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Editorial ***Open Access***

Informed Consent in Medical Research

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Consent may be defined as voluntary, willful compliance, agreement or permission in a sound state of mind[1]. It is classified as expressed consent (verbal, written) and implied consent. Informed consent is usually in written form.

In medical research, informed consent is a fundamental ethical and legal requirement ensuring participants voluntarily agreement to participate after being fully informed about the study, including its purpose, procedures, risks, and benefits. It's a process of providing clear, understandable information and ensuring participants have the capacity to make a rational decision, while respecting their autonomy and right to withdraw at any time.

Informed consent is a basic concept of contemporary and autonomy-based medical practice that facilitates a shared decision-making model for relations between physicians and patients. Thus, the extent to which patients can comprehend the consent they grant is essential to the ethical viability of medicine as it is pursued today. However, research on patients' comprehension of an informed consent's basic components shows that their level of understanding is limited[2].

Written informed consent is considered a basic principle of medical practice. It provides information and shares knowledge between the physician and patient and creates a shared-decision-based healthcare plan[3]. In this regard, the Informed Consent should implement a principle of autonomy, by which a patient's right to deliberately decide for herself whether to accept or refuse the offered treatment must be respected[4,5]. Informed consent must include both a form that patients are required to read and sign, and oral communication to ensure adequate understanding to facilitate voluntary willingness to participate in a clinical trial[6].

The following seven categories are needed to express the component parts of the concept of informed consent, although even this sevenfold list does not adequately express either the meaning or the definition of informed consent. (A) Threshold elements (preconditions) 1. Competence (to understand and decide) 2. Voluntariness (in deciding) (B) Information elements 3. Disclosure (of material information) 4. Recommendation (of a plan) 5. Understanding (of information from 3 and 4) (C) Consent elements 6. Decision (in favor of a plan) 7. Authorization (of the chosen plan)[7-9].

Current biomedical research on human subjects requires clinical trial, which is defined as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions [i.e. drugs, cells or other biological products, surgical procedures, devices] to evaluate the effects on health outcomes[10]. In our modern ethical conception, all research conducted on humans must be pre-emptively accepted by the subjects themselves through informed consent, as stated in the International Council for Harmonization Good Clinical Practice guidelines[11].

Informed consent is documented by means of a written, signed and dated informed consent form. This form is required in the following cases: 1) when the research involves patients, children, incompetent/ incapacitated persons, healthy volunteers, immigrants or others (e.g. prisoners); 2) when the

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research uses/collects human genetic material, biological samples or personal data[12].

The informed consent form must be written in language easily understood by the subjects, it must minimize the possibility of coercion or undue influence, and the subject must be given sufficient time to consider participation. However, informed consent is not merely a form that is signed, but is a process in which the subject has an understanding of the research and its risks, and it is tightly described in ethical codes and regulations for human subject research[11]. Challenges in obtaining informed consent from the real subject may include situations of medical emergency or obtaining consent from "vulnerable" subjects and/or children[13]. The information about the research should be given by a physician or by other individuals (i.e. researchers) with appropriate scientific training and qualifications[14].

Furthermore, the location where the informed consent is being discussed, and the subject's physical, emotional and psychological capability, must be taken into consideration when taking consent from a human subject. After institutional review board (IRB) or independent ethics committee approval is achieved, obtaining informed consent from each human subject prior to his/her participation in clinical trial is mandatory[13]. However, when specific circumstances occur, the informed consent can be waived, and "research without consent" is possible, which allows enrolment of patients without their consent, under strict regulation[15].

In order that research without consent is considered justifiable, the following three conditions have to be met: 1) it is impracticable to obtain consent 2) the research does not infringe the principle of self-determination and 3) the research provides significant clinical relevance. The first condition, of "impracticability", occurs when obtaining informed consent is burdened by high impact in terms of time and economic resources or could compromise the study's validity[16]. The second condition means that, although physicians are requested to ensure that the patient has understood the aim of the research and the risks and/or benefits associated with study participation, the researchers are also advised to respect the patient's decision-making capacity, not interfering with his/her decisions and acting always in the patient's best interest[17]. The third condition leads to justification of waiving consent when the clinical relevance and public health importance are potentially high[16].

Sometimes informed consent are needed to be taken from vulnerable people. A "vulnerable population" is defined as a disadvantaged community subgroup unable to make informed choices, protect themselves from inherent or intended risks, or keep their own interests safeguarded[18]. In the health domain, "vulnerable populations" refers to physical vulnerability (e.g. pregnant women, fetuses, children, orphans, students, employees, prisoners, the military, and those who are chronically or terminally ill), psychological vulnerability (cognitively and intellectually impaired individuals) and social vulnerability (those who are homeless, from ethnic minorities, are immigrants or refugees)[18]. Due to a compromised free will and inability to make conscious decisions, several ethical dilemmas (related to communications, privacy and treatment) often arise when research involves these populations. Guaranteeing protection of rights, safety, data privacy and confidentiality of vulnerable subjects are prerogatives of good clinical practice, and law dispositions are regulated and strictly monitored by the applicable authorities[19].

For a long time, pregnant women were excluded from clinical research because of their "vulnerability". Although pregnant women are able to make informed and conscious choices, they have been considered "vulnerable" due to the potential risks to the fetus, who is also considered as a "patient"[20]. More recently, with the consideration of pregnant women as "scientifically complex" rather than "vulnerable" subjects, it has been permitted to involve this category in research trials[21]. The "scientific complexity" reflects both ethical and physiological complexity. The ethical aspects are secondary to the need to find a balance between interests of the fetus and the mother. The physiological aspects are strictly related to the pregnancy status[22]. No pregnant woman may be involved as a subject in a human clinical research project unless the purpose of the research is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus is minimal[23].

Informed consent is a fundamental patient right. In clinical research, informed consent involves a lot more than just acquiring a participant's signature on a document. It requires a dialogue between the researcher and the participant to ensure that they are aware and comprehend the nature of the study, its objectives, potential risks, and benefits. Before agreeing to joining any study, as a potential participant, everyone must be given the chance to ask questions and have them answered, as well as having the time to really wrap their head around all the information. There are many disorders and conditions that can affect a person's capacity to consent: intellectual and developmental disabilities, stroke, traumatic brain injuries, serious mental illness, intoxication, dementia, Alzheimer's disease, and delirium. In situations where a person's capacity is impaired to the point that they cannot give consent, their Legally Authorized Representative (LAR) can do so on their behalf. This is known as 'third-party consent' or 'consent by proxy'. The role of the Legally Authorized Representative is to give ongoing support and assume decision-making responsibilities and act in the represented person's best interest[6].

Children and minors are considered a vulnerable group in research, due to their lack of autonomy and understanding of what participating in a clinical trial entail, which means that additional safeguards need to be implemented. In cases where the participant is a minor, it is the parents or guardians that need to give consent for them.

When specific circumstances occur, informed consent can be waived: if it is impracticable to obtain consent, if the research does not infringe the principle of self-determination, and if the research provides significant clinical relevance. Verbal Consent Process (Waiver of Documented or Written Consent). In most cases the federal regulations require that informed consent be documented (i.e., signed consent form), but they also provide for some important exceptions. In some circumstances, the IRB may waive the requirement for documented or written consent and allow researchers to obtain verbal consent[24].

A valid consent process includes:

1. Ascertaining that the individual has decision -making capacity.
2. Reviewing the process and any materials to ensure that it is understandable to the study population.
3. Disclosing:

A) the nature of the experimental drug(s), device(s), or procedure(s) to be used in the research

B) any conflicts of interest relating to the research, in keeping with ethics guidance

C) any known risks or foreseeable hazards, including pain or discomfort that the participant might experience

D) the likelihood of therapeutic or other direct benefit for the participant

E) that there are alternative courses of action open to the participant, including choosing standard or no treatment instead of participating in the study

F) the nature of the research plan and implications for the participant

G) the differences between the physician's responsibilities as a researcher and as the patient's treating physician

4. Answering questions the prospective participant has.
5. Refraining from persuading the individual to enroll.
6. Avoiding encouraging unrealistic expectations.
7. Documenting the individual's voluntary consent to participate[25].

Section 90 of the Penal Code of Bangladesh, 1860, states that a consent is not valid if it is given under fear of injury, misconception, or if the person giving consent is unable to understand the nature and consequences due to unsoundness of mind or intoxication[26].

Hence it is the prime duty of all researcher to have clear idea about importance of informed consent in Medical Research.

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Journal of Army Medical College Jashore (JAMCJ) is a leading, open access, peer-reviewed scientific journal on medical science for rapid publication of articles published Army Medical College Jashore, Bangladesh. This journal provides quick initial decisions followed by a high-quality medical editing service and an excellent publishing service to its authors. This journal has been launched since January 2020 and published 2 times per year. This journal aims to publish scientifically written, evidence-based articles from all disciplines of medical sciences and clinical practice, preventive medicine, epidemiology as well as healthcare research. It provides a great scope to publish different kinds of articles including original research papers, reviews of specific topics, case reports and short research communications. Submissions of basic and clinical research both are considered.

JAMCJ publishes studies performed by multi-center groups in the various disciplines of medicine, including clinical trials and cohort studies from large patient populations, specifically phase I, phase II, and phase III studies performed under the auspices of groups such as general clinical research centers, cooperative oncology groups, etc. Reports of patients with common presentations or diseases, especially studies that delineate the natural history and therapy of important conditions are also published. Reviews oriented to the practicing internist and diagnostic puzzles, complete with images from a variety of specialties are also published. Careful physiological or pharmacological studies that explain the 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 also acceptable.

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Aims and Scopes of the Journal

Journal of Army Medical College Jashore (JAMCJ) 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, clinical practice, 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 articles, editorial, reviews, short communications, case reports, letter to the editor and others. In addition to that **JAMCJ** 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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Types of Manuscript: The following categories of manuscripts are accepted for this journal like Original Research Articles, Systematic Review or Meta-Analysis, Review Articles, Short communications, Case reports and Letter to Editor. **Original Research Articles:** It should be arranged into the following sections:

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Abstract and Keywords

Abstract: It must start on a new page carrying the following information: (a) Title (b) Abstract body (c) Key words (d) Running title. It should not exceed 350 words excluding the title and the keywords. The abstract must be concise, clear and informative rather than indicative. The abstract must be in a structured form consisting of background, objectives, methodology, result and conclusion.

Keywords: A list of 3-8 keywords should be provided. The words found in title may be given as keywords. All keywords should be provided according to MeSH terms at: http://www.nlm.nih.gov/mesh/MBrowser.html.

Introduction: This section should state the relevance and background to the study, its rationale and general objective. It should not exceed 450 to 500 words. Last sentence of this section will be the general objective of the study.

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Discussion: This section should deal with the interpretation, rather than recapitulation of results. It is important to discuss the new and significant observations in the light of previous work. Discuss also the weaknesses or pitfalls in the study.

Conclusion: Conclusion must be drawn considering the strengths and weaknesses of the study.

Acknowledgements: Acknowledge only persons who have contributed to the scientific content or provided technical support. Sources of financial support should be mentioned.

References: Papers which have been submitted and accepted but not yet published may be included in the list of references with the name of the journal and indicated as "In press". The "unpublished observations" and "personal communications" may not be used as references but may be inserted (in parentheses) in the text. References are to be cited in the text by superscripted number and should be in the order in which they appear. References cited only in tables or in legends to figures should be numbered in accordance with a sequence established by the first identification in the text of the particular table or illustration. The references must be verified by the author(s) against the original documents. The list of references should be in the Modified Vancouver style.

Tables: The number of table should be 3 or 4 in number. Each table must be self-explanatory and presented in such a way that they are easily understandable. It should be typed with double spacing and numbered consecutively with Arabic numerals. Provide a short descriptive caption above each table with foot notes and/or explanations underneath. The number of observations, subjects and the units of numerical figures must be given.

