintenance may be a prognostic risk factor in survival, but studies have not consistently shown a benefit in slowing disease progression or decreased mortality after PEG placement.

**Objectives:** To assess the functional outcome and survival after PEG placement in ALS patients and identify potential markers that may influence patient outcomes after PEG placement.

**Methods:** A retrospective chart review was conducted for all patients diagnosed with ALS at the University of Maryland Medical Center ALS clinic between January 1, 2007 and June 31, 2015. The need for PEG placement was based on the algorithm in the 2009 AAN Practice Parameter update and ALS patients who had PEG placement were compared to patients who did not have PEG placement. The rate of change in the revised ALS Functional Rating Scale (ALSFRS-R), calculated as the change in ALSFRS/time, was compared between the PEG and control groups using 2-tailed paired t-tests with a p-value <0.05. The rate of change of the patient’s forced
vital capacity (FVC) and patient demographics in the PEG and control group were compared, with categorical variables computed by the Fisher’s exact test. Survival was determined by the mean time to death after PEG placement is recommended.

Results: The medical records of 139 ALS patients were reviewed. Forty seven patients had PEGs and 33 were identified as control. ALS patient who had PEG were older compared to controls. The proportion of ALS patients who had PEG was higher in Caucasians compared to non-Caucasians. The site of symptom onset, duration to diagnosis, gender, Riluzole use, and family history were similar between the two groups. All patients showed a decline in their ALSFRS-R scores, and there was a faster rate of decline in the PEG group compared to the control group (p = 0.017) prior to PEG placement. The rate of decline in the ALSFRS-R did not differ in the 2 groups in the time interval after which the PEG was recommended. The change in FVC was similar in patients who had a PEG compared to the controls. Survival was decreased in the patients who had a PEG compared to controls.

Conclusions: PEG placement may not modify disease progression in ALS and survival may be decreased in ALS patients who have a PEG.

DOI: 10.1080/21678421.2016.1232066/0023

P346 GASTROSTOMY PLACEMENT IN ALS PATIENTS-OUTCOMES AFTER CHANGING CLINICAL PRACTICE FROM PERCUTANEOUS ENDOSCOPIC GASTROSTOMY (PEG) TO RADIOGRAPHICALLY INSERTED GASTROSTOMY (RIG)

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Keywords: nutritional support, feeding tube placement, radiographically inserted gastrostomy (RIG)

Background: Nutritional support through feeding tube placement is a key intervention in ALS care. The method of placement has been controversial with different approaches favored at different centers. Our clinic changed practice from endoscopic placement to radiographic insertion in February of 2012. A study of PEG outcomes at our center had shown high pulmonary complication rates (10.9%) and demonstrated that altered diet at time of feeding tube placement predicted complications more reliably than reduced Forced Vital Capacity (FVC).

Objectives: Our aim was to analyze complication rates at our center after switching the practice of care from percutaneous endoscopic gastrostomy (PEG) to radiographically inserted gastrostomy (RIG).

Methods: Data was captured for all patients that underwent feeding tube placements from May 2012 to May 2014. Dietary changes, indications for the procedure, complications (e.g. prolonged hospital stay (>24h), infection, pain, bleeding, displaced G-tube, nausea, vomiting, respiratory failure, urinary retention or death) and survival were analyzed with logistic regression.

Results: The study set included 48 patients that received RIG, average age at onset was 57 years, 50% female, 35% bulbar. 77% took Riluzole initially (14% of those eventually stopped the drug). The average rate of decline in ALSFRS was 1.2 points/month with median survival of 2.4 years. 50% of patients had multiple indications for feeding tube placements. Indications for feeding tube placement included dysphagia (65%), weight loss (54%), FVC decline (35%) and elective (4%). Diet at time of RIG placement was regular in 16, dysphagia level 3 (soft) in 18, dysphagia level 2 (minced) in 5 and dysphagia level 1 (pureed) in 8 and nothing by mouth in one patient. 35% of patients had a complication: Pain (10%), nausea (8%), displaced G-tube (4%), bleeding (2%), infection (2%) and prolonged hospital stay (>24h, 2%). One patient had hypoxia secondary to excessive pain medication; one had leakage around tube from an underlying hiatal hernia and one mild COPD exacerbation. An additional three patients were not able to get RIG and underwent PEG. One-month survival was 94% and six-month survival was 62%. Six-month survival was strongly predicted by significant alteration in diet at time of feeding tube placement (p=0.004).

