

## Study of Deliberate Self-Poisoning Among Adult Females in A Tertiary Care Hospital

Faisal Bin Yousuf<sup>1\*</sup>, Shyamal Sarker<sup>2</sup>, Tanzila Ferdous<sup>3</sup>, Sayeda Moni Chowdhury<sup>4</sup>

<sup>1</sup>Medical Officer, Medicine Department, Dhaka Medical College Hospital, Dhaka, Bangladesh.

Email: drfaisal8410@gmail.com

Orcid ID: 0000-0002-3911-6313

<sup>2</sup>Ex Prof. of Medicine, Dhaka Medical College Hospital (DMCH) Dhaka, Bangladesh.

Email: drshyamalbd@yahoo.com

Orcid ID: 0000-0002-3911-6313

<sup>3</sup>Specialist, Internal Medicine, Evercare Hospital Dhaka Bangladesh.

Email: tanzilafdrds@gmail.com

Orcid ID: 0000-0002-2501-0841

<sup>4</sup>Specialist, Internal medicine, Evercare Hospital Dhaka Bangladesh.

Email: dr.sayedamoni113@gmail.com

Orcid ID: 0000-0002-1347-2555

\*Corresponding author

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### Abstract

**Background:** Poisoning is a common medico-social problem in our country causing around 300,000 episodes and around 2000 deaths per year. Attempted suicide among adult females are a major public health problem. The number of self-poisoning in females are increasing in our country day by day. The incidence, nature, etiology, age group affected and the outcome of self-poisoning in females of our country is different from that of the western world. **Objective:** The objective of the study was to analysis the socio-demographic profile & pattern of deliberate self-poisoning among adult females admitted in the Medicine Department, Dhaka Medical College Hospital. **Material and Methods:** This was a descriptive cross sectional study conducted in the Department of Medicine, Dhaka Medical College Hospital from January 2016 to June 2016. 100 admitted female participants were enrolled in this study as study population. A purposive sampling method was applied for sampling from study population. **Results:** The age of the participants were from 18 to 55 years with the mean age of 28.19 ( $\pm 9.84$ ) years. Most number of the participants were in 21-29 year's age group (42%) followed by  $\leq 20$  year's (29%). House wife (30%) was the most common occupation followed by student (25%). Most of the participants were from lower economic class (51%), followed by middle class (41%). 48% participants were in primary level, 24% in secondary level and 22% were illiterate. Most of the participants were married (51%), followed by unmarried (35%), divorced (9%) and widow (5%). 62% participants from rural and 38% from urban area. 75% were Muslim and 25% were Hindu. 55% were from the joint family and 45% were from the nuclear family. Most of the self-poisoning occurred between 6 am to 12 pm (42%), followed by 6 pm to 12 am (30%), 12 pm to 6 pm (20%) and 12 am to 6 am (8%). Insecticide was the most common poison materials (43%), followed by drug ingestion (30%), household detergent (13%), rodenticide (6%) and others (8%). Maximum participants reported the reason for self-poisoning was family disharmony (35%) followed by romantic disappointment (27%). 17% participants reported previous suicidal attempt and 11% had previous psychiatric disorder. Nearly half of the participants (43%) sought medical care within 2 hours and one fourth participants (31%) within 4 hours. About two-thirds of the participants (66%) received primary medical care from different govt. hospitals. Most of the female participants with self-poisoning were recovered completely (71%), while 20% participants recovered with complications and 9% participants died. In the study, fatality rate was found 33.3% in rodenticide and 16.3% in insecticide poisoning. **Conclusions:** As evident from the study, by intervene these problems by various measures might be helpful to prevent many of deliberate self-harm. Early diagnosis and prompt institution of appropriate treatment can make a favorable outcome in deliberate self-poisoning of female participants.

