

ORIGINAL ARTICLE

Formal ventilation patient education for ALS predicts real-life choices

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Abstract

Our objective was to evaluate a single-session, hands-on education programme on mechanical ventilation for ALS patients and caregivers in terms of knowledge, change in affect and to determine whether ventilator decisions made after the education sessions predict those made later in life. Questionnaires were administered to 26 patients and 26 caregivers on four separate occasions. The questionnaires assessed knowledge of ventilatory support, feedback on the nature of the education programme, as well as self-reported emotional well-being. All patients were followed until their death or until initiation of invasive ventilation. Both groups demonstrated significant improvements in knowledge as a result of the education session which was retained after one month. There was no change in patient or caregiver reports' self-reported emotional well-being. The choices of ventilatory support expressed at one month (T4) accurately predicted the real-life clinical choices made by 76% of patients. Any difference resulted from choosing palliative care. Hands-on patient and caregiver education results in improved knowledge, assists in decision-making with respect to ventilatory support, and is not associated with a worsening of affect. It also provides for an accurate prediction of real-life choices and avoids undesired life support interventions and critical care admissions.

Key words: *Amyotrophic lateral sclerosis (ALS), decision making, end of life, non-invasive ventilation, patient education*

Introduction

Due to ineffective cough, aspiration from bulbar impairment and respiratory muscle weakness, respiratory failure remains the cause of death in the majority of patients with amyotrophic lateral sclerosis (ALS) (1). Although, in the presence of adequate bulbar function, airway clearance can be well maintained through maximum insufflation capacities and assisted coughing, extended survival can only be obtained with the addition of mechanical ventilation (2–4).

Patients with ALS must be provided with supportive care and the information required to understand and anticipate the complications that will confront them such

as respiratory failure (5–7). Expectations of

negative emotional impact or reluctance of physicians to initiate such discussions have been a barrier to appropriate information sharing, education and establishment of advance directives (8). Indeed, many patients have had no discussion of their wishes until emergency intubation and may have found themselves 'technologically entrapped' without an informed consent for interventions in advance of respiratory failure (9). The health care and

personal burdens of this abrogation of duty to inform are enormous and costly, given the fact that implementing non-invasive ventilation (NIV) can reduce health care utilization (10–12), improve critical care access, and maintain patient independence in the home (13,14).

While mechanical ventilatory support provides the greatest chance for prolonged survival, the

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optimum manner in which ventilatory support should be initiated or how best to assist patients and families in this decision is not known. Guidelines suggest early discussion and recognize that patients have the right to and may change their views and wishes with time (5,15). The complex ethical decisions surrounding these interventions, although critical, cannot be adequately addressed during routine clinical visits. Patients need to understand the nature and limitations of both NIV and invasive ventilation (IV) to make informed choices (9,16).

To help with making decisions about treatment options patients need to be provided not only with information through didactic patient education sessions, but also have an opportunity to try out treatment interventions when possible. These different approaches can be categorized with Bloom's (17) taxonomy of adult learning domains. Knowledge is a type of cognitive learning, behaviour modification is affective learning and skill development is psychomotor learning. In the case of people making important decisions on different ventilatory options, patient education needs to be focused not only on the transmission of information but actually seeing and practising with different ventilator equipment. Therefore we designed and implemented a detailed, hands-on patient education programme for small groups of patients and caregivers in order to assist in this important decision-making process.

Material and methods

Study design

We designed a prospective study to assess the acquisition of knowledge, emotional changes and decision-making with regard to mechanical ventilation. This study was approved by the Research Ethics Board of the Ottawa Hospital Rehabilitation Centre; each participant signed an informed consent.

