Long-Covid-19 Dysphagia: proposal of a standardized evaluation protocol and disease description

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Abstract

Objective The aim of the study is to propose an assessment protocol for evaluating patients who complain of dysphagia during long-Covid-19 and to describe their sings and symptoms.

Methods M.D. Anderson Dysphagia Inventory (MDADI) and Italian Dysphagia Handicap Inventory (I-DHI) questionnaires were administered to the patients. Fiberoptic Endoscopic Evaluation of Swallowing (FEES) was performed and P-score, p-SCA score and PAS scale were applied. Fisher's exact test and the Cohen Coefficient K were used for statistical analysis.

Results MDADI scores revealed mild to moderate dysphagia in 45.5% and 18.2% of the subjects, respectively. I-DHI scores indicated mild, moderate and severe pathological condition in 42.4%, 21.2% and 6.1% of cases. Seventeen out of 33 patients underwent FEES: 11.8% of subjects presented dysphagia for jellified bolus, 17.6% for solids and liquids. Pooling score resulted "non-endoscopic dysphagia signs" even in presence. The p-value was > 0.05. No correlation between MDADI scores and dysphagia for liquid and solids was found; I-DHI self-related score and solid dysphagia were almost perfectly correlated.

Conclusions Long-Covid-19 dysphagia often occurs as mild-to-moderate disorder. I-DHI scores are more reliable than MDADI scores in detecting and quantifying swallowing disorders even though FEES is always necessary.

Keywords: *Long-Covid-19, dysphagia, swallowing impairment, standardized assessment protocol, clinical features*

Introduction

Swallowing disorder commonly occurs as an acute condition caused by intubation and/or post-extubation, laryngeal trauma, muscle weakening and respiratory-swallowing uncoordination. Sars-Cov-2 is also involved in the multifactorial pathogenesis of dysphagia as more severe forms of Covid-19, including hypoxemia (low blood oxygen), bilateral pneumonia and/or acute respiratory distress syndrome (ARDS) (Salian et al., 2020; Seyed Hosseini et al., 2020), necessitate prolonged hospitalization and mechanical intubation, and also because the swallowing network, including cortical, subcortical, and brainstem structures as well as peripheral nerves and muscles, may be potential target of the Sars-Cov2 virus (Mohan et al., 2020; Archer et al., 2021; Dziewas et al., 2020). Neurological complications impact taste, smell, and the sensorimotor function of the pharynx and larynx (Vergara et al., 2021). Typically, patients recover from acute disorders, including

swallowing impairment, within a few weeks, although some may experience dysphagia and other symptoms for a longer duration (Daines et al., 2022).

The permanence of those symptoms, especially dysphagia, significantly impacts everyday life and quality of life in several ways, regardless of the severity of the problem, thus eating and drinking are a natural part of social interactions, functional necessities, and also a pleasurable experience for healthy people. Consequently, the persisting symptoms of Sars-Cov2 infection (lasting more than 90 days after acute infection (Cutler et al., 2022) , has been commonly referred to as long-Covid-19, and officially recognized by the World Health Organization in October 2021[1].

Since these conditions are frequently reported in post-Covid-19 patients and require significant management and hospital resources, it is necessary to establish a standardized assessment tool for evaluating these patients.

MD Anderson Dysphagia Inventory (MDADI) (Schindler et al., 2008) and Dysphagia Handicap Inventory (DHI) (Ginocchio et al., 2021) are self-assessment questionnaires that measure the subjective impact of dysphagia and help clinicians evaluate the severity of the condition. The Bedside Swallowing Evaluation (BSE) is a crucial tool for gathering information about the onset, duration, frequency, and characteristics of swallowing difficulties (Rommel et al., 2022). This evaluation includes mechanical (oromotor) and feeding examinations, which involve observing the range, speed, coordination, and symmetry of muscular movements, in area such as lips, face, tongue, pharynx and larynx. These parameters reflect the functioning of motor and sensory cranial nerves involved in swallowing (Speyer et al., 2022). Based on the findings, hypotheses about the location and the functional impairment of the problem can be made (Carnaby-Mann et al., 2008).