**Keywords:-** Attempted suicide, Deliberate self-poisoning, Incident, Nature of suicide, Etiology, Age group



## INTRODUCTION

A self-poisoning episode may be defined as the self-exposure of an individual by ingestion or inhalation of an amount of substance associated with significant potential to cause harm.<sup>[1]</sup> Particularly in the industrialized world, self-harm has often been thought of as a problem. However recent work has revealed to emphasize its importance in the developing world also. "The Global Burden of Disease study" reported that 593,000 people killed themselves in the developing world in 1990 which was 15% of the total deaths from different reasons in the developing world.<sup>[2]</sup> Suicide is becoming a public health concern in many countries among adult males and females.<sup>[3]</sup> Females are more likely to have suicidal tendencies than males.<sup>[4]</sup> Suicide and suicidal ideation are significant issues in many countries.<sup>[5]</sup> Suicide is the tenth leading cause of mortality among adults in the USA.<sup>[6]</sup> A large-scale epidemiologic study conducted in the USA showed 19% of adults had reported suicidal ideation, 15% made a specific plan to attempt suicide, 8.8% reported a suicide attempt and 2.6% require significant medical attention.<sup>[7]</sup> The major method of suicide in adult males and females is reported to be deliberate self-poisoning.<sup>[7,8]</sup> Suicidal behavior is an increasing phenomenon especially in adult females and a significant public health issue in Bangladesh. However, there are very few studies that have been carried out evaluating and focusing on our adult females' population about attitudes towards the suicide and suicidal

behaviors.<sup>[9]</sup> Numerous studies had examined risk factors for suicide in adult females.<sup>[10]</sup> Factors previously identified include depression and other mental disorders, substance abuse, prior suicide attempt, family history of mental disorder, family history of suicide, family violence including physical or sexual abuse, and exposure to the suicidal behavior of others such as family members, peers, or media figures.<sup>[11-13]</sup> A Turkish study revealed some common factors in the case of adult females' suicides which were family conflicts, quarrels with a spouse, and psychiatric disorders.<sup>[14]</sup> Although factors for self-harm tendency among adult females are more or less the same worldwide but the poisoning agents involved for self-harm in adult females are different. Because the poisoning agents option is mainly based on the social structure, economic status, educational level, awareness of people, and availability of poisoning substances.<sup>[15]</sup> Agrochemical pesticides are a major public health problem throughout the developing world.<sup>[16]</sup> Bangladesh is a developing country that mostly depends upon agricultural resources. As insecticides in the agricultural sector by the farming community, organophosphorus compounds are widely used. For its easy accessibility, self-poisoning in adult female cases in rural areas is mostly by organophosphorus compound (OPC). There are few poisoning studies in Bangladesh. A study demonstrated that 7% of all deaths among 10-50 years old females in Bangladesh were due to poisoning and majority of them following suicidal ingestion of pesticides.<sup>[17]</sup> A



study demonstrated that 44% of all deaths among 10-50-year-old women in Bangladesh were due to poisoning, the majority following suicidal ingestion of pesticides.<sup>[18]</sup> In the urban area of Bangladesh, deliberate self-poisoning in adult females by insecticide is uncommon and mostly by sedative drugs such as benzodiazepines. A study conducted in Dhaka Medical College Hospital in the year of 1994 showed that 36.3% of cases of self-poisoning were due to benzodiazepines and there was no death from benzodiazepines poisoning.<sup>[15]</sup> Medicines are used in 72.0% of cases in Sub-Saharan Africa, 69.0% of cases in Middle Eastern countries, 15.0% cases in India, 87.0% cases in China, 11.0% cases in other Asian countries, and 36.0% cases in Latin America and the Caribbean for self-harming.<sup>[5]</sup> Pesticides are used in 13.0% of cases in Sub-Saharan Africa, 11.0% of Middle Eastern countries, 59.0% of cases in India, 9.0% cases in China, 55.0% cases in Other Asian countries, and 27.0% cases in Latin America and the Caribbean for self-harming.<sup>[5]</sup>

## Objectives

### General objective

The objective of the study was to analyze the socio-demographic profile & pattern of deliberate self-poisoning among adult females admitted to the Medicine Department, at Dhaka Medical College Hospital.

### Specific Objectives:

- To determine the socio-demographic characteristics of adult females with self-poisoning.
- To find out common substances used by adult females in self-poisoning.
- To find out reasons for self-poisoning in adult females.
- To detect the time of self-poisoning in adult females.
- To explore the time duration for seeking treatment after self-poisoning in adult females.
- To assess the outcome of the hospitalized participants of self-poisoning in females.
- To explore the fatality of poisons used by females in self-poisoning.