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Systematic Review or Meta-Analysis: These should be critical assessments of current evidence covering a broad range of topics of concern to those working in the specific field of journal. Systematic reviews should be 4000-5000 words (abstracts to be structured as above). Authors should report systematic reviews and meta-analyses in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.

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The case report should contain abstract (need not be structured), keywords, introduction, case presentation, discussion, conclusion & references (including a maximum of 20 references) in a sequential way. The number of case may be one or two, not more than three.

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Papers should only be submitted for consideration once the authorization of all contributing authors has been gathered. Those submitting papers should carefully check that all those whose work contributed to the paper are acknowledged as contributing authors.

Authorship credit should be based on

1. substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
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3. final approval of the version to be published.

Authors should meet conditions 1, 2, and 3.

When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms.

When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments.

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B. If a research object is human, researchers should follow the Declaration of Helsinki (http://www.wma.net). Details are as follows:

1. Researchers should fully explain the purpose and methods of research as well as possible mental and physical harm that could occur during research participation. If he/she is to publish the research results, he/she has to indicate that on the paper
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3. Research should receive an approval from Institutional Review Board and indicate it on the paper if one wishes to publish the research results

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1. Researchers should indicate what he/she did to minimize the pain or discomfort that experiment subjects went through.
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Original Article ***Open Access***

Evaluating the Impact of *Carica papaya* Leaf Extract on Body Weight, Serum ALT, and Liver Histopathology in Cyclophosphamide-Induced Thrombocytopenic Long Evans Male Rats

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Abstract

Background: Thrombocytopenia, resulting from conditions such as dengue or other etiologies, poses a significant public health challenge, often associated with various hematological abnormalities and subsequent liver and renal dysfunction. Recent studies indicate that Carica papaya leaf extract may have therapeutic potential in addressing these hematological issues. **Objective:** To investigate the hepatoprotective effects of *C. papaya* leaf extract in cyclophosphamide-induced thrombocytopenic Long Evans male rats, specifically by evaluating serum ALT levels, along with histopathological assessments of liver tissues. **Methods:** Conducted in the Department of Physiology at Sir Salimullah Medical College (SSMC), Dhaka, from January 1 to December 31, 2021, this experimental study involved 30 healthy Long Evans male rats (8–10 weeks, 150–250 g). Following a 14-day acclimatization, rats were divided into Control (Group A) and Experimental (Group B) groups. Group A was further subdivided into A1 (Baseline control) and A2 (Cyclophosphamide-induced thrombocytopenic control), with 10 rats in each subgroup. All rats received a basal diet for 23 days, while Group A2 and Group B were administered cyclophosphamide (70 mg/kg/day, subcutaneously) on days 1, 3, and 5 to induce stable thrombocytopenia. Group B also received *C. papaya* leaf extract (400 mg/kg/day) from days 10 to 23. Blood samples were collected on days 1 and 10 via tail vein, and on day 24 through cardiac puncture for serum ALT evaluation. Histopathological examinations of liver tissues were conducted. Statistical analysis was performed using SPSS version 22, with significance set at $p \leq 0.05$. **Results:** On day 24, Group A2 exhibited significantly elevated serum ALT (p<0.001) compared to Group A1. In contrast, Group B showed markedly reduced ALT (p<0.001) relative to Group A2, with values comparable to Group A1, indicating robust hepatoprotective effects. Histopathological analysis revealed liver damage in 60% of the rats in Group A2 and 10% in Group B, while no abnormalities were observed in Group A1. **Conclusion:** *C. papaya* leaf extract demonstrates significant hepatoprotective effects, highlighting its therapeutic potential in mitigating organ damage associated with cyclophosphamide and other toxic insults.

Keywords: Thrombocytopenia, cyclophosphamide, *C. papaya* leaf, Long Evans male rats.

Introduction:

Thrombocytopenia, characterized by a low platelet count in the blood, typically manifests when platelet levels drop below 50,000/µl, with normal levels ranging from 150,000 to 300,000/µl[1]. Common causes include impaired platelet production due to bone marrow failure, megaloblastic anemia, and

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leukemias, as well as increased destruction through conditions like idiopathic thrombocytopenic purpura and viral infections such as dengue and chikungunya[2]. Dengue fever often presents with thrombocytopenia, leading to severe complications like dengue hemorrhagic fever and dengue shock syndrome[3,4]. The global incidence of dengue has escalated significantly, with an estimated 100-400 million infections annually and a concerning rise in severe cases and mortality rates[5]. Currently, no specific treatment exists for severe dengue, making early detection and supportive care crucial[6]. The absence of effective therapies has sparked interest in alternative treatments. *C. papaya* leaf extract has been utilized in traditional medicine in Sri Lanka, Malaysia, and parts of India to enhance platelet counts in dengue patients[7,8]. Its potent antioxidant properties, attributed to vitamin C, flavonoids, and beta-carotene, help prevent oxidative stress and lipid peroxidation, crucial in conditions such as non-alcoholic fatty liver disease (NAFLD) and hepatocellular carcinoma[9]. Furthermore, papaya exhibits anti-fibrotic properties, reducing collagen deposition and liver fibrosis[10]. and has antiviral effects that may help manage viral hepatitis by suppressing viral replication and inflammation[11,12.] Traditionally, it has been used to treat jaundice by promoting bile secretion and detoxification[13,14,15] and studies have shown its potential in protecting against drug-induced hepatotoxicity, such as acetaminophen-induced liver injury[16]. Cyclophosphamide, a synthetic alkylating agent known for its antineoplastic and immunosuppressive properties, induces stable thrombocytopenia and serves as a model for studying the effects of *C. papaya* in reversing this condition[17,18.] Previous research has shown that aqueous extracts of *C. papaya* can effectively reverse thrombocytopenia in cyclophosphamide-treated rat models[7,19,20]. This study aims to further investigate the hepatoprotective effects of *C. papaya* leaf extract in the context of cyclophosphamide-induced thrombocytopenia.

Materials and Methods:

Study Settings and Population: This experimental animal study was conducted at the Department of Physiology, Sir Salimullah Medical College, Dhaka, Bangladesh, over a one-year period from January 2021 to December 2021. The study involved apparently healthy male Long Evans rats, aged 8 to 10 weeks, with body weights ranging from 150 to 250 grams. These rats were sourced from the Animal Resource Facility at the International Center for Diarrheal Disease Research, Bangladesh (ICDDR,B) in Dhaka. Only healthy rats were included, while those showing any signs of illness or disease were excluded from the study.

Grouping of the Rats: After a 14-day acclimatization period, the 30 male Long Evans rats were randomly assigned into two main groups. Group A (control) was subdivided into Group A1, consisting of 10 rats that received a basal diet for 23 days, and Group A2, consisting of 10 rats that received a basal diet along with subcutaneous injections of cyclophosphamide (70 mg/kg) on days 1, 3, and 5. Group B (experimental group) consisted of 10 rats that were given the same basal diet and cyclophosphamide injections as Group A2, but were also administered *C. papaya* leaf aqueous extract (400 mg/kg/day) orally from days 10 to 23.

Intervention: Group A1, serving as the baseline control, consisted of 10 rats that were provided with only a basal diet for the entire 23-day study period. Group A2, comprising 10 rats, acted as the cyclophosphamide-induced thrombocytopenic control group; these rats were fed a basal diet and received subcutaneous cyclophosphamide injections (70 mg/kg body weight) on days 1, 3, and 5. Group B, the experimental group, consisted of 10 rats with cyclophosphamide-induced thrombocytopenia, which received the same injections as Group A2. However, in addition, they were treated with *C. papaya* leaf aqueous extract (400 mg/kg body weight) administered orally via gastric gavage from day 10 to day 23. All treatments, including diets and cyclophosphamide injections, were administered daily between 9:00 AM and 10:00 AM for the full duration of the study.

Study Procedure: This study was approved by the Institutional Ethics Committee (IEC) of Sir Salimullah Medical College (SSMC), Dhaka, Bangladesh. The experiment was conducted at the animal facility of the Institution of Nutrition and Food Science, Dhaka University, under controlled conditions (temperature: 27–28°C, 12-hour

light / dark cycle). Thirty male Long Evans rats were acclimatized for 14 days with free access to food and water. The experimental period lasted 23 days, with body weight measurements taken on day 1 and day 23. On day 1, baseline platelet count, bleeding time (BT), and clotting time (CT) were assessed in all rats. Thrombocytopenia was induced in Groups A2 (cyclophosphamide-induced thrombocytopenic control) and B (experimental) via subcutaneous injections of cyclophosphamide (70 mg/kg) on days 1, 3, and 5. Group A1 (baseline control) received only a basal diet. By day 10, platelet count, BT, and CT were reassessed to confirm the development of thrombocytopenia in Groups A2 and B, with prolonged BT and CT, while Group A1 maintained normal values. From day 10 to day 23, Group B received oral *Carica papaya* leaf aqueous extract (400 mg/kg/day) via gavage, while Group A2 continued on a basal diet. Blood samples were collected again on day 10 to reassess platelet counts, BT, and CT. On day 24, all rats were anesthetized with chloroform (30%) and sacrificed. Complete blood counts (CBC), including platelet, red blood cell (RBC), and white blood cell (WBC) counts, were analyzed using the Sysmex XE-5000 Automated Hematology Analyzer at Bangabandhu Sheikh Mujib Medical University (BSMMU). Bleeding time was measured by Duke's method, and clotting time by the capillary method. Serum alanine transaminase (ALT) and creatinine levels were also measured using standard laboratory procedures.To evaluate the histopathological effects of treatments, liver and kidney tissues were collected from all sacrificed rats. Tissue samples were processed, and histological slides were prepared and examined under a light microscope. Photomicrographs of the liver and kidney sections were taken to document any pathological changes. This histopathological analysis was conducted at the Department of Pathology, Sir Salimullah Medical College, Dhaka. The tissue samples were evaluated for structural alterations, such as necrosis, inflammation, and cellular degeneration, providing insights into the potential protective or damaging effects of *C. papaya* leaf extract on organ health following cyclophosphamide-induced toxicity.

Statistical Analysis: Data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 22. Results were expressed as mean ± standard deviation (SD). To compare differences across groups, a one-way ANOVA was performed, followed by a post hoc Bonferroni test for pairwise comparisons. Where appropriate, paired t-tests and Fisher's Exact tests were conducted. A p-value ≤ 0.05 was considered statistically significant.

Ethical Approval: The study protocol received approval from the Institutional Ethics Committee (IEC) of Sir Salimullah Medical College (SSMC), Dhaka, Bangladesh.

Results:

Comparison between mean initial and final body weight in different groups of rats (N=30):

The initial mean body weights (±SD) of the rats on day 1 were 196.50 ± 34.26 g (group A1), 187.10 ± 21.93 g (group A2), and 198.80 ± 26.68 g (group B). By day 24, the final body weights were 214.40 ± 37.38 g, 179.20 ± 18.25 g, and 206.10 ± 26.48 g, respectively (Figure: 1).

The percentage change in body weight from initial to final was 9.16 ± 2.32% in group A1, -4.01 ± 4.22% in group A2, and 3.74 ± 1.66% in group B.Final body weights increased in groups A1 and B, while a decrease was observed in group A2. The mean percentage change in body weight was significantly lower in groups A2 ($p<0.001$) and B ($p<0.001$) compared to group A1, but significantly higher in group B compared to group A2 ($p<0.001$) (Table 1).

