

Original Article

Amyotrophic Lateral Sclerosis: A Cross-sectional Survey on Sialorrhoea

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ABSTRACT

Objectives: One of the major distressing symptoms related to Amyotrophic Lateral Sclerosis (ALS) is excessive drooling of saliva, also termed sialorrhoea. Evaluating its prevalence and severity among Indian patients with ALS is essential for understanding the magnitude and impact of the problem. A cross-sectional survey was conducted to estimate the prevalence and severity of sialorrhoea among individuals diagnosed with ALS. We also intended to assess the current pharmacological management practice for sialorrhoea in ALS patients.

Materials and Methods: Patients with ALS enrolled in the Neuropalliative Registry of a quaternary care centre for neurological disorders were included in the study. As part of routine follow-up, telephonic interviews were conducted with either the patients or their next of kin. The extent of sialorrhoea was assessed using the sialorrhoea scoring scale.

Results: Seventy patients were included in the study. The mean age at presentation was 51.8 (standard deviation [SD]-12.8) years. The majority were males (74.3%). The mean duration of illness was 21.6 (SD 15.7) months. The majority (80%) had limb onset ALS. Forty per cent of the patients in the study had some degree of sialorrhoea. Mild drooling was present in 15 patients (21.4%), moderate in 9 (12.9%), severe in 2 (2.9%) and profuse drooling in another 2.9% of patients. A total of 9 patients (12.9%) were receiving anticholinergic medication. Patients diagnosed with bulbar onset ALS had a significantly greater degree of sialorrhoea than those with limb onset presentation ($P = 0.008$). In addition, a longer duration of illness showed a positive correlation with the severity of sialorrhoea ($r = 0.30, P = 0.012$).

Conclusion: Sialorrhoea is a prevalent and clinically significant symptom in individuals with ALS. The severity of sialorrhoea is greater in patients with bulbar onset ALS and tends to increase with longer illness duration. A substantial proportion of patients may benefit from recommended treatment for excessive salivation and saliva-related issues. This study underscores the need for screening of distressing symptoms as sialorrhoea, in ALS patients. The treating teams need to have a heightened awareness regarding the same so that treatment options can be offered to the patients.

Keywords: Amyotrophic lateral sclerosis, Distress, Prevalence, Sialorrhoea

INTRODUCTION

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disorder characterised by the degeneration of both upper motor neurons in the primary motor cortex and lower motor neurons in the brainstem and spinal cord. Even though there is worldwide variation, the global prevalence of ALS is estimated to be 6/1,00,000 population.^[1] The profile of ALS is different in India when compared to the Western

population.^[2] It is a relatively uncommon disease in India with a prevalence of about 3–5/100,000 population.^[3] When compared to the Western population, where the average age of onset is between 55 and 65 years, Indians have an average age of onset of one or two decades earlier.^[4]

ALS is primarily characterised by motor symptoms, including muscular weakness and spasticity. Progressive muscle involvement and increasing disabilities are the hallmark of

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ALS. Even though ALS can have a spinal or bulbar onset, both symptoms usually become apparent as the disease progresses. In spinal onset ALS, the symptoms primarily include muscle weakness of the limbs and spasticity; whereas in bulbar onset ALS, the marked symptoms are dysphagia and speech impairment. ALS is also characterised by non-motor symptoms, including neuropsychiatric, autonomic, gastrointestinal and vascular manifestations.^[5] Sialorrhoea in ALS can be considered a motor or non-motor symptom.^[5] Sialorrhoea in ALS is primarily attributed to tongue spasticity, orofacial muscle weakness and palatolingual muscle dysfunction. Impaired coordination of these muscle groups leads to pooling of saliva in the anterior portion of the mouth. Ultimately, this neuromuscular incoordination hampers the initiation of the swallowing reflex, further obstructing the normal transit of saliva from the oral cavity to the oropharynx.^[6]

Autonomic impairment is also involved in the pathophysiology of sialorrhoea in ALS.^[7] Increased saliva flow rates are observed in patients with ALS.^[8] However, it is thought to be of very low significance in the causation of sialorrhoea when compared to the bulbar weakness.

