

# Dysphagia, a Problem Associated with Swallowing Solid Dosage form (SDF) in the General Population

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## Authors' Contributions

1 Conception & Study Design, Data Collection & Processing

2 Data Analysis, Interpretation, drafting final review of manuscript and critical review

3-6 Data Collection & Processing and Critical Review

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## ABSTRACT

**Background:** One highly popular method of drug administration is the oral administration of the medication. However, this can be bothersome as it may exert stress as many individuals may suffer from swallowing problems like dysphagia. It can occur in all age groups but geriatric patients are very much affected by the problem.

**Objective:** Present study was designed to understand the stress of dysphagia in different individuals and to gain knowledge regarding their pill administration experience.

**Method:** The study design was descriptive observational with convenience sampling. Following literature survey a total of 343 participants enrolled in this study. After taking informed consent they were asked to complete the questionnaire. Descriptive analysis along with Pearson's chi squared test of correlation and goodness of fit model was applied to the different questions using SPSS-20.

**Result:** The data showed female preponderance along with the mean age group within 18 – 25 year's age brackets. Test of correlation showed that the concepts of participant whether male or female were same with no statistically different results suggesting the problem is equally affecting both genders. Prevalence could not be calculated as participants already had dysphagia.

**Conclusion:** The study concludes that solid dosage form (SDF) may cause dysphagia in every age group. There is a need for Pharmaceutical Companies to make a plan of monitoring the market regularly on how the population experience pill-induced dysphagia as well as some novel drug delivery system (NDDS) must be introduced to manage this problem.

**Keywords:** Solid Dosage Form (SDF), Dysphagia, Novel Drug Delivery System (NDDS)

## INTRODUCTION

Medication is generally dispensed orally in majority of cases. Mainly it provides best patient compliance because it is easy to take solid medicine orally compared to syrups or injections [1, 2]. Patients with extremes of age are prone to not respond and are not

compliant to the medication mainly due to some physiological or pathological changes in the oral cavity, pharynx or throat [3].

This difficulty in swallowing is known as dysphagia which could be associated with pain [4]. This contributes in difficulty in the administration of the medication orally. A study showed 15–20%

swallowing difficulty of medication in the cohort under study [5]. Certain factors related to medication that affect swallowing may be size, shape or texture of the pill. To overcome this problem recent advances in dosage preparation has shifted to produce dissolving tablets [6] that will be able to overcome the dysphagia and lack of water challenge too [4]. There may be patient related factors too like posture during ingestion of the pill [7, 8]. Patients with dysphagia should be notified to the physician so that they can be treated accordingly.

Purpose of the present study is to identify dysphagia regarding pill intake and to identify the variables that positively or negatively affect the swallowing process.

## METHODOLOGY

### Study aim, area, and period:

A cross-sectional study was conducted from November 2021 to March 22 at each participant's home, or a public place of their convenience. The purpose of the study was well explained to them and then they were interviewed after obtaining their verbal consent.

### Study population, duration, and collection procedure

All participants who have previous dysphagia problems related to the solid dosage form were eligible. Information was collected with the help of a questionnaire by the trained interviewer. The questionnaire was prepared to answer the study objectives by recapturing previous studies it was pretested for correctness and validity and appropriate corrections were made.

### Sample method and sample size:

The sample size was calculated using the population formula, approximately 350 participants were registered in this research, and 343 completed this questionnaire. The sample size was calculated using the sample size calculator by assuming a 95% confidence level, 5% margin of error, and precision level of 50%.

$$n = \frac{(Z_{\alpha/2})^2 p(1-p)}{w^2}$$

.....Equation 1

n (sample size), Z (confidence interval level 95%), P (population 50%), w (margin of error 5%). Using the

above equation we found the minimum sample size of 350.

### Eligibility criteria:

**Inclusion criteria:** Healthy Patients above 12 years of age who were able and willing to provide sufficient information were included in the study.

**Exclusion criteria:** People less than 12 years of age who were unable and unwilling to provide sufficient information were excluded from the study.

### Structure of Questionnaire

A questionnaire with fifteen questions was developed. The individual did not need to be taking pills or Tablets at the time of data collection. A total of 343 participants 145 males and 198 females between the ages of 15 and 55 years were recruited. The questionnaire consisted of five major topics, first four questions were about demographics individual's that is individual's name, age, gender, and marital status. The questionnaire covers the study about which dosage form an individual takes likewise physical properties of tablets, emotional status regards taking tablets, and how much difficulty an individual face during taking tablets.

The second part of the questionnaire included questions regarding types of dosage form their texture and type to therapy. Third part included emotional status of the participants during medication intake and last part covered the posture and smoothness of the dosages form

### Statistical Analysis

All the demographic data was subjected to frequency distribution analysis using SPSS (v. 20). The age group and gender were taken as independent variables and the Pearson's Chi squared test of correlation was applied to see relations ship of age and gender with the dysphagia. The results were considered significant when  $p < 0.05$ .

