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Associate Professor & Head, Pharmacology & Therapeutics  
Army Medical College Jashore  
Jashore Cantonment, Jashore, Bangladesh.  
Cell : +88 01707-543140  
Email: omma.hafsa.anee@gmail.com

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## **Application of Pharmacovigilance in the Field of Clinical Practice: Bangladesh Perspective**

Omnia Hafsa Any

Associate Professor, Head of the Department of Pharmacology & Therapeutics, Army Medical College, Jashore, Bangladesh

The Pharmacovigilance program aims to prevent harm from adverse events in humans arising from the use of authorized or unauthorized medicinal products within or outside the approved indications and promote the safe and effective use of medicinal products, in particular by providing timely information about the safety of medicinal products to patients, health care providers, and the public<sup>1</sup>. The Drug Control Committee was formed according to the direction of section 4 of the Drugs (Control) Ordinance of 1982. As per section 6, this committee is entrusted to evaluate all medicines registered in Bangladesh to ensure safety, efficacy, and usefulness. The Pharmacovigilance system is one source of information that the committee relies on to evaluate safety, efficacy, and usefulness. Pharmacovigilance has been addressed in The National Drug Policy<sup>2</sup>.

Pharmacovigilance is a very significant and inseparable part of clinical research<sup>3</sup>. Both clinical trials safety and post-marketing pharmacovigilance are critical throughout the product life cycle. With a reasonably high number of recent high-profile drug withdrawals, both the pharmaceutical industry as well as various regulatory agencies across the globe have raised the bar. Early detection of signals from the post marketing surveillance studies and clinical trials in early phases have now been adopted by major pharmaceutical companies to identify the risks associated with their medicinal product/s as early as possible<sup>4</sup>.

If any such risk is present then effectively managing the risks by applying robust risk management plans throughout the life cycle of the product is adopted. These risk management plans are also widely known as Risk Minimization Programs/Strategies. Thalidomide which is reintroduced for Multiple Myeloma and Leprosy reactions through the S.T.E.P.S. program (System for Thalidomide Education and Prescribing Safety) is a classic example. Signal detection and risk management/minimization have added a new dimension to the field of pharmacovigilance and have led it to be an evolving discipline; which requires ongoing refinement to increase its applicability and value to public health<sup>5</sup>.

Each year, in hospitals alone, there are 28,000 cases of life-threatening heart toxicity from adverse reactions to digoxin, the most commonly used form of digitalis (drugs that regulate the speed and strength of heartbeats) in older adults. Since as many as 40% or more of these people are

using this drug unnecessarily. Each year 41,000 older adults are hospitalized and 3,300 of these die from ulcers caused by NSAIDs (non-steroidal anti-inflammatory drugs), usually for treatment of arthritis<sup>4</sup>. Thousands of younger adults are hospitalized. At least 16,000 injuries from auto crash each year involving older drivers are attributable to the use of psychoactive drugs, specifically benzodiazepines and tricyclic antidepressants. Psychoactive drugs are those that affect the mind or behavior. Each year 32,000 older adults suffer from hip fractures attributable to drug-induced falls, resulting in more than 1,500 deaths<sup>6</sup>.

It is very important to ensure proper and safe use of all medicines to protect a patient's health. The Directorate General of Drug Administration in Bangladesh has already taken initiatives to ensure the safe use of medicines. Along with them, the patient, his/her family members, doctors, health workers, and pharmaceutical companies should all be equally aware and work together to raise awareness. Innovation in drug safety monitoring needs to ensure that emerging problems are promptly recognized and efficiently dealt with and that information and solutions are effectively communicated<sup>6</sup>. The development of new ways of collecting, analyzing, and communicating information about the safety and effectiveness of medicines by enhancing the drug utilization study<sup>7</sup>.

The creation of purposeful, coordinated, worldwide support amongst politicians, officials, scientists, clinicians, patients, and the general public, based on the demonstrable benefits of pharmacovigilance to the public. It is believed that these reasons will help risks and benefits to be assessed, explained, and acted upon openly and in a spirit that promotes general confidence and trust. Therefore ensures high-quality physicians who understand where to prescribe and where not to prescribe medicines which will improve 'universal health coverage and also ensure 'fundamental rights of the citizen'<sup>6</sup>.

The ultimate goal of pharmacovigilance will be achieved only if the new information is readily and efficaciously integrated into the therapeutic decision-making by health professionals, pharmacists, formulary, and regulatory bodies<sup>3</sup>. This will make it possible to improve the risk-benefit ratio of treatment. Pharmaceutical companies will need to show both regulators and consumers that they are doing everything possible to assure drug safety. A culture of learning about pharmacovigilance should start

early in the professional training of medical and healthcare students. Bangladesh is now considered to be a hub for drug export. The Government of Bangladesh (GOB) has shown its commitment to ensuring the safe use of drugs by establishing the National Pharmacovigilance Program (NPP). Healthcare professionals, consumer groups, NGOs, and hospitals should appreciate GOB and NPP and start reporting actual and suspected ADRs. An in-depth prospective study is strongly advocated for promoting ADRs reporting to safeguard the common people of Bangladesh and also other developing countries where drug control authorities are not that honest, sincere, skilled, equipped, and powerful like the advanced world.

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**Correspondence: Dr. Omma Hafsa Any**, Associate Professor, Head of the Department of Pharmacology & Therapeutics, Army Medical College, Jashore, Bangladesh; **Email:** [omma.hafsa.anee@gmail.com](mailto:omma.hafsa.anee@gmail.com); **Cell No.:** +8801707543140; **ORCID ID:** <https://orcid.org/0000-0002-2319-2127>

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# JOURNAL OF ARMY MEDICAL COLLEGE JASHORE

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### Aims and Scope of Journal

**Journal of Army Medical College (J Army Med Coll Jashore)** is an open access, peer-reviewed, scholarly, scientific medical journal. This journal aims to publish scientifically written, evidence-based articles from all disciplines of medical sciences and clinical practice, and nursing, preventive medicine, epidemiology and healthcare research. Manuscripts should present novel findings addressing significant questions in clinical medicine research and practice, in the form of original article, editorial, review, short communication, case report, letter to the editor, and others. In addition to that **J Army Med Coll Jashore** publishes studies performed by multi-center groups in the various disciplines of medicine, including clinical trials and cohort studies. Careful physiological or pharmacological studies that explain normal function or the body's response to disease as well as analytic reviews such as meta-analyses and decision analyses using a formal structure to summarize an important field are acceptable to publish.

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Executive Editor, Journal of Army Medical College Jashore &

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# Characteristics of Road Traffic Accident Cases Attending in Combined Military Hospital in Rangpur District of Bangladesh

ASM Zulfiqur Ali<sup>1</sup>, Md. Shirajul Islam Khan<sup>2</sup>, ABM Belayet Hossain<sup>3</sup>, Md. Saiful Islam<sup>4</sup>

<sup>1</sup>Assistant Director of Medical Services, 10 Infantry Division, Ramu Cantonment, Cox's Bazar, Bangladesh; <sup>2</sup>Classified Specialist in Dermatology and venereology, CMH Sheikh Hasina Cantonment, Barisal, Bangladesh; <sup>3</sup>Commanding Officer, 10 Field Ambulance, Rangpur Cantonment, Rangpur, Bangladesh; <sup>4</sup>Instructor, AFMI, Dhaka Cantonment, Dhaka, Bangladesh

## Abstract

**Background:** Road traffic accident (RTA) defines as a collision involving a vehicle on a road or in a public area that has caused damage or injury to a person, animal, another vehicle or property. It is one of the leading causes of global disease burden. Road traffic accidents, injuries and fatalities are causing great concern to the community in Bangladesh. **Objective:** The purpose of the present study was to find out the characteristics of road traffic accident cases attending in Combined Military Hospital Rangpur. **Methodology:** This descriptive cross-sectional study was conducted at Combined Military Hospital Rangpur, Bangladesh. All the road traffic accident victims attending at Medical Inspection room (MI Room) of CMH, Rangpur, Bangladesh from April 2019 to September 2019 irrespective of age and sex. All the victims entered in the 'special event statement register'. **Results:** There were 119 Road Traffic Accident victims enlisted and selected all 119 victims by purposive type of sampling technique. Mean age of the respondent was 28.77±5.14 years. Out of 119 respondents, majority (26.9%) were in the age group of 31 to 40 years. Among the victims 99.2% were motorized accident. Majority (33.6%) were due to Bus or Minibus accident, 43.8% victims were motor vehicle passenger. The highest 49.6% victims were passenger, followed by 31.9% were pedestrian. Regarding pattern of injury, majority 39.5% victims sustained Laceration and Cut injury. Majority of the accident (50.9%) happened in the main road, 33.6% happened during Noon (1000-1400 hours) time, followed by 27.7% at afternoon (1400 to 1800 hours) time. **Conclusion:** Among the victims most of them were male and majority of them were within the active age group. Most of accidents by motorized vehicles by Bus or minibus. Pedestrians and motor vehicle passengers were most vulnerable. Cut injury and Laceration was the most common type of injury. Main roads were the commonest site and during day time accident occurred more. [*Journal of Army Medical College Jashore July 2021;2(2):33-37*]

**Keywords:** Characteristics; road traffic accident; military hospital

## Introduction

The road safety situation in Bangladesh has been deteriorating with increasing number of road accident deaths, largely as direct consequences of rapid growth in population, motorization, urbanization and lack of investment in road safety. Current road accidents and injury statistics reveal a deteriorating safety situation in

Bangladesh. In recent past, a very few numbers of studies conducted by government and non-government organizations have tried to find out the causes, characteristics and also discuss the safety remedies as well. Bangladesh is a very densely populated and low income developing country of third world with the 160 million inhabitants living in an area of 144000 sq.km. About 30% of the population is living in the urban areas and more crucially dependent on daily use of transport. The rate of urbanization in Bangladesh over the last decade has been between 7 to 8 percent, a growth, which is alarmingly high when compared with other developing

**Correspondence:** Col. ASM Zulfiqur Ali, MBBS, MPH, M Phil, Assistant Director of Medical Services (ADMS), 10 Infantry Division, Ramu Cantonment, Cox's Bazar, Bangladesh; Email: zulfiqur19@gmail.com; Cell No.: 01711463303

countries and thus this is expected to conversion of rural to urban area up to 50% by the year 2025. The process of rapid urbanization in conjunction with socio-economic parameters have resulted in enormous road traffic accident problems<sup>1</sup>.

According to WHO report on Road traffic injury June'2021, Worldwide it was estimated that approximately 1.3 million people die each year as a result of road traffic crashes. Between 20 and 50 million more people suffer non-fatal injuries, with many incurring a disability as a result of their injury. In response to a growing concern about road traffic injuries, WHO Director General has, for the first time in the history of WHO, devoted a WHD (World Health Day) specifically to road safety. Each year road traffic injuries take the lives of 1.2 million men, women and children around the world, and seriously injure millions more<sup>2</sup>.

The world is moving fast with new mechanized transport media. This fastness saves time, increases skill but gives crucial fate of increasing morbidity and mortality, Due to shortage of skill manpower paramedics, management of RTA victims continues to be problematic. Some effective service delivery system is to be evolved to provide a better service to the road accident victims<sup>3</sup>.

Study at Research Institute for Handicapped and Disabled (RIHD) shows that among all the traumatic cases road traffic accidents are the commonest. About 68% of the casualties take place in urban areas. Pedestrians are more vulnerable group accounting for half of all accidents. Heavy vehicles accounted for 81% of highway casualties and about 28% in the urban areas. On the other hand light vehicles and three wheelers accounts for about 19% of highway casualties and about 72% in the urban areas. Loss of control is marked in three wheeler vehicles. It is responsible for about 15% of urban casualties<sup>4</sup>. The highways running across the capital and other townships also contribute major portion of road accidents<sup>5</sup>.

Evaluating the high incidence of Road Traffic Accidents in Bangladesh, the principal determinants of accidents which are taken into task are adverse roadside environment, poor detailed design of junctions and road sections, excessive speeding, overloading, dangerous overtaking, reckless driving, careless of road users, failure to obey mandatory traffic regulations, variety of vehicle characteristics and defects in vehicles. Others include a low level of awareness of the safety problem by policy makers, safety rules and regulations, inadequate and unsatisfactory education and traffic law enforcement and sanction<sup>6</sup>. Road traffic accidents are major yet neglected public health problem in developing countries. Trends in motorization indicate an increase in road traffic injuries and ranked third in the order of burden of disease. There are human factors, product and environmental factors related to injuries. Most of them are preventable. This present study helps to increase the knowledge about the determinants of road

traffic accident cases and to develop counter measures to deal with the emergency management of road traffic accident victims. The purpose of the present study was to find out the characteristics of road traffic accident cases attending in Combined Military Hospital Rangpur.

### Methodology

This descriptive cross-sectional study was conducted at CMH, Rangpur, Bangladesh with a view to find out certain determinants of RTA victims. Road traffic accident victims who were attended to CMH, Rangpur, Bangladesh for treatment between April 2019 to September 2019 were taken for this study. Data were collected through questionnaire. If the patient were seriously ill then patient's attendant were interviewed. Confidentiality was duly ensured to all participants and informed consent was obtained. After collection data were scrutinized, edited and verified for its consistency. Data were processed and analyzed by computer software SPSS and expressed in frequency, percentage and mean standard deviation.

### Results

The mean age of the respondent was 28.77±5.14 years. Out of 119 respondents, majority (26.9%) were in the age group of 31 to 40 years followed by 26.1% were in the age group 21 to 30 years (Table 1)

Table 1: Distribution of Respondents by Age and sex

Age Group	GBS type		Total
	Male	Female	
1 to 10 Years	5(4.2%)	2(1.7%)	7(5.9%)
11 to 20 Years	6(5.0%)	2(1.7%)	8(6.7%)
21 to 30 Years	25(21.0%)	6(5.0%)	31(26.1%)
31 to 40 Years	28(23.5%)	4(3.4%)	32(26.9%)
41 to 50 Years	17(14.3%)	5(4.2%)	22(18.5%)
51 to 60 Years	15(12.6%)	3(2.5%)	18(15.1%)
61 to 70 Years	1(0.8%)	0(0.0%)	1(0.8%)
<b>Total</b>	<b>97(81.5%)</b>	<b>22(18.5%)</b>	<b>119(100.0%)</b>
Mean ± SD (Years)	28.77±5.14		

Most of the respondents were Muslims (96.6%). Majority (42.9%) of participants were qualified in SSC or equivalent level of education. Regarding occupational status, (45.4%) were military personnel, 27.7% were Business man, House wife, day laborer. Civil service holders were 14.3% cases. Among the victims 99.2% were motorized accident. Majority (33.6%) were due to Bus or Minibus accident, 43.8% victims were motor vehicle passenger (Table 2).