Discussion and conclusion: Our change in practice has resulted in a decline in pulmonary complications. Pain has emerged as the main complication, which is consistent with the literature. Dietary change remains an easily observable predictor of long-term outcomes. Our experience supports gastrostomy tube placement before significant adjustments in diet, as well as proper pain assessment and management when choosing RIG.

DOI: 10.1080/21678421.2016.1232066/0024

P347 CHANGING PRACTICE FROM RADIOLOGICALLY INSERTED GASTROSTOMY (RIG) TO NASAL UNSEDATED SEATED GASTROSTOMY (NUPEG): OUR EXPERIENCE

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Keywords: gastrostomy, weight, nutrition

Background: Enteral feeding via gastrostomy is frequently required to manage nutritional needs and dysphagia in ALS/MND, but the optimal route and timing are currently unknown. A novel technique, Nasal Unsedated seated PEG (NuPEG), was introduced as an option for all patients who required gastrostomy placement at the Cambridge MND Care Centre from 2013. Previously, patients who were deemed to be at high risk of
complications secondary to sedation, or were unable to lie flat, or had signs of respiratory compromise, would be referred for a radiologically-inserted gastrostomy (RIG).

**Objectives:** We set out to evaluate our practice of gastrostomy placement in a single MND Care Centre by determining the outcomes for patients living with MND who underwent NuPEG, compared with the outcomes in those patients who previously underwent RIG.

**Methods:** By analyzing a cohort of patients who attended the Cambridge MND Care Centre between September 2012 and September 2014, we identified all patients who had undergone gastrostomy placement, either by RIG or by NuPEG at Addenbrooke's Hospital, Cambridge. A retrospective study of the medical records of these patients was then performed.

**Results:** Our cohort included nine patients who had undergone a RIG and 13 patients who had undergone a NuPEG. Median duration of disease from symptom onset was 381 days (Range 41 to 2698 days) for RIG and 294 days (Range 130–1059 days) for NuPEG. 40% of patients who underwent a RIG were using NIV, compared to 23% for those who underwent NuPEG. The 30 day mortality rate was zero for all procedure types. Complications such as infection and blockage were more common in RIG-treated patients (44.4%) compared to NuPEG (15.4%). Weight change from 3 months pre- to 3 months post-gastrostomy was −4.94 kg (Range = +0.6 to −9.5 kg) for patients who had undergone RIG, compared to −8.24 kg (Range = +4 to −16.7 kg) for patients who had undergone NuPEG.

**Discussion:** Our data concerning patients attending a single MND Care Centre suggest that NuPEG is a well-tolerated procedure with a low complication rate and is a viable alternative to RIG placement, particularly in patients living with MND with features of respiratory compromise, are unable to lie flat, and where the use of sedation is felt to be high-risk.

DOI: 10.1080/21678421.2016.1232066/0025

**P348 ALS/MND PATIENTS PREFER LOW PROFILE GASTROSTOMY TUBES: ANALYSIS CONFIRMS SAFETY**

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*Keywords: gastrostomy tubes, PEG, diaphragm pacing*

**Background:** Recent ALS/MND data suggests a correlation between a patient’s weight and survival but only 43% of patients who were recommended a percutaneous endoscopic gastrostomy tube (PEG) chose it. With 30% of ALS/MND patients presenting with bulbar onset and 81% of advanced ALS/MND patients having dysphagia, the acceptance of PEG is too low. Patients declined PEG for the following reasons: belief their swallow was adequate, general disdain and lack of knowledge. The low profile gastrostomy tube (button) has been around for over 30 years. Patients’ preference and feasibility of primary button gastrostomy insertion in ALS/MND patients has previously been presented.

**Objectives:** Determine complications and safety of button gastrostomy in long term analysis in a large cohort of patients.

