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**ORIGINAL ARTICLE**

# Fit for purpose? A cross-sectional study to evaluate the acceptability and usability of HeadUp, a novel neck support collar for neurological neck weakness

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**Abstract**

The HeadUp collar (previously known as the Sheffield Support Snood) provides support for neck weakness caused by amyotrophic lateral sclerosis (ALS) and has shown to be superior to alternative options in a small cohort of patients from one single center. Here we report the assessment of the HeadUp collar in a larger cohort of patients, exploring the use in other neurological conditions and expanding to other centers across the UK and Ireland. An interventional cross-sectional study design was implemented to investigate the usability and acceptability of the HeadUp collar. A total of 139 patients were recruited for the study, 117 patients had a diagnosis of ALS and 22 patients presented with neck weakness due to other neurological conditions. Participants were assessed at baseline, fitted a HeadUp collar and followed-up one month later. The performance of the HeadUp collar was rated favorably compared to previously worn collars in terms of the ability to eat, drink and swallow. Findings suggest that the collar also permitted a more acceptable range of head movements whilst maintaining a good level of support. We conclude that the HeadUp collar is a suitable option for patients with neck weakness due to ALS and other neurological conditions.

**Keywords:** *Neck orthoses, cervical orthoses, HeadUp collar, amyotrophic lateral sclerosis, motor neuron disease*

*These authors contributed equally to this work.

Supplemental data for this article can be accessed here.

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## Introduction

Weakness of the neck muscles and/or poor positioning of the head are common symptoms in a number of conditions including amyotrophic lateral sclerosis (ALS)/motor neuron disease (MND), myopathy (1), myasthenia gravis (2) and Parkinson's disease (3). Patients with ALS may present with or later develop a "dropped head" which is caused predominantly by weakness of the neck extensor muscles. Subsequently, the head tends to fall unsupported either forwards or to the side (4,5). The inability to maintain an upright head position can cause problems with communication (causing social isolation), eating, drinking, breathing and vision (6). In some patients, head drop can also cause or exacerbate neck pain (7).

In patients where the underlying cause of the weakness cannot be directly reversed (such as in ALS), a cervical orthosis is usually recommended, the purpose of which is to maintain neck support, provide adequate head positioning and alleviate the discomfort and other issues associated with head drop (8). Neck orthoses have a wide range of uses and there are a number of commercially available devices (9,10). However, Reed et al. (8) highlighted that existing cervical orthoses provided for neck weakness in people living with ALS are either too soft (and therefore do not provide sufficient head support) or too stiff (and cause excessive restriction of head movements). The HeadUp project identified a need for an orthosis that provides flexibility and support, which could be suitable for neck weakness caused by ALS. The development of the HeadUp collar (previously called the Sheffield Support Snood) utilized an interdisciplinary co-design process involving multiple iterative design cycles ensuring that the complex needs of patients were addressed.

After successful completion and evaluation in healthy participants (11), the HeadUp collar was assessed in people living with ALS, using a mixed methods cohort study (12). Twenty patients with both ALS and neck weakness (who had also tried other neck orthoses) were recruited and fitted with the HeadUp collar. The results suggested that the HeadUp collar was superior to existing neck orthoses for this patient group. However, the limitations of the initial evaluation were the small numbers of participants from the single center where the development took place. Here we report an assessment of the HeadUp collar (Figure 1) in 139 patients with neck weakness from 10 centers in the UK and Ireland.

## Materials and methods

### *Procedure*

Ethical approval was obtained from Leeds Bradford NHS Research Ethics Committee. The project was a multi-center, NIHR portfolio-registered study, sponsored by Sheffield Teaching Hospitals NHS Foundation Trust. Research Governance approval (NHS Permissions) was achieved from all sites before commencement using the Co-ordinated System of Permissions (CSP) system.

### *Study design and participants*

This was an interventional cross-sectional study to assess the usability and acceptability of the HeadUp collar in patients with neurological neck weakness. The HeadUp collar is semi-rigid with adjustable support struts that can be fitted to a fabric base in a configuration that meets the specific needs of an individual user. After the initial study, modifications were made to the collar, including adding a temperature regulating material in order to maintain thermal comfort and change to the sizing options available. Eligibility criteria were: 1) a diagnosis of neurological-related neck muscle weakness, with a Medical Research Council (MRC) muscle score of 4 or less in at least one neck muscle; 2) Previously tried a neck orthosis; 3) aged 16 years of age or above, able and willing to participate in the study.