The highest 49.6% victims were passenger, followed by 31.9% were pedestrian (Table 3).

Considering the defect of driving Over Speed was the most common which was 82(68.9%) cases followed by overtaking which was 33(27.7%) cases (Table 4).



Table 2: Distribution of Respondents by Socio-Demographic Characteristics and Other Concerned

Characteristics	Frequency	Percent
<b>Religion</b>		
Muslim	115	96.6
Hindu	04	3.4
<b>Educational Qualification</b>		
Illiterate	13	10.9
Class I-V	17	14.3
Class VI-X	12	10.1
SSC/Equivalent	51	42.9
HSC/Equivalent	13	10.9
Graduation and above	13	10.9
<b>Occupational Status</b>		
Military	54	45.4
Civil Services	17	14.3
Driver and Helper	03	2.5
Student	12	10.1
Others (Business, House wife, etc.)	33	27.7
<b>Class of Vehicle</b>		
Motorized	118	99.2
Non-Motorized	01	00.8
<b>Type of Vehicle</b>		
Bus/Minibus	40	33.6
Car/Jeep/Taxi	32	26.9
Microbus/Pickup	11	9.2
Motor Bike	16	13.5
Auto rickshaw	15	12.6
Truck/Covered van	02	1.7
Train	02	1.7
Rickshaw/Van	01	0.8
<b>Type of Victims</b>		
Pedestrian	38	31.9
Motor Vehicle Passenger	52	43.8
Motor Vehicle Driver	22	18.5
Non-Motor Vehicle Passenger	06	5.0
Rickshaw puller	01	0.8
<b>Total</b>	<b>119</b>	<b>100.0</b>

Regarding pattern of injury, majority 39.5% victims sustained Laceration and Cut injury (Table 5).

Table 3: Distribution of RTA Victims According to Various Characteristics

Characteristics	Frequency	Percent
<b>Victims by their Role</b>		
Pedestrian	37	31.1
Passenger	59	49.6
Driver & Helpers	23	19.3
<b>Victims by Morbidity Pattern</b>		
Abrasion	18	15.1
Cut injury, Laceration	47	39.5
Fracture	19	16.0
Multiple injury	22	18.5
Head injury	05	4.2
Others	08	6.7
<b>Total</b>	<b>119</b>	<b>100.0</b>
<b>Victims by the place of occurrence</b>		
Level crossing	02	1.7
High ways	35	29.4
Main roads	60	50.4
Lanes	22	18.5
<b>Time of Occurrence</b>		
Morning (0600-1000 hrs)	16	13.4
Noon (1000-1400Hrs)	40	33.6
Afternoon (1400-1800)	33	27.7
Evening (1800-2200hrs)	24	20.2
Mid-night (2200-0200hrs)	05	4.2
Late night (0200-0600hrs)	01	0.8

Table 4: Distribution of Respondent by Defect of Driving

Defect of Driving	Frequency	Percent
Over Speed	82	68.9
Overtaking	33	27.7
Impatience	1	0.8
Inattention	1	0.8
Avoidance of Road Sign	1	0.8
Others	1	0.8
<b>Total</b>	<b>119</b>	<b>100.0</b>

Majority of the accident (50.9%) happened in the main road, 33.6% happened during Noon (1000-1400 hrs) time, followed by 27.7% at afternoon (1400-1800 hrs) time (Table 6).

Table 5: Association between Patterns of injury with Place of occurrence

Pattern of Injury	Place of Occurrence				Total
	Level Crossing	Highways	Main roads	Lanes	
Abrasion	0(0.0%)	2(1.7%)	10(8.4%)	6(5.0%)	18(15.1%)
Cut injury and Laceration	0(0.0%)	11(9.2%)	29(24.4%)	7(5.9%)	47(39.5%)
Fracture	0(0.0%)	6 (5.0%)	8 (6.7%)	5 (4.2%)	19(16.0%)
Multiple injury	1(0.8%)	12(10.0%)	8 (6.7%)	1 (0.8%)	22(18.5%)
Head injury	1(0.8%)	3(2.5%)	1 (0.8%)	0(0.0%)	5(4.2%)
Others	0(0.0%)	1(0.8%)	4(3.4%)	3 (2.5)	8(6.7%)
<b>Total</b>	<b>2(1.7%)</b>	<b>35(29.4%)</b>	<b>60(50.4%)</b>	<b>22(18.5)</b>	<b>119(100.0%)</b>



Table 6: Association between Types of Vehicle with Time of Occurrences

Type of vehicle	Time of occurrences						Total
	Morning	Noon	Afternoon	Evening	Mid-night	Late night	
Train	0(0.0%)	0(0.0%)	1 (0.8%)	1 (0.8%)	0(0.0%)	0(0.0%)	2 (1.7%)
Truck/Covered van	0(0.0%)	0(0.0%)	1 (0.8%)	1 (0.8%)	0(0.0%)	0(0.0%)	2 (1.7%)
Bus/Minibus	7 (5.9%)	14(11.8%)	9 (7.6%)	7 (5.9%)	2 (1.7%)	1 (0.8%)	40 (33.6%)
Microbus/pickup	0(0.0%)	5 (4.2%)	1 (0.8%)	5 (4.2%)	0(0.0%)	0(0.0%)	11 (9.2%)
Jeep/Car/Taxi	5 (4.2%)	15(12.6%)	6 (5.0%)	6 (5.0%)	2 (1.7%)	0(0.0%)	32 (26.9%)
Auto-rickshaw	2 (1.7%)	2 (1.7%)	9 (7.6%)	2 (1.7%)	0(0.0%)	0(0.0%)	15 (12.6%)
Motor Bike	2 (1.7%)	4 (3.4%)	7 (5.9%)	2 (1.7%)	1 (0.8%)	0(0.0%)	16 (13.4%)
Rickshaw /Van	0(0.0%)	0(0.0%)	0(0.0%)	1 (0.8%)	0(0.0%)	0(0.0%)	1 (0.8%)
<b>Total</b>	<b>16(13.4%)</b>	<b>40(33.6%)</b>	<b>33 (27.7%)</b>	<b>24(20.2%)</b>	<b>5 (4.2%)</b>	<b>1</b>	<b>119(100.0%)</b>

### Discussion

The study showed that most of the RTA victims were within 21 to 50 years of age. Cases of 21 to 30 years were 26.1% cases, 31 to 40 years age group 26.9% cases and 41 to 50 years age group were 18.5% cases. Total they constitute 71.5% cases. In this study mean age of RTA victims was  $28.77 \pm 5.14$  years. Worldwide, the victims of RTA are the most young, energetic and productive portion of the population. According to the Road traffic accident (RTA) report published by Road safety cell of Bangladesh about 70% of the accident victims are in the age group of 16-50 years, the most economically active age group<sup>7</sup>. Road traffic injuries are one of the top three causes of death for people aged between 5 and 44 years<sup>8</sup>. A study conducted in Dhaka Medical College Hospital showed that adolescent and adult comprised 86.0% of the RTA casualties<sup>9</sup>.

In this study it was revealed that male victims were found 4.5 times higher than female. In this study out of 119 cases male was 81.5% and female 18.5%. Males are predominant victims because males being the bread earners for the family and are involved usually in outdoor activities exposing themselves to accidents. In our society, female are less active and mostly remain indoors<sup>1</sup>. Another prospective study on RTA induced spinal injury showed the sex distribution of cases as male 82.1% and female 17.9% cases<sup>10</sup>.

In this study it was depicted that 96.6% of cases were Muslim, which reflected the socio-demographic characteristic of Bangladesh as well as the characteristic of cases. The major religion practiced in Bangladesh is Islam (89.7%) and minority adheres to Hinduism (9.2%), Buddhists (0.7%), Christians (0.3%) and Animists (0.1%)<sup>11</sup>.

In this study it was shown that 42.9% were SSC qualified, almost half of the sample. Overall literacy rate of Bangladesh is 51.6% of 15+ populations<sup>12</sup>. Inadequate and unsatisfactory education is one of the important factors of RTA in our country<sup>13</sup>. It was observed that, almost all accidents were committed by motorized vehicles, 118 of 119, remaining vehicle was rickshaw.

Regarding involvement of different type of vehicles, this study revealed that Bus/Minibus was found high 33.6% cases. Remaining were Jeep/car/Taxi 26.2% cases. In a study it was shown that trucks, buses and minibuses were the major contributor to road traffic accident and responsible for about 75.0% of pedestrian fatality. It was found that in almost of 90% cases of road deaths in Dhaka, a bus, truck or minibus was involved<sup>14</sup>.

In relation to the type of victims this study revealed that pedestrians were 31.1%, motor vehicle passengers 49.6%, drivers and helpers 19.3%. In a study conducted by Haque et al<sup>15</sup> where it was shown that pedestrian related accidents are by far the greatest among all accident types.

Regarding injury pattern, it was observed that occurrence of laceration or cut injury were 39.5% cases; remaining cases were abrasion-15.1% cases, fracture-16.0% and multiple injury-18.5%. It was observed that the commonest site of accident was main roads 50.4%; remaining were highways 29.4%, in lanes 18.5% and in level crossing 1.7%. Regarding the time distribution of occurrence of accidents it was found that 'day times' especially the 'official working hours' was more vulnerable.

In this study it was shown that most of the injuries occurred in main roads (50.4%) and remaining were at level crossing 1.7%, highway 29.4% and lanes 18.5%. Laceration or cut injury was the common injury type occurred mainly in main roads (24.4%). In this study it was revealed that maximum accidents (33.6%) occurred during Noon (1000-1400 hrs) committed by Bus/Minibus (11.8%).

### Conclusion

In this study it was shown that Road traffic injuries affect mainly male in active and productive period of life. Mean age was  $28.77 \pm 5.14$  years. Males were 4 times more prone to accident than female, thus creating enormous economic hardship due to loss of breadwinners. This study also depicted that over speed and overtaking are important determinant causation or responsible for RTA. Morbidity and disability increases medical expenditure, reduces economic productive period and decreases national.

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**Conflict Of Interest**

The authors have no conflicts of interest to disclose

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**Authors' Contributions**

Ali ASMZ, Khan MSI conceived and designed the study, analyzed the data, interpreted the results, and wrote up the draft manuscript. Hossain ABMB, Islam MS contributed to the analysis of the data, interpretation of the results and critically reviewing the manuscript. Ali ASMZ involved in the manuscript review and editing. All authors read and approved the final manuscript.

**Data Availability**

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

**Ethics Approval and Consent to Participate**

Ethical approval for the study was obtained from the Institutional Review Board. The written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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## Experience in Appendicular Stump Closure Using Single Hem-O-Lok Clip during Laparoscopic Appendectomy in Combined Military Hospital Jashore of Bangladesh

Ashim Kumar Dutta<sup>1</sup>, Md Tanvirul Islam<sup>2</sup>, Md Rezwanaul Haque<sup>3</sup>, Laboni Biswas<sup>4</sup>

<sup>1</sup>Classified Specialist in Surgery, Combined Military Hospital, Jashore, Bangladesh; <sup>2</sup>Advisor Specialist in Surgery, Combined Military Hospital, Dhaka, Bangladesh; <sup>3</sup>Classified Specialist in Surgery, Combined Military Hospital, Jashore, Bangladesh; <sup>4</sup>Lecturer, Department of Biochemistry, Army Medical College, Jashore, Bangladesh

### Abstract

**Background:** An adequate closure of the appendicular stump (CAS) is the most crucial part of appendectomy procedures because most of the complications occur by a leak of the appendicular stump. There are various techniques for the closure of base of appendix while performing a laparoscopic appendectomy like endoloop, extra or intra corporeal knotting, endoclips like Hem-o-lok and endo stapler.

**Objective:** The aim of this clinical study was to evaluate single Hem-o-lok clip for CAS regards operative time, complications, hospital stay and cost. **Methodology:** This is a prospective clinical study of 25 patients had history of acute appendicitis underwent laparoscopic appendectomy using single Hem-o-lok clip for CAS in the Combined Military Hospital Jashore from January 2018 to December 2019. The results were evaluated by a structured proforma focusing on operative time, complications, hospital stay and cost.

**Results:** Mean Operative time was 30 minutes. No intraoperative complication was seen. There was no postoperative leak or intra-abdominal collections. Only two patients had postoperative wound infection. The mean cost of the closure of an appendicular stump was 250 taka for a single Hem-o-lok clip.

**Conclusion:** The use of hem-o-lock endoclip for appendicular stump closure is safe, less time consuming and cost effective. Due to simplicity of the technique it is a useful alternative to the extracorporeal (Roeder's knot) knotting especially for young surgeons. [*Journal of Army Medical College Jashore July 2021;2(2):38-41*]

**Keywords:** Laparoscopic appendectomy; Hem-o-lok clips; closure of appendicular stump

### Introduction

Acute appendicitis is the most common cause of intra-abdominal surgical emergency<sup>1</sup> and hence appendectomy is the most common surgical procedure performed in the department of surgery globally<sup>2-3</sup>. It is usually the first procedure performed by a resident to learn surgery<sup>4</sup>. Laparoscopic appendectomy was first described 30 years ago<sup>5</sup>. With the advancing cutting edge technology it has become an established surgical technique which offers less pain, faster recovery and earlier return to life and work. The laparoscopic technique is especially

preferred in cases of diagnostic uncertainty, female and obese patients.