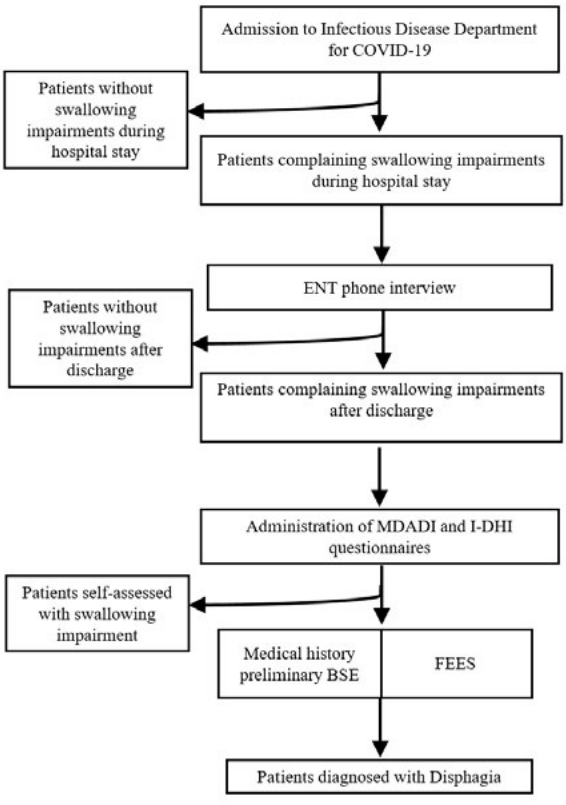
Currently, Fiberoptic Endoscopic Evaluation of Swallowing (FEES) (Langmore et al., 1988) and VideoFluoroscopic Swallowing Study (VFSS) (Logemann et al., 1993) are considered the gold standard instrumental assessments for oropharyngeal dysphagia, pooling of secretions, silent aspiration, and bolus residue.

The aim of this pilot study is to report the most common symptoms and the key endoscopic signs in patients experiencing swallowing difficulties after Sars-cov2 infection and to propose a standardized protocol for assessing this condition.

Materials and methods

Patients who complained of swallowing impairment (dysphagia) during their hospital stay for Covid-19 at the Department of Infectious Disease of Modena's Hospital from 2020 to 2021, were referred to ENT Department after discharge (Figure 1). Informed consent was obtained from all participants included in the study.

Figure 1: Materials and Methods. Flow chart of the decision-making process toward a diagnosis of dysphagia in patients with Covid-19



[1] (https://www.googleadservices.com/pagead/aclk?sa=L&ai=DChcSEwjvstvr8_z_AhWSzncKHTlgA1QYABABGgJlZg&ohost=www.google.com&cid=CAASJeRoYDNlgw768uVfpQrscntDFCGcE1fsF_DEH4HecQcgTcsVKHo&sig=AOD64_2gkICU6U_5Ne3ttklCl8pRngdFXA&q&adurl&ved=2ahUKEwj-w9Dr8_z_AhUJs6QKHce-BOgQ0Qx6BAgKEAE)

Subjects were interviewed by an ENT specialist via telephone to discuss their current symptoms and were asked to complete the Italian version of the MDADI and the DHI questionnaires to self-assess their dysphagia. Patients who reported ongoing swallowing problems were prospectively enrolled in the study and invited to a medical evaluation in person. Their medical history was collected and a preliminary Bedside Examination was conducted by clinicians. The patients also underwent FEES using a Storz endoscope (27 cm length and 4.5 cm diameter), and data were collected with a Xion workstation. The results included the pooling score (p-score) (Farneti et al., 2008), the pooling sensation, collaboration, and age score (p-SCA score) (Farneti et al., 2018) and the Penetration Aspiration scale (Rosenbek et al., 1996). The patients were tested with methylene blue dyed water, pureed jellified water and a cracker as bolus matherials. Patients with more severe symptoms did not complete bolus tests with all consistencies.