Regardless of its underlying cause, drooling presents significant challenges, resulting in clinical and functional complications such as social impairment, including embarrassment and isolation, as well as increased risks of aspiration, skin breakdown, malodour and infection.^[9] Such complications can severely diminish the quality of life in individuals living with ALS.^[8] In ALS patients who require non-invasive ventilation (NIV), the time taken to achieve a satisfactory NIV adaptation is significantly affected by sialorrhoea.^[10] Currently, several effective treatment options are available for problematic drooling in ALS, including external beam radiation therapy.^[11] Determining the extent of the problem related to drooling among ALS patients is crucial for determining the need and urgency of targeted management strategies.

While several studies have examined the prevalence of sialorrhoea in ALS, the results have varied considerably across reports.^[12] This may be attributable to differences in methodologies, estimation approaches, and populations studied. An earlier report from India involved very few patients.^[13] Hence, a cross-sectional survey was undertaken to estimate the prevalence and severity of sialorrhoea in a larger cohort of ALS patients. We also intended to study the current management choices of problematic salivation issues, which can help in future studies.

MATERIALS AND METHODS

Study design

A cross-sectional telephonic survey was conducted involving ALS patients enrolled in the Neuropalliative Registry of a quaternary neuroscience hospital. Patients registered

between December 2021 and March 2022, who were currently receiving home care, were included in the study. As a part of the routine telephonic follow-up, the palliative care team interacts with patients or their primary caregivers, exploring their concerns and extending services. The survey was conducted during such telephonic interactions. Patients or caregivers who could not be interviewed due to a language barrier were excluded from the study.

Data collected included basic demographic details such as age, gender, marital status, geographical location to which the patient belongs, and the details of the clinical condition, which included duration of illness and the symptoms.

Sialorrhoea was assessed using the sialorrhoea scoring scale (SSS), a patient-reported questionnaire that measures the severity of drooling. Originally developed in 2000 to evaluate sialorrhoea in children with developmental disabilities, the SSS has since been utilised in various populations to quantify symptom burden.^[14] The tool has been used widely for the assessment of drooling issues in other disorders such as Parkinson's disease.^[15] It is also used as an outcome measurement for the effect of treatment of sialorrhoea for patients with Parkinson's disease.^[16]

The SSS was developed based on both clinician expertise and patient input. It consists of a single item focused on drooling, offering nine response options that reflect varying levels of severity. Designed as a paper-and-pencil tool, the SSS can be administered as either a patient-reported or caregiver-reported outcome measure, with responses referring to the patient's experience over a preceding period.^[17] The scale consists of a 9-point Likert-type item, with scores ranging from 1 to 9, where 1 indicates no sialorrhoea and 9 denotes profuse drooling, reflecting increasing symptom severity. The SSS scores of 2 and 3 are considered as mild sialorrhoea, 4 and 5 as moderate, 6 and 7 as severe and scores 8 and 9 as profuse sialorrhoea.

Information regarding the drugs that are taken by the patients was also collected. All anticholinergic drugs were identified as having an influence on salivation, and that was recorded. The telephonic follow-up also included open-ended questions regarding how bothersome the symptoms of drooling were for the patients, caregivers and visitors of the patients.

Data collection

Telephonic contact was made with the patient or the caregiver as part of the regular follow-up under the neuro-palliative services.

Data analysis

Data were entered and analysed using the statistical package for the social sciences, version 20.0. Both descriptive statistics (percentages, means, and standard deviations [SDs]) and inferential statistics were employed. Univariate analysis of continuous variables, specifically mean SSS scores,

was conducted using independent samples t-tests for binary categorical variables. The bivariate relationship between two continuous variables—duration of illness and severity of sialorrhoea—was examined using the Pearson correlation coefficient. All tests were two-tailed, and a $P < 0.05$ was considered statistically significant.

Ethics

Ethical approval was obtained from the institute's ethics committee before initiation of the study. Verbal consent was obtained from the respondent during the telephonic conversation, and anonymity was maintained.

RESULTS

During the 4-month study period, a total of 76 ALS patients were included in the neuro-palliative registry. Follow-up was attempted for all participants; however, six could not be contacted via telephone. Hence, a consecutive sample of 70 patients who consented to the study was included. The mean age of the cohort was 51.8 (SD 12.8) years, and it ranged from 25 to 84 years. The majority of them (74.3%) were male. Most of the patients (71.4%) were living in South Indian states. The demographic profile is presented in Table 1.