Closure of the appendicular stump in laparoscopic appendectomy is the most critical part of the procedure. Inadequate closure can lead to intra-abdominal surgical site infection or life-threatening complications such as fistulas, peritonitis and sepsis. Various methods such as ligation using extracorporeal sliding knots, intracorporeal knotting, endostapling, endoloop or endoclips have been described and are currently in use for CAS in laparoscopic appendectomy (LA)<sup>6</sup>. Experienced surgeons prefer intra-corporeal or extra-corporeal knotting to secure the base and consider them safer in cases of friable and inflamed bases. One study has been first time described the use of metallic endoclip in the closure of appendiceal base<sup>7</sup>. The endoclip is an easier time saving alternative to

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**Correspondence:** Lt Col Ashim Kumar Dutta, MBBS, FCPS, Classified Specialist in Surgery, Combined Military Hospital, Jashore, Bangladesh; Email: [asimdr29@gmail.com](mailto:asimdr29@gmail.com); Cell no.: +8801712248899

close the base of appendix in laparoscopic appendectomy<sup>8-14</sup>.

The use of Hem-o-lok clips, which are non-absorbable, polymer structures for ligation of vessels, ureters, and bile ducts, has been documented in many surgical procedures. The aim of this clinical study was to evaluate single Hem-o-lok clip for CAS regards operative time, complications, hospital stay and cost.

### Methodology

This prospective study was carried out on 25 patients admitted to Combined Military hospital Jashore with acute appendicitis and underwent LA and a single Hem-o-lok clip was used for CAS during the period January 2018 to December 2019. Informed consent was taken from all the patients after explaining the risks and alternatives of the procedure. The junior surgeons and residents present at the time of procedure and collected the data on data sheets. All patients were diagnosed as having acute appendicitis on the basis of clinical criteria, ultrasound scan and laboratory results (Alvarado score  $\geq 8-10$ ). There were no exclusion criteria besides the intraoperative finding of a gangrenous base. All patients underwent standard three Trocar LA. Access to the peritoneum begins with a 10mm umbilical port. Two additional ports are placed under vision in the suprapubic region 5 mm and left lower quadrant 10mm. Initial diagnostic laparoscopy was done and diagnosis of inflamed appendix was confirmed. The base of appendix was cleared out by dissecting away the meso-appendix with appendicular artery and electrocauterized by bipolar diathermy. We placed single Hem-o-lok clip for appendicular stump closure and one metallic endoclip was applied 6-8 mm away from the haemoclips Fig.(1). Then the appendix was amputated between the hem-o-lok and metallic endoclip at the base of the appendix. The excised appendix was retrieved through umbilical port. One pelvic drain was kept in 3 patients as there was significant oozing from raw surface of marked adhesions. Final laparoscopy was done in all cases and found alright. Skin incisions were closed using 0 polyglactin suture. The antibiotic regimen Inj Ceftriaxone 1 gm I/V bid and Inj Metronidazole 500 mg tds for 24 hours then oral cefixime 200 mg bid and metronidazole 500 mg tds for 4 to 5 days more in all cases. Patients were discharged on 2<sup>nd</sup> to 3<sup>rd</sup> POD and called for follow up, stitch removal on 8<sup>th</sup> POD. All patients were followed up upto 3 months postoperatively. Ethical consideration: Approval was obtained from the Ethical Committee of CMH Jashore. All data were analyzed using the SPSS version 19.0.

### Results

In this study Patient's age range between 20 and 40 years (mean 30 years). There were 10 males and 15 females. Operative time duration ranged between 20 to 40 minutes (mean 30 minutes) (Table 1).

Table 1: Distribution of Study Population according to Gender

Gender	Frequency	Percent
Male	10	40.0
Female	15	60.0
<b>Total</b>	<b>25</b>	<b>100.0</b>

Among 25 patients included in our study, 5 patients (20%) presented with perforated appendix and the other 20 patients (80%) had acute appendicitis without perforation (Table 2).

Table 2: Per-Operative Findings among the Study Population

Types of Appendix	Frequency	Percent
Acute appendicitis without perforation	20	80.0
Acute appendicitis with perforation	5	20.0
<b>Total</b>	<b>25</b>	<b>100.0</b>

Drains were used in 3 patients to ensure proper intra-abdominal collection drainage. No intra-operative complications were recorded. The results showed no postoperative intra-abdominal collection or leak from appendicular stump. The only postoperative complication we faced were two patients with umbilical port site infection which was managed by regular dressing and antibiotics, the cost of a single Hem-o-lok clip is only 550 tk. Hospitalization time ranged between 2 and 4 days (mean 3 days) (Table 3).

Table 3: Post-Operative Complications

Variables	Frequency	Percent
Wound infection	2	8.0
Fistula Formation	0	0.0
Post-operative ileus	0	0.0
Fistula formation	0	0.0
Intraabdominal abscess	0	0.0



Figure 1: Appendicular Stump with Hem-o-Lok Clip



## Discussion

Laparoscopic appendectomy has now a day become an well accepted techniques throughout the world specially in developed countries. Advantages of laparoscopic appendectomy over open appendectomy are clear; superiority in cases of diagnostic uncertainty in female and obesity, better visualization of peritoneal cavity, less pain, faster recovery and better cosmetic results are a few important factors. The main difficulties during LA encountered during the closure of the stump. CAS with endoclips is simple and does not necessitate special laparoscopic experience and so provides a significant reduction in operative time<sup>1</sup>.

The most important concern in laparoscopic appendectomy is the safety of the method used for the closure of the appendicular stump<sup>12</sup>. Therefore, new techniques such as endoloop, ultrasonic dissection tools, intracorporeal suture, metallic clips, bipolar coagulation and linear endostapler have been applied for the best way to the closure of the appendicular stump<sup>13</sup>. However, debate about the safety and effectiveness of new applications continues and the best technique has not yet been determined. The new applications may extend the duration of the operation or increase cost of LA<sup>15-16</sup>. Many surgeons have either used a stapler or endoloop for the closure of appendicular stump<sup>7,17</sup>. The use of a stapler is safe and fast but expensive, while the endoloop is less expensive but requires good laparoscopic training. Otherwise, clips spilled into the abdominal cavity have been shown to give rise to peritoneal adhesions and may be the cause of intestinal obstruction<sup>18</sup>. Another study reported that using a titanium clip is safe in comparison with other commercially available clips because of its size<sup>11</sup>, which allows the closure of an appendix base greater than 10 mm. In this study single Hem-o-lok clip was used without considering the diameter of the appendix base.

In another study compared the Hem-o-lok clip and the endoloop for CAS<sup>12</sup>. Their results revealed that the use of the Hem-o-lok clip for CAS in LA is a feasible, safe, fast, and cost-effective procedure in patients with a mild to moderately inflamed appendix base of less than 10 mm in diameter. In this study a Hem-o-lok clip was used without considering the diameter of the appendix base but gangrenous base excluded in this study.

One other study compared both clips in CAS and concluded that the use of a Hem-o-lok clip and a metal clip for CAS in LA is a feasible, safe, and cost-effective procedure in patients with an inflamed appendix base less than 10 mm in diameter<sup>8</sup>. In this study also used Hem-o-lok clip in an inflamed base without considering the diameter of the appendix base. In several studies, the operative time and the mean duration of hospital stay when Hem-o-lok clip was used for the closure of the appendix base in LA was between 45-60 minutes and 1 to 7 days, respectively<sup>7,15</sup>. This study data correlate well those studies.

Several studies reported that double Hem-o-lok clip was used in the closure of the base of the appendix<sup>6,9,15</sup>. However, this study used a single Hem-o-lok clip and did not need a second Hem-o-lok in the closure of the appendix base. Currently, the use of single Hem-o-lok clip for the closure of the appendix base also has been suggested by several studies<sup>7,19</sup>.

In this study, the appendix base was closed successfully with single Hem-o-lok clip. We think one of the reasons is that most of the present cases were admitted to the emergency clinic in the early period of acute appendicitis and there was no necrosis or intense edema in the appendix base. In the literature, there were several reports showing higher incidence of appendicular stump leakage, intra-abdominal abscess and fistula formation following LA, especially for complicated acute appendicitis cases<sup>5-6</sup>. In this series, there is no leakage of appendicular stump or intra-abdominal abscess following LA.

One study showed that metal clip costs 7\$ while hem-o-lok clip costs 50\$ showing a statistically significant difference in cost of CAS<sup>20</sup>. In this series we used only one Hem-o-lok clip for closure of appendicular stump. In our country only 250 taka cost for each Hem-o-lok clip and it is acceptable.

Although the cost of the Hem-o-lok clip is still higher but it is very easy to apply which reduce operative time and there is no evidence of post-operative complication like stump leakage and earlier discharge from the hospital and return to work seem to compensate for the little high cost of the Hem-o-lok. So it can safely use single Hem-o-lok clip for closure of appendicular stump in LA. Long term results depends upon meticulously use of surgical technique and proper patient selection. The complications are encountered in this series is acceptable in comparison to other study may be due to a comprehensive approach adopted, meticulous use of surgical technique and early recognition of complication and manage it timely.

## Conclusion

The use of the single Hem-o-lok clip for closure of the appendix base in LA is a feasible, safe, and cost effective procedure in patients with acute appendicitis without necrosis of the base of the appendix.

## Acknowledgements

None

## Conflict Of Interest

Authors also declare that the work has no financial or other relationships that might lead to a conflict of interest,

## Financial Disclosure

The author(s) received no specific funding for this work.

## Authors' contributions

Dutta AK: Conceptual work, data collection, Report writing, manuscript writing; Islam MT: Data Collection; Haque MR: Help in Laboratory Works; Biswas L: Manuscript correction

**Data Availability**

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

**Ethics Approval and Consent to Participate**

Ethical approval for the study was obtained from the Institutional Review Board. The written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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## Comparison of Clinical Profile of Demyelinating and Axonal subtype of Guillain-Barre Syndrome at a Specialized Neurology Hospital in Bangladesh

Md. Zakirul Islam<sup>1</sup>, Mohammad Enayet Hussain<sup>2</sup>, Md. Abdullah Yusuf<sup>3</sup>, Rezaul Karim<sup>4</sup>, Anjuman Ara<sup>5</sup>, Md. Azharul Hoque<sup>6</sup>, Quazi Deen Mohammad<sup>7</sup>

<sup>1</sup>Assistant Professor, Department of Medicine, Kurmitola General Hospital, Dhaka, Bangladesh; <sup>2</sup>Associate Professor, Department of Neurophysiology, National Institute of Neurosciences & Hospital, Dhaka, Bangladesh; <sup>3</sup>Associate professor, Department of Microbiology, National Institute of Neurosciences & Hospital, Dhaka, Bangladesh; <sup>4</sup>Senior Consultant (Medicine), Department of Medicine, Nilpharmary Adhunik Sadar Hospital, Nilphamary, Bangladesh; <sup>5</sup>Assistant Professor, Department of Gynaecology & Obstetrics, TMSS Medical College, Bogra, Bangladesh; <sup>6</sup>Former Head & Professor of Neurology, Department of Neurology, National Institute of Neurosciences and Hospital, Dhaka, Bangladesh; <sup>7</sup>Director & Professor of Neurology, National Institute of Neurosciences & Hospital, Dhaka, Bangladesh

### Abstract

**Background:** Many differences with respect to clinical parameters & outcomes were observed among the demyelinating and axonal subtype of Guillain-Barre syndrome. **Objectives:** The purpose of the present study was to compare clinical profile of axonal versus demyelinating Guillain-Barre syndrome. **Methodology:** This cross sectional study was conducted from Oct, 2017 to September, 2018 in the department of clinical neurology at the National Institute of Neurosciences and Hospital, Dhaka, Bangladesh. All demyelinating and axonal GBS, presented within 2 weeks were included in this study. The clinical parameters were taken for baseline analysis. **Results:** Out of 108 GBS cases 55 (50.9%) demyelinating & 53 (49.1%) were axonal subtype. Mean age was  $40.20 \pm 16.26$  vs.  $32.43 \pm 14.93$  years in demyelinating vs. axonal cases respectively ( $p=0.011$ ). Antecedent events were present 60.0% vs. 81.1% in demyelinating vs. axonal cases ( $p=0.014$ ) and in both group gastroenteritis was the predominant event. Symptom onset, hospitalization time and nadir of weakness are shorter in axonal cases than demyelinating one [ $(8.47 \pm 4.97$  vs.  $12.36 \pm 7.94)$  ( $p=0.017$ );  $(4.70 \pm 2.13$  vs.  $6.75 \pm 5.30)$  ( $p=0.009$ ) and  $(6.7 \pm 4.5$  vs.  $8.36 \pm 4.59)$  ( $p=0.022$ )] days. Facial nerve palsy was more common in demyelinating subtype (49.1% vs. 13.2%). MRC score ( $m \pm sd$ ) and Hughes disability score ( $m \pm sd$ ) were [ $(18.04 \pm 9.85$  vs.  $12.94 \pm 9.91)$  ( $p=0.009$ ) and  $(3.67 \pm 0.94$  vs.  $4.08 \pm 0.87)$  ( $p=0.023$ )] in demyelinating vs. axonal cases. Severe GBS cases were found 85.5% vs. 94.3% in demyelinating vs. axonal cases. **Conclusion:** In conclusion demyelinating and axonal subtype of GBS differ in many aspects like age, antecedent events, severity of clinical symptoms, MRC score, Hughes score. [*Journal of Army Medical College Jashore July 2022;2(2):42-45*]

**Keywords:** Guillain-Barre syndrome; acute inflammatory demyelinating polyneuroradiculopathy; acute motor axonal polyneuroradiculopathy; clinical profiles

### Introduction

Guillain-Barre syndrome (GBS) is an acute immune mediated polyradiculo-neuropathy<sup>1</sup>. Electro-physiologically GBS are categorized as demyelinating (AIDP-acute inflammatory demyelinating polyradiculo-neuropathy), axonal (AMAN-acute motor axonal & AMSAN-acute motor sensory axonal neuropathy) subtype<sup>2</sup>. More than two third of cases are associated with an antecedent events specially

gastroenteritis and RTI<sup>3</sup>. AMAN variety of GBS are strongly associated with Campylobacter jejuni gastroenteritis. Variations are observed in clinical presentation among the different subtypes<sup>4</sup>.