Statistical analysis

Dependent variables (MDADI total score, DHI global score, DHI physical scale, DHI emotional scale, DHI functional scale) and independent variables (gender, age, Covid-19 symptoms during hospital stay, duration of Covid-19 symptoms, days of hospitalization, intubation, duration of intubation, dysphagia onset, duration of dysphagia symptoms, current presence of dysphagia, comorbidity, ENT comorbidities) were statistically correlated using linear regression analysis.

Fisher's exact test was conducted to determine the p-value, with a significance level set at <0.05. The Cohen's K coefficient was utilized to assess the level of agreement between the qualitative variables obtained from questionnaire scores and FEES (subjective and objective responses, respectively). Agreement between subjective and objective variables was categorized as follows based in Cohen's K coefficient: 0-0.20 none, 0.21-0.39 minimal, 0.40-0.59 weak, 0.60.0.79 moderate, 0.80-0.90 strong, >0.90 almost perfect.

This study was approved by the Ethical Committee Approval of the Emilia Nord Health District (Ref N° 177/2020 of protocol number 177/2020, March 11th, 2020) and the University Hospital Committee (Direzione Sanitaria dell'Azienda Ospedaliero-Universitaria, Modena, protocol number 7531, March 11th, 2020). The research was conducted ethically, following the principles outlined in World Medical Association's Declaration of Helsinki. Written informed consent was obtained from all participant/patient for the involvement in the study and for the publication of their data.

Results

538 patients were admitted to the Department of Infectious Diseases at Modena Hospital from February 2020 to February 2021. Among these, 50 patients reported swallowing impairments during their hospital stay. During the telephone interview (Table I), 33 patients reported ongoing dysphagia after discharge and completed the MDADI and I-DHI questionnaires for a preliminary screening and evaluation of the condition.

Out of the total, 17 patients (mean age 60.2, SD 12.4 yrs) sought assessment at the ENT Department for their swallowing issues. A preliminary BSE revealed that 12 patients were able to consume a regular diet, four had restrictions on solid foods, and one needed restrictions on both solids and liquids (Table II). Based on the p-SCA score, 14 patients had no concerns with sensitivity, 14 exhibited collaborative behaviour, 8 were under 65 years of age, 5 were between 65 and 75 years old, and one patient was over 75 years old.

Questionnaire scores

In MDADI questionnaire, patients had a minimum score of 48.5 and a maximum of 100, with a mean score of 75.31 +/- 13.88 and a median score of 73.7 (Table III). Figure 2A shows the minimum and maximum scores obtained by patients for each MDADI subscale, including MDADI-P for the physical subscale, MDADI-E for the emotional scale, MDADI-F for the functional subscale.

Out of the patients, 12 had no swallowing problems, while 15 reported mild swallowing problems and 6 had moderate swallowing impairments. None of the patient had a score indicating severe dysphagia (Figure 2B).

Table I: Anamnestic schedule

Gender	Male/Female
Covid-19 Symptoms	Yes/No
Duration of Covid-19 symptoms	< 7 days/ 7-28 days/ > 28 days
Hospitalization	Yes/No
Intubation	Yes/No
Duration of intubation	None/ < 7 days/ 7-28 days/> 1 month
Dysphagia onset	Before/during/after Covid-19
Dysphagia symptoms	Yes/No
Duration of dysphagia	< 7 days /7 days – 1 month/1 month – 6 months/ 6 months – 1 year/> 1 year
Current presence of dysphagia	Yes/No
Comorbidity	Yes/No
Type of Comorbidity (Cardiovascular, Neurological, Physiatric, Endocrinological, Pneumological, ENT, others)	Yes/No
Previous/current pharmacological Therapy	Yes/No
Type of pharmacological therapy (Cardiovascular, Neurological, Physiatric, Endocrinological, Pneumological, ENT, others)	Yes/No
Follow up	Yes/No

