

# Impact Of Psychological Dysphagia On Patient Compliance In Public Hospitals Of Karachi

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## ABSTRACT

The aim of this paper was to find out the impact of psychological dysphagia on patients' compliance in public sector hospitals of Karachi. An effort was made to find out the problems and difficulties experienced by the patients while taking tablets and capsules. Adopting deductive approach, hypotheses were formulated after in-depth review of relevant literature. Primary quantitative data were collected via a structured questionnaire. Non-probability convenience sampling technique was used and 565 questionnaires were distributed to the patients of public sector hospitals of Karachi. The data analysis reveals that there is a significant impact of psychological dysphagia on patient acceptance of oral solid dosage forms. There is also a significant impact of psychological dysphagia on patient preferences of innovative new dosage forms. This research is likely to help the healthcare providers to select appropriate dosage forms for the patients to improve their compliance. This research is likely to help the pharmaceutical industry to emphasize on research and development of new innovative dosage forms to ease out the swallowing difficulties of patients.

**Keywords:** Psychological dysphagia, Patients' compliance, Patients acceptance, Patients preferences, Active pharmaceutical ingredient, Dosage forms.

## 1. INTRODUCTION

During the past 20 years, numerous advancements have been made in drug formulation and routes of administration. Enhanced understanding of drug transport across tissues has improved the patient adherence to the treatment regimen and pharmacologic response. Various routes of drug administration have been developed that deliver the benefit of being comparatively painless. In addition, the existence of potential for greater flexibility in diversified clinical situations helps to focus on the pros and cons

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of alternative routes of drug administration. Verma P., A.S. Thakur, K. Deshmukh, Dr. A.K. Jha & S. Verma (2010) illustrated the route of drug administration as the passageway through which the dosage forms are administered into patient's body for the purpose of treatment and management of numerous diseases and disorders. These routes of administration have a significant repercussion on the bioavailability of the active drug moiety in the body. Robert A. Steiger, MD, David Write (2011) mentioned that capsules and tablets are the most frequently prescribed because of their inexpensive production. Their coating can alter the absorption characteristics and they are generally appropriate for the patients, both for consumption and transportation. This study examines the experiences of patients towards intake of oral solid dosage forms and helps in focusing on the deficiencies in the clinical practices to resolve potential problems regarding psychological dysphagia. Following three public sector hospitals were approached for data collection:

- **Jinnah Postgraduate Medical Centre (J.P.M.C.), Karachi**
- **Abbasi Shaheed Hospital (A.S.H.), Karachi**
- **Sindh Government Hospital Saudabad, Karachi**

### **1.1 Problem Statement**

Researchers have observed that when it is a challenge to swallow a pill, a patient may not take medicine as regularly as prescribed. This can influence pain levels, general wellbeing, as well as capacity to exercise and participate in . Likewise, if patients are non-compliant, it could significantly affect the treatment results and could lead to clinical consequences, particularly when patients are receiving treatment for chronic illnesses (Jin, J., Sklar, G. E., Min Sen Oh, V., & Chuen Li, S., 2008). According to Wischke, C., Neffe, A. T., Steuer, S., & Lendlein, A. (2010), gulping pills is not only a problem for children; grown-ups who can't hold the pills down face the same mental obstruction. So, psychological dysphagia should be recognized and addressed, because inconvenience in intake of tablets and capsules can put a person at liability for other complications. Through this study an effort was made to find out impact of psychological dysphagia on patient compliance in public sector hospitals of Karachi.

### **1.2 Research Objectives**

Research objectives for the study are:

- To determine the impact of psychological dysphagia on patient acceptance of oral solid dosage forms.
- To examine the impact of psychological dysphagia on patient preferences of innovative new dosage forms.