## RESULT

### Participants and response rates

Total participants who participated in the study were 343 related to pill swallowing difficulties and dysphagia. The responsive group was more of females 198 (58%) than males 145 (42%). The sociodemographic characteristics are summarized in Table 1. As seen from the table, the main age group of the participants 302 (88.04%) was from 15 to 25.

**Table 1. Sociodemographic Presentation of Participants.**

Sociodemographic feature of Participants			
Characteristics		Participants	%
Gender	Male	145	42.3
	Female	198	57.7
Age	15 to 25	302	88.04
	26 to 35	26	7.6
	36 to 45	6	1.7
	46 to 55	9	2.62
Marital Status	Married	42	12.2
	Un-Married	301	87.7

**Prevalence and burden of swallowing difficulties.**

Participants were found to face difficulty in swallowing solid dosage forms ( $\chi^2 = 161.035$ ,  $p < 0.005$ ) like tablets ( $n = 170$ , 50 %) and capsules ( $n = 109$ , 32%). According to the participant’s physical characteristics like pill size ( $n = 219$ , 63%), shape ( $n = 18$ , 5.2%), smell ( $n = 47$ , 13.7%) and texture ( $n = 59$ , 17.5%) influence swallowing and also contributes in dysphagia. Many participants complained that major swallowing problem arise with antibiotics ( $n = 152$ , 44%) and least with anti-hypertensive agents ( $n = 30$ , 9%) mainly due to the size of the dosage form. Out of 343 most of the participants ( $n = 220$ , 64.1%) do not like tablets whereas 11% ( $n = 37$ ) find it appealing and 25% ( $n = 86$ ) take tablets apathetic.

**Administration habit.**

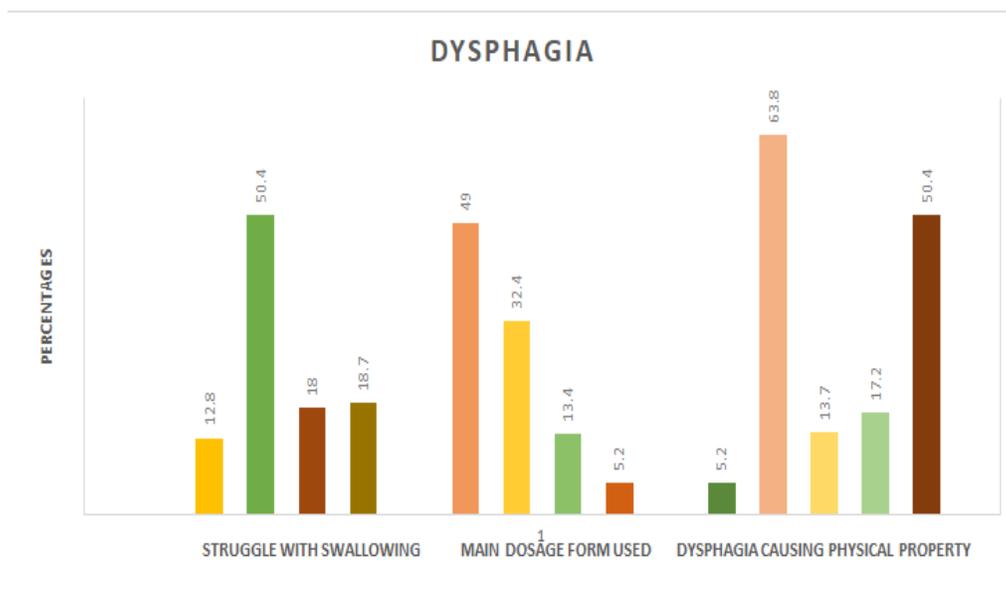
Around 55% participants mentioned that ( $n = 189$ ) they change their head posture to enhance the swallowing experience comparatively 16% ( $n = 55$ ) participants mentioned that changing their head position does not enhance their swallowing experience.

30% participants mentioned that their ability to swallow pills was improved by smooth coating ( $n = 102$ ) whereas 14.9% said smooth coating does not affect their swallowing experience.

**Pearson’s  $\chi^2$  test of correlation**

Age groups of participants and gender were considered independent variable to study the correlation with the variables and it was found that age groups had no significant effect on the variables that is medicine taking ability.

The test was then conducted with the gender as independent variable and it was found that the experience of dysphagia or no dysphagia was not dependent on gender. Both the groups have same experiences Table 2. The variable in which it was asked about the total number of medications taken per day the result was found significantly different as the responders in large number of medication intake belonged to female group ( $\chi^2 = 10.92$ ,  $p < 0.05$ ).