Table II: Preliminary BEDSIDE examination

Patient	**Pooling-sensation**	**Collaboration**	**Age**	**P-SCA**
1	/			
2	-1	-1	2	0
3	/			
4	-1	-1	1	-1
5	/			
6	-1	-1	2	0
7	-1	-1	1	-1
8	-1	-1	2	0
9	-1	-1	1	-1
10	-1	-1	1	-1
11	-1	-1	1	-1
12	-1	-1	1	-1
13	-1	-1	1	-1
14	-1	-1	2	0
15	-1	-1	3	1
16	-1	-1	2	0
17	-1	-1	1	-1

Table III: MD Anderson Dysphagia Inventory Score (MDADI)

Patient	MDADI GS	MDADI CS	MDADI PS	MDADI ES	MDADI FS
1	4	85.3	82.5	83.3	92
2	4	91.6	90	86.7	100
3	2	69.5	70	60	80
4	1	83.2	85	80	84
5	3	80	77.5	80.5	84
6	4	75.8	75	73.3	80
7	2	60	52.5	66.7	64
8	4	100	100	100	100
9	5	82.1	82.5	70	96
10	1	66.3	47.5	80	80
11	2	48.4	40	36.7	76
12	5	67.4	82.5	60	52
13	2	71.6	65	70	84
14	4	69.4	50	80	88
15	1	78.9	87.5	73.3	72
16	2	52.6	35	63.3	68
17	1	50.5	30	56.7	72
18	5	96.8	97.5	96.7	100
19	4	61	52.5	66.7	68
20	4	70.5	62.5	70	84
21	5	88.4	97.5	86.7	76
22	4	87.4	87.5	76.7	100
23	4	76.8	75	76.7	80
24	2	67.4	55	70	84
25	1	60	55	60	68
26	5	87.4	82.5	86.7	96
27	5	91.6	92.5	86.7	96
28	2	58.9	47.5	70	64
29	4	92.6	92.5	86.7	100
30	1	72.6	70	63.3	88
31	4	71.6	70	73.3	72
32	5	95.8	100	86.7	100
33	4	73.7	75	66.7	80

Figure 2A: self-rated severity of Dysphagia at MDADI-CS

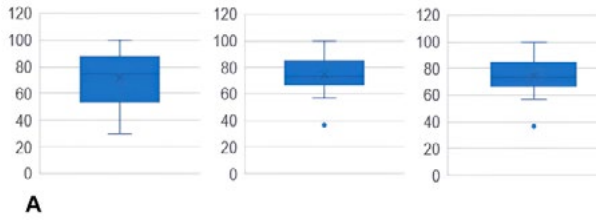
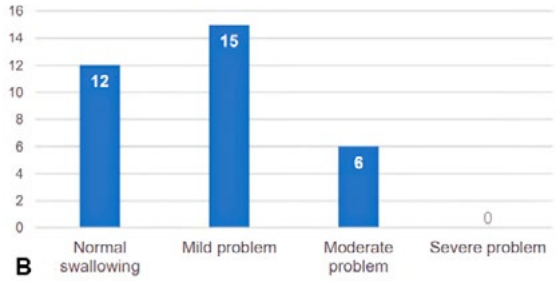


Figure 2B: Median Score of MDADI-P, MDADI-E, MDADI-Fm



When analysing the global score on the I-DHI (Table IV), 5 patients had a normal score, while 28 had a pathological score. The minimum score obtained was 0 and the maximum score was 82. The mean score was 20.12 (SD 16.91).

Figure 3A shows the minimum and maximum scores obtained by patients for each I-DHI subscale, including emotional, functional, and physical subscales. The analysis of the global I-DHI score showed that 5 patients had a normal score, while 28 had a pathological score. The minimum score obtained was 0 and the maximum score was 82. The mean score was 20.12 (SD 16.91).

Overall, 10 patients reported no swallowing problems, 14 patients had a score indicating a mild swallowing problems and 7 patients had moderate swallowing impairment. 2 patients reported a severe swallowing problems (Figure 3B).