## 2. LITERATURE REVIEW

### 2.1 Psychological Dysphagia

Swallowing is a complex sensory motor process that involves sequential excitation and inhibition at different levels of the central nervous system. The whole process comprises of three phases, i.e. oral, pharyngeal and esophageal and all of them require coordination of the mouth, tongue, larynx, pharynx and esophagus. According to Frederick AD Kaona, Mary Tuba, Seter Siziya and Lenganji Sikaona (2004), difficult swallowing i.e. dysphagia indicates taking extra time and exerting while food or liquid movement from the mouth to the stomach. It can be caused by problems with nerves or muscles. When food is swallowed, the airways are closed and breathing is stopped for a moment. According to Julia T. Schiele, Renate Quinzler, Hans-Dieter Klimm, Markus G. Pruszydlo and Walter E. Haefeli (2013), occasionally difficulty in swallowing occurs when one eats too fast or food is not chewed well enough, but continuous dysphagia may designate a serious medical condition that requires treatment. They also indicated that swallowing difficulties may also be allied with pain and in some cases, swallowing may be impossible. Olle Ekberg, Shaheen Hamdy, Virginie Woisard, Anita Wuttge, Hann Primitivo Ortega (2002) identified the impact of dysphagia on the quality of the patient's life and explored its relationship with a frequency and diagnosis of diseases. Venkata S. P. B. Durvasula (2014) noted that swallowing disorders can be diagnosed at all ages including paediatric patients. They further stated that it could be a risk factor leading to near-fatal choking episodes and death of elderly patients because of aspiration and pneumonia.

### 2.2 Significance of Patient Compliance

DiMatteo, and Robin M. (2004) pointed out the significance of patient compliance in medicine, as it outlines the degree to which a patient's behavior accurately coincide with the medical recommendations. Generally, it is attributed to medication compliance, but it is also applicable to other situations such as the use of the medical device, caring for oneself, self-supervised exercises or sessional therapies. Rainer , & (2001) recognized compliance with medical recommendations as a multifaceted dare since it was identified by Hippocrates approximately 2400 years back. Martje et (2005) studied that non-compliance with medications in heart failure (HF) patients leads to aggravation of symptoms and may result in hospitalization. Comparatively, patients with overall compliance had significantly acquired more benefits of medications. As a result, these compliant patients inclined to have fewer depressive symptoms. Frederick AD Kaona et al. (2004) related the discrimination at healthcare facilities with tuberculosis and AIDS patient compliance. According to them, discrimination of these patients in t healthcare facilities based on disease sometimes worsens problems with their compliance. Discriminatory behavior of health care providers at the clinics results in

battling of the patients during the collection of their drug supplies (Wischke 2010).

### **2.3 Oral Solid Dosage Forms**

R. Dusing R. (2001) stated that with the overall evolution of the pharmaceutical industry, it is somewhat surprising that there is a great advancement in drug discovery and development. The discovery of novel drugs and their modification into marketable products has taken place across the comprehensive scope of the pharmaceutical industry. The most critical function of packaging is to ensure the safety and packaging of the pharmaceutical product by protecting them from the destructive effects of the external environment such as air, moisture, or light. According to Edward M. Rudnic and Joseph B. Schwartz (2005), drug substances are most frequently administered orally by means of the solid dosage form such as tablets and capsules.

Stephen O. Majekodunmi (2015) described lozenges as one of the commonly used solid dosage forms. These dosage forms contain medicament and are intended to be placed in the mouth or pharynx. Due to the impractical size of sublingual lozenges, buccal lozenges have been formulated for placement between the cheek and the gums. Zajicek A., (2013) stated that lozenges have a dissolution time of about 30 minutes but it can fluctuate with the patient. Regulation of the rate of dissolution and hence the rate of absorption can be achieved by sucking them until their complete dissolution.