Figure 1.. HeadUp collar (previously known as Sheffield Support Snood). The A-frame and supports (far left), the HeadUp collar (middle) and the HeadUp collar with selection and placement customized for the participant (far right). Available sizes include small (33–40 cm/13–16 inches), medium (38–44 cm/15–17.5 inches) and large (43–51 cm/17–20 inches).

*Assessments*

An assessment using a questionnaire was completed at two time-points; the first at baseline (before fitting the HeadUp collar) and the second one month later. The initial patient visit included a baseline questionnaire to evaluate the severity of the neck weakness. Open-ended questions were also asked regarding experiences of previous collar use.

At this visit, patients were fitted with a HeadUp collar and offered the opportunity to take the device home to trial for one month, experimenting with different support configurations to suit their individual requirements. Patients with a collar size outside of the limits of those available at the time of the trial were not able to take a collar home. Their size requirements were collected to inform future collar production.

After using the HeadUp collar for one month, the second patient visit included a patient evaluation questionnaire relating to their experience of the HeadUp collar. Open-ended questions were used to explore if patients wanted to keep the collar for continued use or to return it. The decision was recorded, along with any other feedback from the patients and carers regarding their experience of using the collar. Anonymized photographs of the configuration of supports preferred by each participant (if consent for this was obtained) were also collected. Clinicians at each participating site were also given questionnaires to complete. (See Supplementary Appendix A: Study Diagram; a flowchart outlining the main study components and see Supplementary Appendix B for all the evaluation questionnaires used at baseline and at follow-up).

*Data analysis*

Descriptive and summary statistics were used to analyze the study population and compare the findings at baseline with those after 1 month (Wilcoxon test) for the closed questions. The responses received from the open-ended questions were reviewed (Supplementary Appendix C), quotes were extracted and relevant themes were identified (Supplementary Appendix D) (13). The safety, acceptability and usability profiles were studied by calculating the proportion of participants experiencing problems with the collar (e.g., additional discomfort, fitting difficulty). All statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) software (v. 25.0; SPSS, Chicago, IL, USA).

## Results

A total of 139 patients were recruited for the study, 117 patients had a diagnosis of ALS and 22 patients presented with neck weakness due to other neurological conditions (with a predominance of patients with post radiation myopathy). A breakdown of the diagnoses is shown in Table 1.

*Collar evaluation*

To evaluate usability and acceptability, we asked participants to evaluate the HeadUp collar. In the baseline questionnaire, all 139 participants were asked what type of collar they were currently wearing or had previously worn (Table 2) and were asked questions about their experiences. The type of collars previously used were classified into three main categories: rigid, semi-rigid and soft. A table reporting the breakdown of the names of the collars used and how each collar was categorized is shown in Table 2.

After using the HeadUp collar for one month, participants were asked to complete a follow up questionnaire, giving ratings for the same questions for their HeadUp collar experience. We compared participant ratings of previously worn collars to those of the HeadUp collar using the same 11

Table 1. Distribution of participant by diagnosis.

| | | Neck Flexion Score | | Neck Extension Score | |
|---|---|---|---|---|---|
| Diagnosis | Number of Participants | Mean | SD | Mean | SD |
| Motor Neuron Disease | 117 | 3.0 | 1.1 | 2.7 | 1.1 |
| Post Radiation Myopathy | 11 | 3.5 | 1.0 | 3.0 | 1.0 |
| Multiple Sclerosis | 3 | 3.0 | 1.0 | 3.3 | 0.6 |
| Fascioscapulohumeral dystrophy | 1 | 4 | n/a | 2 | n/a |
| Kennedy's Disease | 1 | 4 | n/a | 4 | n/a |
| Duchenne Muscular Dystrophy | 1 | 4 | n/a | 3 | n/a |
| Mitochondrial Myopathy | 1 | 2 | n/a | 2 | n/a |
| Multiple System Atrophy | 1 | 4 | n/a | 2 | n/a |
| Myasthenia Gravis | 1 | 4 | n/a | 3 | n/a |
| Spinal Muscular Atrophy | 1 | 2 | n/a | 3 | n/a |
| Progressive Supranuclear Palsy | 1 | 4 | n/a | 2 | n/a |
| Total | 139 | 3.1 | 1.2 | 2.8 | 1.2 |

Neck flexion and extension scores; mean and standard deviation (SD) from MRC scoring (0–5). N.B. Standard deviation (SD) not available (n/a) for those disorders in which only one participant was recruited.

questions on a 7 Likert Scale (Table 3). Not all participants replied to all questions.