**Figure 1. Factors associated with Dysphagia**

**Table 2. Pearson's  $\chi^2$  Test of Correlation Between Variables and Gender as Independent Dichotomous Variable.**

Variables		Gender		Total	Chi-Square (p-value)
		Male	Female		
What type of dosage form cause swallowing problem	Capsule	52	59	111	1.962 (0.580)
	Dispersible tablets	20	26	46	
	Syrups	6	12	18	
	Tablets	67	101	168	
	Total	145	198	343	
Which type of therapy causes swallowing problem	Analgesic	10	16	26	3.631 (0.604)
	Antibiotics	62	90	152	
	Antidiabetic	9	7	16	
	Antihypertensive	15	15	30	
	Vitamin supplement	24	27	51	
	Others	25	43	68	
	Total	145	198	343	
Which physical property of solid dosage form causes s	Shape	12	6	18	7.230 (0.065)
	Size	90	129	219	
	Smell	15	32	47	
	Texture	28	31	59	
	Total	145	198	343	
How much difficulty do you face when swelling tablets	Difficult	78	95	173	4.308 (0.230)
	Easy	24	38	62	
	No Difficulties	21	43	64	
	Very difficult	22	22	44	
	Total	145	198	343	
What is the emotional status of your when you see the tablets	Apathetic	40	46	86	2.101 (0.350)
	Appealing	12	25	37	
	Do not like it	93	127	220	
	Total	145	198	343	
How much pills you can consume in a day	2 to 4	114	172	286	<b>10.917 (0.012)</b>
	6 to 4	29	19	48	
	10 to 15	2	2	4	
	15 to 22	0	5	5	
	Total	145	198	343	
Are you taking your medication prescribed by the doctors or self-medicate	Prescribed by the doctor	119	164	283	0.033 (0.483)
	Self-medication	26	34	60	
	Total	145	198	343	
Does pills width affect your swallowing experience	May be	54	71	125	1.256 (0.534)
	No	22	23	45	
	Yes	69	104	173	
	Total	145	198	343	
Dose smooth coating of pills enhances your swallowing experience	May be	45	57	102	2.588 (0.274)
	No	26	25	51	
	Yes	74	116	190	
	Total	145	198	343	
Change the head position enhances your swallowing experience	May be	41	58	99	2.040 (0.361)
	No	28	27	55	
	Yes	76	113	189	
	Total	145	198	343	

>0.05 non-Significance

≤ 0.05 Significant

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## DISCUSSION

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At the extremes of age, the process of swallowing is difficult which may be due to structural or functional alteration of throat. Aging has inverse relationship with swallowing process and put the elderly and pediatric population on risk [9]. Patients even don't mention this problem to their physician [10] which may consequently may progress to clinically significant swallowing problems with solid oral dosage forms. Abnormal swallowing, like other sensory and motor functions, also shows disease-related decline patterns over time and must be considered from both a geriatric and gerontological perspective [11]. While the clinical definition of dysphagia encompasses a wide range of physiological changes and forms of swallowing impairment, the individual implications vary. They can manifest as an acute occurrence or a gradual progression, and they can last for a short time or become chronic. Malnutrition, dehydration, and psychological and social stress are all linked to swallowing problems [12]. This survey was developed to assess patients' concerns related to swallowing problems.

Dysphagia is related to different medicines like analgesics, antibiotics, anti-diabetes, antihypertension, and vitamin supplements and their different physical properties as dosage forms like their shape, size, smell, and texture. As according to a forecast the geriatric patients will be about one third of the world's population by 2050, [13] it is very important to consider their problem and trouble shoot it beforehand. Present study included patients with a self-reported history of a swallowing problem. They were prompted to complete the entire survey; patients with no swallowing problems stopped after the history and demographic items therefore their data was not included in the study.

Demographically, a total of 343 volunteers of age group range of 15-25 age group 302 (88.04%) participated, in the study related to pill swallowing difficulties dysphagia. They were more females 198 (57.7%) than males 145 (42.3%), this data was supported by the study in 2013 [5, 14].

Geriatric patients need a large number of medications. In hospital settings they are given medicines after crushing them and that can be of hazard as many drug lose their efficacy this way [13]. Tablets can be crushed but capsules may not be able to provide desired pharmacological effect [15].

Present study showed that mostly tablets were used by 49% (n = 168) followed by 32% using capsules (n = 111) and syrups and dispersible tablets were used by 18 (5.2%) and 46 (13.4 %) respectively, as shown in Figure 1.

Physical properties caused swallowing issues in participants. 63% had problems with size (n = 219), 50% had problem with width (n = 173) followed by shape 18 (5.2%), smell 47 (13.7%), and texture 59 (17.2%) the relatable problems reported by [16]. Swallowing problems may be increased when the tablet diameter was more than 7 mm which can be overcome by changing head position [17].

It is also suggested in several studies that size reduction, film coating can help in safely administering medicine in elderly patients [15].

As emotional assessment it was observed that people did not like different dosage forms. These findings were in accordance with other reported studies [18]. People tend to change head positions too during pill uptake which is shown in other studies to help improve the swallowing. A related research in 2021[19] also showed that changing head posture affects swallowing of medications.

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## CONCLUSION

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It can be concluded by present study that dysphagia related to oral dosage forms is common, in all age groups but it becomes very problematic as the age progress. Dysphagia should be mentioned to the physician before the start of the treatment so that physician could suggest medication according to the problem. It is also noticed that size reduction, and coatings of the medication can improve the problem to some extent.

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