### **2.4 Psychological Dysphagia Related to Oral Solid Dosage Forms**

Godman H., (2017) argued that the expression “a hard pill to swallow” is not just a metaphor because swallowing pills can be a difficult and absolutely unpleasant experience for the patients. It might cause gagging, vomiting or choking in one in every three people. It can prevent the people from adhering to their medication routines, thus decreasing the patient compliance which can make them sicker. According to her, some people can easily swallow food and liquid, but face difficulty while swallowing pills. Julia T. Schiele (2012) evaluated the commonness of swallowing difficulties related to oral solid dosage forms in a universal population. Similarly, Zajicek A. et al. (2013) noted that even though it is fact that a substantial fraction of the inhabitants' face difficulty while swallowing tablets and capsules, these dosage forms are endured to be of the inadequate standard. The large size of the tablet or capsule, incorrect dosage strength and poor palatability result in failure of patients particularly children. This leads to patient non-compliance and therapeutic failure.

F. Liu (2014) stated that the child age of acquiring expertise to swallow tablets and capsules safe and sound is a matter of debate. Previous literature denotes 6 years as an ideal age for considering tablets and capsules appropriate for children, but the current evidence shows that the ability to

swallow tablets and capsules may be already acquired by the children at an earlier age, or may be learned by behavioral training interventions. Marquis J. (2013) stated that the majority of the patients belonging to the age group of 18 years and older, experience swallowing difficulties at each single dose of medication, with a single medication that may last for less than 12 months. These swallowing difficulties are independent of the number of the tablets taken and impair the daily life of a number of patients. They observed that some old age people do not face difficulties when swallowing larger volumes of medicines as compared to other patients.

## **2.5 Patient Acceptance of Oral Solid Dosage Forms**

Jeremy Fields, Jorge T. go and Konrand S. S.SSchulze (2015) stated that pills, including tablets and capsules are extensively used for the administration of prescription drugs as well as for the intake of supplements such as vitamins. According to them, it is not well known that to what degree hard-to-swallow pills might adversely affect the treatment consequences or interfere with compliance with prescribed medications or lead to clinical complications. Pierre Michel Lorea (2011) stated that several patients face discomfort while attempting to engulf tablets and capsules. It is a common problem, but it is seldom conversed between patients and physicians. It occurs due to the morphology of the oropharynx and esophagus, which are not sound for swallowing stiff items occupying small volumes.

K. Bin Liew, K. Khiang Peh and Y. Vonne Tze Fung Tan (2014) found out that some of these patients have undergone choking while taking these dosage forms due to the large size. These difficulties result in the patient non-compliance to prescribed medications as they give up taking them. Most of patients who are known to be non-compliant with the treatment belong to paediatric and geriatric population. Julie A. Mennella (2013) stated that many active pharmaceutical ingredients (APIs) are aloof to both children and many adults due to their bitter taste. A research by Kirkevold and Engedal K. (2010) mapped out the degree to which medications are being crushed and mixed into the food and beverages before administration to the patients. Yady Juliana Manrique-Torres (2014) evaluated the release and dissolution of crushed tablets mixed with foods and drinks and compared them with the whole tablets.

## **2.6 Patient Preferences of Innovative New Dosage Forms**

Diana Witticke (2012) discussed the results of earlier studies stating that when patients were questioned to postulate their preferences regarding the characteristics of appropriate medication regimen, they undoubtedly pointed out the regimens that have been allied with improved compliance. Monali Bhosle, Joshua S. Benner, Mitch DeKoven, Jeff Shelton (2009) highlighted that these user-friendly dosage forms are provided opportunities to the pharmaceutical industry for product line extension which improves the patient compliance.

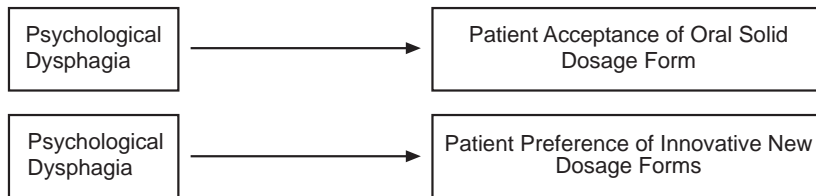
Konapure (2011) discussed that oral drug delivery is presently considered the best merit in the pharmaceutical industry because it is harmless, most suitable and most cost-effective means of drug delivery that have the highest patient compliance. Fang Liu (2014) regarded chewable tablets as a suitable dosage form for paediatric and geriatric patients who face difficulties to swallow traditionally sized monolithic intact dosage forms. Hirani J. J., DA Rathod and KR Vadalía (2009) also defined orally disintegrating tablets (ODTs) as a preferred substitute to traditional tablets and capsules due to improved patient compliance.