The duration of illness ranged from 4 to 72 months, with a mean of 21.6 (SD 15.7). The duration since confirmatory diagnosis of ALS ranged from 1 month to 55 months, with a mean of 12.2 (SD 12.3). The clinical profile of the patients is presented in Table 2.

A total of 28 patients (40%) reported some degree of drooling or saliva-related impairment. Of these, 15 patients (21.4%) experienced mild drooling, 9 (12.9%) had moderate symptoms, while 2 patients each (2.9%) reported severe and

profuse drooling, respectively. None of the patients were using any home remedies to reduce salivation.

On exploring the impact of sialorrhoea on patients, caregivers and visitors, the respondents mentioned that they had gotten used to the drooling. None of the respondents mentioned that drooling was an issue, which made the family or the visitors feel uncomfortable. They mentioned that even though the symptom is bothersome, they were used to dealing with it. The prevalence of sialorrhoea among the patients is presented in Figure 1.

The association of demographic and clinical variables with the severity of sialorrhoea is presented in Table 3. Compared to patients with limb-onset presentation, patients with bulbar-onset ALS experienced a significantly higher degree of sialorrhoea ($P = 0.008$). Sialorrhoea among ALS patients by onset type is presented in Figure 2.

Pearson correlation analysis revealed a positive association between duration of illness and severity of sialorrhoea ($r = 0.30$, $P = 0.012$).

Table 1: Socio-demographic characteristics of the patients ($n=70$).

| Characteristics | Frequency (%) |
|--|---------------|
| Age in years | |
| 20–40 | 17 (24.3) |
| 40–60 | 36 (51.4) |
| >60 | 17 (24.3) |
| Gender | |
| Male | 52 (74.3) |
| Female | 18 (25.7) |
| Marital status | |
| Married | 63 (90) |
| Single | 5 (7.1) |
| Widowed/separated | 2 (2.9) |
| The Indian region to which the patient belongs | |
| South India | 50 (71.4) |
| Central and North India | 6 (8.6) |
| Eastern and North-Eastern India | 14 (20) |

Table 2: Clinical characteristics of the patients ($n=70$).

| Characteristics | Frequency (%) |
|---|---------------|
| Duration of illness (months) | |
| 1–12 | 30 (42.1) |
| 13–24 | 19 (27.1) |
| 25–36 | 6 (8.6) |
| >36 | 15 (21.4) |
| Duration since confirmatory diagnosis of ALS* (months) | |
| 1–12 | 47 (67.1) |
| 13–24 | 12 (17.1) |
| 25–36 | 8 (11.4) |
| >36 | 3 (4.3) |
| ALS phenotype | |
| Limb onset | 56 (80) |
| Bulbar onset | 13 (18.6) |
| Current mode of feeding | |
| Oral feeds | 69 (98.6) |
| Ryle's tube | 1 (1.4) |
| Practicing oral motor exercises regularly | |
| Yes | 7 (10) |
| No | 63 (90) |
| Experienced difficulty in communication due to excessive salivation | |
| Yes | 5 (7.1) |
| No | 65 (92.9) |
| Experienced difficulty in eating due to excess salivation | |
| Yes | 4 (5.7) |
| No | 66 (94.3) |

*ALS: Amyotrophic lateral sclerosis

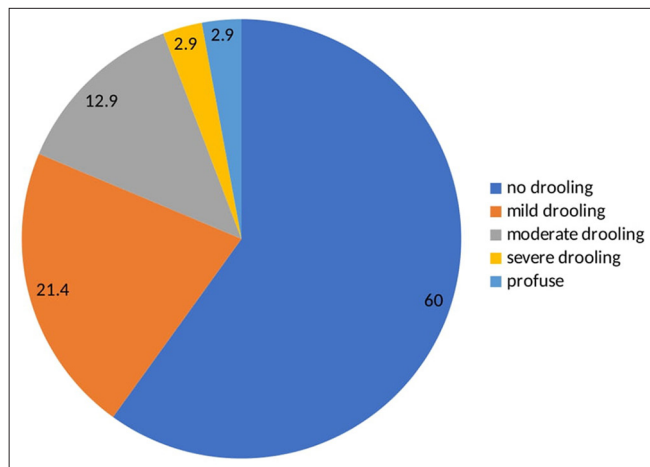


Figure 1: Prevalence of sialorrhoea among amyotrophic lateral sclerosis patients.