## MATERIAL AND METHODS

This study was a descriptive type of cross-sectional study. The study was conducted from January 2016 to June 2016 at the department of medicine Dhaka Medical College Hospital, Dhaka, Bangladesh. A total of 100 samples were selected by the purposive sampling method.

### Inclusion criteria

- All adult female participants who were admitted to medicine units of Dhaka Medical College Hospital with a history of deliberate self-poisoning by different substances.
- Self-poisoned adult females who were eligible to or whose attendant gave consent for this study.

### Exclusion Criteria

- Self-poisoned participants who were not adults.
- Participants with a history of accidental, homicidal or travel-related poisoning.

- Unwilling to give informed consent by participants or participants' legal guardians.

### Data processing and analysis

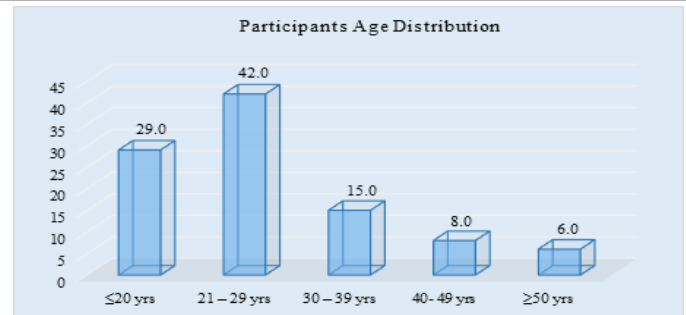
All data were processed and analyzed by SPSS (Statistical Package for Social Science) windows version 22. Categorical data were presented as frequency and percentage and continuous data were presented as mean with standard deviation. A p-value of <0.05 was considered to indicate statistical significance.

### Ethical issue

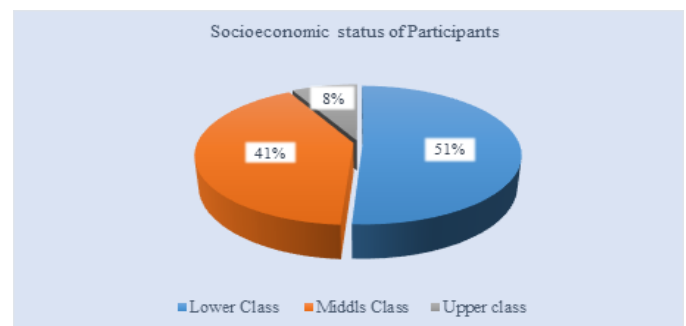
Prior to conducting the study, ethical clearance was taken from the ethical review committee of Dhaka Medical College Hospital.

## RESULTS

[Table 1] showed the distribution of the participants on the basis of age group. Most numbers of the participants were in the 21-29 year age group (42%) followed by ≤20 years (29%). The age of the participants from 18 to 55 years with a mean age of 28.19(±9.84) years. Here it was markedly noticeable that 71% of participants were aged below 30 years. Most of the self-poisoning participants (62%) were from rural and 38% of participants were from urban. Among self-poisoning female participants, 75% participants were Muslim and 25% participants were Hindu; 55% were from a joint family and 45% were from a nuclear family; 17% of participants reported previous suicidal attempts.