## 2.7 Research Hypotheses

**H1:** There is significant impact of psychological dysphagia on patient acceptance of oral solid dosage forms.

**H2:** There is significant impact of psychological dysphagia on patient preference of innovative new dosage forms.

## Theoretical Framework



## 3. RESEARCH METHODOLOGY

It is an explanatory and descriptive research as it was conducted to see the impact of independent variable, i.e. psychological dysphagia on dependent variables including patient acceptance of oral solid dosage forms and patient preferences of innovative new dosage forms. In this study population includes the patients of three public hospitals of Karachi. These are: Jinnah Postgraduate Medical Centre (J.P.M.C.), Abbasi Shaheed Hospital (A.S.H.) and Sindh Government Hospital Saudabad. The target population of these three hospitals was 3330 patients. A total sample size of 565, both males and females, was selected from out-patient department of three public hospitals in Karachi, for data collection. Non-probability convenience sampling technique was adopted, and data were collected from those patients in the hospitals who had taken or were taking tablets, capsules and related oral dosage forms.

**Primary data** is used for this research and data is collected through the use of a questionnaire, adopted from the existing literature on previous studies conducted by Jeremy Fields, Jorge P Go and Konrad S. Schulze (2015). Data were analyzed with the help of statistical tools including, Correlation and Regression.

## 4. ANALYSIS

### 4.1 Test of Reliability

The reliability was tested through reliability coefficient Cronbach's Alpha. The Cronbach's Alpha values (table-4.1) for the research variables, being greater than .7, indicate that the constructs are reliable.

**Table 4.1: Reliability Statistics**

Variable	Cronbach's Alpha	N of Items
Problems while Swallowing Tablets and Capsules	.852	12
Patient Acceptance of Oral Solid Dosage Forms	.768	8
Patient Preferences of Innovative New Dosage Forms	.904	5

### 4.2 Hypotheses Testing

#### 4.2.1 Pearson's Correlation Test:

The relationship of the variables was checked through Pearson's Correlation; the results in table 4.2 indicate that the relationship of the variables ('r' value being 0.422 and .398) is positive, although the relationship is not strong, but it is significant as value of p is .000 which is less than .01.

**Table 4.2: Correlations**

		PD	PA	PP
PD	Pearson Correlation	1		
	Sig. (2-tailed)			
	N	565		
PA	Pearson Correlation	.422**	1	
	Sig. (2-tailed)	.000		
	N	565	565	
PP	Pearson Correlation	.398**	.316**	1
	Sig. (2-tailed)	.000	.000	
	N	565	565	565

\*\* . Correlation is significant at the 0.01 level (2-tailed).

The data show that there is a positive relationship between psychological dysphagia and patient acceptance of oral solid dosage forms and p value is .000 (<.01). Hence, H1 is accepted. Similarly, the correlation value  $r = 0.398$  shows that relationship of psychological dysphagia with patient preference of innovative new dosage forms is positive and it is significant because  $p=.000$ . Hence, H2 is accepted.

#### 4.2.2 Regression Analysis

Regression analysis predicts how the value of dependent variable varies with change in the independent variable. This regression analysis covers model summary, the ANOVA table and co-efficient table to indicate the variance of the model.