List of Tables:

Table 1: Multiple comparisons mean body weight in different groups of rats (N=30)

Group	p-value		
	Initial body weight in day 1	Final body weight in day 24	% Change of weight
A1vs A2vs B	0.620ns	0.027*	<0.001***
A1vs A2	1.000ns	<0.031*	<0.001***
A1vs B	1.000ns	1.000ns	0.001***
A2vs B	1.000ns	0.134ns	<0.001***

Data are expressed as mean ± SD. For statistical analysis one-way ANOVA test was performed for comparison among the groups and then post hoc-Bonferroi test to compare between groups. Figures in parentheses indicate ranges. Group A1

represents the baseline control group, Group A2 is the cyclophosphamide-induced thrombocytopenic control group, and Group B is the experimental group where thrombocytopenic rats were treated with *C. papaya* leaf extract. The total number of rats is denoted by N, and the number of rats in each group is denoted by n. Statistical significance is indicated as follows: ns for non-significant, * for significant at $p<0.05$, and *** for significant at $p<0.001$.

List of Figures:

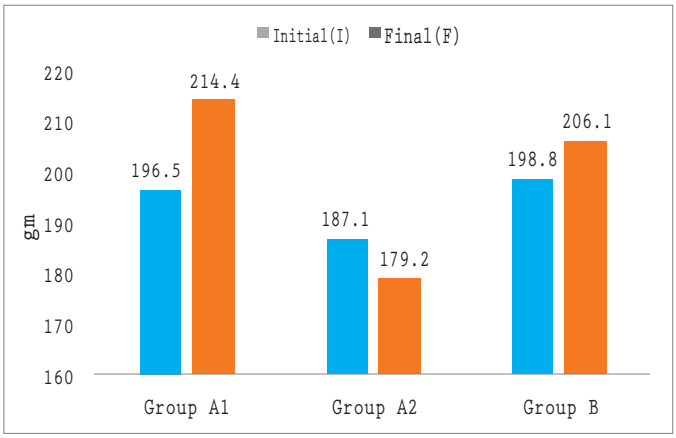


Figure 1: Comparison between Initial & Final Mean Body Weight

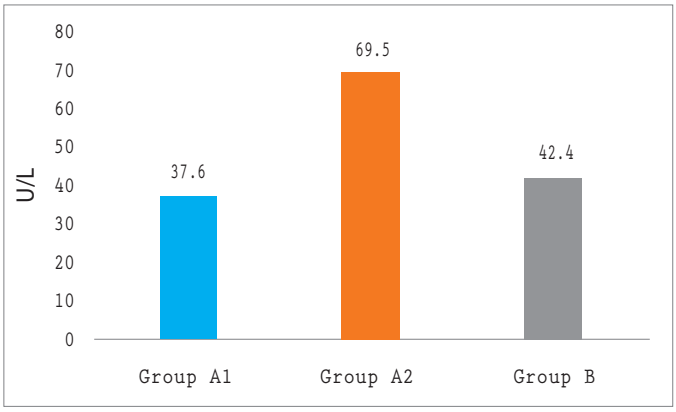


Figure 2: Mean serum ALT level in different groups of rats (N=30)

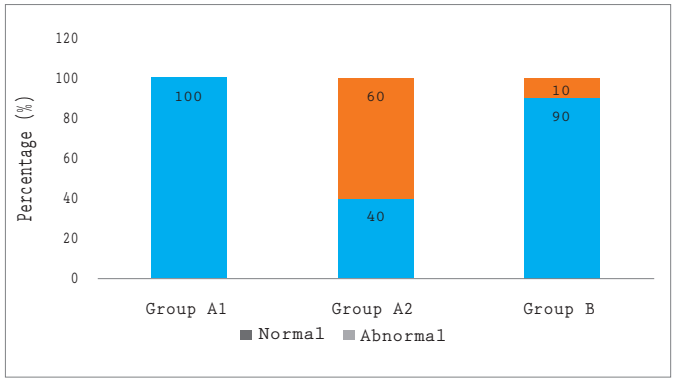


Figure 3: Mean distribution of rats by histopathological findings in liver (N=30); Group A1: Baseline control group; Group A2: Cyclophosphamide induced thrombocytopenic control group; Group B: Thrombocytopenic rats with *C. papaya* leaf treated group; N= Total number of rats

Enzyme levels as biomarker of hepatotoxicity and hepatoprotection:

The mean (± SD) serum SGPT (ALT) level were 37.60 ± 8.14, 69.50 ± 19.23 and 42.40 ± 6.22 U/L, in group A1, A2 and B respectively (Figure 2). Cyclophophamide-induced thrombocytopenic rats exhibited strong hepatotoxicity through elevated levels of ALT in group A2 whereas hepatoprotection could be achieved in cyclophophamide-induced thrombocytopenic rats when treated with *C. papaya* leaf extract (Group B)

The mean ± SD serum ALT level was significantly lower in group A1 ($p<0.01$) and group B ($p<0.05$) compared to group A2. However, the ALT levels between group A1 and group B were almost identical, with no statistically significant difference observed (Table 2).

Table 2: Multiple comparison of mean serum ALT Levels at day 24 in different groups of rats (N=30)

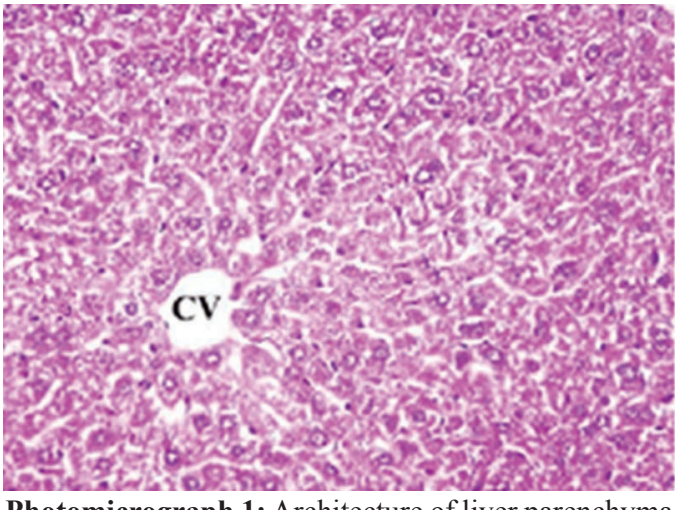
Group	ALT (U/L)
Group A1 (n=10)	37.60 ± 8.14 (17.00 - 46.00)
Group A2 (n=10)	69.50 ± 19.23 (42.00 - 92.00)
Group B (n=10)	42.40 ± 6.22 (33.00 - 50.00)
	ALT p-value
A1vs A2vs B	<0.001***
A1vs A2	<0.001***
A1vs B	1.000 ns
A2vs B	<0.001***

Table 3: Multiple comparisons of mean distribution of Rats Liver by the histopathological findings of liver (N=30)

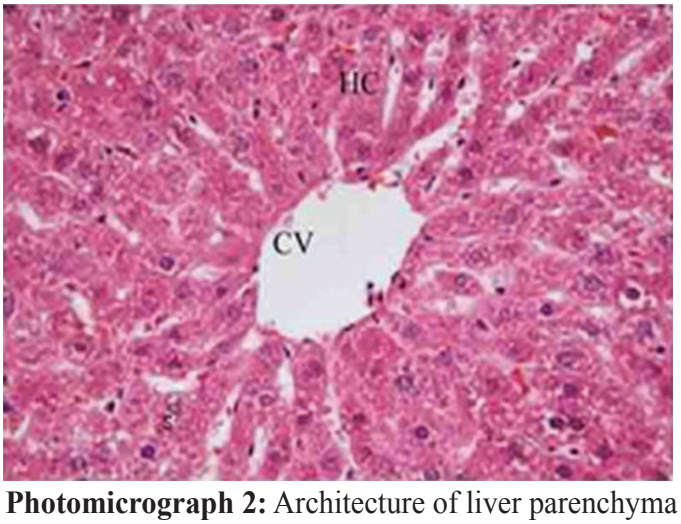
Group	Histopathology of liver
	p-value
A1vs A2vs B	0.003**
A1vs A2	<0.014*
A1vs B	1.000ns
A2vs B	0.060ns

Statistical analysis was done by Fisher's exact test. Figures in parentheses indicate ranges.

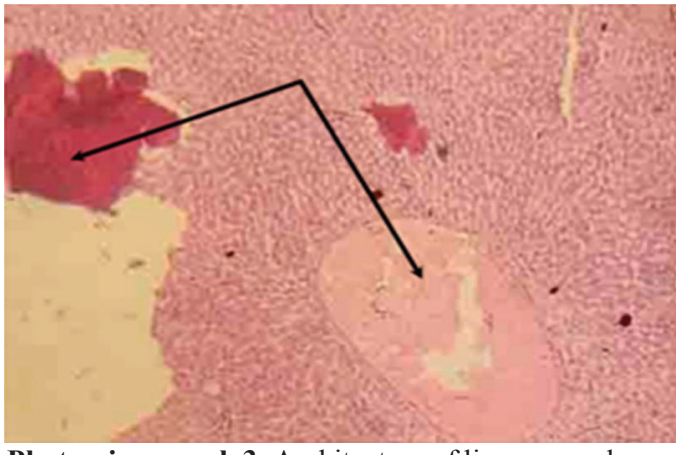
Amelioration of cyclophosphamide-induced hepatotoxicity by *C. papaya* leaf extract:
Histopathological analysis was performed to reveal the hepatoxic effect of cyclophosphamide, as revealed in photomicrograph 1-4. Photomicrograph 1 and 2 are x400 and x100 images of liver from baseline control rats that clearly demonstrate the healthy hepatic tissue with clear central vein and hepatic cord. The hepatic cells were of perfect shape with distinct nucleus and minimal vacuolar presence. However, clear blood clots and large vacuoles were observed in the hepatic tissues of cyclophosphamide-induced thrombocytopenic rats (Photomicrograph 3 and 4). Restoration of normal architecture of liver parenchyma in thrombocytopenic rats was observed when treated with *C. papaya* leaf extract (Photomicrograph 5 and 6).



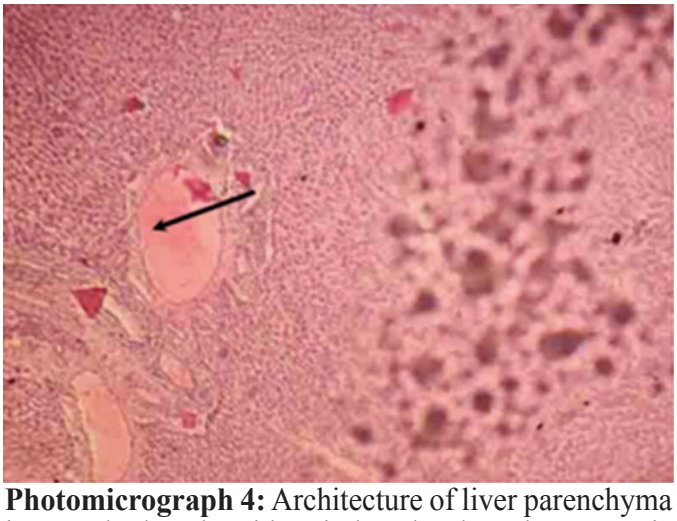
Photomicrograph 1: Architecture of liver parenchyma in baseline control group of rats (here CV represents central vein and HC represents hepatic cord; X 100)



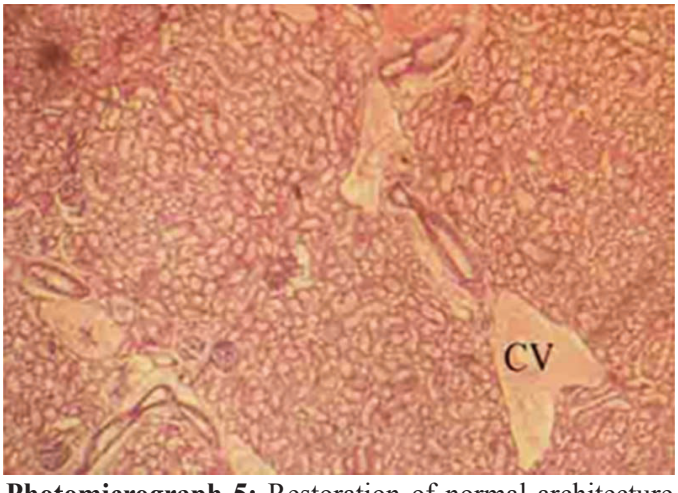
Photomicrograph 2: Architecture of liver parenchyma in baseline control group of rats (X 400)