Table IV: Dysphagia Handicap Index Score (DHI)

Patient	DHI-G	DHI-P	DHI-E	DHI-F
1	20	12	0	8
2	20	12	4	4
3	20	10	6	4
4	10	10	0	0
5	14	10	2	2
6	0	0	0	0
7	32	16	12	4
8	4	4	0	0
9	20	12	4	4
10	14	0	4	10
11	40	18	10	12
12	16	8	2	6
13	18	10	4	4
14	34	20	4	10
15	16	14	2	0
16	44	18	12	14
17	82	26	24	32
18	4	4	0	0
19	36	16	8	12
20	20	10	6	4
21	10	6	0	4
22	2	2	0	0
23	6	6	0	0
24	22	18	2	2
25	48	20	12	16
26	2	2	0	0
27	2	2	0	0
28	34	12	8	14
29	10	10	0	0
30	22	12	4	6
31	18	14	2	2
32	4	4	0	0
33	20	10	2	8

Figure 3A: normal and pathological scores of I-DHI scales compared

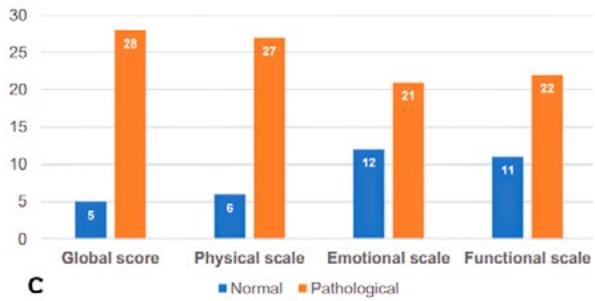
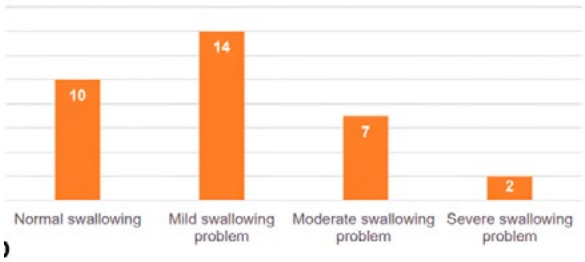


Figure 3B: self-reported severity of dysphagia according to I-DHI



None of the patients experienced bolus penetration or aspiration. The p-score was determined by considering the site, amount, and management sub-scores. When assessed for jellified bolus, 12 patients had a minimum score indicating no endoscopic signs of dysphagia (score 4-5) and one patient had a low score associated with mild dysphagia (score 6-7). One subject had moderate dysphagia (score 8-9) and another had severe dysphagia (score 10 -11). For liquid bolus, the p-score corresponded to no dysphagia in eleven cases (score 4-5), and mild dysphagia in three patients (score 6-7). For solids, 11 patients were classified as having no dysphagia (score 4-5), and 3 patients as having mild dysphagia (score 6-7).

Statistical analysis

According to linear regression analysis, a positive correlation was observed between the variables "dysphagia" and "intubation" (p=0.003). The p-value of 0.05 for age and dysphagia suggests that there a was a close to statistically significant correlation. The p-value of 0.505 for the "hospitalization" and "dysphagia" variables suggested the presence of an independent correlation. There was no evidence of a causal relationship (p>0.05) among the other variables. There was no agreement between MDADI and any FEES severity for liquid (K=0.03) and solids (K=0.12), while a weak correlation was detected for jellified (K=0.59). A weak correlation was observed between the emotional DHI subscale and the severity of findings in FEES for each bolus consistency (0.42<K<0.49). Instead, an almost perfect correlation was found between the self-related I-DHI and FEES severity for solids (K=0.95). In all other cases, there was minimal agreement between the variables (0.24<K<0.38).

Discussion

The prevalence of long-Covid-19 disease patients appears to be increasing, so it is recommended to establish a standardized protocol for screening and evaluating this population (Chen et al., 2019).