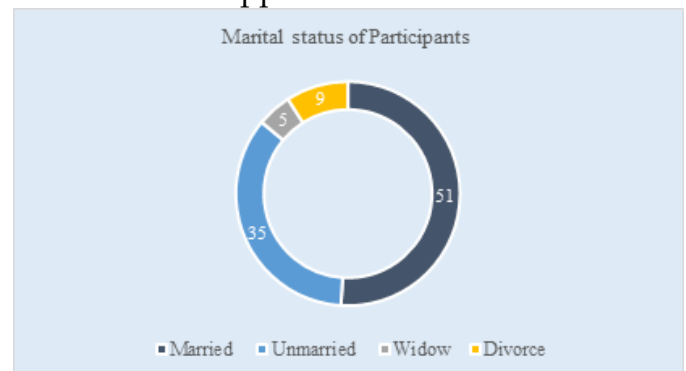


**Figure 1:** Bar chart showed age-wise participants (N=100)



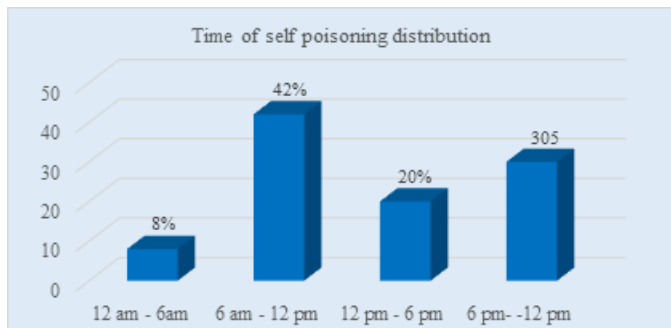
**Figure 2:** Pie chart showed the socioeconomic status of the participants (N=100)

[Figure 2] showed the distribution of the socioeconomic status of the participants. Most of the self-poisoning participants were from the lower economic class (51%), followed by the middle class (41%), and (8%) of participants were from the upper class.

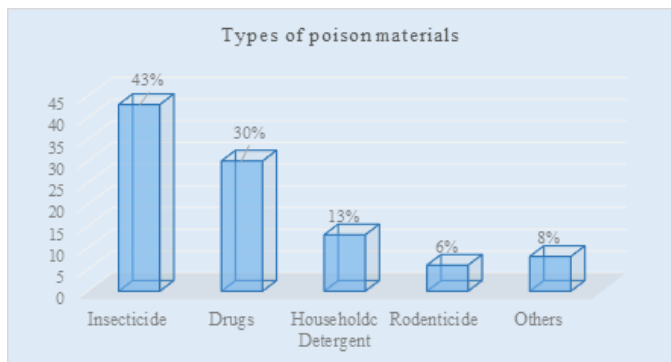


**Figure 3:** Ring chart showed the marital status of the participants (N=100)

[Figure 3] showed the distribution of participants according to marital status. Most of the self-poisoning participants were married (51%), followed by unmarried (35%), divorced (9%), and widows (5%).



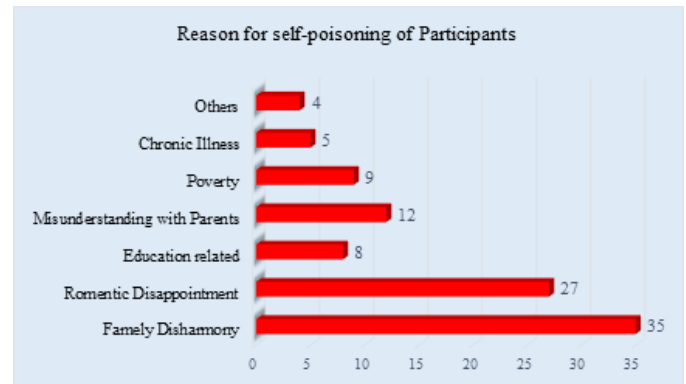
**Figure 4:** Bar chart showed time of self-poisoning of participants (N=100)



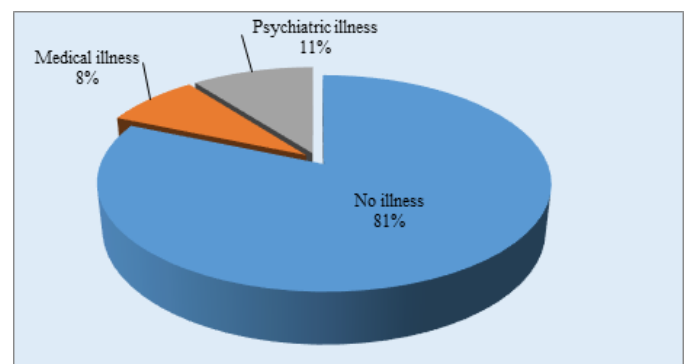
**Figure 5:** Bar chart showed types of poison materials of the participants (N=100)

[Figure 4] showed the distribution of participants according to the time of self-poisoning. Most of the self-poisoning occurred between 6 am to 12 pm (42%), followed by 6 pm to 12 am (30%), 12 pm to 6 pm (20%), and 12 am to 6 am (8%).

[Figure 5] showed the Distribution of participants on the basis of types of poison materials. Insecticide was the most common poison material (43%), followed by drug ingestion (30%), household detergent (13%), rodenticide (6%), and others (8%).