**Methods:** Subgroup analysis of all ALS/MND patients who were being evaluated for diaphragm pacing (DP) and were offered gastrostomy at a single institution. Patients were offered a choice between standard PEG and button. The pros/cons of each were reviewed.

**Results:** Between 2011 and May 2016, 180 patients were evaluated for DP and PEG. An additional 27 patients had existing standard feeding tubes. Forty-seven patients had bulbar symptoms at the evaluation and only 13 of them presented with a PEG. Forty-three of the patients without PEG also had a FVC below 49% (22–49). Eighty-seven patients having DP surgery received the low profile button and ten had their standard PEG changed to a button. Two patients received standard PEG. Patients that chose the button ranged in age from 28 to 81 years with an average age of 57. The average FVC was 56% (17–110%). Thirty-six patients choosing the button had a FVC above 60% and no bulbar symptoms. After two months, two patients required conversion to standard PEG due to body habitus.

Two patients had button dislodgment within the first two months. The 6 month survival is 87%. The median survival is 17.6 months.

**Discussion and conclusion:** When given a choice, patients overwhelmingly selected the button. All patients preferred the aesthetics of it. Button placement is safe and has a very low complication rate. The dislodgement rate of 2% is the same as the standard PEG dislodgement rate of 1–13.4%. Button changes are easily performed with minimal discomfort and can be easily converted to a standard PEG if needed. A limiting factor in offering a button is abdominal size. Also, utilization requires the abdomen to be exposed and greater finger/hand dexterity to access it. One of our patients chose the standard PEG so he could perform his own feeds. Offering direct button placement could affect ALS/MND patients’ acceptance of a feeding tube allowing for placement at a safer stage of their disease and a mechanism to provide necessary nutrition before weight loss occurs.

DOI: 10.1080/21678421.2016.1232066/0026

**P349 GASTROSTOMY, BODY WEIGHT LOSS AND SURVIVAL IN AMYOTROPHIC LATERAL SCLEROSIS: A POPULATION-BASED STUDY**

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Keywords: PEG, survival, population-based study

Objective: To assess the role of gastrostomy insertion and its timing on ALS survival, and to study prognostic factors of survival before and after gastrostomy placement in a population-based setting.

Methods: We included 210 patients needing gastrostomy out of an incident cohort of 545 patients from the Emilia Romagna Registry for ALS diagnosed from 2009 to 2013. Of these, 169 underwent gastrostomy, whereas 41 did not undergo the procedure.

Results: Patients who did not undergo gastrostomy among the eligible ones had the same tracheostomy-free survival of patients who did (25 vs. 29 months, p=NS). Using stratified analysis, gastrostomy placement did not prolong survival either in bulbar or in younger patients. Overall median survival from gastrostomy insertion to death was 16 months (95% CI: 12–21); 30 days after overall death was 16 months (95% CI: 12–21). There was no significant difference in median survival of patients who did (25 vs. 29 months, p=NS) or those who had a gastrostomy placement before a median of 6 months (95% CI: 3–10). Conclusions: Our study showed an increased survival for patients who underwent gastrostomy placement before a significant weight loss occurred, while all the remaining potential prognostic factors related to gastrostomy did not influence prognosis. Should this association be confirmed by further studies, it would have important implications on disease management.

DOI: 10.1080/21678421.2016.1232066/0027

P350 GLUCOSE CLEARANCE AS A CONTRIBUTING FACTOR FOR ALTERED ENERGY NEEDS IN ALS

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Keywords: metabolism, glucose clearance, disease progression

Background: Impairments in metabolic homeostasis are common in ALS, and may contribute to the rate of disease progression. Through understanding the impact of metabolic responses in ALS progression, we may develop strategies to alter the course of disease. We evaluated metabolic needs of ALS patients relative to clinical parameters of disease and early postprandial glucose clearance.

Methods: Age, sex and body composition matched non-diabetic ALS (n=30) and control (n=20) subjects were recruited at the Royal Brisbane and Women’s Hospital, and attended a research clinic at the University of Queensland Centre for Clinical Research. Body composition was assessed using air displacement plethysmography (BodPod, COSMED). Fasting energy expenditure at rest (REE) was assessed by indirect calorimetry (Quark RMR, COSMED). Blood glucose levels were assessed following an overnight fast and 15 min following the consumption of a standardized mixed meal (Sustagen, Nestle). Disease severity was assessed using the revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R), and respiratory function tests.