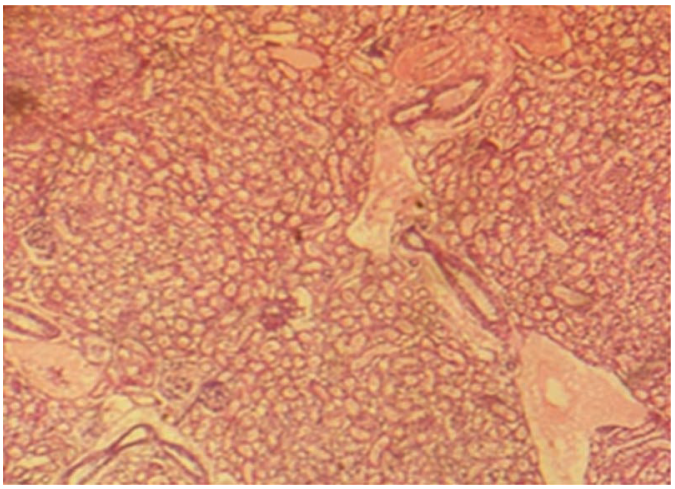
Photomicrograph 3: Architecture of liver parenchyma in cyclophosphamide induced thrombocytopenic control group of rats (here black arrow represents vacuole formation and clotted blood in x 100)



Photomicrograph 4: Architecture of liver parenchyma in cyclophosphamide induced thrombocytopenic control group of rats (here black arrow represents dilated blood vessels, in x 400)



Photomicrograph 5: Restoration of normal architecture of liver parenchyma in thrombocytopenic rats treated with *C. papaya* leaf (here CV represents central vein x 100)



Photomicrograph 6: Restoration of normal architecture of liver parenchyma in thrombocytopenic rats treated with *C. papaya* leaf (X 400)

Discussion:

This study aimed to evaluate the hepatoprotective effects of *C. papaya* leaf extract in cyclophosphamide-induced thrombocytopenic rats. Serum alanine aminotransferase (ALT) levels were measured to assess liver function, while histopathological analysis of liver tissue was conducted to examine microscopic changes and confirm the protective effects of the extract.

Body weight: In the present study, the final body weight increased in thrombocytopenic rats treated with *C. papaya* leaf extract. Similar finding was also observed by some other researchers[21]. Whereas, the final body weight was decreased in cyclophosphamide induced thrombocytopenic control group which was similar to the observations of those investigators[22]. Again, the % change of body weight was significantly ($p<0.001$) lower in cyclophosphamide induced thrombocytopenic control group in comparison to that of baseline control group. Similar findings were also observed by some other investigators[22]. Again, this level was significantly ($p<0.001$) higher in thrombocytopenic rats with *C. papaya* leaf treated group in comparison to that of cyclophosphamide induced thrombocytopenic control group which is similar to those of other researchers[23].

Serum Alanine Aminotransferase (ALT): In the current study, by day 24, serum ALT levels were significantly elevated ($p<0.01$) in the cyclophosphamide-induced thrombocytopenic control group compared to the baseline control group, consistent with findings reported by Cox et al[24]. However, in the group of thrombocytopenic rats treated with *C. papaya* leaf extract, ALT levels were significantly reduced ($p<0.05$) relative to the cyclophosphamide-induced thrombocytopenic control group, aligning with results observed in studies by Anjum et al21 and Halim et al[25]. In contrast, Barineet al26 reported a non-significant increase in ALT levels in rats treated with *C. papaya* leaf extract, possibly attributable to mild hepatic cell necrosis. These variations in findings may reflect differences in experimental conditions, doses, or the duration of treatment.

Histological changes in liver: In this study, significant histological abnormalities were observed in the cyclophosphamide-induced thrombocytopenic control group, including clotted blood, centrilobular necrosis, dilated sinusoids, lymphocytic infiltration, Kupffer cell activation, vacuolar degeneration in hepatocytes, pyknotic nuclei, and dilated blood vessels. These findings are consistent with those of Anjum et al[20]. Cyclophosphamide, a widely used alkylating chemotherapeutic agent, is known for its dose-dependent hepatotoxic effects. Its metabolic activation in the liver generates reactive oxygen species (ROS) and acrolein, leading to oxidative stress, lipid peroxidation, and hepatocellular damage. In contrast, most thrombocytopenic rats treated with *C. papaya* leaf extract showed nearly normal liver histological architecture, indicating a hepatoprotective effect, as similarly reported by Panditet al[27]. Although both the control and *C. papaya* treated groups exhibited cyclophosphamide induced thrombocytopeniaevidenced by slightly elevated serum ALT levels and moderate liver architectural changesthe histopathological alterations were likely due to increased free radical production and subsequent lipid peroxidation. However, treatment with *C. papaya* leaf extract significantly attenuated the ALT elevation, suggesting a non-toxic and protective effect against liver and kidney complications associated with thrombocytopenia[7,20].The hepatoprotective properties of *C. papaya* leaf extractare attributed to the presence of tannins, flavonoids, saponins, triterpenoids, and vitamin E which exhibit antioxidant potential by significantly inhibiting malondialdehyde (MDA) levels[23,27]. The experimental group's significantly lower mean serum ALT levels suggest that the extract lacks hepatotoxicity. However, due to the absence of oxidative stress marker measurements, the role of free radicals in mediating liver protection remains unconfirmed. Further research

is necessary to investigate oxidative stress pathways and key markers, such as free radicals, to elucidate the protective mechanisms of the extract.

Conclusion:
The study concludes that *C. papaya* leaf extract exhibits significant hepatoprotective effects in cyclophosphamide-induced thrombocytopenic Long Evans male rats. Future research should focus on evaluating the effects of varying dosages of C. papaya leaf extract and investigating the specific bioactive compounds responsible for its therapeutic action. Moreover, it is recommended to assess key antioxidant enzymes, including superoxide dismutase (SOD), catalase (CAT), and glutathione peroxidase (GPx), to further elucidate the molecular mechanisms underlying the extract's hepatoprotective properties.

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Conflict of interest:
The authors declare no conflict of interest arising from any sources regarding this manuscript.

Financial Disclosure:
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Authors' Contributions:
Akhter F conceptualized, reviewed relevant literature, conducted experimentation, interpreted the findings and participated in writing the manuscript. Begum M and Islam KD jointly formulated the research hypothesis, provided the intellectual foundation of the experimental design, carried out supervision during the study period, interpreted the data and contributed in the manuscript. Poly AA, Islam A, Hossain HMR contributed in data acquisition, interpretation of the experimental findings, statistical analysis and manuscript preparation.

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.

Ethical 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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Original Article ***Open Access***

A Study of Combined Terbinafine-Itraconazole Treatment in Patients with Widespread Superficial Dermatophytes

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Abstract

Background: Dermatophytosis, a common fungal infection, is caused by fungi such as Trichophyton, Epidermophyton, and Microsporum. Treatment typically combines systemic and topical anti-fungal medications, although localized, untreated Tinea may be an exception. However, a concerning trend of treatment resistance to standard therapies has emerged in recent years. **Objective:** To evaluate the safety and effectiveness of combined itraconazole and terbinafine treatment in individuals with widespread superficial fungal infections. **Methods:** This study was a randomized clinical trial involving 100 patients diagnosed with dermatophytosis which was conducted between October 2022 and September 2024 at the department of Dermatology, Khwaja Yunus Ali Medical College (KYAMC), Enayetpur, Sirajgonj. This trial evaluated the efficacy of a combined terbinafine and itraconazole treatment regimen. Patients received treatment for six weeks, with a follow-up in every two weeks, including relevant investigations. The outcomes of the treatment were assessed at both fourty and sixty weeks. All statistical analyses were performed using a SPSS version 25. **Results:** This study found that the majority of patients were aged between 16-30 years (57%), with an average age of 32.38 ±12.42 years. The study population was predominantly male (79%). Tinea corporis was the most common diagnosis (50%) followed by Tinea cruris (18%), Tinea faciei (12%), and Tinea incognito (20%). Most participants (83%) reported having the condition for 12 months or less. The most frequently affected areas were the trunk (30%), whole body (14%), and genital area (11%). Severe itching was the most prevalent symptom (56%), followed by moderate (34%) and mild itching (10%). Treatment demonstrated significant improvement, with the percentage of participants showing improvement increasing from 65% after 2 weeks to 83% after 4 weeks. The cure rate also increased steadily, reaching about 91% after 6 weeks of treatment. **Conclusion:** The combined effect of itraconazole and terbinafine showed a higher clinical success rate than the combination of terbinafine and griseofulvin. However, the observed cure rate was lower than reported in previous studies. Importantly, neither combination of systemic anti-fungal medications was effective in treating tinea infections that had been previously treated with topical steroid creams.

Keywords: Terbinafine, itraconazole, treatment, superficial, dermatophytes.

Introduction:

Dermatophytosis is a common widespread skin condition caused by superficial fungi that invade and grow within tissues like the skin, hair, and nails. It is primarily caused by fungi such as Trichophyton, Microsporum, and Epidermophyton.Tinea, the term for this condition, affects approximately 20-25% of the global population[1-4]. Over the past four decades, significant advancements have been made in

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treating dermatophytosis. Nowadays, treatment options have evolved from basic antiseptics with a limited anti-fungal properties to the more specific anti-fungal medications[1,4-7].

Recently, there has been an increase in difficult-to-treat tinea infections, including those that are resistant to treatment, recurrent, or chronic[3,5,8]. Several factors contribute to this rise, including climate change, hot and humid environments, increased travel, sedentary lifestyles, obesity, the usage of tight fitting and synthetic clothes, the uprising incidence of Trichophyton mentagrophytes, and decreased adherence to treatment[1,6,9]. The widespread misuse of over-the-counter and prescription topical steroid-antifungal creams is another significant factor[8,10]. Terbinafine, the main drug for tinea, acts as a first-line treatment by inhibiting squalene epoxidase, an enzyme essential for fungal cell membrane production[9,11]. Itraconazole inhibits 14 α-demethylase, resulting in fungistatic activity, while griseofulvin disrupts microtubule formation, thereby interfering with cell wall synthesis of fungi[10,12,13].

A combined therapy using systemic anti-fungal agents with various mechanisms have been found to enhance success rates and reduce the risk of drug resistance, leveraging the synergistic and additive effects of multiple medications. Several studies have highlighted the efficacy of both terbinafine and itraconazole in treating tinea infections[7-13]. From a clinical standpoint, it is essential for healthcare providers to evaluate the relative effectiveness of these two drugs in typical clinical settings. Therefore, the present study was undertaken to evaluate the safety and efficacy of a combined regimen of itraconazole and terbinafine in patients with widespread superficial dermatophyte infections.

Materials and Methods:

A non-blinded randomized clinical trial was conducted with 100 dermatophytosis cases who visited the outpatient department of dermatology at Khwaja Yunus Ali Medical College, Enayetpur, Sirajgonj, between October 2022 and September 2024. The study included individuals diagnosed with Tinea corporis, Tinea cruris, and Tinea faciei, with at least 50% body surface area involvement. Exclusion criteria included pregnant and lactating women, individuals with known allergies to itraconazole or terbinafine, those with a history of oral anti-fungal use in the recent months, and patients with hepatic, cardiac, or renal impairment, abnormal results in complete blood count (CBC), liver function tests (LFT), and renal function tests (RFT). An informed written consent was taken from the eligible participants who met the inclusion criteria before joining the study. Treatment consisted of itraconazole and terbinafine administered twice daily till/until lesion cured or for a maximum of 6 weeks. In this study, cure was defined as the absence of erythema, pruritus and scaling, with a negative KOH test.