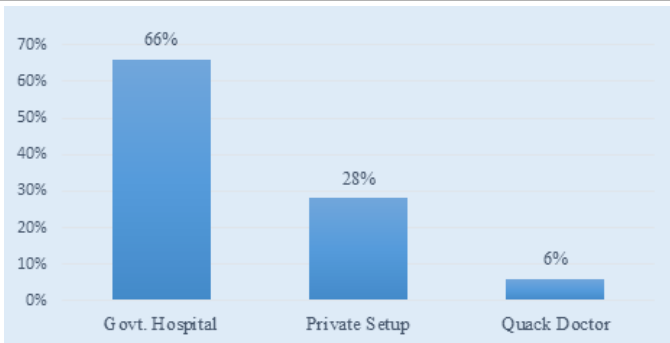
**Figure 6:** Bar chart showed reason for self-poisoning of participants (N=100)



**Figure 7:** Distribution of participants in terms of past illness (N=100)

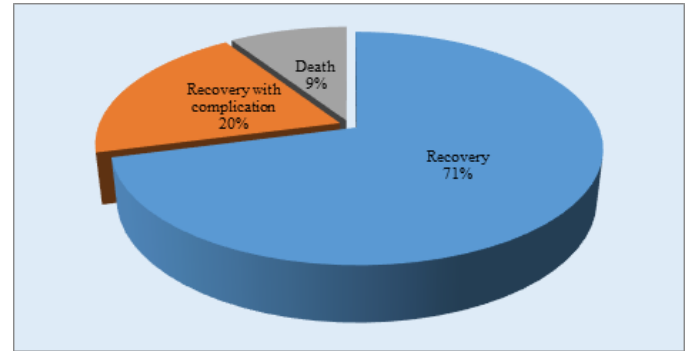
[Figure 6] showed the distribution of participants according to the reason for self-poisoning. Maximum participants reported the reason for self-poisoning was family disharmony (35%) followed by romantic disappointment (27%), education-related (8%), misunderstanding with parents (12%), poverty (9%), chronic illness (5%) and others (4%).

[Figure 7] showed the distribution of participants according to past illnesses. Most of the self-poisoning participants had no previous illness (81%). 11% of participants had a previous psychiatric disorder and 8% of participants had previous medical illness.



**Figure 8:** Distribution of the respondents according to the place of first treatment (N=100)

Before admission to DMCH, nearly two-thirds of the participants (66%) received primary medical care from different Government hospitals. The rest of them got primary treatment from private setups (28%) and quack doctors (6%).



**Figure 9:** Distribution of participants according to outcome (N=100)

Most of the participants with self-poisoning recovered completely (71%), while 20% of participants recovered with complications, and 9% of participants died during hospital stay observation.

**Table 1:** Demographic profile of the study population (N=100)

Variables	Frequency (n)	Percentage (%)
Age Group (years)		
≤20 yrs.	29	29.0
21-29 yrs.	42	42.0
30-39 yrs.	15	15.0
40-49 yrs.	8	8.0
≥50 yrs.	6	6.0
Mean ±SD	28.19 ± 9.84 (18-55)	
Residence		
Rural	62	62.0
Urban	38	38.0
Religion		
Muslim	75	75.0
Hindu	25	25.0
Type of family		
Joint	55	55.0
Nuclear	45	45.0
Previous suicidal attempt	17	17.0

**Table 2:** Distribution of participants according to the occupation (N=100)

Group	Occupation	Frequency (n)	Percentage (%)
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Dependent group (68%)	Student	25	25%
	Housewife	30	30%
	Unemployed	13	13%
Earning group (32%)	Housemaid	12	12%
	Garment worker	8	8%
	Day labor	7	7%
	Service holder	5	5%

**Table 3:** Distribution of participants according to educational status (N=100).

Educational status	Frequency (n)	Percentage (%)
Illiterate	22	22
Primary (Up to class VIII)	48	48
Secondary (Up to class XII)	24	24
Graduate or above	6	6

[Table 2] showed the distribution of participants according to occupation. Housewife (30%) was the most common occupation in self-poisoning adult female participants, followed by the student (25%), unemployed (13%), housemaid (12%), garment worker (8%), day labor (7%) and service holder (5%). It was also observed that the dependent group (68%) females are more prone to commit suicide than earning group (32%).