Participants

Inclusion criteria included: diagnostic criteria for definite ALS, age 18 to 85 years, fluent in English or French and either 1) signs and symptoms of sleep disordered breathing (two patients); 2) vital capacity at or under 70% predicted (20 patients); or 3) an expressed desire to learn more about ventilatory alternatives (four patients). All patients were diagnosed with ALS as definite or probable by board certified neurologists using clinical and electrophysiological data consistent with the El Escorial criteria (18,19). Exclusion criteria included cognitive impairment that would preclude completion of the questionnaire and coincident severe comorbid conditions that would interfere with participation or cause mortality including diagnosis with dementia. Patients with ALS are referred to the rehabilitation centre respiratory programme by neurologists. Recruitment of participants occurred over a one-year period.

extending from 1999 to 2000. Potential patients and caregivers were approached to participate in the study by a research assistant at a routine clinical visit that did not include a clinical encounter with the physician. Participants were followed up to 10 years, at which point all subjects had made a final ventilatory decision or had died. During the study 37 patients with ALS were referred for ventilation education as part of their routine clinical care, using convenience sampling; all 37 patients were approached to be part of the study. Of the 37, five subsequently died or declined participation in the study prior to the education session. Six more patients who did receive the education session were unable to participate; four of the six (Francophone) patients had an education session prior to the availability of the French version of the questionnaires, one patient of the six did not receive a T1 questionnaire, and one patient declined to complete the test-retest questionnaire at T2. Therefore, a total of 26 patients and 26 caregivers were enrolled into the study. Data for four patients and their corresponding caregivers were unavailable at T4 due to the unexpected deterioration in the patient's health or an inability to participate. For comparison, T3 responses were used for these participants.

Demographics

There were eight males and 18 females with an average age of 63 years (range 44–83 years). The average time from diagnosis to the first education session was 12 months (range 4–30 months).

Intervention

Each patient and family member took part in a single patient educational session. The standardized educational sessions included 2–3 patients and their caregivers. The overall objective of the education sessions was to improve patients' and caregivers' knowledge and understanding of both NIV and IV to help facilitate an informed choice of ventilatory treatment. All sessions were held in a private room with the same, experienced registered respiratory therapist (RRT) (except those for two Francophone participants who had the same bilingual therapist) and lasted for 1.5–2.0 h. A didactic/interactive component was followed by a video depicting IV (20) (please see

Table I for the key topics covered in the education session). The interactive hands-on component provided participants with an opportunity to see, examine and practise using bi-level ventilators, volume ventilators and non-invasive masks (nasal and full facial) and handle tracheostomy tubes. Discussion topics included the pathophysiology of respiratory failure, cough capacity and airway clearance techniques, differing features of NIV and IV, financial implications of each treatment modality (such as government financial support) as well as the particular challenges of bulbar impairment. Patients and

Table I. Key topics covered in the ALS education session.

Knowledge (didactic and interactive)

1. Includes advantages and disadvantages of:
 - a. Non-invasive /invasive positive pressure ventilation
 - b. Bi-level vs. volume ventilator systems
2. Bulbar involvement
3. Signs and symptoms of hypercapnia, changes in blood gases
4. Brief overview of the history of ventilation and non-invasive ventilation
5. Tracheostomy tubes

Skills (hands-on component)

Mechanical breathing apparatus (volume ventilator, bi-level pressure device) including circuits and interfaces

Behaviour (facilitated discussion topics)

1. Family support
2. Ability to learn /direct care
3. Funding sources
4. End of life (advance directives)

English. Face validity of both the French and English questionnaires was established by physicians and respiratory therapists experienced

caregivers were informed that IV could follow NIV if and/or when NIV became inadequate. Emotional support from an experienced psychologist was available for any patient or caregiver following the session.

Data collection tools

All questionnaires were completed one week prior to the scheduled education session (T1), immediately before the session (T2), immediately after the session itself (T3), and one month later (T4). The first two results served to assess the stability of responses. The questionnaire was completed by hand or with the manual assistance of a research assistant as required. Patients and caregivers were separated to avoid influencing each other's responses.