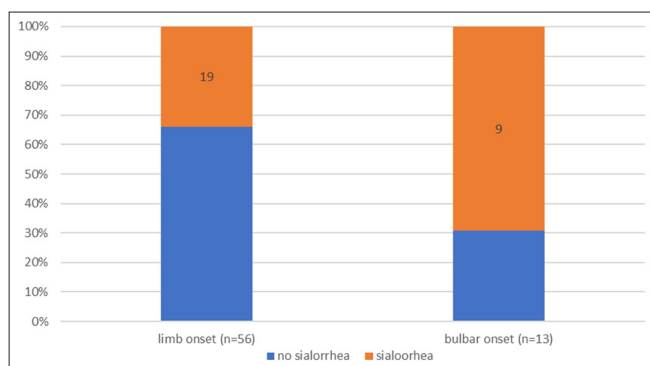


Figure 2: Sialorrhoea among amyotrophic lateral sclerosis patients by onset type.

Table 3: Association between severity of sialorrhoea and clinical variables.

| Characteristic | Category | Mean sialorrhoea scoring scale | F-value | P-value |
|-------------------|-----------|--------------------------------|---------|---------|
| Gender | Male | 2.10 | 0.014 | 0.9 |
| | Female | 1.94 | | |
| Onset of symptoms | Limb | 1.78 | 7.75 | 0.007* |
| | Bulbar | 3.38 | | |
| Age | <40 years | 2.12 | 0.05 | 0.82 |
| | >40 years | 2.04 | | |

*Significant at p<0.01

Management of sialorrhoea

Anticholinergic medications were prescribed to nine patients, accounting for 12.9% of the study population. The most common anticholinergic drugs used were glycopyrrolate, amitriptyline and trihexyphenidyl.

Out of the patients who had a problem with salivation, 7 (25%) were already on some anticholinergic drug. Seven

(5.7%) patients were currently practising oral motor exercises.

DISCUSSION

ALS is characterised by a range of debilitating motor and non-motor symptoms. In addition to prominent motor impairments such as muscle weakness, frequent falls and spasticity, extra-motor symptoms such as drooling can also contribute significantly to patient distress. As symptomatic management remains the cornerstone of ALS care, understanding the burden of sialorrhoea is essential. This study was therefore undertaken to examine the extent of drooling-related problems among patients with ALS in India. The profile of ALS patients observed in this survey is very similar to the previous reports. The cohort consisted mostly of younger patients, with the majority of them between 40 and 60 years of age. A quarter of them were aged <40 years. A study by Sondhi *et al.*, describing the profile of patients with ALS from Western states of India, reported the mean age to be 53 years.^[2] In comparison to the global picture, Indian patients are considered to be younger at the age of onset of illness.^[18]

With regard to the site of onset, most of the patients (80%) had limb onset disease. In studies from various countries, there is an overall predominance of limb onset ALS when compared to bulbar onset ALS, with reports ranging from 58 to 82%.^[19]

The mean duration of illness among the patients in this study was 21.6 months. The majority of the patients were in the 1st year after the disease onset. Other studies from India also report a mean duration of illness as 17.7^[4] and 19.2 months,^[2] which are higher than Western reports.

In this study, the problem of salivation was found in 40% of the patients. Studies from various countries have reported varying prevalence of sialorrhoea in patients with ALS, ranging from 20% to 44.2%.^[12] A pooled prevalence of 30.8% was observed in a meta-analysis that involved 17 studies across the globe.^[12] A clinic-based study in India found that 52% of the ALS patients had sialorrhoea.^[20] The study also reported that 40% of the patients had severe or profuse drooling. On the contrary, in the current study, we found that only a quarter of the patients had moderate-to-severe symptoms. Correspondingly, a meta-analysis also reported that 21.7% of the patients had moderate-to-severe symptoms.^[12]

A higher proportion of patients with bulbar-onset ALS exhibited sialorrhoea in this study, with greater severity observed in this group as well. Bulbar onset has also been identified as a significant predictor of sialorrhoea in previous research.^[20,21] The disease pathology involving the bulbar muscles and the resultant weakness explains this. Age and gender were not found to be factors associated with sialorrhoea. This finding was concurrent with other

studies.^[21] In the present study, we observed that the longer the duration of the illness, the more severe the symptoms of salivation. This corresponds with the natural progression of the illness and can be explained by the increasing weakness related to it.