Patients were assessed for the severity of clinical parameters, particularly erythema, using a four-point scale: 0 = none, 1 = mild, 2 = moderate, and 3 = severe. Evaluations were conducted at baseline, at second week, and at fourth week, including CBC, LFT, and Electrocardiography (ECG). Patients were also enquired about any side effects related to the treatment. Follow-ups were scheduled at two-week intervals for up to eight weeks (four weeks post-treatment or till/until cure, whichever came first). Monitoring covered the completed treatment duration and an extra four weeks after completed treatment. The 'Rule of 9' was employed to calculate the Body Surface Area (BSA). Outcomes were categorized as cured (complete clinical resolution), partially cured (more than 50% improvement in total BSA involvement), or failure (worsening condition, no improvement after four weeks of anti-fungal treatment, or less than 50% improvement in total BSA involvement). All data were analyzed using a Statistieal Package for the Social Sciences (SPSS) Version 25.

Results:

The majority of participants are aged 16–30 years (57%), followed by those aged 31–45 years (33%). A smaller proportion falls within the 46–60 years of age group (7%), and only 3% are above 60 years. The average age is 32.38 years, with a standard deviation of 12.42. Regarding gender, males constitute the majority (79%), and most participants are married (77%) (Table 1).

Table 1: Demographic profile among the study participants (n=100)

Profile trails	Frequency	Percentage (%)
Age in years		
16-30	57	57.0
31-45	33	33.0
46-60	7	7.0
>60	3	3.0
Mean±SD	32.38±12.42	
Sex		
Male	79	79.0
Female	21	21.0
Marital status		
Married	77	77.0
Unmarried	23	23.0

Table 2: Distribution of disease duration among the study participants (n=100)

Duration	Frequency	Percentage (%)
≤12 months	83	83.0
1-3 months	9	9.0
>3 months	8	8.0

Most participants (83%) had the disease for 12 months or less, while 9% had it for 1–3 months, and 8% for more than 3 months (Table 2).

Table 3: Diagnosis of the study participants' conditions (n=100)

Diagnosis	Frequency	Percentage (%)
Tinea corporis	50	50.0
Tinea incognito	20	20.0
Tinea curis	18	18.0
Tinea faciei	12	12.0

The most common diagnosis wasTinea corporis (50%), followed by Tinea cruris (18%), Tinea faciei (12%), and Tinea incognito (20%) (Table 3).

Table 4: Location of the disease among the study participants (n=100)

Site of disease	Frequency	Percentage (%)
Genital area	11	11.0
Whole body	14	14.0
Trunk	30	30.0
Axilla	10	10.0
Back of the chest	5	5.0
Peri-oral region	4	4.0
Buttock	4	4.0
Left thigh	5	5.0
Scrotum	4	4.0
Face	3	3.0
Groin	3	3.0
Neck & chest	3	3.0
Hands	2	2.0
Lower back	2	2.0

The most frequently affected areaswere the trunk (30%), the whole body (14%), and the genital area (11%). Other affected sites includedwere the face, peri-oral region, neck, hands, axilla, chest, buttocks, thighs, scrotum, groin, and lower back (Table 4).

Table 5: Itching of the study participants (n=100)

Itching	Frequency	Percentage (%)
Mild	10	5.0
Moderate	34	17.0
Severe	56	28.0

Severe itching was reported by 56% of participants, while 34% experienced moderate itching, and 10% reported mild itching (Table 5).

Table 6: Follow up of the study participants (n=100)

Follow up	Frequency	Percentage (%)
After 2 weeks		
Improved	65	65.0
Not improved	27	27.0
Cured	8	8.0
After 4 weeks		
Improved	83	83.0
Not improved	6	6.0
Cured	11	11.0
After 6 weeks		
Improved	6	6.0
Not improved	3	3.0
Cured	91	91.0

The majority showed improvement, with cure rates increasing from 67% at 2 weeks to 83% at 4 weeks, and a significant 91% at 6 weeks (Table 6).

Discussion:

Dermatophytosis is a common superficial fungal infection worldwide[1-3]. Over the years, many anti-fungal medications have been developed, with additional treatments currently under research. Among these, terbinafine is one of the most commonly used anti-fungal agents for superficial mycosis, owing to its broad-spectral fungicidal properties. It has consistently shown high

effectiveness against tinea infections, achieving cure rates above 90% when administered at a daily dose of 250 mg for two weeks[14].

Recent reports highlight cases of failed clinical cases and relapses with terbinafine in cases with dermatophytosis, coinciding with a rise in terbinafine resistance[15]. Although terbinafine resistance remains relatively uncommon in clinical settings, some studies have documented its presence in clinical isolates[6-8]. For instance, it was found that only 43 out of 100 patients achieved sustained clinical and fungal cure following a two-week course of oral terbinafine, underscoring the issues of incomplete fungal cure and relapse after a recommended therapy for tinea corporis and tinea cruris[15].

Reduced in effective drug concentration is one of the key mechanisms driving anti-fungal resistance[16]. It is particularly evident with terbinafine, as its standard dosing regimen of 250 mg daily leads to significant storage in skin and fatty tissues[9].This raises concerns that the present standard terbinafine dosage of 250 mg/day could be inadequate, especially in the context of rising fungal drug resistance fueled by increased use, irrational prescribing, and over-the-counter availability of anti-fungal agents[10-11]. Although there is no conclusive evidence on the optimal approach to preventing resistance, historically, the most widely recommended strategies have been included the prudent use of anti-fungal agents and ensuring appropriate dosing, particularly by avoiding low-dose anti-fungal treatments[14-15]. Increasing the dosage of terbinafine has emerged as a practical approach to tackle these challenges. A study demonstrated that higher doses of terbinafine were associated with greater trough and peak plasma concentrations, as well as higher area under the curve values. These pharmacokinetic parameters correlated with a lower minimum inhibitory concentration (MIC) values and enhanced anti-fungal efficacy[17].

Our study reported that the mean age of patients was 32.38±12.42 years. Regarding gender distribution, 79% of the cases were male, and 57% of the cohort fell into the 16–30 age range. Additionally, 83% of patients had a disease duration of 12 months or less. These findings were consistent with previous studies[3-8,10]. For example, authors reported a mean patient age of 36.47±11.03 years, with 64.9% of participants being female and 66.7% belonging to the 18–40 years age group. Furthermore, 75.4% of patients in their study had a disease duration of six months or less[1].

This study reveals that tinea corporis was the most common variant, representing 50% of cases, which aligns with findings from previous studies[1,14-17]. Similarly, authors reported tineacorporis as the predominant variant, accounting for 71.9% of cases in their study[1].

This study aimed to evaluate the efficacy and safety of combined terbinafine and itraconazole once daily in patients with tinea infections. The results demonstrated a gradual improvement, with 65% of patients showing progress in the 2-week group, 83% in the 4-week group, and 91% achieving clinical success in the 6-week group. These findings were consistent with prior studies. For instance, scientists reported an 87% clinical success rate in patients with tinea corporis treated with terbinafine at 500 mg daily[15]. Similarly, authors observed a 100% success rate in patients with tinea pedis treated with terbinafine at 250 mg twice daily[16]. Some researchers reported an 81.3% clinical success rate and a 75% fungal success rate in patients with onychomycosis treated with only terbinafine[17].

This study has certain limitations. Being observational in nature and based on a survey design, it is not entirely free from the risk of selection bias. Furthermore, the study did not consider the use of other anti-fungal treatments, such as topical agents, which might have impacted the results. Long-term comparative clinical studies are necessary to overcome the limitations identified in this present study.

Conclusion:

This study demonstrated that combining itraconazole with terbinafine leads to a increased rate of clinical cure. However, neither combination was effective against dermatophytosis previously treated with topical steroid-containing formulations. There is an urgent need for stringent regulations to prevent the irrational use of combined corticosteroid-antifungal creams. Educating general practitioners about the inappropriate use of such

preparations is essential. Additionally, increasing public awareness about preventive measures against dermatophytosis and ensuring proper treatment for affected family members and close relatives can help reduce the overall burden of the tinea infections.

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Conflict of interest:
No conflict of interest.

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Authors' Contributions:
Basak AK and Debnath J conceived and designed the study. Basak AK, Debnath J, Monowar T and Jui FN analyzed the data, and interpreted the results. Basak AK, Debnath J, Monowar T and Jui FN wrote up the draft manuscript. Monowar T was involved inthe 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.

Ethical 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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Original Article ***Open Access***

Drug Addiction among Street Children in Dhaka City: An Uprising Problem

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Abstract

Background: Drug addiction is a burning problem in Bangladesh affecting vast population especially the street children. The spread of multi drug use has aggravated the overall situation affecting their personal, economical and social life, impairing health status, increasing crime and other unwanted risky behavior. These damages are not naively confined to them only, rather negatively fall on entire society. **Objective:** To assess the prevalence and patterns of drug addiction among street children in Dhaka City and examine the socio-economic factors contributing to drug addiction. **Methods:** The selection of both research area and participants was executed using purposive and accidental sampling methods. A dual qualitative and quantitative methodology, utilizing a sample survey as its primary research technique was followed during January 2023- December 2023. This research, mainly employed participant observation, semi-structured interview and in-depth interview methods, collected information from 37 respondents to understand the prevalence, pattern, reasons and socio-economic factors contributing to drug addiction among the street child with greater focus on their life reality and rehabilitations. Respondents have been chosen from Karwan bazar, Nilkhet, Suhrawardy Uddan, Kamalapur Railway station, Bhasantek, Manikdi, Mirpur Darussalam and Gabtoli area of Dhaka City. **Results:** Most of the respondents were male 31(83.78%), belonged to age group 15-16 years 15(40.54%) and educational qualification was primary level 16(43.24%). Most of them resided at Kamalapur Railway station 12(32.43%), involved in carrying luggage at market 24(64.87%), daily income was around 251-350 taka 22(59.46%), separated from family 32(86.49%). Commonly used drug included aica 10(27.02%), tobacco mixed with ganja 8(21.62%), cannabis 7(18.92%). Most common cause of drug addiction was easy availability 15(40.54%) and influence of peers and adults 12(32.43%). Effects included loss of appetite 32(86.49%), involved in illegal activities 32(86.49%, increase risk of violence 31(83.78%). **Conclusion:** A comprehensive intervention strategy needed to be developed involving various stakeholders such as government agencies, non-governmental organizations, community leaders and healthcare professionals. These strategies should encompass prevention, treatment and rehabilitation programs tailored to the unique needs of street children.

Keywords: Drug addiction, Street children, Dhaka city.

Introduction:

Drug problem is continuing to have a grave impact on the world community, causing immense sufferings ranging from individuals to state concerns. It put a pressure upon health system, crippling the development, creating multiple setbacks and escalating security system. Bangladesh

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is situated close to two major drug producing and trafficking belts: the Golden Crescent and the Golden Triangle[1]. It is hard to deny that such geographical location is by far responsible for drug inflows into our soil. Beyond that, the rapid expansion of global connectivity, edging up of advanced technology and after all the hybridization or blending of on and off-line life made this discomfort more severe. It is very important to iron out this menace to build a drug-free nation for our next generation.

Street children represent one of the most vulnerable and marginalized groups in our society, facing a multitude of challenges that undermine their physical, emotional and psychological wellbeing. Among these challenges, drug addiction stands as a particularly formidable threat, perpetuating a cycle of despair, poverty and vulnerability[2,3]. Despite global efforts to address drug addiction and its associated consequences, street children remain largely excluded from main stream interventions and policies[4].

Objective:

To assess the prevalence and patterns of drug addiction among street children in Dhaka city and examine the socio-economic factors contributing to drug addiction.