Positive and negative affect schedule (PANAS) scale

The impact of the education programme on self-reported emotional well-being was determined by use of the validated PANAS scale (21). The PANAS scale was used to determine whether ventilation education resulted in significant changes in participants' self-reported emotional well-being. This 20-item scale comprises two mood scales, one measuring positive affect and the other measuring negative affect. Each item is rated on a 5-point Likert scale from 1 = very slightly or not at all, to 5 = extremely.

Knowledge and ventilatory choice questionnaires

The ALS Education Programme Questionnaire for patients with ALS and The ALS Education Programme Questionnaire for caregivers included questions that reflected the objectives and content of the education session. The questionnaires were available in French and

in the care of people living with ALS. The questionnaires were reviewed by people living with ALS for readability and ease of use. Separate questionnaires were designed for patients and caregivers.

Sixteen multiple choice questions (MCQ) assessed knowledge acquisition, four MCQ assessed decision-making related to the choice of mechanical ventilation, and five questions used a visual analogue scale (VAS) to assess anxiety associated with ventilation decisions and the quality and content of the education session itself, with 'strongly disagree' as one anchor and 'strongly agree' as the opposite anchor. Finally, participants were asked to rate 15 statements in terms of importance from 'very low importance' to 'very high importance' (e.g. "having my family member/friend attend with me"). Two other questions asked patients and caregivers to select the main reasons for choosing or not choosing ventilatory support (e.g. "worried about the burden it will place on my family") and rated them from 'very important' to 'not important'.

The two questionnaires given after the education programme (T3, T4) also included 14 questions that elicited feedback about the programme itself. Participants were also asked whether or not the same information could have been adequately delivered by a pamphlet or video alone. (Questionnaires are only available in the online version of the journal. Please find this material with the following direct link to the article: <http://www.informahealthcare.com/> (DOI number: 10.3109/17482968.2011.626053.)

Results

Two-tailed Student's *t*-tests were used to analyse the data for patients and caregivers between the four time-points.

Patient results

PANAS results indicate that patient's self-reported emotional well-being did not significantly differ between any of the time-points during the study. Significant differences in patient knowledge of respiratory issues and ventilatory options were found between T1 ($X = 8.22$, $SD = 2.3$) and T3 ($X = 10.7$, $SD = 2.7$) ($t = 5.9$, $p < .001$) and between T1 ($X = 8.2$, $SD = 2.3$) and T4 ($X = 10.7$, $SD = 2.3$) ($t = 8.1$, $p < .001$). No significant differences were found

between T1 and T2 or between T3 and T4 on the knowledge questions.

A significant difference was found between T3 ($X = 4.8$, $SD = 3.0$) and T4 ($X = 3.4$, $SD = 2.9$) ($t = 2.3$, $p < .05$) on the VAS question: "Having to make a decision about ventilation makes me feel anxious", indicating that patients were less anxious at T4 than at T3.

Over 90% of patients agreed or strongly agreed that the education session helped them to make a decision about preferred treatment options. This

response was maintained for at least one month after the session. Ninety-six percent of participants agreed or strongly agreed that the session was helpful and also that it made it easier for them to talk to friends and family members. Over 90% of participants stated that a video or a pamphlet could not replace the presentation made by the respiratory therapist and 83% of patients stated that one session was enough to make a decision regarding ventilation.

Caregiver results

Significant increases in caregiver knowledge of respiratory issues and mechanical ventilation (MV) options were found between T1 ($X = 8.6$, $SD = 1.9$) and T3 ($X = 11.7$, $SD = 2.0$) ($t = 8.0$, $p < .001$) as well as T1 ($X = 8.6$, $SD = 1.7$) and T4 ($X = 11.10$, $SD = 1.9$) ($t = 6.2$, $p < .001$). No significant differences were found between T1 and T2 although there was a significant decrement between T3 ($X = 11.95$, $SD = 2.0$) and T4 ($X = 11.1$, $SD = 1.9$) ($t = 2.9$, $p < .05$). At T3, 87.5% of respondents agreed or strongly agreed that the education session had helped them to decide about what treatment they would prefer and 84% agreed or strongly agreed that the education session would make it easier for them to talk to their family member about ventilation.