Table 2. Distribution of different collar types between participants.

| Collar Name | Type of Collar | Frequency | Percentage |
|---|---|---|---|
| Headmaster | Semi-rigid | 47 | 33.8 |
| Soft collar | Soft | 18 | 12.9 |
| Foam collar | Soft | 12 | 8.6 |
| Hereford | Soft | 9 | 6.5 |
| Strio II | Soft | 4 | 2.9 |
| Oxford | Rigid | 4 | 2.9 |
| Miami J | Rigid | 2 | 1.4 |
| Adams | Semi-rigid | 2 | 1.4 |
| Aspen Vista | Rigid | 2 | 1.4 |
| Philadelphia Adjustable | Rigid | 1 | 0.7 |
| Hensinger | Soft | 1 | 0.7 |
| Hard collar | Rigid | 1 | 0.7 |
| Saratoga | Rigid | 1 | 0.7 |
| Trulife airflow | Rigid | 1 | 0.7 |
| Other | Homemade | 4 | 2.9 |
| Information not available | N/A | 30 | 21.4 |

*Head movement and support*

The HeadUp collar offered a considerably more acceptable range of movements (2.68 vs. 4.51 mean, $p < 0.0005$) whilst maintaining a good level of support (2.07 vs. 3.27 mean, $p < 0.0005$). The level of support was particularly appreciated by patients as it improved their quality of life: "This collar gives support but also more freedom of movement—I can wear it to drive" Site I, Participant 34. "Spreads the load, no particular pressure point. Flexible and adaptable" Site E, Participant 01.

The improved support and freedom of movement meant that the collar could be worn for longer periods of time: "Other, more rigid collars were painful—I couldn't wear them for too long, I can wear this collar for 8 hours straight—I wear it at work" Site I, Participant 08.

*Eating, drinking and swallowing*

Overall the HeadUp collar ranked better than previous collars in relation to eating (3.65 vs. 5.00

Table 3.. Neck collar questionnaire responses.

| Questions | Previous collar mean rating (Mean and SD) | HeadUp collar mean rating (Mean and SD) | Wilcoxon signed rank test for paired samples |
|---|---|---|---|
| 1. This collar causes no restriction to my natural breathing | $n = 91$<br>2.98<br>1.921 | $n = 97$<br>2.42<br>1.707 | $n = 67$<br>$z = -1.951^{P}$<br>$p = 0.051$ |
| 2. I experience no additional difficulties eating a meal due to wearing this collar. | $n = 69$<br>5.00<br>2.149 | $n = 81$<br>3.65<br>2.075 | $n = 48$<br>$z = -3.3563^{P}$<br>$\mathbf{p < 0.0005^{\star}}$ |
| 3. I experience no additional problems drinking due to wearing this collar. | $n = 74$<br>4.38<br>2.194 | $n = 87$<br>3.03<br>1.926 | $n = 54$<br>$z = -3.886^{P}$<br>$\mathbf{p < 0.0005^{\star}}$ |
| 4. This collar causes no restriction to my natural swallowing | $n = 84$<br>3.57<br>2.180 | $n = 91$<br>2.86<br>1.912 | $n = 60$<br>$z = -2.001^{P}$<br>$\mathbf{p = 0.045^{\star}}$ |
| 5. I feel that this collar offers support. | $n = 92$<br>3.27<br>1.742 | $n = 99$<br>2.07<br>1.342 | $n = 69$<br>$z = -4.071^{*}$<br>$\mathbf{p < 0.0005^{\star}}$ |
| 6. I experience no perspiration around my head, shoulders or neck as a result of wearing this collar | $n = 92$<br>3.43<br>2.093 | $n = 98$<br>3.17<br>2.000 | $n = 68$<br>$z = -0.712^{P}$<br>$p = 0.476$ |
| 7. I find this collar visually attractive. | $n = 90$<br>5.49<br>1.493 | $n = 97$<br>3.62<br>1.610 | $n = 68$<br>$z = -5.857^{P}$<br>$\mathbf{p < 0.0005^{\star}}$ |
| 8. I have an acceptable range of head movement wearing this collar | $n = 92$<br>4.51<br>1.975 | $n = 94$<br>2.68<br>1.461 | $n = 67$<br>$z = -5.046^{P}$<br>$\mathbf{p < 0.0005^{\star}}$ |
| 9. I find this collar very easy to fit on my own | $n = 86$<br>5.47<br>2.022 | $n = 98$<br>6.33<br>1.091 | $n = 64$<br>$z = -3.363^{N}$<br>$\mathbf{p = 0.001^{\star}}$ |
| 10. I feel no frustration at all whilst wearing this collar. | $n = 92$<br>4.93<br>1.932 | $n = 98$<br>3.76<br>1.867 | $n = 69$<br>$z = -3.874^{P}$<br>$\mathbf{p < 0.0005^{\star}}$ |
| 11. I am extremely satisfied with this collar | $n = 92$<br>5.11<br>1.824 | $n = 99$<br>3.16<br>1.800 | $n = 69$<br>$z = -4.722^{P}$<br>$\mathbf{p < 0.0005^{\star}}$ |