Results: REE varied greatly between ALS patients (641 to 2406 kcal/day; Mean ± SEM = 1543 ± 85.82), with hypermetabolism observed in 40% of ALS subjects. REE in ALS subjects did not correlate with functional status (ALSFRS-R, r² = -0.05, 95% CI = -0.409 to 0.33, p = 0.81; FVC (% of predicted), r² = -0.23, 95% CI = -0.57 to 0.16, p = 0.23; SNP (% of predicted), r² = -0.30, 95% CI = -0.62 to 0.12, p = 0.14), or the duration of disease (time since symptom onset (months), r² = -0.25, 95% CI = -0.57 to 0.13, p = 0.18; time since diagnosis (months), r² = -0.29, 95% CI = -0.61 to 0.13, p = 0.16). The difference between predicted and measured resting metabolic needs increased relative to a worsening in postprandial blood glucose control (r² = 0.41, 95% CI = 0.062 to 0.67, p = 0.02).

Conclusions: Results from this study show that energy needs in ALS vary considerably, without association with disease severity or duration. Rather, impairments in blood glucose control appear to contribute to increasing energy needs. When considered alongside reports of impaired insulin function, and reports of impairments in muscle glucose use, our data suggest that alterations in metabolic needs of ALS patients might occur due to impairments in processes that mediate glucose uptake.

Acknowledgements: This research was supported by the MNDRIA through a Cunningham Collaboration Grant. F.J.S. is a recipient of a Jenny and Graham Lang Collaboration Award. S.T.N. was a recipient of a Scott Sullivan MND Research Fellowship (QBI, RBWH Foundation, and the MND and Me Foundation) and UQ.

DOI: 10.1080/21678421.2016.1232066/0028

P351 BODY COMPOSITION ANALYSIS OF PATIENTS WITH MOTOR NEURONE DISEASE BY BIOELECTRICAL IMPEDANCE

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Keywords: weight loss, nutritional status, body composition

Background: Due to symptoms such as increased metabolism and oropharyngeal dysphagia, depletion of nutritional status is often observed in motor neurone disease (MND) patients and with this, there are changes in body composition. The method of bioelectrical
impedance analysis (BIA) determines lean mass and fat mass by estimating total body water.

Objective: To assess the body composition of patients with MND/ALS.

Methods: We included patients over the age of 20 years, with a conclusive diagnosis of MND. We classified the nutritional status and BMI according to age group (WHO, 1967). The analysis of body composition was performed by the method of bioelectrical impedance Biodynamics 450.

Results: Twenty-seven patients were evaluated, 51.9% men and 48.1% women, 55.5% were elderly. For manifestations of the disease, 77.7% with appendicular and 22.3% bulbar. All bulbar patients showed weight loss since the initial manifestation of symptoms. For the classification of nutritional status, it was observed that 83.3% of bulbar patients were classified as low weight, and only 16.7% as normal weight. For appendicular patients, 28.5% were classified as underweight and 52.8% normal weight. When analyzing body composition, discrete differences of distribution of lean body mass and fat mass in both forms of manifestation of disease, were observed.

Discussion: The more depleted nutritional status was observed in bulbar compared to appendicular patients, especially the slower evolution occurs if involvement is of a neuron. For body composition, there was no significant difference between the different forms of manifestation of disease in this sample, however, it seems that bulbar patients have a larger amount of body fat.

Conclusion: Greater involvement of nutritional status occurs in bulbar patients. The nutritional status is an independent prognostic factor for disease evolution, and the body evaluation can assist in the adoption of practices to prevent weight loss.

DOI: 10.1080/21678421.2016.1232066/0029

P352 BODY COMPOSITION ANALYSIS AND ENERGY REQUIREMENT ASSESSED BY BIOELECTRICAL IMPEDANCE ANALYSIS IN PATIENTS WITH ADVANCED ALS

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Keywords: nutrition, body composition, energy requirement

Objectives: The purpose of our study is to assess body composition and clarify the energy requirement in patients with advanced ALS managed by mechanical ventilation.