Swallowing disorders are common after Covid-19, possibly due to intubation and/or ICU stay, and may persist over time, negatively affecting patients' quality of life. This study aims to propose a reliable protocol for assessing dysphagia in patients who report impairments in swallowing.

Our sample suggest that no variable, except for intubation, is statistically correlated with the severity of dysphagia (p<0,005); age and hospitalization show independent correlation.

A general observation is that dysphagia is present in our sample, but with reduced severity, although it still impacts on quality of life. Questionnaires administered to our patients reinforce this general observation, which needs to be considered in relation to the consistency being tested. The discrepancies between the results of the proposed questionnaires and the severity parameters verified through endoscopy indicate a need for an assessment protocol that can accurately define the extent of the disorder and track its progression over time. The protocol suggested in this paper seems to fulfill this objective and shed light on some of the reported inconsistencies.

The general analysis of the self-assessed questionnaires revealed significant impairments in swallowing solid foods and liquids,

Table V: Pooling score - SITE AMOUNT MANAGEMENT

	Vallecola	**Marginal zone**	**Pyriform sinus**	**Vocal cords**	**Lower vocal cords**	**Coating**	**Minimun (<1/2)**	**Maximun (>1/2)**	**<2**	**>2<5**	**>5**	**P-SCORE**
1	/											
2	Jel.wat:1 Liquid: 1 Solid:1	Jel.wat:0 Liquid: 1 Solid:0	Jel.wat:0 Liquid: 1 Solid:1	Jel.wat:0 Liquid: 1 Solid:0	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:1 Solid:1	Liquid: 2		Jel.wat:2		Liquid:4 Solid:4	Jel.wat:4 Liquid: 6 Solid:7
3	/											
4	Jel.wat:0 Liquid: 0 Solid:1	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:1	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:0	Solid:1			Solid:2			Jel.wat:1 Liquid: 1 Solid:1
5	/											
6	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:0							Jel.wat:0 Liquid: 0 Solid:0
7	Jel.wat:1 Liquid: 1 Solid: 1	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:0 Liquid: 0 Solid:0	Jel.wat:1 Liquid: 1 Solid: 1			Jel.wat:2 Liquid: 2 Solid: 2			Jel.wat:4 Liquid: 4 Solid: 4
8	Jel.wat:1 Liquid: 1 Solid: 1		Jel.wat:2 Liquid: 2 Solid: 2			Jel.wat:1 Liquid: 1 Solid: 1			Jel.wat:2 Liquid: 2 Solid: 2			Jel.wat:6 Liquid: 6 Solid: 6
9	Jel.wat:1 Liquid: 1 Solid: 1	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:1 Liquid: 1 Solid: 1			Jel.wat:2 Liquid: 2 Solid: 2			Jel.wat:4 Liquid: 4 Solid: 4
10	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0							Jel.wat:0 Liquid: 0 Solid: 0
11	Jel.wat:1 Liquid: 0 Solid: 1	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0		Jel.wat:2 Solid: 2		Jel.wat:2 Solid: 2			Jel.wat:5 Liquid: 0 Solid: 5
12	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0							Jel.wat:0 Liquid: 0 Solid: 0
13	Jel.wat:0 Liquid: 0 Solid: 1	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Liquid: 1 Solid: 1			Liquid: 2 Solid: 2			Jel.wat:0 Liquid: 3 Solid: 4
14	Jel.wat:0 Liquid: 0 Solid: 1	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Solid: 1			Solid: 2			Jel.wat:0 Liquid: 0 Solid: 4
15	Jel.wat:0 Liquid: / Solid: 1	Jel.wat:0 Solid: 1	Jel.wat:0 Solid: 0	Jel.wat:0 Solid: 0	Jel.wat:0 Solid: 0		Solid: 2			Solid:3		Jel.wat:0 Solid: 6
16	Jel.wat:1 Liquid: 1 Solid: /	Jel.wat:0 Liquid: 0	Jel.wat:0 Liquid: 0	Jel.wat:0 Liquid: 0	Jel.wat:0 Liquid: 0	Liquid: 1	Jel.wat:2				Jel.wat:4 Liquid: 4	Jel.wat:8 Liquid: 7
17	Jel.wat:0 Liquid: 0 Solid: 1	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 1	Jel.wat:0 Liquid: 0 Solid: 0	Jel.wat:0 Liquid: 0 Solid: 0	Solid: 1			Solid: 2			Jel.wat:0 Liquid: 0 Solid: 5