AMAN variety has a rapid evolution of clinical course and reaches to nadir very quickly and usually more severe than AIDP<sup>5</sup>. Diagnosis is based on typical clinical presentation along with CSF albuminocytological dissociation like increase CSF protein in the absence of increase cell. Nerve conduction study is done for classifying the subtyping<sup>6</sup>. Other investigations include serum electrolytes to exclude electrolyte imbalance. Definitive management of GBS is either with Plasmapheresis or IVIg therapy with equal

**Correspondence:** Dr. Md. Zakirul Islam, Assistant Professor, Department of Medicine, Kurmitola General Hospital, Dhaka, Bangladesh; Email: zakir.doc@gmail.com; Cell no.: +8801748994027



efficacy<sup>7</sup>. AIDP is associated with rapid & usually complete clinical recovery while AMAN and AMSAN have poorer outcome & has a longer clinical course<sup>8</sup>. The purpose of the present study was to compare clinical profile & outcome at 12 weeks in demyelinating compared to axonal subtype of GBS.

### Methodology

This cross sectional study was conducted from Oct, 2017 to September, 2018 in the department of clinical neurology at the National Institute of Neurosciences and Hospital, Dhaka, Bangladesh. A total 108 patient were selected according to the selection criteria and after confirmation by electrophysiological study. Details of the study that included nature, purposes & procedure of the study, type of investigations & their risk, definite treatment & their side effects and management were well briefed to the patient and their attendant. Written consent was taken from patient or their legal attendant. Details history was taken and meticulous examination were performed to collect the data according to the variable of interest. All necessary investigations were done at an optimum time. NCS & CSF were done after 1st week of onset of the symptoms in the respective department of the institute. All patients were regularly monitored especially respiratory function for diagnosis of early impending respiratory failure and managed them accordingly. The collected data were analyzed by using SPSS version 22.0. Statistical significance was determined by using Pearson chi-square test for all categorical data and student 't' test for all continuous data and result were expressed by frequency and percent & mean with standard deviation respectively. P value of <0.05 was taken as statistically significant.

### Results

Baseline analysis were performed among the 108 patients. 6 patients died during hospital stay, so 102 patients were discharged from the hospital. Additional 3 patients died and 15 were lost to follow up at 12 weeks. Ultimately 84 patients were brought into follow up and outcome analysis was performed among the 93 patients (84+6+3=93). The present prospective study is intended to compare clinical profile as well as outcome at short term (12 week) between demyelinating and axonal subtypes of GBS among the 108 patients; of them 55 were demyelinating and 53 were axonal subtype. Mean age was  $36.39 \pm 16.03$  years. Males were predominantly affected with a male and female ratio 76:32. Maximum, 31(28.7%) cases had primary level of education. Students, businessman and housewives were more commonly affected which were 26(24.1%); 17(15.7%) and 22 (20.4%) cases. People of high income group affected more 53 (49.1%) than middle and low income group; 27(25.0%) cases and 28(25.9%) cases respectively. Urban people were more affected than rural 60(55.6%) vs 48(44.4%). Highest number of cases were observed in the spring which was 43 (39.8%) and in the summer 40(37.0%) (Table 1).

The mean age was  $40.20 \pm 16.26$  vs  $32.43 \pm 14.93$  years among the demyelinating vs axonal subtypes ( $p=0.011$ ). M:F was ~2.4:1 (76:32%); in demyelinating group it was ~2:1 (36:19) and in axonal group it was ~3:1 (40:13). Axonal variety was more common in summer (25 vs 15) whereas demyelinating in the spring (24 vs 19) ( $p$  value 0.026). Antecedent events were reported by 33 (60.0%) of demyelinating and 43 (81.1%) of axonal cases which was statistically significant ( $p=0.014$ ). Gastroenteritis was the commonest antecedent infection in both group; 22 (40.0%) in demyelinating and 32 (56.4%) in axonal cases ( $p=0.027$ ). RTI was reported by 7 (12.7%) demyelinating and 11 (20.8%) axonal cases. Time interval from antecedent events to symptoms onset was  $8.47 \pm 4.97$  &  $12.36 \pm 7.94$  days in axonal and demyelinating cases respectively ( $p=0.017$ ).

Table 1: Baseline Demographic Characteristics of the Study Participants

Baseline Demographic Characteristics	Frequency (%)
Mean Age (m $\pm$ sd)	36.39 $\pm$ 16.03
Age category	
18 to 40 years	73 (67.6)
41 to 60 years	28 (25.9)
>60 years	7 (6.5)
Gender	
Male	76 (70.4)
Female	32 (29.6)
M : F	76 : 32
Occupation	
Service	24 (22.2)
Businessman	17 (15.7)
Students	26 (24.1)
Cultivator	7 (6.5)
Laborer	9 (8.3)
House wife	22 (20.4)
Others	3 (2.8)
Monthly income	
<10000/BDT	28 (25.9)
10000 to 20000	27 (25.0)
>20000	53 (49.1)
Living background	
Urban	60 (55.6)
Rural	48 (44.4)
Season of disease occurrence	
Summer	40 (37.0)
Rainy	17 (15.7)
Winter	8 (7.4)
Spring	43 (39.8)

m $\pm$ sd: mean  $\pm$  standard deviation, BDT: Bangladeshi taka

The interval from symptom onset to hospitalization was also significantly shorter in axonal cases; which was  $4.70 \pm 2.13$  days, and in demyelinating cases  $6.75 \pm 5.30$  days ( $p=0.009$ ). Nadir of weakness developed rapidly in axonal

than demyelinating cases which were  $6.70 \pm 2.57$  days and  $8.36 \pm 4.59$  days respectively ( $p=0.022$ ). Pain was reported by 25 (45.5%) of demyelinating and 29 (54.7%) of axonal cases (Table 2).

Table 2: Comparison of Clinical Profile among demyelinating and axonal GBS

Demographic profile	GBS type		P value
	Demyelinating n=55 (%)	Axonal n=53 (%)	
Age (mean $\pm$ SD)	40.20 $\pm$ 16.26	32.43 $\pm$ 14.93	0.177*
Gender			
Male	36 (65.5)	40 (75.5)	0.026*
Female	19 (34.5)	13 (24.5)	0.165
M:F	36:19 (~2:1)	40:13 (~3:1)	0.379
Seasonal influence			0.265
Summer	15 (27.3)	25 (47.2)	
Rainy	11 (20.0)	6 (11.3)	
Winter	5 (9.1)	3 (5.7)	
Spring	24 (43.6)	19 (35.8)	

m $\pm$ sd: Mean  $\pm$  Standard deviation. BDT: Bangladeshi taka. \*Pearson chi-square test was used to determine the level of significance. \*\*independent sample T test was used to determine the p value. P value <0.05 was taken as statistically significant. Mean MRC score were 18.04 ( $\pm$ 9.85) and 12.94 ( $\pm$ 9.91) in demyelinating and axonal cases respectively and the difference was statistically significant (\*\* $p=0.009$ ). Mean disability score recorded as 3.67 ( $\pm$ .94) in demyelinating and 4.08 ( $\pm$ 0.87) in axonal cases which was also statistically significant (\*\* $p=0.023$ ). Defining the severity of GBS 8 (14.5%) cases were mild and rest 47 (85.5%) cases were severe GBS in demyelinating group in contrast to axonal GBS where only 3 (5.7%) cases were mild and rest 50 (94.3%) cases were severe disease (Table 3).

Table 3: Comparison of motor features (mean MRC, mean disability) and GBS severity between demyelinating and axonal Variety of GBS at Nadir

Variables	GBS type		P value
	Demyelinating	Axonal	
MRC score (m $\pm$ sd)	18.04 $\pm$ 9.85	12.94 $\pm$ 9.91	0.009**
HGFS score (m $\pm$ sd)	3.67 $\pm$ .94	4.08 $\pm$ 0.87	0.023**
GBS severity			
• Mild GBS	8(14.5%)	3(5.7%)	0.113*
• Severe GBS	47(85.5%)	50(94.3%)	

MRC: medical research council score. HFGS: Hughes functional GBS score, Mild GBS: Hughes disability score 0 to 2; Severe GBS: Hughes disability score  $\geq$  3. \* Pearson chi-square test was done to determine the level of significance.\*\*Independent sample T test was performed to determine the level of significance. P value of less than 0.05 was considered as statistically significant.

## Discussion

The main focus of this study is to observe the differences in various clinical parameters as well as the differences of

clinical & electrophysiological outcome at 12 weeks among demyelinating and axonal variety of GBS. The study includes 50.9% demyelinating and 49.1% axonal subtypes of GBS. Previous studz<sup>8</sup> has demonstrated that there is a marked variation of GBS worldwide with respect to clinical pattern, severity, electrophysiological subtypes and outcome. The predominant electrophysiological subtype is demyelinating throughout the world- 55% in Europe-America, 45% in Asia and in Bangladesh 40.0% cases<sup>8</sup>. Axonal GBS is reported in 3.0% to 17.0% cases in Europe<sup>9</sup>, 23 to 65% cases in Asia<sup>10</sup> and up to 67.0% cases in Bangladesh<sup>11</sup>. The result of this study is consistent with that of other studies.

The mean age of participant is  $40.20 \pm 16.26$  years and  $32.43 \pm 14.93$  years among the demyelinating and axonal subtypes respectively. All over the world frequency of GBS increases with age. Similar age distribution was reported previously<sup>12</sup>. In Bangladesh, patients are younger than other parts of the world which is supported by a previous study<sup>11</sup> where mean age was 21 years, lower than the present study probably due to the inclusions of pediatric group of patients. In this study axonal patients are younger than demyelinating one which is also supported by previous study<sup>8</sup>.

Males are more frequently affected than female with a ratio ~2.4:1 (76:32); in demyelinating group it was around ~2:1 (36:19) and in axonal group it was around ~3:1 (40:13). Previous studies also reported higher male- female ratio<sup>13</sup> in all age categories and regions. The present study also has found that males develops axonal GBS 3 times more because of their greater risk of exposure to C. jejuni infection. There is a strong relationship between C. Jejuni gastroenteritis and axonal GBS<sup>11</sup>.

This study has revealed that the axonal subtype is common in urban area and demyelinating in rural area [34 (64.2%) vs 29 (52.7%)]. It has not been found any previous literature to compare this variable. However, overcrowding and water pollution in the urban area might lead to more C. jejuni gastroenteritis which is responsible for more axonal GBS cases in urban area.

Seasonal influences on the occurrence of demyelinating and axonal type of GBS, demonstrates a clear relationship of axonal cases with the summer than demyelinating one (47.2% Vs. 27.3%). Similar relationship has also been described previously in an Indian study<sup>14</sup>. On the other hand demyelinating cases are slightly higher in frequency than axonal cases in the spring (43.6% vs. 35.8%). However, Kalita et al<sup>14</sup> has described more demyelinating cases in rainy season.

Significant differences between demyelinating and axonal subtype of GBS with respect to onset of symptoms, hospitalization and nadir of weakness has been observed in this study. Following an antecedent event; onset of symptom is rapid in axonal cases than demyelinating one;  $8.47 \pm 4.97$  vs.  $12.36 \pm 7.94$  days and a quick hospitalization:  $4.70 \pm 2.13$  vs.  $6.75 \pm 5.30$  days in axonal vs. demyelinating subtype of GBS. In contrast to demyelinating cases Nadir of weakness also develops more rapidly in axonal cases;  $6.70 \pm 2.57$  Vs.  $8.36 \pm 4.59$  days. All the findings of the present study are consistent with the results of the previous studies<sup>8</sup>.

Mean MRC score was found  $18.04 \pm 9.85$  Vs.  $12.94 \pm 9.91$  in demyelinating vs. axonal cases ( $p=0.009$ ). Mean disability score is  $3.67 \pm .94$  Vs.  $4.08 \pm 0.87$  in demyelinating vs. axonal

cases ( $p=0.023$ ). Lower mean MRC score & higher mean disability score was also observed in axonal subtype than demyelinating one in an earlier study<sup>10</sup>. Mild GBS is found in 8 (14.5%) Vs. 3 (5.7%) cases and severe GBS cases are found in 47(85.5%) Vs. 50(94.3%). Previous study<sup>9</sup> revealed similar higher percentage of severe disease in axonal than demyelinating subtype of GBS.

### Conclusion

This study compares the clinical profile as well as short term outcome between demyelinating and axonal subtypes of GBS among the adult population. As per search, this is the first ever comparative study among demyelinating and axonal variety of GBS on adult population in Bangladesh. The present study reveals both subtypes exist almost in equal frequencies. About two-third of the cases are associated with a preceding event. These two variant differs in many aspects of clinical parameter such as age, antecedent events, speed of onset, time to hospitalization, time to nadir of weakness, facial palsy, mean MRC score & mean disability score at nadir and at discharge. Differences are also observed in outcome at 12 weeks. Prognosis is more favorable in demyelinating subtype than axonal with respect to MRC, disability and electrophysiological parameters at the end of the study period.

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### Conflict Of Interest

The authors have no conflicts of interest to disclose

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### Authors' contributions

Islam MZ, Hussain ME, Yusuf MA conceived and designed the study, analyzed the data, interpreted the results, and wrote up the draft manuscript. Hussain ME, Yusuf MA contributed to the analysis of the data, interpretation of the results and critically reviewing the manuscript. Karim R, Ara A, Hoque MA, Mohammad QD involved in the manuscript review and editing. All authors read and approved the final manuscript.