Comparison between patients and caregivers

At T1, 75% of patients and 65% of caregivers were either undecided about or had not thought about MV (Figure 1). Following delivery of the education programme (T3) only 4% of patients (one patient) were unsure about MV and 24% of caregivers remained unsure about what they would choose for their loved one. By T4, 68% of the patients preferred NIV compared to 17% at T1. Interestingly, two

persons who had decided not to have MV before the session also did not want MV after the session. At T4, 45% of family members had decided that non-invasive ventilation was their preference for their family member. Almost all participants (90%), both patients and caregivers, felt that one education session was sufficient to help them make a decision with respect to ventilation and felt the session was helpful.

Patients were somewhat less worried at T2 ($X = 4.6$, $SD = 3.1$) than caregivers ($X = 6.1$, $SD = 3.0$) ($t = 2.6$, $p < .05$) and at T4 ($X = 2.9$, $SD = 2.9$) compared to caregivers ($X = 5.0$, $SD = 3.0$) ($t = 2.2$, $p < .05$). At T4, the statement "Learning about breathing problems that can happen in ALS made me feel anxious" showed a statistically significant difference between patients ($X = 4.2$, $SD = 3.0$) and caregivers ($X = 6.3$, $SD = 2.8$) ($t = 2.2$, $p < .05$), i.e. patients were less anxious. Patients and caregivers differed significantly at T2 and T4 in their response to the statement "Having to make a decision about ventilation makes me feel anxious". Patients indicated that they were less anxious at T2 ($X = 4.8$, $SD = 3.1$) than caregivers ($X = 6.9$, $SD = 2.1$) ($t = 2.6$, $p < .05$), and at T4 (patients $X = 3.4$, $SD = 2.9$, caregivers $X = 6.1$, $SD = 2.8$) ($t = 3.0$, $p < .01$) and to the statement "I am worried about having to make a decision about ventilation". Patients were somewhat less worried at T2 ($X = 4.6$, $SD = 3.1$) than caregivers ($X = 6.1$, $SD = 3.0$) ($t = 2.6$, $p < .05$) and at T4 ($X = 2.9$, $SD = 2.9$) compared to caregivers ($X = 5.0$, $SD = 3.0$) ($t = 2.2$, $p < .05$). At T4, the statement "Learning about breathing problems that can happen in ALS made me feel anxious" showed a statistically significant difference between patients ($X = 4.2$, $SD = 3.0$) and caregivers ($X = 6.3$, $SD = 2.8$) ($t = 2.2$, $p < .05$), i.e. patients were less anxious.

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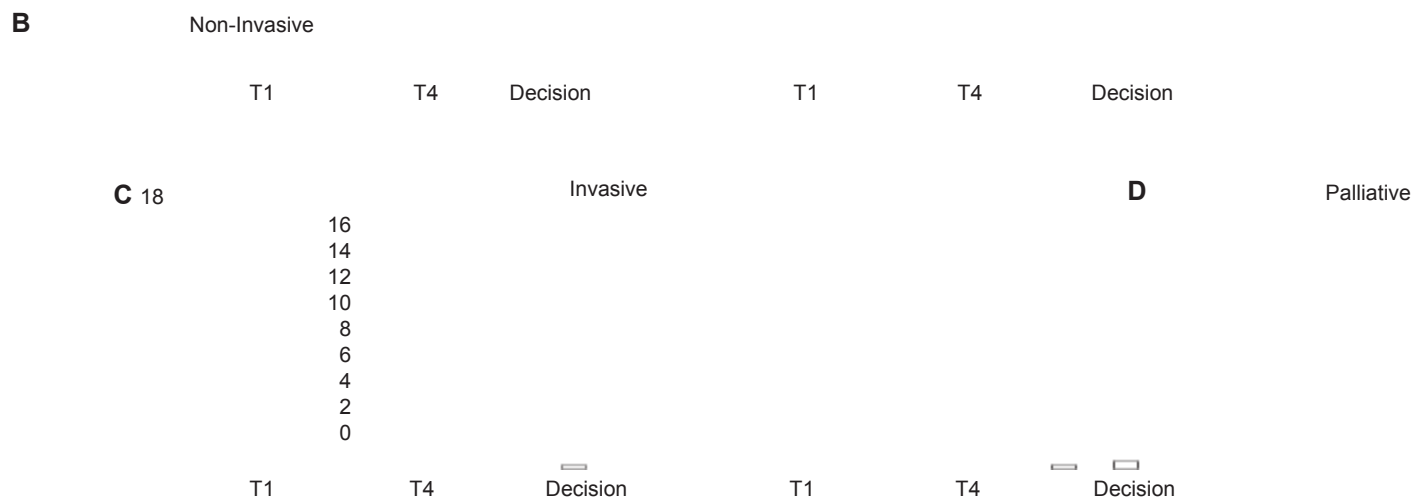