[Table 3] showed the distribution of participants according to their educational status. In self-poisoning participants, 48% of participants had the educational status of primary level, 24% of participants had a secondary level, 22% participants had no education and 6% participants had graduate or above educational level.

**Table 4:** Time interval between poisoning and first treatment (N=100)

Time Interval (in hours)	Frequency (n)	Percentage (%)
0-1hr.	17	17
1-2 hrs.	43	43
2-4 hrs.	31	31
4-6 hrs.	6	6
>6 hrs.	3	3

Nearly half of the participants (43%) sought medical care within 2 hours. Nearly one-fourth of participants (31%) within 4 hours, (17%) of participants within 1 hour, and (6%) of participants within 4 to 6 hours. Only (3%) asked for medical care 6 hours after poisoning.

**Table 5:** Fatality rate according to poison materials

Poison material	Number of cases	Number of died cases	Fatality rate
Insecticide	43	7	16.3%
Drugs	30	0	0.0%



Household detergent	13	0	0.0%
Rodenticide	6	2	33.3%
Others	8	0	0.0%

[Table 4] showed the fatality rate of poison materials among the study population. According to the study result it was revealed that fatality rate was more in case of rodenticide poisoning (33.3%) followed by insecticide poisoning (16.3%).

## DISCUSSION

In our study, most of the victim of self-poisoning was 21-29 years of age group (42%) followed by  $\leq 20$  years (29%), 30 – 39 years (15%), 40 - 49 years (8%) and  $>50$  years (6%). Younger aged females were found prone to self-poisoning than older aged. The age of the participants ranged from 18 to 55 years with the mean age of 28.19 ( $\pm 9.84$ ) years. All these findings correlate with other study in home and abroad. A cross sectional study carried out at teaching hospital Peradeniya, Sri Lanka<sup>[29]</sup> revealed that median age of self-poisoning participants was 22 years and 61% of the participants were below 25 years. So younger females were more involved in self-poisoning than older females. Another large scale study in Bangladesh conducted by Dewan [30] showed that highest number of participants belonged to age group of 21 to 30 years (38.1%) followed by participants aged under 20 years (33.8%). This shows that adolescents and young females are the most vulnerable population of the country to this kind of poisoning. It was found that majority of the participants comprised of housewife (30%) followed by

student (25%), unemployed (13%), housemaid (12%), garment worker (8%), day laborer (7%) and service holder (5%). It was also observed that dependent group (68%) is more prone to commit suicide than earning group (32%). Findings are similar with the study of Dewan<sup>[30]</sup> where 18.3% of participants were student, 16.7% housewife, 11.7% unemployed, 1.7% service holder. In another study, 47% of participants were housewife, 16% student and 13% unemployed.<sup>[31]</sup> The current study showed that most of the self-poisoning female were from lower economic class (51%) followed by middle class (41%) and upper class (8%). These findings were similar to other Bangladeshi studies where 48% were from low income group, 47% from middle income and 5% from high income group.<sup>[32]</sup> In this study maximum participants had education level primary (48%) followed by secondary (24%), illiterate (22%) and graduate or above 6%. A report by WHO<sup>[27]</sup> showed that education status has an impact on suicidal tendency. The illiterate and low level educated females are more vulnerable group for suicide. Our study findings were also consistent with the report. In the current study, most of the self-poisoning participants were married (51%) followed by unmarried (35%), divorced (9%) and widow (5%). These findings were in agreement with the findings of Howlader et al.<sup>[33]</sup> This study was done in 2007 at Sir Salimullah Medical