Methods: This study was conducted from November 2014 to May 2016. Among the ALS patients in our hospital, six patients (one male and five females) were recruited into this study. All patients were bedridden and clinically stable using mechanical ventilation management (one NIPPV, five TPPV) and tube feeding, and did not have any infection such as pneumonia. They underwent at least 1 bioelectrical impedance analysis (BIA) based assessment, and three patients underwent at least two assessments. Data regarding age, weight, body mass index, ALS functional rating scale score, fat-free mass, skeletal muscle mass and fat mass were collected. We estimated resting metabolic rate (RMR) from measuring body composition and total daily energy expenditure (TDEE) from the ALSFRS-R by using these models.

Results: The patients were 51–78 years old, and had a total clinical course of 7–194 months, and 1–136 month-long courses under mechanical ventilation. They are classified into the three groups; totally locked-in state (3 patients), complete tetraplegia (2 patients), and incomplete tetraplegia (1 patient). The body fat percentage was 37.56–51.71%, which was higher than suggested by their BMI (14.3–24.2 kg/m2). TDEE using ALSFRS-R ranged from 781 kcal/day to 1066 kcal/day. We estimated RMR by various methods. The RMR estimated by the Wang (740–1034 kcal) and Cunningham equation (763–1005 kcal) using fat free mass (FFM) was smaller than the RMR estimated by the Harris–Benedict equation (949–1154 kcal), and similar to TDEE using six questions from ALSFRS-R. The calorie intake in five of six patients was lower than the TDEE, the RMR estimated by the Harris–Benedict, Wang, and Cunningham equation. But the body weights and percent body fat were maintained, and in one patient the body weights and percent body fat was increased.

Discussion and conclusions: Patients during advanced ALS with mechanical ventilation management and tube feeding showed fat accumulation even under low calorie intake less than estimated by RMR. Daily amount of calorie intake should be restricted at the advanced stable stage to avoid fat accumulation and hyperglycemia.

DOI: 10.1080/21678421.2016.1232066/0030

P353 VALIDATION OF ANTHROPOMETRICALLY-DERIVED BODY COMPOSITION AGAINST DEXA IN ALS

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Keywords: anthropometric equations, body composition, disease progression

Background: Accurately measuring body composition in ALS patients is critical to follow disease progression and undertake nutritional rehabilitation (1,2). Anthropometric analyses have been used to record loss of fat mass (FM) and fat-free mass (FFM) for clinical assessment of patients (1,2). However, anthropometrically-derived body composition has not been studied in disease progression nor has an ALS-specific equation to estimate body composition been created.

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Objectives: Use anthropometric equations to estimate body composition in ALS patients (3–5); compare FFM and FM estimated from anthropometric equations with values measured by DEXA; create a validated ALS-specific anthropometric equation using demographic and disease-related measures for use in patients; examine the effects of changes in body composition estimated by the ALS-specific equation on progression and survival in a separate clinic cohort of patients.

Methods: Both anthropometric and DEXA data is available in 29 ALS patients and will be used for objectives 1 and 2 to establish objective 3. The ALS-specific equation will allow estimation of body composition in the clinic cohort, and permit an analysis of its effect on disease progression and survival. Appropriate statistical comparisons will be employed.

Results: In 29 patients (72% male, 83% with limb-onset ALS) the baseline demographics (mean) were: age 57.4 years, disease duration 24 months, BMI 24.6 kg/m2, ALSFRS 29.3, and predicted FVC 86.3%. Compared to DEXA, estimated FM and FFM showed high correlations ($r=0.80$) using all anthropometric equations. The most precise values were obtained using the Deurenberg equation (3). Data, including that from the ALS-specific equation, and effect of changes in body composition on progression and survival in the clinic cohort, will be presented.

Discussion and conclusions: We believe that body composition estimated using the ALS-specific equation will reliably predict rate of disease progression and survival in ALS.

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DOI: 10.1080/21678421.2016.1232066/0031