### Data Availability

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

### Ethics Approval and Consent to Participate

Ethical approval for the study was obtained from the Institutional Review Board. The written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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## Victims Profiles of Death Cases due to Suicidal Hanging at Tertiary Teaching Hospital in Bangladesh

Kazi Dilshad Jahan<sup>1</sup>, Rakibul Hasan Khan<sup>2</sup>, Mitra Biswas<sup>3</sup>, Khaleda Parveen<sup>4</sup>, Ismat Jerin Talukder<sup>5</sup>

<sup>1</sup>Assistant Professor, Dhaka Community Medical College & Hospital, Dhaka, Bangladesh; <sup>2</sup>Assistant Professor & Head, Department of Forensic Medicine, Sheikh Hasina Medical College, Tangail, Bangladesh; <sup>3</sup>Assistant Professor, Department of Forensic Medicine, H.M. Shamorita Medical College, Dhaka, Bangladesh; <sup>4</sup>Assistant Professor, Department of Forensic Medicine, Prime Medical College, Rangpur, Bangladesh; <sup>5</sup>Assistant Professor, Department of Pharmacology, Dhaka Community Medical College & Hospital, Dhaka, Bangladesh

### Abstract

**Background:** Hanging is always suicidal unless and otherwise proved. It is a form of violent asphyxia death, where the constricting of the neck is forming a ligature encircling the neck, the constricting force being the weight of the body. **Objective:** The aim of this study was to find out the cause of suicide, socio-economic characteristics of victims, common ligature material used by victims for hanging and post-mortem findings. **Methodology:** The retrospective study was done in the Department of Forensic Medicine at Rangpur Medical College, Rangpur, Bangladesh mortuary in the period of January 2017 to 2018. During this period data were collected from 647 cases of medicolegal autopsies by purposive sampling of which suicidal hanging contributed to (n-128) of cases. Various data regarding suicidal hanging collected from the period of 2017 to 2018 which was obtained by during autopsy, from police inquest report and history from relative of deceased which include socio-demographic data, various medical data like nature of ligature material, external and internal post mortem findings. Data was presented by a descriptive frequency and percentages. **Results:** A total died of 647 cases were analyzed of which 169(26.0%) cases were died of violent asphyxia where hanging cases were 128(20.0%) cases. Among them upper class family 15(2.0%), middle class family 60(9.27%), lower class 53(8.0%), male 56(43.75%) and female 72(56.0%). Cyanosis of nail bed and fingertips was the commonest 98.0% findings in case of asphyxia death was due to hanging. **Conclusion:** Tendency of suicidal hanging observed more within the age group ranging from 21-30 years in this study. [*Journal of Army Medical College Jashore July 2022;2(2):46-49*]

**Keywords:**Keywords: Suicidal hanging; ligature mark; asphyxia

### Introduction

Asphyxia in Greek means “Absence of pulsation”, but in forensic parlance it means interference with oxygenation<sup>1</sup>. Hanging or self-suspension is a form of ligature strangulation where the pressure is produced by the weight of the body itself<sup>2</sup>. The body needs not to be completely suspended, as death may result from hanging even in a sitting, kneeling or half lying position<sup>3</sup>. The weight of the head (5 to 6 kg), chest and arms act as the constricting force.

The whole weight of the body is not necessary and only a comparatively slight force is enough to produce death<sup>4</sup>. It is almost invariably suicidal except in some masochistic accidental cases<sup>5</sup>. Suicide by hanging is one of the major causes of unnatural death especially in young female in our country.

Suicide is defined as a self-inflicted cause of death<sup>6</sup>. Hanging produces painless death for the victims and there is no costs involvement other than that of the ligature material. A thin rope around the neck will cause unconsciousness within 15 second and regarded as painless form of death<sup>7</sup>.

### Methodology

This was a retrospective study which was done in Rangpur

**Correspondence:** Dr. Kazi Dilshad Jahan, Assistant Professor, Dhaka Community Medical College & Hospital, Dhaka, Bangladesh; Email: kazidilshad@hotmail.com; Cell No.:01912727190; ORCID: 0000-0003-0164-8792



Medical college at Department of Forensic Medicine for a period of 2017 to 2018 and total 647 autopsies were conducted, among which (n=128) 19.78% cases were suicide by hanging included and other suicidal method excluded. Data were collected on socio demographic variables (age, sex, marital status, economic status and others), nature of ligature material and external and internal findings during autopsies. Data were presented by a descriptive frequency. Data were analyzed manually.

### Results

A total died of 647 cases were analyzed of which 169(26.0%) cases were died of violent asphyxia where hanging cases were 128(20.0%) cases. In this study female was more vulnerable to suicidal hanging rather than male (Table 1).

Table 1: Gender Variation in Hanging (n=128)

Gender	Frequency	Percent
Male	56	56.0
Female	72	44.0
<b>Total</b>	<b>128</b>	<b>100.0</b>

Persons ranging from 21 to 30 years of age (55%) are more vulnerable to suicidal death by hanging in comparison with other age group (Table 2).

Table 2: Age Variation in Suicidal Hanging (n=128)

Age Group	Frequency	Percent
10 to 20 Years	5	4.0
21 to 30 Years	70	55.0
31 to 40 Years	35	27.0
41 to 50 Years	10	8.0
51 to 60 Years	8	6.0

The distribution as per causes of suicidal hanging were recorded where marital conflict was the leading and alarming cause of death that accounts for 43% cases (Table 3).

Table 2: Age Variation in Suicidal Hanging (n=128)

Motive	Frequency	Percent
Marital conflict	5	4.0
Poverty	70	55.0
Dowry	35	27.0
Business Loss	10	8.0
Disappointment in Love	8	6.0
Failure in exam or scolding at this account by guardian		
<b>Total</b>		

The orna commonly used in hanging for suicide among the study population. In this study soft material was preferred over hard ligature material. Hard ligature material in the present study comprised of nylon ropes, electrical wire

easily available in domestic use (Table 4).

Table 4: Distribution according to Ligature Material Used in Hanging Cases (n=128)

Ligature material	Frequency	Percent
Orna	62	48.0
Nylon rope	40	31.0
Sari	10	8.0
Electrical wire	12	9.0
Gumcha	6	5.0
<b>Total</b>	<b>128</b>	<b>100.0</b>

Cyanosis was found in 98.0% of cases, placement of ligature mark is oblique and non-continuous in nature and base of the ligature mark is pale, hard and parchment like in 98.0% of cases and dribbling of saliva 62.0% cases. Discharge of semen and urine or faeces 40.0% cases and 12.0% cases respectively (Table 5).

Table 5: Post mortem findings on External Examination Cases (n=128)

Findings	Frequency	Percent
Cyanosis	126	98.0
Placement of ligature mark at neck	125	98.0
Oblique, non-continuous		
Base of ligature mark pale hard and parchment like	126	98.0
Dribbling of saliva	80	62.0
Discharge of semen	50	40.0
Discharge of urine/faeces	15	12.0

About 99.0% of subcutaneous tissue underneath the ligature mark shows pale hard and glistening with Petechial hemorrhage 98.0%, subconjunctival haemorrhage 43.0% cases. In 5.0% of cases hyoid bone fractured and 12% damage to neck muscle fibers at the sternocleidomastoid muscles sternal end (Table 6).

Table 6: Post-Mortem findings on internal Examination cases (n=128)

Internal Findings	Frequency	Percent
Subcutaneous tissue underneath the ligature mark White, hard and glistening	127	99.0
Fracture of thyroid	6	5.0
Fracture of hyoid	16	12.0
Subconjunctival haemorrhage	55	43.0
Petechial haemorrhage	125	98.0
Injury to subcutaneous tissue underneath the ligature mark	20	16.0
Injury to the neck muscle	15	12.0

### Discussion

A total of 647 cases were brought for post mortem

examination at the mortuary of Rangpur medical college during the year of 2017 to 2018. After post mortem examination and correlated with the history received from the police, it was confirmed that among them 169 died of violent asphyxia and 128 cases were due to suicidal hanging. The rate of suicide is sharply increasing in Bangladesh according to data from Police headquarters. In year 2017, 11,095 people committed suicide in Bangladesh<sup>8</sup> which means on an average 30 people kill themselves every day, 569 of them hanged themselves, 3467 took poison and 59 people set themselves on fire.

In WHO latest data published in 2018 suicidal death in Bangladesh reached 9,544 or 1.23% of total deaths<sup>9</sup> and according to the WHO Mortality Database, 85% of suicides in the world occur in low- and middle-income countries and In Bangladesh suicide rate is higher in comparison to the other south Asian countries<sup>10</sup>. In this study we observed that majority cases were within 21 to 30 (55%) years of age group, study also shown that people belong to this age group were also common in other countries. Among them 57% were female and rests were male (49%) and 51% were married. Various studies showed that less educated people are more likely to hang themselves<sup>11</sup>. Marital conflict (43%) and familial quarrel was the commonest cause for suicidal hanging in our study. In case of female cause of death due to conflicts relating to marriage like dowry harassment, Family quarrel among husband and wife was also an important cause in this group<sup>12</sup>. Psychiatric illness, nuclear family, alcoholism physical and, economic condition were the other factors that contributed to self-suspension. Suicide may be an important indicator of mental instability.

In middle- and higher-class family member of this group belong to student community on the contrary in low socio-economic family mostly these are the earning member of the family like garments or other industrial workers and they commit suicide due to failure of love affairs 13%, marital conflict, early marriage, unwanted pregnancy, low literacy and mental depression. Most of the victims used Orna (common), nylon rope, sari and electrical wire. Sari and Orna is most common ligature used in suicidal hanging due to its availability<sup>13</sup>.

Another study shows, the ligature mark in the neck which is one of the surest signs of hanging placed obliquely, non-continuous, above the level of thyroid cartilage along with cyanosis of fingertips and nail beds of both hands was the commonest findings, which was followed by pale, hard, white and glistening subcutaneous tissue underneath the ligature mark and dribbling mark of saliva. These are the important signs of asphyxia which are mostly mentioned in every literature available<sup>14</sup>.

These study highlights the influence of socioeconomic factors and demographic factors are main alarming cause for suicidal hanging especially in middle class family. The lower income group also shows same trend but on lesser scale, which indicates the incidence of suicidal hanging death is more psychological origin.

## Conclusion

In conclusion most of the victims has died due to hanging and female gender with the younger age group. Number of females are significant who have marital conflict due to

many reasons which are alarming and awareness need from the level of family and community to combat this. 'Orna' commonly is used as ligature material. The other factors which is influencing an individual for attempt to suicide should also be consider for prevention. The number of suicidal hanging cases is increasing day by day. A well designed and comprehensive program is needed to identify the causative factors and prevention of suicidal behaviors.

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The authors have no conflicts of interest to disclose

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## Authors' contributions

DR Kazi Dilshad Jahan: Conceptual work, data collection, Report writing, Manuscript writing; Dr Rakibul Hasan khan: Supervisor; Dr Mitra Biswas : Data Collection; Dr Khaleda Parveen: Help in Laboratory Works; Dr Ismat Jerin Talukder: Manuscript correction;

## Data Availability

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

## Ethics Approval and Consent to Participate

Ethical approval for the study was obtained from the Institutional Review Board. The written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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## Extraction of Arsenic from Isolated Liver Tissues in Experimental Rat by *Allium sativum* (Garlic): An Experimental Animal study

Andalib Mustafa Iqbal Ira<sup>1</sup>, Mir Misbahuddin<sup>2</sup>, Sujit Kumar Sarker<sup>3</sup>, Shakila Akter<sup>4</sup>, Sheikh Ziarat<sup>5</sup>, Sabina Jesmin<sup>6</sup>

<sup>1</sup>Associate Professor, Department of Pharmacology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh; <sup>2</sup>Professor, Department of Pharmacology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh; <sup>3</sup>Associate Professor, Department of Pharmacology, Dhaka Medical College, Dhaka, Bangladesh; <sup>4</sup>Assistant Professor, Department of Pharmacology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh; <sup>5</sup>Associate Professor, Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh; <sup>6</sup>Associate Professor, Department of Pharmacology, National Institute of Neurosciences & Hospital, Dhaka, Bangladesh

### Abstract

**Background:** *Allium sativum* (Garlic) has different role in the metabolism of the body. **Objective:** The purpose of the present study was to see the ability of *Allium sativum* (Garlic) for the removal of arsenic from isolated liver tissues of experimental rat. **Methodology:** This animal study was carried out on isolated liver tissues of Long Evans Norwegian adult healthy male rats weighing 160 to 200 g. The rats were 3 to 6 months of age obtained from animal house of Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh January 2004 to December 2005 for a period of two years. Measurements and all tasks were performed in a very careful manner. Atomic Absorption Spectrophotometer with Hydride Generator was used to measure the arsenic level. Extracts of garlic were supplied from the Department of Pharmacology, BSMMU. Hexane and methanol (G1 and G2) extracts of *Allium sativum* (Garlic) were studied. **Result:** Accumulation of arsenic in liver tissues of rat after incubation with arsenic was  $249.02 \pm 21.16$   $\mu\text{g/g}$  of protein. After extraction of hexane extract the amount of arsenic was  $22.80 \pm 5.98$   $\mu\text{g/g}$  of protein. There was 94.19% removal of arsenic compared with the arsenic loaded value. The calculated value was statistically significant ( $p < 0.001$ ). **Conclusion:** In conclusion hexane extract of *Allium sativum* (garlic) has the ability to remove the arsenic from the experimental liver tissue of rat. [*Journal of Army Medical College Jashore July 2022;2(2):50-54*]

**Keywords:** *Allium sativum*; arsenic; liver tissues; experimental rat

### Introduction

Mass contamination of ground water with toxic level of arsenic has reported in Bangladesh<sup>1</sup>. Underground water collected through hand pump is primary source of drinking water in Bangladesh. Before introduction of deep tube well the surface water is the source of water of human use throughout Bangladesh. However, this ground water

becomes a source of chronic arsenic poisoning which is known as arsenicosis. There are 57 million people are suffering from arsenicosis of which 69.0% cases are malnourished<sup>2</sup>.

Withdrawal of further intake of arsenic contaminated water improves cases; however, chelation therapy, vitamins and nutritious diet enhance the recovery<sup>3</sup>. Arsenic is a hydride gas with potent hemolytic effects and it is manufactured predominantly for use in the semiconductor industry; however, it may also be generated accidentally when arsenic containing ores come in contact with acidic solutions<sup>4</sup>. It is of historical interest that Fowler's solution, which contains 1% potassium arsenite, is widely used as a medicine for many conditions from the eighteenth century

**Correspondence:** Dr. Andalib Mustafa Iqbal Ira, Associate Professor, Department of Pharmacology, National Institute of Cardiovascular Diseases, Sher-E-Bangla Nagar, Dhaka, Bangladesh; Email: andalibira0104@gmail.com; Cell No.: +8801713121793; ORCID: <https://orcid.org/0000-0003-3589-8044>

through the mid twentieth century<sup>5</sup>. Organic arsenicals were the first pharmaceuticals antibiotics and were widely used for the first half of the twentieth century until supplanted by penicillin and other more effective and less toxic agents<sup>6</sup>.

Bangladesh has a poor socioeconomic structure. Rural people are largely has to use ground water for their everyday household work. Contamination of potable water (well water) with arsenic is a serious problem in Bangladesh. Arsenic contamination in shallow tube well in Ganges Delta area including Bangladesh has been reported in recent decade<sup>7</sup>. Arsenic contamination in Bangladesh is the severest in the world and it has been estimated that about 80 million people in Bangladesh are exposed to high level of arsenic contamination<sup>1</sup>. There are about 11 million tube wells in Bangladesh out of which 5 million tube wells are highly arsenic contaminated and about 57 million people of the affected districts are at risk and total number of patients suffering from arsenicosis are more than 40,000 and out of which about 200 persons already died<sup>8</sup>.