with 45% and 33.3% of patients reporting difficulties, respectively. Additionally, 33.3% of patients experienced an increase in mealtime. Some patients felt embarrassed about eating in the presence of others and tended to isolate themselves (18.2%). Overall, 63% of patients reported mild to moderate dysphagia symptoms, indicating that Covid-19 greatly compromises overall health, increases stress levels, and reduces quality of life. Upon completing the I-MDADI and I-DHI questionnaires, the majority of patients showed mild swallowing problems, with 45% scoring in the mild range on the MDADI questionnaire and 42% on the I-DHI questionnaire. Moderate scores were reported by 18% and 21% of patients on the MDADI and I-DHI questionnaires, respectively. Only 6% of patients reported severe swallowing problems on the I-DHI questionnaire. Literature suggests that Covid-19-related dysphagia can resolve rapidly (Salian et al., 2020), although patients with more complex conditions may experience or exacerbate swallowing difficulties. This study highlights a correlation between the severity reported in the questionnaires and the severity observed during FEES, suggesting that even patients with mild swallowing problems are greatly impacted by Covid-19 in terms of their quality of life, particularly in the emotional domain.

FEES assessment is mandatory to confirm the presence and severity of dysphagia. Our study found that most patients who complained of swallowing impairments did not have significant endoscopic signs of dysphagia. Specifically, a great percentage (88.2%) of patients tested with jellified water did not present endoscopic signs of dysphagia, and 82.3% of patients did not have dysphagia when tested with liquids and solids. A small percentage of patients had mild dysphagia, and only one subject had moderate dysphagia when tested with jellified water. The p-score values align with I-DHI scores, with I-DHI scores having a strong agreement with dysphagia for solids and a moderate agreement with other consistencies.

These findings indicate that I-DHI scores can be a useful tool for early identification of dysphagia in patients with Covid-19 and long-Covid-19 disease.

Conclusions

After Sars-Cov2 infection a significant percentage of patients may develop mild dysphagia.

This pilot study has demonstrated that the utilization of a standardized and specific assessment protocol for evaluating dysphagia is valuable in screening and identifying patients with early swallowing difficulties. These protocols should incorporate a self-assessment questionnaire and a comprehensive bedside swallow evaluation (BSE). Additionally, a flexible endoscopic evaluation of swallowing (FEES) assessment is imperative in confirming the presence and severity of dysphagia.

Conflicts of interest.

Authors declare no conflicts of interest to disclose.

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Authors' contributions.

Conceptualization: [Valeria Caragli], [Maria Consolazione Guarnaccia] [Elisabetta Genovese]; Methodology: [Valeria Caragli], [Maria Consolazione Guarnaccia], [Giovanni Guaraldi], [Luca Pingani]; Formal analysis and investigation: [Simona Boca], [Francesca Dondi] [Valeria Caragli], [Maria Consolazione Guarnaccia]; Writing - original draft preparation: [Valeria Caragli]; Writing - review and editing: [Valeria Caragli], [Daniele Farneti]; Supervision: [Daniele Farneti], [Elisabetta Genovese].

Ethical consideration.

This study was approved by Ref N° 177/2020 of the Ethical Committee Approval dell'Area Vasta Emilia Nord, protocol number 177/2020, March 11th, 2020) and by the University Hospital Committee (Direzione Sanitaria dell'Azienda Ospedaliero-Universitaria di Modena, protocol number 7531, March 11th, 2020). The research was conducted

ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki. Written informed consent was obtained from each participant/patient for study participation and data publication.

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