Materials and Methods:

This research employs a dual qualitative and quantitative methodology, utilizing a sample survey as its primary research technique. The selection of both research area and participants was executed using purposive and accidental sampling methods. To gather quantitative data, we developed a structured survey focusing on addiction among street children. Simultaneously, alongside the qualitative survey, we conducted several case studies. This research, mainly employed participant observation, semi-structured interview and in-depth interview methods, collected information from 37 respondents to understand the reasons of drug addiction among the street child with greater focus on their life reality. Respondents have been chosen from Karwan bazar, Nilkhet, Suhrawardy Uddan, Bhasantek, Manikdi, Mirpur Darussalam and Gabtoli area of Dhaka City during January 2023-December 2023.

Street children constitute a very different body of knowledge, their life is full of diverse experiences which they most of the time intentionally hide from us and conversely, sometimes exaggeratedly expose themselves to us. Therefore, only quantitative approach to understand their life, especially, sensitive issues like reasons of drug addiction are very inadequate. Qualitative approach has also been chosen to conduct this study because conventional survey-based quantitative approaches are unable to create a trust relationship between the interviewer and child[5].

Result:

Table-1 showed among the 37 respondents most were male 31(83.78%) and maximum belonged to age group 15-16 years 15(40.54%) followed by 13-14 years 11(29.73%). Most of the children were Muslim 35(94.59%) and their educational qualification were of primary level 16(43.24%) followed by a group of illiterate14(37.83%).

Table-1:

Distribution of street children as per demographic characteristics. (n= 37)

Demographic characters		Total	Male	Female
Gender		37(100%)	31(83.78%)	6(16.22%)
Age group	Less than 10 years	3(8.11%)	3(100%)	0
	11-12 years	8(21.62%)	7(87.5%)	1(12.5%)
	13-14 years	11(29.73%)	9(81.81%)	2(18.19%)
	15-16 years	15(40.54%)	12(80%)	3(20%)
Religion	Muslim	35(94.59%)	30(85.71%)	5(14.29%)
	Hindu	2(5.41%)	1(50%)	1(50%)
Education	Primary	16(43.24%)	11(68.75%)	5(31.25%)
	Secondary	7(18.92%)	7(100%)	0
	illiterate	14(37.83%)	13(92.86%)	1(7.14%)

Table-2 showed maximum respondents resided at Kamalpur Railway station 12(32.43%) followed by Karwan bazar area 11(29.73%). They used to sleep at railway station 12(32.43%) followed by bus station 10(27.02%). All of them took their lunch regularly but at dinner the number was less 22(32.43%). Only a few took their breakfast 9(24.32%). Majority used railway station washrooms 12(32.43%), bus station toilets 10(27.02%) and public toilets 8(21.62%) for their various needs.

Table-2:
Frequency distribution of habitat, sleeping place, intake of food, toilet & bathing place characteristics. (n= 37)

		Total-37	Male-31	Female-6
Residence area/ habitat	Kamalapur Railway station	12(32.43%)	9(75%)	3(25%)
	Karwan bazar	11(29.73%)	10(90.90%)	1(9.10%)
	Mirpur Darussalam	4(10.81%)	4(100%)	0
	Suhrawardy Uddan	3(8.11%)	1(33.33%)	2(66.67%)
	Nilkhet	2(5.41%)	2(100%)	0
	Gabtoli	2(5.41%)	2(100%)	0
	Manikdi	2(5.41%)	2(100%)	0
	Bhasantek	1(2.70%)	1(33.33%)	0
Sleeping place at night	Railway station	12(32.43%)	9(75%)	3(25%)
	Bus station	10(27.02%)	10(100%)	0
	Open space	4(10.81%)	2(50%)	2(50%)
	Market place	4(10.81%)	4(100%)	0
	Foot over bridge	3(8.11%)	2(66.67%)	1(33.33%)
	Mazar	3(8.11%)	3(100%)	0
	other	1(2.70%)	1(100%)	0
Regular intake of Food (same respondent take food in multiple time)	Breakfast	9(24.32%)	7(77.78%)	2(22.22%)
	Lunch	37(100%)	31(83.78%)	6(16.22%)
	Dinner	22(59.46%)	18(81.82%)	4(18.18%)
Bathing place	Railway station wash room	12(32.43%)	9(75%)	3(25%)
	Bus station wash room	10(27.02%)	9(90%)	1(10%)
	Pond	7(18.92%)	7(100%)	0
	Public wash room	4(10.81%)	2(50%)	2(50%)
	CNG pump wash room	3(8.11%)	3(100%)	0
	other	1(2.70%)	1(100%)	0
Toilet use	Public toilet	8(21.62%)	5(62.5%)	3(37.5%)
	Railway station toilet	12(32.43%)	9(75%)	3(25%)
	Bus station toilet	10(27.02%)	10(100%)	0
	CNG pump toilet	3(8.11%)	3(100%)	0 0
	Mazar toilet	3(8.11%)	3(100%)	
	other	1(2.70%)	1(100%)	0

Table-3 revealed maximum respondents 22(59.46%) earned 251-250 taka daily and way of income included porter/carrying luggage at markets 24(64.87%), street beggar 4(10.81%), selling flower 3(8.11%), water 3(8.11%), newspaper 2(5.41%). Most of them were separated from family 32(86.49%).

Table-3:
Frequency distribution of occupation, daily income, parents' status. (n= 37)

		Total-37	Male-31	Female-6
Occupation/ Type of work involved	Tokai at market, luggage carrying/ porter,	24(64.87%)	24(100%)	0
	Street beggar/ rag picking	4(10.81%)	3(75%)	1(25%)
	Flower selling	3(8.11%)	0	3(100%)
	Water selling	3(8.11%)	1(33.33%)%)	2(66.67%
	Newspaper distribution	2(5.41%)	2(100%)	0
	Other	1(2.70%)	1(100%)	0
Daily Income in Taka	Below 150	4(10.81%)	4(100%)	0
	151- 250	9(24.32%)	9(100%)	0
	251-350	22(59.46%)	16(72.72%)	6(27.28%)
	More than 350	2(5.41%)	2(100%)	0
Relation with family	Living with family	1(2.70%)	1(100%)	0
	Separated from family	32(86.49%)	27(84.38%)	5(15.62%)
	No family	4(10.81%)	3(75%)	1(25%)
Parent's living status	Both father, mother living	5(13.51%)	5(100%)	0
	Only father alive	6(16.21%)	4(66.67%)	2(33.33%)
	Only mother alive	22(59.46%)	19(86.36%)	3(13.64%)
	No parents	4(10.81%)	3(75%)	1(25%)

Table-4 exhibit most common drug used was aica/ toluene 10(27.02%), followed by tobacco mixed with ganja 8(21.62%), various forms of cannabis 7(18.92%), yaba 4(10.81%), sedatives/ sleeping pill 3(8.11%).

Table-4:
Frequency distribution of commonly used drugs. (n= 37)

	Total-37	Male-31	Female-6
Toluene/ aica	10(27.02%)	6(60%)	4(40%)
Tobacco mixed with ganja	8(21.62%)	7(87.5%)	1(12.5%)
Cannabis/ ganja/ siddi/ sabji/	7(18.92%)	6(85.71%)	1(14.29%)
Yaba	4(10.81%)	4(100%)	0
Barbiturate/ sedatives / chakti/ sleeping pill	3(8.11%)	3(100%)	0
Alcohol/ Toddy	1(2.70%)	1(100%)	0
Phensidyl syrup	2(5.41%)	2(100%)	0
Opium derivatives (vicodine, methadone)	1(2.70%)	1(100%)	0
Heroin/ Pethidine	1(2.70%)	1(100%)	0

Table-5 signify that most common cause of drug addiction among street children was easy accessibility and affordability 15(40.54%), followed by peer influence 12(32.43%), absence of parental guidance 3(8.11%), isolation and emotional distress 3(8.11%), deprivation of fundamental needs 2(5.41%) and turmoil in the home environment 2(5.41%).

Table-5:
Frequency distribution showing causes of drug addiction. (n= 37)

	Total-37	Male-31	Female-6
Easy Accessibility and Affordability	15(40.54%)	13(86.67%)	2(13.33%)
Influence of Peers and Adults	12(32.43%)	10(83.33%)	2(16.67%)
Isolation and Emotional Distress	3(8.11%)	2(66.67%)	1(33.33%)
Absence of Parental Guidance and	3(8.11%)	3(100%)	0
Abuse Deprivation of Fundamental Needs	2(5.41%)	1(50%)	1(50%)
Turmoil in the Home Environmen	2(5.41%)	2(100%)	0

As showed in table-6, most common side effects of drug addiction was loss of appetite 32(86.49%), involvement in illegal activities 32(86.49%), increase risk of violence 31(83.78%) loss of trust with neighbors/ community 29(78.39%). Some of the drug users felt good 25(67.57%), had blurred vision 20(54.05%), weakness 19(51.35%), headache 19(51.35%) etc.

Table-6:
Frequency distribution showing effects of drugs on respondents. (n= 37)
(same respondent has different effects)

	Total-37	Male-31	Female-6
Loss of appetite	32(86.49%)	27(84.37%)	5(15.63%)
Involved in Illegal activities	32(86.49%)	27(84.37%)	5(15.63%)
Increase risk of violence	31(83.78%)	27(87.10%)	4(12.90%)
Loss of trust with neighbors/ community	29(78.39%)	25(86.21%)	4(13.79%)
Involvement in unprotected sexual activities	22((59.46%)	16(72.72%)	6(27.28%)
Feeling good	25(67.57%)	22(88%)	3(12%)
Blurred vision	20(54.05%)	16(80%)	4(20%)
Weakness	19(51.35%)	15(78.95%)	4(21.05%)
Headache	19(51.35%)	18(94.74%)	1(5.26%)
No worry	18(48.65%)	14(77.78%)	4(22.22%)
Sleep well	12(32.43%)	9(75%)	3(25%)
More attention to work	8(21.63%)	7(87.5%)	1(12.5%)

Discussion:

Drug addiction is a chronic, relapsing disorder in which compulsive drug-seeking and drug-taking behavior persists despite serious negative consequences[6]. Bangladesh, though not a drug producing country has now become a victim of drug. This problem is based on its historical perspectives, geographic location, ethnicity, tradition and heritage, rapid urbanization, increase of population, vast development, use of internet & IT, lack of social awareness etc. The international narcotics producing zone, Golden Crescent, consisting Pakistan, Afghanistan and Iran is located in its North-west. The Golden Triangle consisting Myanmar, Laos and Thailand is located at its South-East corner. It is estimated that over Taka 70 million every day are spending on illegal narcotics[1].

In this study maximum respondents belonged to age group 15-16 years 15(40.54%) followed by 13-14 years 11(29.73%). Similar age group was also identified in previous studies. The number of the Dhaka City's young population is relatively high due to age selective rural-urban migration[7,8]. According to Khan[9] 44.26% of youths in the country became addicted to drugs in 2014 while the number was 53.27% in 2012.A rapid situation assessment on drug and substance use was conducted by UNICEF in 2008. The study was focused in selected divisional cities and convergence districts of Bangladesh namely Dhaka and Gazipur in Dhaka division and other district of the country, Findings from the rapid assessment revealed that the average age of the drug users was 16 years, with 42 % of them being below the age of fifteen years, 17% of the injecting drug users have shared syringe/ needles[8]. The main initiation age 11 years to 15 years, during this age 79% of the children had initiation to sex. 82% of the girls had ever sold sex for buying[7]. McGarvey EL et al found in their study that the mean age of first-time drug/inhalant abusers was 13 years[10].