Figure 1. Number of patients and ventilation choice at T1, T4 and final real-life ventilation decision. A: undecided; B: non-invasive ventilation; C: invasive ventilation; D: palliative.

Table II. Main reasons for preferring ventilation by patients and caregivers.

| Main reasons for preferring ventilation | | T1 | T4 |
|---|-------------------|---------|---------|
| Wish to improve quality of life | Patient/caregiver | 52%/67% | 33%/48% |
| Wish to live longer | Patient/caregiver | 48%/52% | 38%/48% |
| Wish to live until a cure | Patient/caregiver | 33%/23% | 19%/24% |
| Family member wants to use ventilation | Patient/caregiver | 14%/38% | 5%/43% |

There was no statistically significant difference between the two groups in measured knowledge gained at any time-point. The main reasons indicated by patients at T1 and T4 for preferring ventilation compared to caregivers are listed in Table II. Table III lists the main reasons for preferring no ventilation by percentage of patients and caregivers.

Real-life decision-making

Each of the 26 patients who participated in the study was followed to death or initiation of IV. One patient developed cognitive impairment and that individual's data were removed from analysis. The remaining 25 eventually made choices with respect to ventilatory support, over a 10-year period. Of these 25 patients, 19 (76%) chose the same option that they indicated was their preference following the education programme (five palliation and 14 NIV) (Figure 2). One patient who used NIV for 14 months and also indicated a desire for IV, did undergo elective tracheostomy ventilation. All patients who elected at T4 to forgo any ventilatory support received no ventilation during their clinical care and received palliative care (five patients). Six patients, who chose NIV as a result of the education session, instead received palliative care due to an inability to tolerate NIV. None of the participants in the study required emergency intubation or ICU admission.

Limitation

A possible limitation to this study was the number of women compared to men who participated. This is particularly noteworthy given the usual ratio of men to women with ALS (1.7: 1). This observation was not made until after recruitment was complete. No systematic differences in recruitment were present for men or women. Precisely why so few men participated is uncertain. More women (seven) than men (five) declined participation, so this does not appear to account for the difference. There may have been more male patients who declined education entirely and opted for palliative care from the time of their initial assessment and would therefore be

under-represented. It is equally likely that this is a chance occurrence and that with larger numbers, men and women would be more appropriately represented. This observation is not likely to limit the generalizability of the results of this study to the ALS population.

Discussion

The objective of this study was to evaluate the effect of a formal, structured, hands-on education programme on knowledge, self-reported emotional well-being and decision-making of patients and caregivers. The results of the study highlight that this unique educational programme is an invaluable addition to a comprehensive respiratory management and end-of-life decision-making process for patients with ALS (and their caregivers). Instead of awaiting the onset of respiratory failure, this educational intervention allowed advanced discussion of ventilatory choices by patients and their caregivers and resulted in the mechanical ventilation of only those who desired it. With such a programme it is anticipated that 'crisis intubations' and undesired emergency and ICU admissions are avoided by providing informed consent and elective transition to IV if desired, understood and supported.