College Hospital which showed that highest number (62%) of the participants were married, 20% were unmarried and 12% were separated. In another study<sup>[34]</sup> showed that 63% of the victims of self-poisoning were married and marital disharmony was the prime cause. But another study in abroad showed poisoning was more common among unmarried people.<sup>[35]</sup> In our study majority of participants were from rural background (62%). This finding correlate with a report by WHO,<sup>[27]</sup> demonstrated that higher percentage from rural areas in cases of self-poisoning in females. In this study 75% participants were Muslim by religion and 25% participants were Hindu. The study of Rahman et al.<sup>[36]</sup> showed that 93.2% of the respondents were Muslim and 6.8% were Hindu. The study of Ali et al.<sup>[34]</sup> showed that 91.2% of their participants were Muslim and 7.4% were Hindu. But this study result was differed from the study of Narang et al.<sup>[37]</sup> that among their 137 participants with attempted suicide Hindus constituted almost 3/4th of the total study sample, Christians slightly less than 1/5th and Muslims numbered only 15. Narang et al.<sup>[37]</sup> conducted the study in a Hindus majority country but this study was conducted in a Muslim majority country, this may be the cause of the difference. In the present study 55% were from the joint family and 45% were from the nuclear family. These findings were almost similar to the study of Rahman et al.<sup>[36]</sup> that 74.6% lived in the joint family and 25.4% in nuclear family. But this result was differed from Narang et al.<sup>[37]</sup> and Srivastava et al.<sup>[38]</sup> Narang et al.<sup>[37]</sup>

observed 46% were from joint family and 54% in nuclear family. Srivastava et al.<sup>[38]</sup> found 23.4% were from joint family and 76.6% were from nuclear family. This difference was probably due to most of the respondents in this study was from rural areas and most of the rural population in our country lived in a joint family. In this study, most of the self-poisoning occurred between 6 am to 12 pm (42.6%) followed by 6 pm to 12 am (30%), 12 pm to 6 pm (20%) and 12 am to 6 am (8%). Rahman et al.<sup>[36]</sup> reported similar findings that the most of the respondents attempted to commit suicide between 6 am to 12 pm (45.5%), others between 6 pm to 12 am (27.1%), 12 pm to 6 pm (22.0%) and 12 am to 6 am (5.1%). Ali et al.<sup>[34]</sup> found attempting to commit suicide between 13 to 18 hours (41.2%) followed by between 7 to 12 hours (32.4%), 19 to 24 hour (17.6%), and 0 to 6 hours (8.8%). In this study insecticides were the most common poison (43%), followed by drug ingestion (30%), household detergent (13%), rodenticide (6%) and others (8%). This result was supported by Dhanya et al.<sup>[39]</sup> that the most common substance used in poisoning was pesticides accounted for 37.3% followed by unspecified drugs accounted for 17.9%. In this regards Chowdhury et al.<sup>[28]</sup> reported the most commonly found toxic agent was organophosphorus compounds (27.64%) followed by unknown substance (16.03%), Copper-sulphate (14.03%) and Sedative (13.35%). Khadka et al.<sup>[40]</sup> also reported the organophosphorus was the most common poisoning agent (19.4%) in adults. Desalew et al.<sup>[41]</sup> found household cleansing agents were the



leading causes of poisoning (43.1%) followed by organophosphate (21.6%) and phenobarbitone (10.3%). But Islambulchilar et al.<sup>[42]</sup> reported drugs were the most common cause of poisonings (60.8%), followed by pesticides (20.49%), cleaning agents (4.24%), rat poison (super-warfarin's) (3.72%). The reason for such a high ratio of drug poisoning is probably the extensive prescribing of these drugs and their easy availability at home. Furthermore, most of these drugs are sold without a prescription in the region of the study place. In the current study, the maximum (35%) participants reported the cause of self-poisoning was family disharmony followed by romantic disappointment (27%), education related frustrations (8%), misunderstanding with parents (12%), poverty (9%), chronic illness (5%) and others (4%). In this regard, Desalew et al.<sup>[41]</sup> found reasons for committing self-harm was quarrel with another person (51.6%), emotional disturbance (27.4%), underlying mental illness (19.4%) and exam failure (1.6%). Rahman et al.<sup>[36]</sup> reported disease process (39.0%) was the most frequent cause of attempted suicide, followed by family problem (33.9%), quarrel with spouse (11.8%), quarrel with boy/girl-friend (8.5%), poverty (3.4%) and failure of examination 1.7% of the respondent. Kurihara et al.<sup>[43]</sup> found interpersonal problems with spouses (20.0%), a boy/girl-friend (6.7%) and family members like parents, brothers, sisters and others (28.3%). Ali et al.<sup>[34]</sup> found family problem (41.2%), love disappointment (11.8%), marital problem (11.8%) and financial problem (5.9%). In the present study 17%