In an effort to find out scientific basis for a more cost-effective approach to management of arsenicosis, the present study was undertaken. The extracts of garlic have been studied on arsenic loaded isolated liver tissues of rat.

### Methodology

The experimental animal study was conducted in the Department of Pharmacology at Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh from January 2004 to December 2005 for a period of two years. This experiment was carried out on isolated liver tissues of Long Evans Norwegian adult healthy male rats. The rats were 3 to 6 months of age weighing 160 to 200 gram and was obtained from animal house of Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh. These were housed in standard plastic cages with a light or dark cycle of 12 hours at room temperature in a well-ventilated room. Extracts of *Allium sativum* (garlic) were supplied from the Department of Pharmacology at Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh. Hexane and methanol (G1 and G2) extracts of garlic were studied in order to prepare stock solution of arsenic trioxide (As<sub>2</sub>O<sub>3</sub>) 2 mg/ml, 132 mg of As<sub>2</sub>O<sub>3</sub> was taken in a 50 ml volumetric flask. Then the ingredients of Tyrode solution were added and 5N NaOH was added up to the 50 ml mark. Finally, the stock solution was preserved in a refrigerator and labeled as stock solution (2 mg/ml). By giving a midline incision, the abdomen was opened and the liver was taken out and it was immediately immersed into Tyrode solution. The beaker containing Tyrode solution was always kept in ice bath and the temperature of Tyrode solution was maintained at 0 to 40 C. By keeping isolated liver tissues in Tyrode solution, it was chopped into 2 mm X 2 mm X 2 mm size. The procedure was conducted in a Petri dish that was kept also on an ice bath to maintain the temperature at 0 to 40 C. There were two sets of test tubes and labeled appropriately. Each sample had duplicate. All the test tubes were placed in ice bath. Sample I (test tube 1 and 2) contained only 2 ml

Tyrode solution and it was considered as blank (none, no arsenic or no extracts were added). Twenty milliliter Tyrode solution was taken in a beaker and 25 mL of stock solution of As<sub>2</sub>O<sub>3</sub> (2 mg/ml) was added to the beaker. Thus the final concentration of As<sub>2</sub>O<sub>3</sub> was 2.5 gm/ml in that beaker's solution. From this beaker 2 ml Tyrode solution was added to each test tube (except test tube 1 and 2). Then 20 pieces of chopped liver tissues were added to each test tube. All the test tubes were placed in water bath with shaker for 45 minutes at 370 C. The reaction was stopped by placing the test tubes immediately into ice bath. The tissues were washed with Tyrode solution for two times to remove loosely bound arsenic externally. Before second incubation extracts that would be examined were added to the samples except sample I (test tube 1 and 2) and sample II (test tube 3 and 4), as they were considered as blank and standard. Second incubation was for 45 minutes at 370 C in water bath with shaker. After second incubation all test tubes were immediately placed under ice bath as before. These all were washed with Tyrode solution and again placed under ice bath. All tissues were, then homogenate by hand tissue homogenizer and made up to 5 ml with deionized water. From these homogenates, 20 µl for protein and 1 ml for glutathione estimation were separated. Rests of the homogenates were digested for arsenic estimation.

Table 1: Experimental Design for *Allium sativum* (Garlic)

Sample No.	Incubation of liver tissues of rat with During 1s' Incubation*	During 1s' Incubation*
I	None (Blank)	None
II	Arsenic 2.5 µg/ml	None
III	Arsenic 2.5 gg/ml	G1 (Hexane extract 20 Uml)
IV	Arsenic 2.5 gg/ml	G2 (Methanol extract 20 tl/ml)
V	Arsenic 2.5 µg/ml	G1 + G2 (Hexane + Methanol extract = (10 µUml +10 µl/ml)

\*Each incubation was for 45 minutes at 370 C; None = no arsenic or extracts were added; All tissues were washed twice properly after both incubations with Tyrode solution

### Results

The effects of extracts of garlic, Gi (hexane) and G2 (methanol) on the removal of arsenic from the arsenic loaded liver tissues of rat have been shown. Only twenty small pieces of liver tissues were incubated in 2 ml Tyrode solution in sample number I. There was no arsenic added in both 1st and 2nd incubation. The amount of arsenic was found  $7.23 \pm 3.51$  gg/g (mean  $\pm$  se) of protein. This value was termed as none (blank). In the first incubation liver tissues were incubated with 2.5 gg/ml of arsenic for 45 minutes at 37°C and nothing was added in second incubation. The amount of accumulated arsenic in the tissues was  $249.02 \pm 21.16$  tg/g of protein and this was considered as standard. The value of none was deducted from the value of standard and the value of control was determined. The value of control was estimated as  $241.79 \pm$

Table 2: Removal of Arsenic by Different Extracts of Garlic from Isolated Liver Tissues of Rat

Number of Sample	Incubation of Liver Tissues of Rat Wit		n	Amount of Arsenic $\mu\text{g/g}$ of Protein (Mean $\pm$ SE)	Removal of Arsenic	P value
	1st Incubation	2nd Incubation				
I	None (blank)	None	6	7.23 + 3.51	-	-
II	Arsenic 2.5 $\mu\text{g/ml}$ (standard)	None	6	249.02 $\pm$ 21.16	-	-
III	Arsenic 2.5 $\mu\text{g/ml}$	G1 (Hexane extract) <sup>1</sup>	6	22.80 $\pm$ 5.98	94.19%	<0.0014
IV	Arsenic 2.5 $\mu\text{g/ml}$	G2 (Methanol extract) <sup>2</sup>	6	210.60 $\pm$ 16.51	15.77%	NS5
V	Arsenic 2.5 $\mu\text{g/ml}$	G1 + G2 (Hexane + Methanol) <sup>3</sup> extract	6	136.40 $\pm$ 14.23	46.48%	NS

Each incubation was for 45 minutes at 370 C; Control was (249.02  $\pm$  21.16 - 7.23  $\pm$  3.5 1= 241.79  $\pm$  65). Sample values were compared with control; G1 (Hexane extract) - 20  $\mu\text{l/ml}$ ; G2 (Methanol extract) - 20  $\mu\text{l/ml}$ ; G, +G2 (Hexane extract 10  $\mu\text{l/ml}$  +Methanol extract-10  $\mu\text{l/ml}$ )

17.65  $\mu\text{g/g}$  of protein. None was deducted from all sample values and those values were compared with control. The arsenic loaded tissues were incubated for the second time with G1 extract (hexane extract of garlic, 20  $\mu\text{l/ml}$ ) for another 45 minutes at 37°C and the amount of arsenic was reduced to 22.83  $\pm$  5.98  $\mu\text{g/g}$  of protein. There was 94.19 % removal of arsenic. This difference was statistically highly significant using student's 't' test (P<0.001). The arsenic loaded tissues were also incubated with G2 (methanol extract, 20  $\mu\text{l/ml}$ ) for 45 minutes at 370 C and the amount of arsenic was reduced to 210.60  $\pm$  16.51  $\mu\text{g/g}$  of protein. The removal of arsenic was 15.77%. This difference was statistically not significant by student's 't' test. Combination of G1 + G2 (hexane and methanol) extracts of garlic (10  $\mu\text{l/ml}$  + 10  $\mu\text{l/ml}$ ) were added to arsenic loaded tissues for 45 minutes at 37°C and the amount of arsenic was reduced to 136.40  $\pm$  14.23  $\mu\text{g/g}$  of protein. This time removal of arsenic was only 46.48 %. This difference was statistically not significant calculating through student's 't' test (Table 2).

accumulated arsenic from isolated liver tissues of rat and prevented depletion of intracellular glutathione. This work is very important in present perspective of Bangladesh when arsenicosis has been reported as the largest environmental health hazard in the world and there is no specific treatment. The results revealed that the hexane extract of garlic reduced accumulated arsenic from isolated liver tissues of rat and the value was highly significant. These cause less depletion of glutathione from arsenic loaded tissues. It is thought that the cytotoxic action of arsenic is mediated through the generation of free radicals induced by the element<sup>9</sup>. The efficiency of antioxidant system is also important for detoxification of free radicals. It was suggested that arsenic could suppress the activities of antioxidants in the liver of rats<sup>10</sup>.

Garlic is moderately soluble in hexane and non-polar. The curative action of garlic has been shown for a long time<sup>11</sup>. It was previously shown the chemoprotective role of diallyl disulfide (DADS), a naturally occurring anticancer agent in garlic. They also increase the amount of glutathione in the liver and for stomach tissue of mice treated with diallyl monosulfide to diallyl disulfide<sup>12</sup>. It has been found that the sulfur compound found in garlic reacts with cysteine, which involves the thiol disulphide exchange and oxidation of garlic sulfur compounds, and cysteine of the animal tissue thereby brings about some changes in quantities of glycogen, lipid and protein etc. It is suggested that synthesis of protein is increased by garlic<sup>13</sup>.

Arsenic is an important toxicant, which has both natural and industrial sources<sup>14</sup>. Arsenic predominantly exists in two oxidation states As (v) and As (III) and each species hypothesized to act through different mechanisms<sup>11</sup>. A number of intracellular reducing agents, such as ascorbate, vitamin E and beta-carotene are able to reduce and thus detoxify oxygen intermediates in cells. Consumption of foods rich in these 'antioxidant' compounds has been correlated with a reduced risk of certain types of cancer as well as decreased frequency of other chronic health problems<sup>15</sup>.

In the present hexane extracts of garlic tried to recover the depletion of glutathione from arsenic loaded tissues that can be important to detoxify arsenic trioxide. Methylation is considered the detoxification pathway of inorganic arsenic and it occurs mainly in liver<sup>16</sup>. Population thriving on diets low in methionine is likely to suffer more from arsenic toxicity due to decreased methylation and increased accumulation of inorganic arsenic. The mechanisms by which hexane extracts of garlic caused removal of arsenic

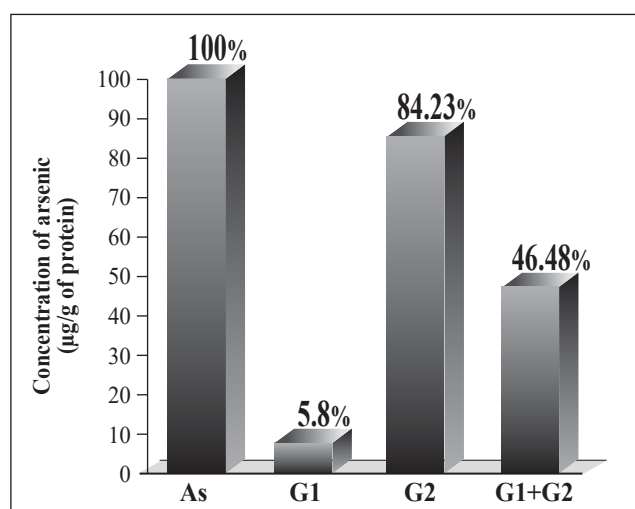


Figure I: Effects of different extracts of garlic on arsenic loaded (2.5  $\mu\text{g/ml}$ ) tissues in second incubation (G1 extract = Hexane - 20  $\mu\text{l/ml}$ ; G2 extract = Methanol- 20  $\mu\text{l/ml}$ ; (G1 + G2) Hexane + Methanol extract = (10  $\mu\text{l}$ +10  $\mu\text{l}$ /ml)

## Discussion

The present study was carried out to experiment whether the hexane and methanol extracts of garlic could remove the

from liver tissues and recovered depletion of glutathione is not known.

Glutathione may enhance elimination of arsenic by producing metabolites (MMA, DMA), which are mainly excreted by kidneys<sup>17</sup>. It was found that garlic increased the amount of glutathione in the liver of mice. Among other functions, glutathione participates in reductive processes that are essential for the synthesis and degradation of proteins and in the protection of cells against reactive oxygen compounds and free radicals. It can also act as a coenzyme for several enzymatic reactions and transport form of cysteine<sup>18</sup>. A decrease in the glutathione level of hepatocyte rat primary culture has been studied. The recovery of the normal levels of this thiol and its stabilization can be obtained by addition of methionine. The link between methionine metabolism and glutathione synthesis is established through cysteine. The amino acid can be obtained from the diet or it can be synthesized from methionine through the transsulfuration pathway in the liver.

### Conclusion

In conclusion hexane extract of *Allium sativum* (garlic) has the ability to remove the arsenic from the experimental liver tissue of rat. Arsenic is metabolized by living system using oxidation, reduction and methylation reactions. Reduced glutathione has been shown to be important in that metabolism. Though here specific studies will be needed to find out the mechanisms of action, the present study indicates that hexane extract of garlic may be of value in the removal of arsenic.