## Psychological Dysphagia and Patient Acceptance of Oral Solid Dosage Forms

**Table 4.3: Model Summary**

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.422a	.178	.177	.58341

### a. Predictors: (Constant), PD

As mentioned in table 4.3, R value is 0.422: it shows the correlation between the observed and predicted values of the dependent variable. The value of R-Square is 0.178 which explains 17.8% impact of independent variable (Psychological Dysphagia) on the dependent variable (Patient Acceptance)

**Table 4.4:**

### ANOVA<sup>A</sup>

	Model	Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	41.514	1	41.514	121.968	.000b
	Residual	191.629	563	.340		
	Total	233.143	564			

a. Dependent Variable: PA

b. Predictors: (Constant), PD

As per ANOVA results (table 4.4), the F value is 121.968 which indicates that model as a whole has statistically significant predictive capability. The significant value is 0.000 ( $p < 0.05$ ) which indicates that the model is a useful predictor of the dependent variable (Patient Acceptance).

**Table 4.5:**

### Coefficients<sup>A</sup>

1	Model	Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	T	Sig.
	(Constant)	1.856	.156		11.873	.000
	PD	.435	.039	.422	11.044	.000

a. Dependent Variable: PA

The coefficients values are 1.856 and 0.435 whereas  $p = 0.000$  which indicates that there is positive impact of IV on DV and their relationship is quite significant. Hence, H1 is accepted.



## Psychological Dysphagia and Patient Preference of Innovative New Dosage Forms

**Table 4.6:**

### Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.398a	.158	.157	.56998

a. Predictors: (Constant), PD

As depicted in table 4.6, the R value is 0.398; value of the R-Square is 0.158 which indicates that this model explains 15.8% impact of independent variable (Psychological Dysphagia) on the dependent variable (Patient Preference). Similarly, the value of an adjusted R Square is 0.157 which is a modified version of R-square. A decline in adjusted R-squared shows that the predictors have improved the model by less than expected by chance.

**Table 4.7: ANOVA<sup>A</sup>**

	Model	Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	34.342	1	34.342	105.708	.000b
	Residual	182.907	563	.325		
	Total	217.250	564			

a. Dependent Variable: PP

b. Predictors: (Constant), PD

The value of F displayed in table 4.7 is 105.708 which indicates that the model as a whole has statistically significant predictive capability. The significant value  $p=0.000$ , which is  $< 0.05$ ; hence, the model is statistical significant i.e. it is good fit for the data. Hence, the model is a useful predictor of the dependent variable (Patient Preference).

**Table 4.8 Coefficients<sup>A</sup>**

	Unstandardized Coefficients			Standardized Coefficients		
	B	Std. Error		Beta	T	Sig.
1 Model (Constant)	2.550	.156			16.698	.000
PD	.396	.039		.398	10.281	.000

a. Dependent Variable: PP

Table 4.8 shows the predictor variable and dependent variable; the coefficients values ( $a = 2.550$ ,  $b = 0.396$  and  $p = 0.000$ ) indicate that there is a positive impact of IV on DV. The value of  $p = 0.000$  which is less than 0.05 indicates that the impact is significant. Hence,  $H_2$  is accepted.

## **5. DISCUSSION**

### **5.1 Psychological Dysphagia and Patient Acceptance of Oral Solid Dosage Forms**

Psychological Dysphagia and Patient Acceptance of Oral Solid Dosage Forms With reference to first variable, the results in table 4.2 indicate that  $r$  value is 0.422 which shows a weak and positive relationship between psychological dysphagia and patient acceptance of oral solid dosage forms. This relationship is significant as  $p$  value is 0.000 which is less than 0.05. The result of first hypothesis indicates that there is an impact of psychological dysphagia on patient acceptance of oral solid dosage forms. Fang Liu (2014) demonstrated that patient-related factors affect the capability of an individual to engulf tablets and capsules such as the body position of the patient has an effect on their retention in the oesophagus. Jean S Tubbs, Camilla Haw and Geoff Dickens (2008) discussed that several old age patients experience difficulty while engulfing the tablets and capsules. In order to overcome this issue, nurses crush the tablets or open the capsules before giving these medications to geriatrics. Gazala Akram and Alexander B. Mullen (2012) found out that mixing of medication with foodstuff is a prevalent practice and most of the people are ignorant of issues related to potential stability and degradation of the drug as well as the clinical consequences of such practices. Stubbs J. (2008) stated that many people have trouble while taking tablets which may be due to psychological factors apart from physical factors. The tablet sticking once into the oesophagus experienced by the patient can link it with the sense of discomfort. The rough surface of the tablet can scratch the oesophagus while passing through it. In addition, patients might face swallowing difficulty due to disagreeable taste and smell of the tablets. These all factors contribute to patient non-compliance.

