Haemodynamic and Respiratory Responses to Abdominal Muscle FES – A Pilot Study

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Introduction

Spinal cord injury (SCI) at T6 level and above results in paralysis of the lower trunk muscles, and reduced ability to perform forced expiratory manoeuvres in comparison to their SCI counterparts with spared innervation to abdominal musculature. The resulting paralysis leads to inefficient coughing and increases risk for pulmonary complications. Sitting posture and bed mobility are adversely affected and, diaphragmatic splinting has been reported in the sitting position[1]. It is well recognised that numerous factors affect respiratory function of people with tetraplegia, including age, body weight, health status, lesion level, ASIA classification, duration of injury, spasticity, breathing technique, posture and cigarette smoking. A study by Linn et al[2] of people with chronic tetraplegia showed that forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) are reduced to approximately 50% of predicted values for the reference population. Several studies have associated higher lesion level and duration of injury with greater impairment of respiratory function[2], leading to a reduced ability to clear pulmonary secretions. Therefore, the tetraplegic population is at high risk of hypoventilation, atelectasis, retention of airway secretions, respiratory tract infection and respiratory failure, leading to hospital admission and mortality. The role of paralysis of the abdominal musculature and the ability to overcome this with electrical stimulation remains unclear.

Various FES techniques have been used successfully to activate trunk musculature in people with tetraplegia. These studies have demonstrated effective short-term ventilation for respirator-dependent patients[3], enhanced cough[4] and reversal of post-prandial hypotension[5]. However these clinical reports were either single cases or small case series and tended to use non-standardised abdominal muscle functional electrical stimulation (AMFES) protocols. Therefore evidence is required to demonstrate the safety and efficacy of the AMFES intervention and its role in the management of people with tetraplegia, in particular its effects upon the sympathetic nervous system and the potential to trigger autonomic dysreflexia (AD)[5].

This pilot study aimed to determine the safety and efficacy of AMFES in the management of respiratory function in people with chronic tetraplegia, and establish stimulation parameters and refine protocols as a preliminary step for a multi-centre study of the role of AMFES in the management of tetraplegia. The study was approved by the Human Research Ethics Committee of the Royal Adelaide Hospital.

Subjects and Method

The study used a double-blind, self-controlled study, using repeated-measures within-subjects design to compare AMFES and sham conditions in subjects with chronic tetraplegia in both sitting and lying positions. Subjects were screened for suitability for the study, recording gender, age, lesion level, duration of injury, method of bladder management, postural symmetry and other physical and health characteristics. Eight volunteers were screened for suitability, resulting in selection of five healthy subjects (Table 1). Four subjects were active participants in various sports and all were naïve to AMFES, although four had participated in other FES studies.

A commercially available stimulator (Respond Select, EMPI) delivered a standardised stimulation current via surface electrodes (40-1004 and 40-1006, Myles Medical, Inc. Amherst NH) arranged in a rectangular grid (Figure 1). Forced expiratory manoeuvres (FEM) and haemodynamic parameters were tested in lying and then in a reclined sitting position. Maximal expiratory pressure [MEP] (tested without and with stimulation) and maximal inspiratory pressure [MIP] were determined using a custom made manometer, followed by the other tests. Respiratory flow rates (FEV_1, peak expiratory flow rate [PEF], peak inspiratory flow rate [PIF]) and volume (FVC) were measured using a Vitalograph Compact II. In each position, test manoeuvres were performed under 4 sham and 4 AMFES conditions delivered in random order with 2 minutes rest between each procedure. Blood pressure was monitored throughout.

Data were analysed using the maximum values derived from a minimum of three expiratory manoeuvres. FEV_1, FVC and MEP in each position were compared using paired t-tests. Pearson correlations were used to assess interactions of test position with injury level and duration of injury. Data were analysed using the SPSS statistical software package and a probability value < 0.05 was deemed statistically significant.

Table 1. Subjects Characteristics

Gender	Age	Duration of Injury	Level of Injury	ASIA	BMI $kg.m^{-2}$	Smokers	History of AD
M	25	1	C5 / 6	A	21.3	N	Y
M	28	4	C6	A	24.7	N	N
M	20	4	C6 /C7	A	26	N	N
F	23	3	C7 C8	A	19	N	Y
M	32	9	C6	B	22.9	Y	Y