### Acknowledgements

None

### Conflict of Interest

The authors have no conflicts of interest to disclose

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### Authors' contributions

Andalib Mustafa Iqbal Ira: Conceptual work, data collection, Report writing, manuscript writing; Mir Misbahuddin: Supervisor; Sujit Kumar Sarker: Data Collection; Shakila Akter: Help in Laboratory Works; Sheikh Ziarat: Manuscript correction; Sabina Jesmin: Manuscript correction

### Data Availability

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

### Ethics Approval and Consent to Participate

Ethical approval for the study was obtained from the Institutional Review Board. The written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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# Diagnostic Validity of Ultrasonography for the Detection of Macrosomia among Pre-gestational and Gestational Diabetic Pregnant Women

Shamsun Nahar<sup>1</sup>, Kashefa Khatun<sup>2</sup>, AS Mohiuddin<sup>3</sup>, Selina Akter<sup>4</sup>

<sup>1</sup>Junior Consultant (Gynaecology & Obstetrics), Upazila health Complex, Sonaimuri, Noakhali, Bangladesh; <sup>2</sup>Associate Professor, Department of Gynaecology & Obstetrics, Shaheed Suhrawardy medical College, Dhaka, Bangladesh; <sup>3</sup>Professor & Head, Department of Radiology & Imaging, Bangladesh Institute of Research and Rehabilitation for Diabetes, Endocrine and Metabolic Disorders, Dhaka, Bangladesh; <sup>4</sup>Senior Consultant, Department of Obstetrics & Gynaecology, Central Police Hospital, Rajarbag, Dhaka, Bangladesh

## Abstract

**Background:** Ultrasonography is frequently used to evaluate the pregnancy profiles. **Objective:** The purpose of the present study was to see the diagnostic validity of ultrasonography for the detection of macrosomia among pre-gestational and gestational diabetic pregnant women. **Methodology:** This cross-sectional study was carried out in inpatient Department of Obstetrics and Gynecology and in outpatients Department of Radiology and Imaging at BIRDEM, Dhaka, Bangladesh during the period of April 2005 to March 2007. Pregnant women with diagnosed case of DM or GDM selected for caesarean section or induction of labour, gestational age of 36 weeks having 2370 gm by clinical method were included in this study. First clinical estimation of fetal weight was done by the investigator; then estimation by ultrasonography of the fetal weight was performed without knowing the expected fetal weight by clinical method. The actual birth weight was estimated after the birth of the babies. **Results:** A total number of 69 pregnant women were recruited for this study. The mean age of the study population was 30.8 years with standard deviation 15.1 years. The mean ( $\pm$ SD) sonographically estimated fetal Weight was 4095.6 $\pm$ 287.7.1 gm. The mean ( $\pm$ SD) actual birth weight was 4169.5 $\pm$ 397.1 gm. The difference between sonographically estimated fetal weight and actual birth weight was not statistically significant. The sensitivity, specificity and accuracy of sonographic evaluation of macrosomia were 68.2%, 52.0% and 62.3% respectively. **Conclusion:** In conclusion the diagnostic accuracy of ultrasonography for the detection of macrosomia is medium among pre-gestational and gestational diabetic pregnant women. [Journal of Army Medical College Jashore July 2022;2(2):55-59]

**Keywords:** Diagnostic validity; ultrasonography; macrosomia; pre-gestational; gestational diabetic; pregnant women

## Introduction

Diabetes mellitus (DM) complicating pregnancy may be classified as presentational DM & Gestational DM<sup>1</sup>. Pregestational diabetes affects approximately 1 to 3 pregnancies per 1000 birth<sup>2</sup>. Many women come for medical care for the first time during pregnancy. Gestational diabetes mellitus (GDM) is defined as glucose intolerance that has its onset or first recognition during pregnancy and it complicates approximately 3.0 to 4.0% of pregnancies<sup>3</sup>.

**Correspondence:** Dr. Shamsun Nahar, Junior Consultant (Gynaecology & Obstetrics), Upazila Health Complex, Sonaimuri, Noakhali, Bangladesh; Email: drsweety.nahar@gmail.com; Cell no.: +8801775339803

Evaluating fetal weight is an important part of obstetrics<sup>4</sup>. Accurate estimation can help in deciding the timing and mode of delivery of macrosomic fetuses. Methods of evaluating fetal weight include clinical and ultrasonographic methods. Since ultrasonographic facilities are expensive, not easily available and trained personnel are required, it would be immensely useful to know if other simpler clinical methods can estimate fetal weight with the same degree of accuracy<sup>5</sup>.

In a study clinical estimates of fundal height and fetal size and ultrasound estimates of abdominal circumference and head circumference were routinely carried out of gestational age of 28, 34 and 38 weeks or before delivery<sup>6</sup>.



Prediction improves with closeness to delivery. There is no difference in the prediction power for macrosomia between clinical and ultrasound measurement. In the above context the present work has been designed to correlate the clinical findings of macrosomia with ultrasonographic findings of macrosomia in pregestational and gestational diabetic mothers and actual birth weight<sup>7-10</sup>. The purpose of the present study was to see the diagnostic validity of ultrasonography for the detection of macrosomia among pre-gestational and gestational diabetic pregnant women.

**Methodology**

This was a prospective cohort study. This study was carried out in the department of Obstetrics and Gynecology, BIRDEM in collaboration with the department of Radiology and Imaging department of the same institute. The study was carried out for a period of two years from April 2005 to March 2007. Prior to the commencement of this study, the research protocol was approved by the Local Ethical Committee of BIRDEM Academy. Pregnant women with pregestational and gestational diabetes mellitus having fasting blood sugar level 2 6.1mmol/l aged from 20-40 years and gestational age 236 Weeks admitted in inpatient Department of Obstetrics and Gynecology, BIRDEM and attending in outpatient Department of Radiology and Imaging of the same institute are selected as subjects. Non-randomized consecutive sampling. Pregnancy with 36 weeks with diagnosed pregestational DM and GDM selected for caesarean section or induction of labour, accurate gestational age regular menstrual cycle with exact last menstrual period and having early ultrasonography, longitudinal lie, cephalic presentation, intact membranes and estimated fetal weight by clinical method were included in this study. Pregnancy less than 36 weeks, pregnancy with pregestational DM or GDM with complication like hypertension, ketoacidosis or presence of uterine tumour or ruptured membranes, malpresentation, multiple pregnancies, diagnosed fetal anomaly, excessive obesity of the mothers where symphysio-fundal height cannot be easily measured, were excluded from this study. Written consent was taken from the patients. Ultrasonographic estimation of fetal weight was done by a Radiologist without knowing the estimated fetal weight by clinical method. Birth weight was estimated by calibrated weight machine. The data sheets were 100% scrutinized to check the quality of the raw data. The hundred percent cross check were done after editing. Collected data were entered into the computer and processed by it. Data were analyzed by, software SPSS (Statistical Package for Social Science). Paired ‘t’ test and Chi-square test were used where it was applicable. The results were presented in Tables and Figures and were expressed as mean with Standard Deviation. For the validity of the study outcome, sensitivity, specificity and accuracy of clinical estimation of fetal Weight and sonographic estimation of fetal weight were calculated. The relationship between clinical estimation of fetal weight, sonographic estimation of fetal weight and actual birth weight was

examined using Pearson’s “coefficient correlation (r) analysis. Difference was considered statistically significant if p value was less than 0.05.

**Results**

A total number of 69 pregnant women were recruited for this study. The mean age of the study population was 30.8 years with standard deviation 15.1 years and ranged from 20 to 40 years. The maximum pregnant woman was found between 26 to 30 years age range (Table 1).

Table 1: Age Distribution of the Study Subjects (n=69)

Age Group	Frequency	Percent
20 to 25 Years	27	39.1
26 to 30 Years	30	43.5
31 to 35 Years	8	11.6
36 to 40 Years	4	5.8
<b>Total</b>	<b>69</b>	<b>100.0</b>
Mean±SD	30.8±15.1 (Years)	

The mean (±SD) gestational age of the subjects was 37.5±1.5 weeks and ranged from 36 to 41 weeks. Highest (39.1%) percentage was found in 37 weeks of gestation and lowest (4.3%) was in 41 weeks of gestation (Table 2).

Table 2: Distribution of Gestational Age (n=69)

Gestational Age	Frequency	Percent
36 weeks	16	23.2
37 weeks	27	39.1
38 weeks	10	14.5
39 weeks	9	13.0
40 weeks	4	5.8
41 weeks	3	4.3
<b>Total</b>	<b>69</b>	<b>100.0</b>
Mean±SD	37.5±1.5 Weeks	

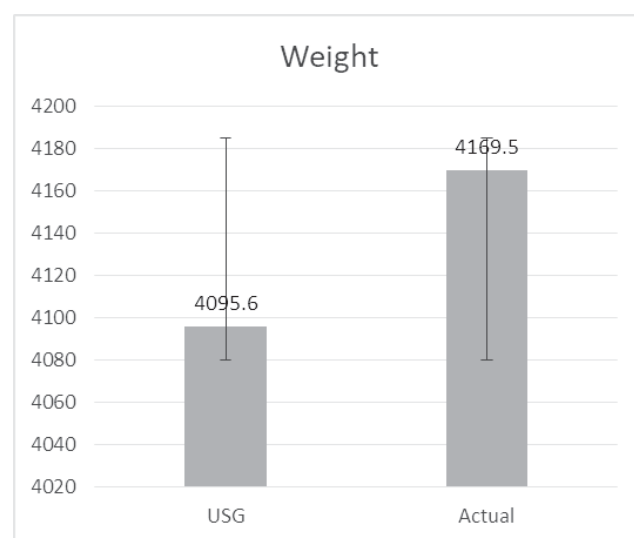


Figure 1: Mean Distribution of Sonographically Estimated Fetal Weight and Actual Birth Weight (p=0.054)

The mean ( $\pm$ SD) sonographically estimated fetal Weight was 4095.6 $\pm$ 287.7.1 gram. The mean ( $\pm$ SD) actual birth weight was 4169.5 $\pm$ 397.1 gram. The difference between sonographically estimated fetal weight and actual birth weight was not statistically significant ( $p > 0.05$ ) (Figure I).

The USG assessment of macrosomia and actually observed macrosomia were compared. It was found that in 60.9% cases macrosomia and rest 39.1% .cases was normal birth weight at USG diagnosis; whereas after taking actual birth weight 63.8% case was macrosomic and rest 36.2% was normal birth weight. The difference between sonograpgraphically estimated macrosomia and actual macrosomia was not statistically significant (as here  $p > 0.05$ ) (Table 3).

Table 3: Comparison between Sonographically Measured Macrosomia and Actual Birth weight (n=69)

Weight	USG Estimated	Actual Birth weight
Macrosomia	42(60.9%)	44(63.8%)
Normal BW	27(39.1%)	25(36.2%)
<b>Total</b>	<b>69(100.0%)</b>	<b>69(100.0%)</b>

BW=Birth weight; Chi-square test as performed to see the level of significance; p value=0.725

The pregnant women having macrosomia diagnosed sonographically were associated with the actual birth weight. Out of 69 cases 44 cases had findings of macrosomia and 25 .cases were negative for macrosomia (normal) in actual birth weight. Whereas in USG findings detected 42 cases as macrosomia and 27 cases as normal. Out of these 42 macrosomic cases detected sonographically 30 cases were actually macrosomia and 12 cases were normal after birth. Out of 27 normal cases detected sonographically 14 cases were macrosomic and 13 cases were actually normal. The difference between sonographically detected macrosomia and actual macrosomia, between sonographically detected normal and actual normal cases was not statistically significant ( $p > 0.05$ ) (Table 4).

Table 4: Association between USG Diagnosis of Macrosomia and Actual Birth Weight (n=69)

USG Diagnosis	Actual Macrosomia	
	Present	Absent
Macrosomia Present	30	12
Macrosomia Absent	14	13
<b>Total</b>	<b>44</b>	<b>25</b>

Chi-square test as performed to see the level of significance; p value=0.098

The sensitivity, specificity and accuracy of sonographic evaluation of macrosomia were 68.2%, 52.0% & 62.3% respectively (Table 5).

Table 5: Sensitivity, Specificity and Accuracy of Ultrasonography in Evaluation of Macrosomia

Validity Test	Values	95% CI
Sensitivity	68.2%	52.42% to 81.39%
Specificity	52.0%	31.31% to 72.20%
PPV	71.43%	61.33% to 79.76%
NPV	48.15%	34.35% to 62.23%
Accuracy	62.3%	49.83% to 73.71%

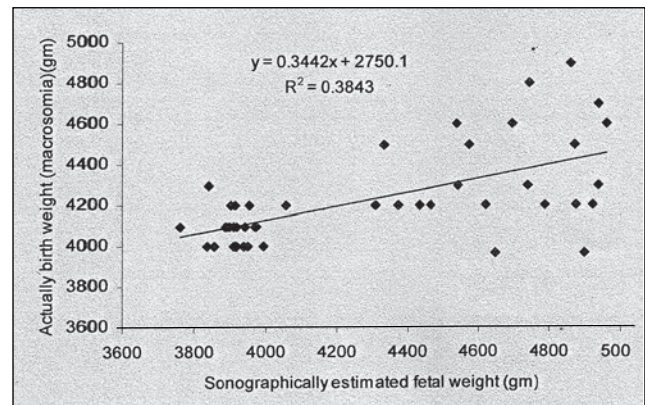


Figure II: The scatter diagram shows significant relationship ( $r=0.6199$ ) between sonographically estimated fetal weight (gm) and actual birth weight (macrosomia) (gm)

Sonographically estimated fetal weight (gm) of 69 cases were expressed in gm and actual birth weight (macrosomia) were also expressed in gm. A significant positive correlation was found between sonographically estimated fetal weight (gm) and actual birth weight (macrosomia) (gm). The value of Pearson's correlation coefficient was 0.6199 and it was significant ( $p < 0.05$ ). Therefore, there was significant correlation sonographically estimated fetal weight (gm) and actual birth weight (macrosomia) (gm) in the study population (Figure II).

**Discussion**

Macrosomia is generally used to refer to fetuses with an estimated fetal weight greater than or equal to 4000 gram<sup>11</sup>. Nahum<sup>12</sup> with his colleagues developed an equation for predicting fetal macrosomia based on maternal demographic and pregnancy-specific factors alone and by using this equation, they predicted term birth and they choose a cut off value of 3775g for prediction of fetal macrosomia. Several studies have documented mean errors of estimation of fetal weight by clinical method is about 300 gram<sup>13</sup>. In the above context, this study included clinically estimated fetal weight 3700 gram as inclusion criteria for macrosomia though macrosomia actually means 4 kg<sup>14</sup>. This prospective study was carried out with an aim to correlate the clinical evaluation of macrosomia with ultrasonographic evaluation of macrosomia in diabetic mother and actual birth weight. A total number of 69 pregnant women were recruited for this study. The mean age of the study population was 30.8 years with standard deviation 15.1 years and ranged from 20 to 40 years. The maximum pregnant woman was found between 26 to 30 years age range and minimum was found between 36 to 40 years age range. Several studies have documented

mean errors of estimation of fetal weight by clinical method is about 300 gram<sup>15</sup>.

This study was carried out with an aim to correlate the macrosomia with ultrasonographic evaluation of macrosomia in diabetic mother and actual birth weight. Banerjee et al<sup>16</sup> have also made almost identical observations. According to that study clinical method of evaluating fetal weight is as good as ultrasonographic estimation. The difference between between sonographic evaluation of macrosomia and actual macrosomia was not statistically significant.