The Asia- Pacific region serves as the domicile for almost half of the global child population, encompassing a significant segment of street children. In the context of Bangladesh, around 42 million individuals (accounting for 32.2% of the total population) belong to the age group of 5 to 17 years. Particularly within Dhaka city estimations suggesting a street children count of approximately two million. This corresponds to the criteria outlined by the 1989 International Convention on the Rights of the Child, which designates individuals up to the age of 18 as children[11]. As revealed by officials from the Narcotic Control, approximately 14.5% of the total street children in Bangladesh and 17% of the total street children in Dhaka City are addicted to drug[12].Street children, especially those ensnared by addiction, present themselves before us in our daily urban lives, often bearing a pallid countenance, tattered clothing, and unkempt hair. Despite their visible presence, their underlying life realities largely remain concealed from our view. A comprehensive study conducted by the Foundation for Research on Educational Planning and Development (FREPD) in 2003 sheds light on these hidden aspects[13,14].

This study revealed maximum respondents 22(59.46%) earned 251-250 taka daily and way of income included carrying luggage at markets 24(64.87%), street beggar 4(10.81%), selling flower 3(8.11%), water 3(8.11%), newspaper 2(5.41%). This findings coincides with previous study by Sultana MT[15] which described most of the respondents (50%) were classified as 'Tokai'/porter, 24% as 'Street Beggars'.

This study found most common cause of drug addiction among street children was easy accessibility and affordability 15(40.54%), followed by peer influence 12(32.43%), absence of parental guidance 3(8.11%), isolation and emotional distress 3(8.11%), deprivation of fundamental needs 2(5.41%) and turmoil in the home environment 2(5.41%). Most of them were separated from family 32(86.49%). The core of the parent-child relationship lays the foundation of family bonding[16], emphasize the crucial role of parental monitoring and supervision in the realm of drug abuse prevention[17]. Felsman (1989) found that 97 per cent of his sample of Colombian children in street situations had actively abandoned their households due to a non-conducive family environment[18]. Other researchers such as Veale's (1992) study[19] on drug addicted street children in Sudan and Ireland also found similar result regarding family relationship and street involvement.

The issue of drug addiction among street children in Dhaka city demand noteworthy attention. Dhaka, as one of the most densely populated urban centers in Bangladesh, grapples with its reputation as a crime hotspot, further amplifying the susceptibility of its children to drug addiction[20,21]. Health related issues discovered in this study coincides with other studies performed earlier which showed positive sensations of well-being (13.85%), weakness (14.82%) and dizziness (12.5%), blurred vision (8.82%), restlessness (21.32%), breathlessness (1.47%), disorientation (12.35%), restful sleep (12.35%), and relief from distressing thoughts (11.98%)[15].

Considering food intake pattern this study found all the respondent 37(100%) used to take their lunch, 22(59.46%) took dinner and 9(24.32%) took breakfast. Foundation for Research on Educational Planning and Development survey (2003)[22] unveiled that among the respondents from the street children population, 57% managed to consume three meals daily, 39% had access to two meals, while a marginalized 4% had less than two meals a day. Notably, a significant 88% of these children procured their sustenance from street vendors, 5% resorted to begging, and a negligible portion of less than 1% scavenged from dustbins[23]. Study performed by Sultana et al.[15] found 4% of the respondents work for a long hour having no adequate food or starvation, inner pain, grief and therefore they take different drugs to release their stress and hunger. Besides, 26% of respondents explained that they could afford those addicted materials cheaply. Street children live in a group with peers and other adults, among them 14% explained that they got used to taking sub stance by their influence and assistance. About 10% of street children expressed about drug addiction due to social isolation and depression, and others, 12% described their issue about turmoil in the home environment. Furthermore, 12% of respondents got drug-addicted because of having absence of parental guidance and abuse.Shama and Suresh Joshi emphasize that the challenges faced by street children are particularly pronounced in developing countries, estimating that over 100 million children live and labor on the streets in such nations. The circumstances leading to the emergence of street children are multifaceted and include factors like poverty, overpopulation, and illiteracy[24].

This study found that most common drug used by street children was aica/ toluene 10(27.02%), followed by tobacco mixed with ganja 8(21.62%), various forms of cannabis 7(18.92%), yaba 4(10.81%), sedatives/ sleeping pill 3(8.11%). Methods of taking aica include 'Sniffing' (nasal inhalation) of vapours directly from an open container or a surface soaked with the substance, 'Bagging' which involves breathing in and out of a paper or plastic bag filled with a small amount of a volatile substance and 'Huffing' (oral inhalation) from a rag or cloth soaked in a volatile substance that is held over the mouth or nose.Rahman FN et al. found in previous study that highest rate of addicted young in Dhaka city was with barbiturates (56.14%), amphetamine (49.12%), marijuana (36.84%), alcohol (29.82%) etc[25]. Sultana et al[15] also reported that common substances of abuse among these young individuals include cannabis-laced cigarettes and a type of adhesive called 'Dandy'/aica.

Sarker MJA[26,27] found 50% of the respondents of this study started smoking cigarette first and then turned to drug addiction. 'Glue sniffing' is second in the list. Use of 'glue sniffing', cannabis, 'Zakki' and different types of tablets like Ten, Baba, Sonali etc. are much more frequent than other because they are less expensive and easily collectable compared to other types of drugs. Alam et al. found during 1999 the rate of nicotine or nicotine users were 95.08%, which is far more than our findings[28]. Sarker AK in their recent study of 2023 found that nicotine or nicotine users was highest (about 95.08%) among the drug addicted participants. The second most used drug among the addicted people was alcohol (63.93%) and the third one was Marijuana/ Hashish/Bhang (44.26%). Apart from these, among the addicted respondents 44.62% tried out tobacco, 16.39% tried out sedatives, 24.59% tried out amphetamines, and 4.92% tried out both heroin and solvents/glue[29]. It has been observed due to passage of time choice of drugs for addiction has been changed probably due to availability of different variety of drugs and cost efficiency.

This study described 32(86.49%) of respondents were involved in illegal activities, 31(83.78%) showed increase risk of violence, 29(78.39%) lost trust with neighbors/ community, 22 (59.46%) were

involvement in unprotected sexual activities. Sources at the Drugs and Narcotic Control intelligence wing found that around 10,000 cases are filed and 9,000 people are arrested every year in connection with drug related violence and crimes[30]. Mahmud et al[31] found in previous study that 60%respondents reported of having unprotected sex were in the age group of 11 to 15 years. Street children in Dhaka city were characterized by their residence outside of familial homes, a significant proportion of whom have been forsaken and left exposed to the perilous allure of drug addiction. This vulnerability subsequently entangles these disadvantaged children within harsh, unforgiving realities, frequently leading them down the path of criminality[32].

In a survey conducted among 118 street children living on Kathmandu valley, reasons for being on the streets included domestic violence, deprivation/lack of food at home, seeking employment and friends' influence[33]. While in a survey conducted in 12 Zambian towns, 23% of 1584 street children involved in crime and drug reported arrest by police as a major problem faced by them on the streets[34]. Another study established a connection between low self-control and violent behavior, with low self-control emerging as the most potent predictor of violent offenses[35]. Hence, both of these aspects are pertinent, underscoring this study's illumination of the origins of juvenile drug addiction. Furthermore, these viewpoints substantiate Sutherland's 'Differential Association Theory' (1947), which posits that criminal behavior is acquired through inter personal interactions within closely-knit circles[36].

Conclusion:

A comprehensive intervention strategy needed to be developed involving various stakeholders such as government agencies, non-governmental organizations, community leaders and healthcare professionals. These strategies should encompass prevention, treatment, and rehabilitation programs tailored to the unique needs of street children.Ensuring access to quality education for street children is very essential. Establishment of rehabilitation centre and safe place, counseling and mental health support, community engagement and awareness campaign, stronger legal protections are also required for their better future.

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Rahman FN, Ahmad M designed and drafted the study, collected and analyzed the data, interpreted the results, completed literature review and wrote up the draft manuscript. Ali M, Sultana F, Siddique T, Moin S and Sarker MFR were involved in data collection, the manuscript review and editing. All authors read, gave the final critical review of the manuscript and approved it.

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.

Ethical 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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Impact of Father's Self-Esteem and Parenting Attitude Practice on Adolescent

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Abstract

Background: A parent's involvement in raising a child is distinct. A father's contribution to a child's upbringing cannot be replaced, even though the mother plays a crucial part. This study aims to understand the dynamics between paternal self-esteem and parenting attitudes. By promoting fathers' self-esteem and offering targeted interventions to enhance parenting skills, one can contribute to the overall well-being and development of adolescents within the family context. **Objectives:** To assess the fathers' self-esteem and how it affects attitudes toward parenting having an adolescent. **Methods:** In this cross-sectional study, 188 fathers who had at least one adolescent were chosen from a specific rural area of Jashore district using a convenient sampling technique. Data were gathered through in-person interviews using a semi-structured questionnaire. Rosenberg's self-esteem scale and the attitude toward parenthood scale were two of the tools used to examine the fathers' behavioral traits. Following the goals of the study, the data were analyzed using the Statistical Package for Social Science (SPSS). Informed consent was obtained before data collection, and several phases of the investigation addressed ethical issues. **Results:** The results showed that the fathers' mean age was 44.55±8.515 years, with the 30-45-year-old group having the highest frequency (59.6%). The results of the study revealed that 94.1% of the participants were Muslims, and 41.5% of them were mostly in agriculture. Of the respondents, 38.8% had finished primary school, while a sizable portion (33%), had no formal education. The mean self-esteem score was 32.36±2.955, and the average score on the attitude toward parenthood scale was 6.45±0.512. Although it was an important factor, fathers' parenting attitudes did not significantly correlate with their self-esteem ($r = 0.084$, $p = 0.251$). The parenting attitudes of the participating fathers did not show significant mean differences between their family type ($p = 0.667$) and their religion ($p = 0.678$). **Conclusion:** This study revealed that a father's self-esteem has no bearing on his parenting.This demonstrates the universality of fatherhood.

Keywords: Parenting attitudes, Self-esteem, Adolescent.

Introduction:

Parenting is a complex and deeply personal journey, influenced by a myriad of factors including cultural norms, personal experiences, and individual attitudes. At the heart of effective parenting lies the attitude of the parent, which shapes interactions, decisions, and the overall upbringing of children. The growing interest in the interdependence of both parents' roles in childrearing coincided with the change in focus away from fathers and toward mothers. To adopt a family system, view on parenting and parent-child relationships, the father's active involvement must provide a strong

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foundation. The value of fathers in parenting cannot be replaced[1].

Attitude is a key component of human psychology, which is frequently defined as the "lens" through which people see and react to the world around them Parenting behavior and skills are both a part of the parenting attitude[2]. A positive parenting mindset combined with positive parenting practices leads to a healthy parent-child relationship. Conversely, unfavorable views about parenting have little effect[3].

Fathers' involvement and parenting attitudes vary from society to society according to their cultural beliefs and values[4]. It may be positive or, negative and involves a degree of self-evaluation. self-esteem is how he feels about those[5]. Numerous scholars have examined the crucial social psychology topic of self-esteem. In their research, they refer to oneself as having self-esteem or to other similar concepts (such as self-evaluation, self-respect, or self-confidence[6]. The majority of studies on self-esteem focus on global self-esteem, or a person's attitude toward their entire being, whether it be good or negative.

Self-confidence and self-deprecation were the two components of the Rosenberg Self-Esteem Scale. Owenshas reaffirmed the existence of the self-confidence and self-deprecation components of self-esteem. Additionally, he showed that both elements were well-fitting into a second-order construct of global self-esteem, with a significantly stronger correlation between self-confidence and global self-esteem than between self-deprecation and it[7].

The dualistic notion that mothers should be the primary caregivers while fathers' ought to play the role of providers has long-held appeal in traditional society. There was a growing demand for fathers to be involved in joint child-rearing because of the shifting family structure, rise in dual-income families, and feminist ideas[8]. Stated differently, men are supposed to take on a more developed and customized role in co-parenting as their children grow and mature, rather than being helpers[9]. Furthermore, research has been conducted on the perception of fathers, the establishment of a parenting scale, and the connection between father involvement and child development[10]. However, the majority of fatherhood research focuses on how fathers' actual parenting styles and parenting time affect the development of their kids, with varying degrees of success reported by researchers[8]. Although these researches helped to increase recognition of the significance of fathers' roles, the objective of this article is to examine the relationship between fathers' self-esteem and their parenting attitudes toward adolescents, exploring how variations in paternal self-esteem may influence parenting styles, interactions, and outcomes within the adolescent-parent dynamic.