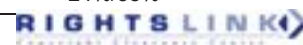
The results indicate a significant reduction in the uncertainty by patients about ventilatory decisions from 75% to 4%, and for their caregivers from 65% to 24%. This is an important contribution to overall care, allowing patients and caregivers to become better informed to discuss and clarify further questions with regard to NIV or IV with health-care providers and family. Provision of early education and awareness does not result in a greater number of patients choosing IV. On the contrary, the early provision of comprehensive education may lead to a significant proportion of patients choosing NIV and thus benefiting from its effect with improved quality of life, sleep quality and

survival, as well as avoiding IV (2,3,22,23).
 Only one patient (4%) elected to undergo
 tracheo- stomy ventilation and this was done

simply, elec- tively and after the experience
 of living with NIV for

Table III. Main reasons for preferring no ventilation by patients and caregivers.

| Main reasons for preferring no ventilation | | T1 | T4 |
|--|-------------------|---------|---------|
| Concerns about burden on family | Patient/caregiver | 43%/24% | 14%/19% |
| Emotional health | Patient/caregiver | 29%/14% | 14%/5% |
| Do not want to rely on health care professions | Patient/caregiver | 33%/29% | 29%/29% |
| Concerns about poor quality of life | Patient/caregiver | 38%/48% | 24%/38% |



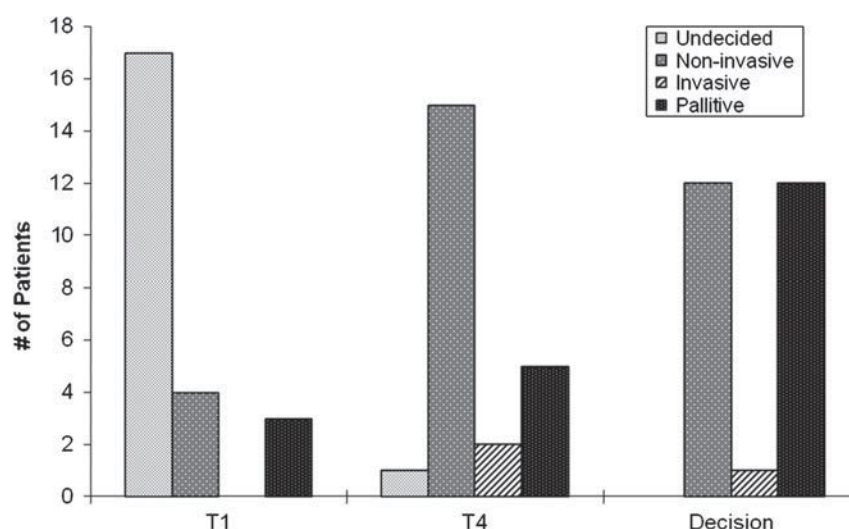


Figure 2. Relationship of decisions at T4 with real-life choices of patients.

14 months. Although the time-frame of the educational intervention was relatively short, the decisions made by patients and caregivers were sustained over a long period. There was immediate and sustained improvement in knowledge for patients and immediate but less sustained improvement in knowledge for the caregivers.

The close correlation (76%) between expressed views with respect to both palliative care and ventilation at T4 and choices made in real life is a reflection of the utility of the education programme in confirming or establishing informed decisions, and also clearly illustrates that patients with ALS who are informed can control and influence their health care delivery. In spite of possible anxieties about the discussion of life support for a potentially acute, life threatening condition, all but one patient stated that the education session reduced (not increased) their anxiety with respect to ventilatory decisions. In this fatal and currently untreatable condition we submit that a formal ventilation patient education programme is of benefit in respecting patients' wishes and fully informing a critical decision-making process.

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Supplementary material available online

ALS EDUCATION PROGRAMME
QUESTIONNAIRE FOR PEOPLE
WITH ALS