It is worth noting that, on exploration during the telephone interviews, none of the caregivers mentioned drooling as a cause of major distress for them or the visitors of the patient. While this study did not employ a formal qualitative methodology, the researchers incorporated informal observations and spontaneous discussions with patients and caregivers during interactions. These insights, though not systematically collected, are reflected in the narrative description. Even though they mentioned drooling to be bothersome, the weakness and disability predominated the conversations. Drooling was another symptom among the multiple other problems that the family caregivers were battling. This highlights the need for awareness among treating teams about the distressing symptoms that need to be screened among patients who need palliative care. It also points to the fact that patients or caregivers may not always bring up their symptoms for discussion unless they are very highly concerned about them. However, given the availability of choices in treatment for these symptoms, clinicians may need to address them as part of the routine evaluation of these patients. It is acknowledged that issues such as aspiration risks, hygiene challenges and the overall discomfort associated with sialorrhoea warrant deeper exploration. Future research using structured qualitative methods^[22] could provide a more comprehensive understanding of caregiver and patient experiences.

In the present study, only a quarter of patients who had problems related to salivation were on anticholinergic drugs. A study conducted in the UK showed that 52.7% of the patients who had complaints related to excess salivation received pharmacological management.^[21] The low rates of treatment observed in this study could be due to several factors, such as overshadowing of the issue of salivation by more severe complaints, clinician hesitancy, side effects of drugs and lack of awareness among patients and caregivers that excessive salivation is potentially treatable. This needs further exploration. The most common drugs used for excess salivation among the patients included glycopyrrolate and amitriptyline. In the UK, the most commonly used medications were hyoscine, amitriptyline, carbocisteine, glycopyrrolate and atropine.^[21]

This study brings attention to sialorrhoea, an often underrecognised yet distressing symptom in patients with ALS. Our findings highlight the differing prevalence based on onset type, suggesting the need for heightened clinical vigilance, particularly in those with bulbar onset. In addition, while our study emphasises prevalence, we recognise that

integration of routine screening and management strategies into standard palliative care protocols remains an important, yet currently underdeveloped area.^[23,24] Addressing this gap could significantly improve symptom control and overall patient comfort. Future studies should assess the effectiveness of medications, botulinum toxin and non-pharmacological approaches for sialorrhoea.

Limitations

This was a single-centre, cross-sectional survey where the current problem of salivation in patients with ALS was assessed. The cross-sectional nature of the study does not account for symptom evolution, which is intrinsic to ALS. We acknowledge this as a limitation and recommend that future longitudinal research be undertaken to explore the trajectory of sialorrhoea and its impact on quality of life and care needs. As our study involved data collection over telephonic follow-up, there could be over- or under-reporting. The SSS, while commonly used in other conditions, has not been formally validated in ALS populations; its use in this study reflects a pragmatic choice, and this limitation should be considered when interpreting the findings. Moreover, it assesses only the severity of salivation. The quality of saliva in terms of thick tenacious salivation was not assessed in the present survey. The effect of the anticholinergic drugs on salivation is not reported and is outside the scope of this study.

CONCLUSION

Sialorrhoea is a common and often distressing symptom for patients living with ALS and their caregivers. Therefore, palliative care services must incorporate effective management of drooling into their care models. Both pharmacological and non-pharmacological interventions should be implemented for patients experiencing significant symptoms. Current practices in managing sialorrhoea can be enhanced by regular reassessment of patients over time, allowing for the timely initiation of evidence-based treatment options. Further follow-up of patients regarding the effectiveness of treatment is essential to ensure effective solutions. This approach will help in alleviating the multifaceted challenges faced by families, ensuring a better quality of life for those affected by this debilitating disease.

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Ethical approval: The research/study was approved by the Institutional Review Board at the National Institute of Mental Health and Neurosciences, approval number NIMHANS/28th IEC (BS and NS DIV)/2021, dated 23rd June 2021.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts

will be made to conceal their identity, but anonymity cannot be guaranteed.

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