Rating derived from seven-point Likert scale: 1 strongly agree; 2 agree; 3 agree somewhat; 4 neither agree nor disagree; 5 disagree somewhat; 6 disagree; 7 strongly disagree. Rating for pain was categorized as 1 = No discomfort and 7 = Severe pain. $^{N}$ based on negative ranks. $^{P}$ based on positive ranks. * highlights significant values.

mean, $p < 0.0005$), drinking (3.03 vs. 4.38 mean, $p < 0.0005$) and swallowing (2.86 vs 3.57 mean, $p < 0.045$). One participant noted: "My ability to eat & drink is improved versus other supports" Site I, Participant 01; these improvements were also noticed by carers: "Particularly useful when drinking as it enables him to flex his head to achieve an effective swallow and then with the support from the collar he is still able to lift his head up to look forwards again" Carer of Site A, Participant 06.

### *Pain and discomfort*

Assessment of the level of discomfort experienced whilst wearing a collar was recorded using a Likert scale. Only the patients who completed the full data collection were included in this evaluation (102 patients). The HeadUp collar was associated with less discomfort ($p = 0.001$) compared with previously worn collars.

In the baseline questionnaire, 52% of participants did not use painkillers, this increased to 59.8% at follow-up. The percentage of those using the HeadUp collar who needed painkillers was 44.1% at baseline which decreased to 32.4% at follow-up ($p = 0.003$). Only one patient commented specifically on pain in their feedback questionnaire: "No neck pain while wearing the collar. Had been taking OxyNorm—but not currently requiring it" Site A, Participant 08

### *Fitting the collar*

One aspect where the HeadUp collar consistently scored negatively in comparison to other collars was the ability to self-fit it (6.33 vs. 5.47 mean, $p = 0.001$). Individual comments confirmed how patients struggled with this aspect if trying to fit it on their own, although some patients pointed out how it could be easily fitted by carers. One participant explained: "I am unable to put it on by myself, but my carers can easily put it on" Site I, Participant 15.

### *Appearance*

The appearance of the HeadUp collar was judged favorably compared to previously worn collars (3.62 vs. 5.49 mean, $p < 0.0005$). Patients commented on how visually attractive they felt the HeadUp collar was: "[I] like the look of the collar—can hide it more as a snood" Site I, Participant 11; "Comfortable—I feel more confident when out in public. [It] Looks good everyone who sees me in it says it looked brilliant—like a polo neck. Less self-conscious now" Site I, Participant 14.