Sonographically estimated fetal weight (gram) of 69 cases were expressed in gram and actual birth weight (macrosomia) were also expressed in gm. A significant positive correlation was found between sonographically estimated fetal weight (gram) and actual birth weight (macrosomia) (gram). The value of Pearson's correlation coefficient was 0.6199 and it was significant ( $p < 0.05$ ). Therefore, there was significant correlation sonographically estimated fetal weight (gram) and actual birth weight (macrosomia) (gram) in the study population. In the present study, it was observed that sensitivity, specificity and accuracy of clinical evaluation of macrosomia were 61.4%, 52.0% and 58.0% respectively and of ultrasonographic evaluation of macrosomia were 68.2%, 52.0% and 62.3% respectively.

Nahum and Stanislaw<sup>12</sup> studied different techniques like clinical estimation, patients' self-estimation, sonographic estimation and maternal characteristics for predicting term fetal macrosomia. The sensitivity and specificity of clinical and sonographic estimation of that study was 54.0% & 95.0% and 59.0% & 90.0% respectively. The findings are in agreement with the present study. There was a significant correlation between clinically estimated fetal weight and actual birth weight, between sonographically estimated fetal weight and actual birth weight and between clinically and sonographically estimated fetal weights in the study population.

The pregnant women having macrosomia diagnosed sonographically were associated with the actual birth weight. Out of 69 cases 44 cases had findings of macrosomia and 25 cases were negative for macrosomia (normal) in actual birth weight whereas in USG findings detected 42 cases as macrosomia and 27 cases as normal. Out of these 42 macrosomic cases detected sonographically 30 cases were actually macrosomia and 12 cases were normal after birth. Out of 27 normal cases detected sonographically 14 cases were macrosomic and 13 cases were actually normal. The difference between sonographically detected macrosomia and actual macrosomia, between sonographically detected normal and actual normal cases was not statistically significant ( $p > 0.05$ ). Noumi et al<sup>16</sup> have shown that coefficient of correlation between the clinical and sonographic EFW and the actual birth weight were 0.62 ( $p < 0.001$ ) and 0.66 ( $p < 0.001$ ) respectively. The sensitivity, specificity, positive and negative predictive values of predicting macrosomia by both modalities were 50.0%, 95.0%, 97.0% and 50.0%, 97.0%, 50.0% and 97.0% respectively. The results of the present study agree with these investigations.

From the results of the present findings as well as the findings obtained by a number of investigators, it is

conceivable that clinical method can be used instead of ultrasonography for prediction of macrosomia in diabetic mother. However, further studies are recommended to use clinical method for prediction of macrosomia in diabetic mother.

### Conclusion

In conclusion the difference between sonographically estimated macrosomia and actual macrosomia was not statistically significant. Again, the difference between sonographically detected macrosomia and actual macrosomia, between sonographically detected normal and actual normal cases was not statistically significant. Estimation of macrosomia by the above methods correlates well with the actual birth weight. As the study was conducted with a small number of subjects, further study may be undertaken in future with large number of subjects.

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The authors have no conflicts of interest to disclose

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### Authors' contributions

Nahar S: Conceptual work, data collection, Report writing, manuscript writing; Khatun K: Data Collection; Mohiuddin AS, Akter S: Manuscript correction

### Data Availability

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

### Ethics Approval and Consent to Participate

Ethical approval for the study was obtained from the Institutional Review Board. The written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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# Different Clinical Types with their Bacteriological Etiology of Neonatal Sepsis: A Review Update

Rafia Afreen Jalilin

Assistant Professor, Department of Microbiology, Green Life Medical College, Panthopath, Dhaka, Bangladesh

## Abstract

Sepsis is a significant cause of mortality and morbidity in the newborn, particularly among those of very low birth weight and premature infants. The World Health Organization (WHO) estimates that worldwide 1.6 million newborn babies die every year from neonatal infections. Individual units have reported case fatality rates as low as 2 to 3% and as high as 50%, but the average overall mortality from neonatal sepsis reported from many neonatal intensive care units in developed countries is around 20%. Despite recent advances in neonatal intensive care and current strategies to treat neonatal sepsis, mortality rates have not fallen for over three decades except in babies born to mothers who have received intrapartum prophylaxis for Group B Streptococcus (GBS). Whilst intrapartum prophylaxis has been successful in significantly reducing the incidence of early onset Group B Streptococcus disease in the newborn it has led to an increase in Gram negative infections in institutions where antibiotics other than penicillin are used for intrapartum prophylaxis. However, both short and long term neurodevelopmental morbidity in survivors of neonatal sepsis is also significant. [*Journal of Army Medical College Jashore July 2022;2(2):60-63*]

**Keywords:** Clinical types; bacteriological etiology; neonatal sepsis

## 1.0. Introduction

The term neonatal sepsis is used to designate a systemic condition of bacterial, viral, or fungal (yeast) origin that is associated with haemodynamic changes and other clinical manifestations and results in substantial morbidity and mortality<sup>1</sup>. It is defined as a clinical syndrome characterized by signs and symptoms of infection with or without accompanying bacteremia in the first month of life. It encompasses various systemic infection of the newborn such as septicaemia, meningitis, pneumonia, arthritis, osteomyelitis etc. Superficial infections like thrush are not included in neonatal sepsis<sup>2</sup>.

## 2.0. Classification

Neonatal sepsis can be classified into two subtypes depending upon whether the onset of symptoms is within 72 hours of life (Early Onset Neonatal Sepsis-EONS) or later

(Late Onset Neonatal Sepsis-LONS). A few papers distinguish between very early onset (within 24 hours), EONS (24 hours to six days), and LONS (more than six days)<sup>3</sup>. Very late onset sepsis is demarcated by onset at >30 days of age. These definitions have contributed greatly to diagnosis and treatment by identifying which microorganisms are likely to be responsible for sepsis during these periods and the expected outcomes of infection<sup>4</sup>.

## 3.0. Early-Onset Neonatal Sepsis

Early-onset neonatal sepsis (EONS) has been variably defined based on the age at onset with bacteremia or bacterial meningitis occurring at  $\leq 72$ h in infants hospitalized in the neonatal intensive care unit (NICU), versus less than 7 days in term infants<sup>5-7</sup>. In preterm infants, EONS is most consistently defined as occurring in the first 3 days of life and is caused by bacterial pathogens transmitted vertically from mother to infant before or during delivery<sup>6</sup>. Early-onset infections are caused by organisms present in the maternal genital tract. It can occur due to ascending infection following rupture of membranes or during the passage of the baby through infected birth

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**Correspondence:** Dr. Rafia Afreen Jalil, Assistant Professor, Department of Microbiology, Green Life Medical College, Panthopath, Dhaka, Bangladesh; Email: [rafiaafreen133@gmail.com](mailto:rafiaafreen133@gmail.com); Cell no.: +8801784662404



canal and at the time of resuscitation<sup>8</sup>.

### 3.1. Risk Factors of Early-Onset Neonatal Sepsis

Risk factors for early-onset sepsis include foetal factor and maternal factor. Prematurity, low birth weight, congenital anomaly and low APGAR score are important risk factors. Maternal risk factors include prolonged rupture of membranes (>18 hours), maternal fever, difficult or prolonged labour, urogenital infection, chorioamnionitis, aspiration of meconium, vaginal colonization with Group B Streptococcus (GBS) and Group B Streptococcus bacteriuria<sup>5</sup>. Poor or late prenatal care, low socioeconomic status of the mother, poor maternal nutrition, maternal substance abuse, male sex, ethnic and social factors are associated with neonatal sepsis<sup>9</sup>.

### 3.2. Etiology of Early-Onset Neonatal Sepsis

The organisms most frequently involved in early onset neonatal sepsis of term and preterm infants together are Group B Streptococcus and Escherichia coli, which account for approximately 70% of infections combined. Additional pathogens to consider, which account for the remaining minority of cases, are other Streptococci which is the most commonly viridians group Streptococci species but also Streptococcus pneumoniae<sup>10</sup>, Staphylococcus aureus, Enterococcus species, Gram-negative enteric bacilli such as Enterobacter species, Haemophilus influenzae virtually all nontypeable Haemophilus spp. in the Haemophilus influenzae type b [Hib] vaccine era and Listeria monocytogenes<sup>10-12</sup>. When preterm and VLBW infants are considered separately, the burden of disease attributable to Escherichia coli and other gram-negative rods is increased, making Gram-negative sepsis the most common etiology of EONS in this population<sup>6,10</sup>.

### 3.3. Habitat of Organism of Early-Onset Neonatal Sepsis

In pregnancy, Group B Streptococcus is harbored asymptotically in mucous membrane sites including the genital, rectal, and pharyngeal mucosa. Escherichia coli harbours in intestine. Viridans Streptococci are resident flora of mouth and urogenital tract.

### 3.4. Pathophysiology

Early-onset neonatal sepsis occurs in utero from either a transplacental or, more commonly, ascending bacteria entering the uterus from the vaginal environment following membrane rupture. Additionally, the newborn child might become infected when exposed to potentially pathogenic bacteria, viruses, or fungi during passage through the birth canal. The human birth canal is colonised with aerobic and anaerobic bacterial organisms that can be vertically transmitted from an ascending infection of the amniotic fluid or natal infection of the neonate<sup>13</sup> during labour or delivery<sup>14</sup>. Though the intensity of maternal colonization is directly related to risk of invasive disease in the neonate, many mothers with low-density colonization give birth to infants with high-density colonization who are therefore at

risk. Amniotic fluid contaminated with meconium or vernix caseosa promotes growth of group B Streptococcus and Escherichia coli. Hence, the few organisms in the vaginal vault are able to proliferate rapidly after PROM, possibly contributing to this paradox. Organisms usually reach the bloodstream by fetal aspiration or swallowing of contaminated amniotic fluid, leading to bacteremia<sup>15</sup>.

### 4.0. Late-Onset Neonatal Sepsis

Late-onset sepsis (LONS) is sepsis occurring after 72 hours in NICU infants and 7 days of life in term infants, has been variably defined as occurring up to the age of  $\leq 90$  or 120 days, and maybe caused by vertically or horizontally acquired pathogens<sup>6-18</sup>. LONS can be divided into two distinct entities; disease occurring in otherwise healthy term infants in the community, and disease affecting premature infants in the NICU. The latter is often referred to as hospital-acquired sepsis, as the risk factors for LONS in premature infants are related to the necessities of their care like the presence of central lines and the bacteria that cause LONS are often acquired in the NICU.

### 4.1. Risk Factors

Risk factor for LONS includes invasive procedures such as resuscitation in delivery room, intubation, mechanical ventilation, central venous catheters, surgical procedures, prolonged staying in NICUs, total parenteral nutrition and its duration and disruption of skin integrity. The use of broad spectrum antibiotics is a risk factor for fungal neonatal sepsis<sup>19</sup>. These factors enhance the entry of organisms into blood stream of neonates as immune defense of neonate is poor comparing older children and adults. Poor hygiene is associated with LONS. It should be noted that genetic factors such as polymorphisms in immunity associated genes may also be implicated in neonatal susceptibility to LONS<sup>20</sup>.

### 4.2. Etiology

Organisms that are associated with late onset sepsis include Staphylococcus aureus, coagulase negative Staphylococcus (CoNS), MRSA, Escherichia coli, Klebsiella species, Acinetobacter species, Pseudomonas species, Candida albicans and anaerobes. Trends in late-onset sepsis shows an increase in coagulase negative Staphylococcus sepsis. Late onset disease has a higher case fatality rate when gram negative bacteria are involved<sup>19</sup>.

### 4.3. Habitat of Organism

Klebsiella species, Acinetobacter species and Pseudomonas species are commonly found in hospital environment. Klebsiella species infections are most well-known organism in hospitals environment, spreading easily and rapidly through person-to-person contact by contaminated hands of surrounding people, whether an employee or a patient or an attendant, but can't spread through the air<sup>21-22</sup>. Pseudomonas species thrives not only in normal atmospheres, but also in low-oxygen atmospheres, thus

capable of colonizing many natural and artificial environments. This bacterium is also found on and in medical equipment including catheters, causing cross-infections in hospitals and clinics. *Acinetobacter* species survive on dry and moist surfaces including exposure to various common disinfectants, allowing some *Acinetobacter* species to survive in a hospital environment<sup>23</sup>. Up to 27.0% of hospital sinks traps and 20.0% of hospital floor swabs have yielded isolates of *Acinetobacter* species. The bacteria have been found to contaminate respirators and hospital environment, as well as nearby bed blankets and bed curtains, especially in presence of colonized patients.

#### 4.4. Pathophysiology

During the first 3 months of life, the innate immune system, including phagocytes, natural-killer cells, antigen presenting cells, and the complement system, provide a defense against pathogens. Decreased function of neutrophils and low concentrations of immunoglobulins increase the susceptibility of preterm infants to invasive infection<sup>1</sup>. Neonates have a low neutrophil storage pool and their existing neutrophils have impaired capacity to migrate from the blood to sites of infection<sup>24</sup>. Contact with hospital personnel, family members, nutritional sources, and contaminated equipment all represent opportunities for pathogen exposure. Hand contamination is the most common source of postnatal infections in infants admitted to hospital, underscoring the importance of hand hygiene<sup>1</sup>. Late-onset bloodstream infections occur more frequently in neonates with central venous access than in infants without central venous access who are usually older, and these infections are more likely to be attributed to Gram-positive organisms, including coagulase negative *Staphylococci* and *Streptococci* species<sup>1</sup>. Gram-negative enteric bacteria are usually derived from the patient's endogenous flora, which may have been altered by antecedent antibiotic therapy or populated by resistant organisms transferred from the hands of personnel the major means of spread or contaminated equipment. Therefore, situations that increase exposure to these bacteria like crowding, inadequate nurse staffing, or inconsistent provider hand washing result in higher rates of hospital-acquired infection<sup>15</sup>.

#### 5.0. Conclusion

Neonatal sepsis continues to be a significant cause of increased morbidity and mortality. The deficiencies of host defense mechanisms and the exposure to a variety of virulent organisms make the neonate extremely vulnerable. High index of suspicion for diagnosis of neonatal sepsis is required especially in the presence of risk factors and baby presenting with non specific clinical features. Prompt diagnosis and appropriate antimicrobial therapy is necessary to prevent sepsis and reduce disease severity, improve short and long term outcomes, and lessen the burden for the society.

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