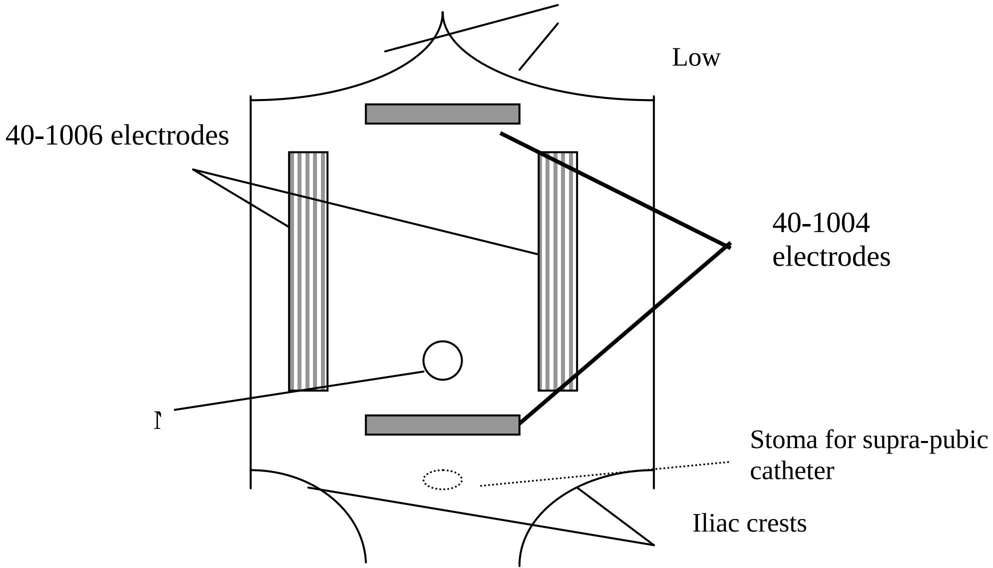

Figure 1. – Grid pattern for the electrode placement for AMFES

Results

Table 2. Respiratory function values for sham and AMFES conditions [mean (SD)] * $p < 0.05$

Variable	Sham	AMFES
FVC lying (litres)	3.3 (0.5)	3.5 (0.5)*
FVC sitting (litres)	3.3 (0.4)	3.5 (0.3)*
FEV$_1$ lying (litres)	2.8 (0.5)	2.9 (0.4)
FEV$_1$ sitting (litres)	2.8 (0.5)	3.1 (0.3)
MEP lying (cm H$_2$0)	48 (18.7)	53 (18.9) *
MEP sitting (cm H$_2$0)	52 (19.6)	51 (17.4)

AMFES augmented FVC in both lying and sitting positions, reaching statistical significance ($p < 0.05$) (Table1). Values for FEV$_1$, PIF and PEF were not significantly different for the test and sham conditions in either lying or sitting position. AMFES significantly increased MEP in lying ($p < 0.05$), but not in the sitting position ($p > 0.05$). For all measures, results in sitting were not significantly different to results in lying, when comparing stimulation and sham conditions ($p > 0.1$). For each individual, a gradual reduction in measured responses was observed ($p > 0.05$) for the repeated tests, suggesting either an effect from fatigue, or other factors may account for this decay in performance.

The study showed that AMFES is safe and well tolerated in experimental conditions in healthy subjects with chronic tetraplegia. This intervention significantly increased FVC in comparison to sham conditions in both lying and sitting. One subject was observed to have reduced respiratory performance due to trunk asymmetry, which may be exacerbated by AMFES-induced spasticity, particularly when AMFES was delivered in the sitting position. Small differences in FEM between lying and sitting did not reach significance. Consistent with other reports, level of injury was observed to influence the efficacy of FEM in this group.

FVC and FEV$_1$ were analysed using Pearson Correlation coefficients in stimulation and sham conditions, in both test positions. A high degree of association was identified for these parameters irrespective of test conditions. Correlational analysis of FEM by level of injury (in both lying and sitting), and duration of injury (in both lying and sitting) are shown in Table 3.

Table 3. Pearson Correlation coefficients for FVC and FEV_1 with level and duration of injury in both test positions ($p > 0.05$).

		FVC (R^2)		**FEV_1 (R^2)**	
Condition	Position	Sham	AMFES	Sham	AMFES
Injury Level	Lying	0.9	0.7	0.4	0.1
	Sitting	0.8	0.6	0.4	0.3
Injury Duration	Lying	-0.2	-0.0	-0.5	-0.6
	Sitting	0.4	0.5	-0.5	-0.6

Diastolic blood pressure in lying was significantly elevated in AMFES in comparison to sham conditions ($p < 0.05$) but only in the lying position. Whilst no evidence of autonomic dysreflexia (AD) was observed during AMFES conditions, one subject showed signs of transient bradycardia which resolved spontaneously. Apart from this one observation, AMFES was safe and well tolerated by these subjects.

Discussion

Measures of respiratory function from this pilot study are consistent with those of other studies after SCI. These include variation according to level and duration of injury. All subjects were fully independent in ADL, and most were active sports participants, so it is likely that they are less prone to respiratory disease than less active individuals with tetraplegia. This study showed modest but significant increases in FVC in response to AMFES and non-significant increases in FEV_1 in sitting and lying. Other pulmonary function tests did not differ significantly between sham and AMFES conditions. Testing of the associations between FVC and FEV_1 with level and duration of injury supported the relationships of those measures to level of injury and duration of injury. Lack of a significant change in FEV_1 may reflect the small sample size, and warrants investigation in a larger study.

Taylor et al (2002) showed increased blood pressure in response to AMFES, inducing AD in a subject with post-prandial hypotension. AMFES led to a modest but significant increase in MAP, but no change in SBP or DBP in this study, despite a history of AD in three subjects. An effect of AMFES on blood pressure may be different in a sample including subjects with current health problems.

Conclusions

The effect of AMFES upon several respiratory parameters appeared greater for people with higher level tetraplegia.

Use of AMFES may help mitigate the degree of respiratory impairment or enhance respiratory function, which declines with time since injury.
Further investigation is warranted in a larger and more diverse group to confirm the effects in non-experimental conditions.

References

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