### **5.2 Psychological Dysphagia and Patient Preference of Innovative New Dosage Forms**

The result of second hypothesis testing shows that there is a positive impact of psychological dysphagia on patient preference of innovative new dosage forms. Correlation value of 0.398 shows a weak positive relationship between these two variables. The significant value of 0.000 indicates that this relationship is significant. Diana Witticke (2012) stated that it is a significant prerequisite to evaluate the self-determined attitudes of patients towards medication-related features that are known to weaken the patient compliance and to evaluate their prevalence among patients. It helps in

eliminating the problems related to characteristics of medications that are problematic for patients and also aids in consideration of patient preferences. Fang Liu.(2014) found out that alternatives medications are every so often required when the medications are not preferred by patients such as due to their bitter taste or unpleasant smell. It demands the formulation of more sophisticated dosage forms such as encapsulation of drug particles.

## **6. CONCLUSION**

This study investigates the impact of psychological dysphagia on patient compliance in public hospitals of Karachi. Dysphagia is a medical terminology that indicates the symptoms of difficulty while swallowing. It is a secondary condition with other illnesses, but it can also be correlated with an array of causes such as fear, pain or other cognitive, anatomical or physiological problems. However, the complexities of this condition are still not well-understood as this condition may be psychological in nature, occurring as a result of stress or anxiety. Similarly, distress and escaping from swallowing pills is one of the most common sources of anxiety for individuals. This constant challenge for numerous individuals to swallow pills either results in delay in the intake of dose of the medication or skipping of the dose completely. This leads to non-compliance of patients with the regimens prescribed to them, leading to failure to achieve the desired clinical outcomes or worsening of the condition. In a nut shell, poor medication compliance is a crucial interference on battling the challenges of patients' health in public sector hospitals.

## **7. RECOMMENDATIONS**

Following recommendations are proposed to improve patient compliance, based on weaknesses highlighted in the analysis:

- Patients should be permitted to express their clear preferences with respect to medication-related characteristics and emphasized about the significance of adherence to the treatment in order to achieve desired clinical outcomes.
- Health care providers should prescribe, dispense and administer suitable oral dosage forms or modified dosage forms to dysphagic patients that are easy to swallow.
- Awareness programs should be arranged to address the problematic administration of oral solid dosage forms among the patients and doctors as well as within the pharmaceutical industry.
- Swallowability should be made an obligatory principle for the designing and licensing of oral medications by the industry and regulatory bodies.

- Patient-centered drug products should be designed on the basis of the target patient group, their biological and physiological environment, disease or disorder, active pharmaceutical ingredients, routes of drug administration and drug delivery technologies.
- Techniques to swallow pills should be taught to the children at an earlier age as they require comparatively less training than old age.
- Regulatory environment should develop a new set of guidelines for the introduction of new innovative dosage forms as the present guidelines have become less effective.
- Pharmaceutical companies should offer one-on-one coaching to the patients and their caretakers with certified educators so that patients can receive educational and therapeutic guidance.

## **8. SUGGESTIONS FOR FUTURE RESEARCHERS**

The present study was done on the patients visiting outpatient department. Hospitalized patients might take more number of tablets and capsules and experience more difficulties while swallowing them as compared to outpatients. So, another research can be conducted to see the impact of psychological dysphagia on the compliance of inpatients. A comparative study should be done on the impact of psychological dysphagia on patient compliance in Private and public sector hospitals to study the differences. Future researchers may conduct research to determine the healthcare system factors that lead to patient non-compliance such as the relationship of the patient with his healthcare provider and differences in means of communication between patient and healthcare provider.

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