### *Overall satisfaction*

Overall satisfaction ratings were higher for the HeadUp collar than for previously worn collars (3.16 vs. 5.11 mean; a lower score signified greater agreement with the questions, $p < 0.0005$) and at follow up 70.9% of patients chose to keep the HeadUp collar in preference to others. In general, the HeadUp collar received positive comments in the questionnaire and interview: "Comfortable all round—other collars dug into my chest." Site I, Participant 08: "Soft collars didn't provide the necessary support. The rigid collar supported the head when standing but [I] couldn't look down to the ground so didn't like wearing it. This is more comfortable and more supportive" Site A, Participant 08.

### *Collar use*

The number of hours the HeadUp collar was worn per day by participants was slightly higher compared to other orthoses (5.42 hours compared to 5.24 hours mean) but with a very high standard deviation, reflecting great variations in individual experiences, with the range being between 2 and 12 hours per day.

### *Screen failures*

In total we recorded 25 screen failures (see study diagram in Supplementary Appendix A), 24 of these were patients with a diagnosis of MND and one had a diagnosis of spinal muscular atrophy. Most of the screen failures ($n = 16$) were due to the patient needing a larger or smaller size than those that were available at the time of the study. Of the nine patients who did not tolerate the HeadUp collar at the screening assessment, seven reported that they found it restrictive and were unhappy with the configuration of supports. Interestingly, all of the patients who did not tolerate the HeadUp collar had reported on their baseline questionnaires that they had also either struggled with other previously used collars, or they had no experience of wearing a collar before. The degree of severity of neck weakness did not correlate in a predictable way with patients' tolerance of the HeadUp collar. Of the 25 screen failures, seven had neck weakness which their physiotherapist had classed as "severe," nine had been classified as "moderate," five as "mild" and in four cases, the data had been omitted from the returned questionnaires (Supplementary Appendix E ).

### *Analysis of support configurations*

Patient photographs were returned from 78 participants of the 114 who were successfully fitted with a collar and six sites returned photographs, an

Table 4. Clinician feedback on experience of collar fitting on baseline visit.

| | Q1. Experience of fitting | | | | Q2. Time taken for first fitting (in minutes) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Site | VE | E | D | VD | <5 | 5–10 | 10–15 | 15–20 | 20–25 | >25 |
| Site A | 0 | 2 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 5 |
| Site B | 0 | 5 | 2 | 0 | 0 | 2 | 3 | 0 | 0 | 2 |
| Site C | 2 | 2 | 3 | 0 | 1 | 1 | 2 | 1 | 1 | 1 |
| Site D | 1 | 8 | 5 | 3 | 0 | 0 | 1 | 7 | 7 | 2 |
| Site E | 1 | 14 | 3 | 0 | 0 | 4 | 4 | 3 | 7 | 0 |
| Site F | 2 | 7 | 0 | 0 | 0 | 1 | 1 | 2 | 4 | 1 |
| Site G | 0 | 2 | 3 | 0 | 0 | 0 | 0 | 2 | 0 | 3 |
| Site H | 3 | 1 | 1 | 0 | 0 | 0 | 2 | 2 | 0 | 1 |
| Site I | 2 | 26 | 3 | 2 | 0 | 1 | 2 | 5 | 16 | 9 |
| Site J | 3 | 2 | 2 | 0 | 0 | 0 | 0 | 1 | 3 | 3 |

Q1. Experience of fitting at each site; degree of difficulty of fitting was categorized as: VE; very easy, E; easy, D; difficult, VD; very difficult. The experience for each participant was noted, each site provided totals for each category. Q2. Time taken for first fitting (in minutes); assessed at baseline and categorized into <5; 5–10, 10–15, 15–20, 20–25 and >25 minutes. N.B Line totals for Q1 and Q2 do not match as some sites returned incomplete data.

example of which can be seen in Figure 1. Information on support configurations was collected in the follow up questionnaires. Descriptive analysis of the information from the follow up questionnaires from clinical staff, patients and carers showed that the most frequently used support struts were: A Frame supports ($n = 66$); jaw supports (Z shaped) ($n = 59$); strong straight supports ($n = 45$); standard straight supports ($n = 43$); lateral support ($n = 28$).

Many study participants adopted different support configurations for different activities, for example, using fewer supports while sitting at rest in a chair, and then adding further supports for walking, driving or going out.