participants reported previous suicidal attempt and 83% participants reported no previous suicidal attempt. In this regards Sorodoc et al.<sup>[44]</sup> found a total of 77.8% of participants was the first attempt for suicide, 11.7% participants had history of two suicide attempts and 10.5% had history of more than two. Rahman et al.<sup>[36]</sup> found first attempt in 84.7% of respondents, second attempt in 10.2%, third attempt in 3.4% and more than three attempts only 1.7% of the respondents. Yamada et al.<sup>[45]</sup> found first attempt in 56.4%, second attempt in 22.5% and third attempt or more in 21.1% cases. In the present study, most of the self-poisoning participants had no previous illness (81%), 11% participants had previous psychiatric disorder and 8% participants had previous medical illness. Sorodoc et al.<sup>[44]</sup> found previous psychiatric disorder in 13.81% of the cases. Rahman et al.<sup>[36]</sup> found that 11.2% participants had past history of psychiatric disorder. Our result was also consistent with Ali et al.<sup>[34]</sup> that 16.2% of suicide attempters had previous history of psychiatric disorder. Nearly half of the participants (43%) sought medical care within 2 hours. Nearly one fourth participants (31%) within 4 hours, 17% participants within 1 hour and 6% participants within 4 to 6 hours. Only 3% asked for medical care 6 hours after poisoning. Delay beyond an hour indicated that the participants were at risk of having complications of poisoning. In all cases medical care was seek by their relatives or their guardians. Several factors like transport, decision to bring the patient to hospital, to know that illness was due to poisoning etc. were

factors for the time taken by the attendants to seek the medical help. In this study nearly two-third of the participants (66%), who sought medical care before hospital admission, received medical care from Govt. hospital. Rest of them consulted in private setup (28%) and quack doctors (6%). In this study, most of the participants with self-poisoning were recovered completely (71%), while 20% participants recovered with complications and 9% participants died. Fatality rate was 16.3% in insecticide and 33.3% in rodenticide. Similar findings were reported by Chowdhury et al.<sup>[28]</sup> in their study the fatality rate was 7.3%. In another study in Dinajpur Medical College Hospital by Haque et al.<sup>[46]</sup> reported inpatient mortality was 18%; while 79% completely recovered and 3% recovered with complication. This is also similar to the study by Desalew et al.<sup>[41]</sup> in Ethiopia that the fatality rate of poisoning was 8.6%. Dhanya et al.<sup>[39]</sup> reported mortality rate was 10.85% in acute poisoning cases in India. Other studies reported mortality rate was 11.7% in Tehran-Iran in 2003<sup>[42]</sup> and 15% at Bangalore, South India.<sup>[47]</sup> As because psychological assessment and counseling were not mentioned in objectives, psychological assessment and counseling was not done. During treatment period they were not in position to be assessed psychologically. Moreover, for counseling follow ups were needed which was not possible due to the type of cross sectional study.

### Limitations

The limitations of the present study are as follows:

- Small sample size of the study population.
- Sample were taken by purposive method in which question of personal biasness might arise.
- It was a single center study. Only participants admitted in Dhaka Medical College Hospital (DMCH) were taken for the study. So this may not reflect the overall picture of the country.
- Study was conducted in a tertiary care hospital which may not represent primary or secondary centre.
- Proper psychological assessment, counseling and follow after discharge from hospital were not possible.

### CONCLUSIONS

In our country, self-poisoning in females is a major public health problem to be addressed like any other medical condition. From the present study, it is found that younger aged females are more prone to commit deliberate self-poisoning and most of them are housewife or student. Majority of the participants are from low socioeconomic condition and illiterate with rural background. Daytime is the peak period for commit self-poisoning and insecticide is the most common material for self-poisoning in females. Among the reasons behind the self-poisoning, familial disharmony and romantic disappointment are the most frequent. A small but significant percentage of these female participants had previous history of suicidal



attempt and psychiatric illness. As evident from the study, by intervene these problems by various measures might be helpful to prevent many of deliberate self-harm. Early diagnosis and prompt institution of appropriate treatment can make a favorable outcome in deliberate self-poisoning participants.

### Recommendation

- Study period should be extended.
- Sample size should be large.
- Further multi-center study should be carried out.

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