### *Clinical staff feedback*

Clinical staff from each of the 10 trial sites were asked for feedback at baseline regarding their experience of the degree of difficulty they experienced in fitting the collars and also how long each collar fitting session took. We received a total of 106 responses (Table 4).

Clinicians were also asked what conditions (in addition to ALS) they felt the collar would be suitable for. Their responses included Parkinson's disease, any neurological conditions with neck weakness, any medical conditions with neck weakness, traumatic brain injury and stroke.

## Discussion

We have evaluated the use of the HeadUp collar as an orthosis for patients with ALS and other neurological conditions experiencing neck weakness. Previous assessment of the orthosis was completed in only a small group of twenty patients with ALS in one single center, suggesting a positive experience for patients (12). Consequently, there was a need to explore the use of the collar in a larger number of patients, expanding to other conditions and more clinical centers.

This cohort of participants included 117 people with ALS and 22 patients with other neurological conditions in 10 different centers within the UK and Ireland. Furthermore, the HeadUp collar was compared with 15 other existing neck orthoses, with the Headmaster collar being the most widely used. The views from both patients and healthcare professionals were explored during the study period.

Participants rated the performance of the HeadUp collar favorably in terms of the ability to eat, drink and swallow compared to other collars. It is important that any neck orthosis is able to assist with or at least not hinder these functions, as patients who have difficulty with eating and drinking are at risk of both malnutrition and dehydration. For people living with ALS, these factors have been shown to have a direct impact on survival (14,15). These positive results were not observed in the initial assessment of the HeadUp collar (12) and may be a result of modifications made to the HeadUp design or due to the larger sample size.

The HeadUp collar was also perceived to facilitate easier head movements compared with previously used orthoses. This freedom to move does not come at the cost of reduced support, with the HeadUp collar providing as much support as the more rigid Vista collar (11). Maintaining head position and being able to move the head freely enables the individual to maintain eye contact and therefore communicate more effectively. Consequently, these results highlight that the HeadUp collar may help social interaction and potentially improve psychological wellbeing. Visual attractiveness was also rated higher for the HeadUp collar which could reduce potential stigma and social embarrassment (8).

Pain and discomfort appeared to be less common with the HeadUp collar when assessed

against previously worn orthoses. These findings were corroborated, with the reduction in use of pain relief medications observed with the use of the HeadUp collar.

Although the HeadUp collar was originally designed for people living with ALS, the design would be anticipated to support neck weakness and/or poor position regardless of the underlying pathology. Our findings demonstrate that the ALS and non-ALS groups evaluated the HeadUp collar similarly. This suggests that there is potential benefit of using the HeadUp collar in other conditions, particularly in post radiation neuro/myopathy which represented the largest non-ALS group of participants in this cohort. Future studies could evaluate the collar in a greater number of patients for each neurological condition.

The main negative finding from this study was that the orthosis was considered difficult to put on independently, and therefore patients relied on others to fit the device. These results were also seen in the initial assessment (12). This is a problem for those who live alone, although the results indicated that carers found it easy to fit HeadUp for the participants.

Despite these factors, the overall satisfaction ratings were substantially higher for the HeadUp collar when compared with others and 70.9% of patients chose to keep the device. The rigid collar designs received the lowest satisfaction of all the different collar types, which suggests that these designs are the least appropriate support for patients with neurological causes of neck weakness, particularly in people with ALS and post radiation myopathy.

During the design of the HeadUp collar a key factor was to ensure the device would not be a barrier to use. Although the cost of the HeadUp collar does vary in differing markets, it is generally comparable to the cost of rigid collars.

Limitations of this study included the relatively short observation period, the small number of patients representing each non-ALS neurological condition and the absence of a control group. Furthermore, a number of patients were unable to receive a collar due to the restricted size range available at the time of the study. Their size requirements were collected to inform future collar design and production. This meant that feedback was not obtained from patients who had a larger neck and a need for these alternative sizes.

In conclusion the HeadUp collar was found to provide support whilst facilitating an acceptable range of movement compared to other support collars. The user centered design process employed in the creation of the HeadUp collar has resulted in an orthosis which had high satisfaction levels from participants in this study. The findings demonstrate the benefits of an interdisciplinary co-design approach to medical devices.

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