Materials and Methods:

Study design and study population:

This descriptive type of cross-sectional study was carried out in a selected rural area of the Jashore district of Bangladesh from January 1 to December 31, 2021. Fathers who had an adolescent child were the study population. Fathers who were mentally unfit or did not want to participate were not included in the study.The survey comprised 188 fathers in all. Convenience sampling was utilized to choose the participants.

Data collection:

The father of the adolescent was interviewed in person to gather the data. Interviews were done at their homes. Responders were fully informed about the study before data was collected, and their written agreement was secured. Every day's work concluded with checking and verifying the collected data.

The questionnaire was designed by utilizing the variables that were chosen following the specific objectives. It was prepared by looking through both qualitative and quantitative literature for pertinent items. The questionnaire asked questions about fathers' roles in parenting based on a scale of attitudes toward parenthood. To assess the fathers' parenting views in this study, the attitude toward parenthood scale was utilized. The fathers were asked to answer nine statements on a seven-point Likert scale, ranging from strongly disagree to strongly agree.

Rosenberg's self-esteem scale, a four-point Likert scale was used to measure self-esteem and to analyze the effectiveness of communication between the father and the adolescent. The 10

statements were rated from 4 (strongly disagree) to 1 (strongly agree) where statements 2, 5, 6, 8, and 9 were scored in reverse order. A total self-esteem score is obtained by adding up all of the responses; greater scores correspond to higher levels of self-esteem.

The questionnaire was pretested among respondents of similar characteristics. The questionnaire was then finalized after necessary modification according to the findings of pretesting.

Data analysis:

SPSS was used as a tool for data analysis. Frequency tables, bar diagrams and pie charts were employed for the descriptive statistics. For categorical variables, the proportion was shown in the tables, whereas for continuous variables, the mean ± SD was presented. The study objectives were met through the use of Pearson's correlation analysis and t-test.

Ethical consideration:

For conducting the study, formal ethical approval was obtained from the Ethical Institutional Review Board (IRB) of the National Institute of Preventive and Social Medicine (NIPSOM). Before data collection informed written consent was obtained from every respondent after explaining the aim and purpose of that study. All the participants were treated equally and with respect. Privacy and confidentially was maintained strictly and were interviewed in a separate place with care. Some of the self-esteem questions may have been humiliating, but they were asked politely. Prior to the interview, the participants were informed that they would have the freedom to withdraw from the study at any moment. They were told once again that the information gathered during the study would not be shared with anyone other than the research team and would be used in such a way that the participant's name would not be revealed.

Results:

The age of the respondents ranged from 30 to 67 years. Among the respondents, a majority (59.6%) were between 30-45 years of age group. A large number of respondents have no formal education (33%). Maximum fathers completed their primary education (38.8%). Among others, only 4.3% graduated, and 3.7% postgraduate respectively. As the study background was a rural area of Bangladesh, the main occupation of a large number of rural fathers 78 (41.5%) was agriculture. Among others, 42 (22.3%) businessmen, 31 (19.7%) service holders, and 37 (16.5%) were in other occupations. The average working hour of the father was 8.56±1.868 hours. Among 188 fathers, 58 (30.9%) fathers worked 5-7.9 hours a day, 101 (53.7%) fathers worked 8-10.9 hours a day and 29 (15.4%) fathers worked 11-14 hours a day. Among all, the majority of the fathers 146 (77.7%) had an income of monthly 5000-15000 taka, which is an indicator of their low socioeconomic status. Other 25 (13.3%) in between 15001-30000 taka and 17 (9%) are above 30000 taka. The minimum income was 5000 taka and the maximum income was 65000 taka. Among the respondents' wives, the majority 183 (97.3%) were housewives and only 5 (2.7%) were working mothers. This demonstrates the rural areas' demographics.

Table 1: Distribution of the respondents by their socio-demographic characteristics

Categories	Frequency	Percentage
Age (Years)		
30-45	112	59.6
46-60	68	36.2
≥61	8	4.3
Mean±SD		44.55±8.515
Educational qualification		
No formal education	62	33.0
Primary	73	38.8
Secondary	31	16.5
Higher Secondary	7	3.7
Graduate	8	4.3
Postgraduate	7	3.7
Occupation		
Businessman	42	22.3
Service holder	31	16.5
Agriculture	78	41.5
Others	37	19.7
Occupation of respondents' wives		
Housewives	183	97.3
Working mother	5	2.7

Working hours		
5-7.9	58	30.9
8-10.9	101	53.7
11-14	29	15.4
Mean±SD		8.56±1.868
Total family members		
3-4	101	53.7
≥ 5	87	46.3
Total	188	100.0

Religion of the respondents

Among the respondents, the majority 94.1% were followers of Islam, and the rest of them were Hindu [Figure-1].

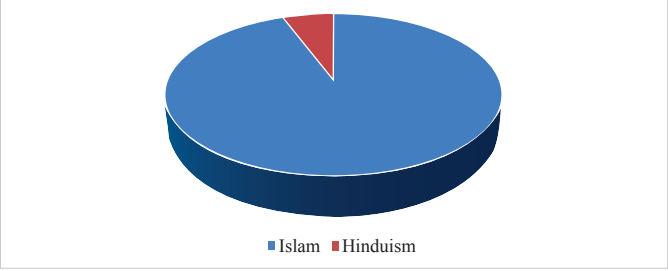

Figure 1: Distribution of the respondents by their religion

Family characteristics of the respondents
Type of family

Most of the respondents, 179 (95.2%) belonged to a nuclear family. Only 9 (4.8%) lived in a joint family [Figure2].

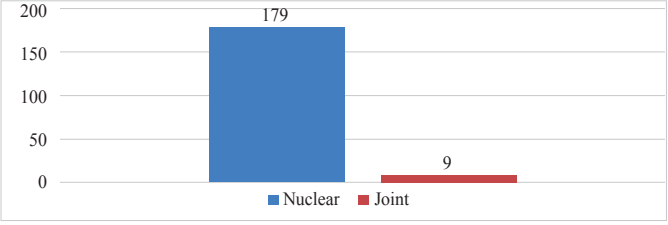

Figure 2: Distribution of the respondents by their family type

Total family members

Among the respondents, 53.7% had 4 members and below. Others had 5 or, more family members [Table 2].

Table 2: Distribution of the respondents by their total family member

Total family members	Frequency	Percent
3-4	101	53.7
≥ 5	87	46.3
Total	**188**	**100.0**

Parenting attitude of the fathers:

This study evaluated fathers' attitudes about parenting using the attitude toward parenthood measure. The fathers were asked to respond to nine items using a seven-point Likert scale that went from strongly disagree to strongly agree. Higher scores on the test were correlated with positive views about parenting. Answers to any of these questions are not either correct or incorrect. After reading each sentence, use the following scale to select the number that best represents the answer: 1, 2, 3, 4, 5, 6, 7 (strongly disagree to strongly agree). Add the numbers and divide by 9 after assigning a number to each item. The higher the number (7 is the highest), the more positive the attitude and the stronger the commitment to parenting. The lower the number (1 being the lowest), the more dismal the attitude and the weaker the commitment to parenting. The Attitude towards parenthood scale had an average score of 6.45±0.512 and a range of 5 to 7.

Total number of family members of the respondents and parenting attitude:

The correlation between fathers' parenting attitude and the total number of their family members was not statistically significant [Table 3].

Table 3: Association between fathers' parenting attitude and their total number of family members

Bivariate correlation	Fathers' parenting attitude	
	r	p-value
Total number of family members of the respondents	0.055	0.453

Religion and parenting attitude

The independent t-test revealed that there was no significant mean difference in parenting attitude concerning the respondents' religion [Table 4].

Table 4: Parenting attitude concerning fathers' religion

Parenting	Religion	N	M	SD	t	df	P-value
attitude	Islam	177	6.45	0.513	-0.416	186	0.678
	Hinduism	11	6.52	0.503			

Family type and parenting attitude:

There was no significant mean difference in parenting attitude to the family type of the respondents, as the independent t-test between them was not statistically significant [Table 5].

Table 5: Parenting attitude to fathers' family type

Parenting attitude	Family type	N	M	SD	t	df	P-value
	Nuclear	179	6.46	0.499	0.446	8.362	0.667
	Extended	9	6.35	0.748			

Self-esteem of the fathers:

In this study, the Rosenberg self-esteem scale was employed to assess self-esteem. It was a ten-point scale with items ranging from 1 (strongly disagree) to 4 (strongly agree) on a four-point Likert scale. Items 2, 5, 6, 8, 9 are reverse scored. The range of scores is 25 to 38, with a mean score of 32.36±2.955. A total self-esteem score is calculated by summing all responses, with higher scores indicating higher levels of self-esteem. The table shows the frequencies and percentages of the 10 statements scores on this scale.

Table 6: Distribution of the respondents by Self-esteem

SL No.	Questions	Strongly Disagree f(%)	Disagree f(%)	Agree f(%)	Strongly Agree f(%)
1	On the whole, I am satisfied with myself.	0	4(2.1)	55(29.3)	129(68.6)
2	At times I think I am no good at all.	1(0.5)	79(42)	7(3.7)	1(0.5)
3	I feel that I have a number of good qualities.	1(0.5)	8(4.3)	152(80.9)	27(14.4)
4	I am able to do things as well as most other people.	1(0.5)	7(3.7)	125(66.5)	55(29.3)
5	I feel I do not have much to be proud of.	52(27.7)	131(69.7)	0	5(2.7)
6	I certainly feel useless at times.	105(55.9)	71(37.8)	12(6.4)	0
7	I feel that I'm a person of worth, at least on an equal plane with others.	0	18(9.6)	136(72.3)	34(18.1)
8	I wish I could have more respect for myself.	0	58(30.9)	123(65.4)	7(3.7)
9	All in all, I am inclined to feel that I am afailure.	106(56.4)	76(40.4)	5(2.7)	1(0.5)
10	I take a positive attitude toward myself.	1(0.5)	7(3.7)	121(64.4)	59(31.4)

Relationship of fathers' parenting attitude with their self-esteem:

A correlation analysis was used to determine the association between fathers' parenting attitudes and their self-esteem. The results revealed a weak correlation that was not statistically significant because the p-value was more than 0.05. This indicates that fathers' parenting attitude is not related to their self-esteem [Table 7].

Table 7: Association between fathers' parenting attitude and their self-esteem

Variables	Fathers' parenting attitude r; p-value
Fathers' self-esteem	0.084; 0.251

Discussion:

The present study extended the research on enlightening the aspects of fathers' parenting concerning their self-esteem in the community setting.This study only included fathers of adolescent children since the researchers were interested in learning more about their viewpoints. The mean age of the fathers in this study was 44.55±8.515 years, with a range of ages from 30 to 67 whether the standard deviation of 4.78 years and the mean age of 42.97 years was found in another study[11].

Among all, 33% of the respondents were not in any formal education. 38.8% of fathers finished their primary schooling. According to Hawkins, 20% of the sample was made up of graduates and post-graduates[12]. Their educational background is a bit limited, as they are from a rural area. Low awareness and the existence of several stresses could be the cause of this, which could impact reporting. It's possible that the higher socioeconomic classes were more conscious than the lower ones.

Since the fathers in the study resided in rural areas, farming was their main source of income. Concerning their spouses, a substantial portion (97.3%) were homemakers, and 14.4% had never attended school. Some people received at least a primary education. It portrays the overall state of the village.

The Attitude toward Parenthood scale was utilized in

this study to measure parental attitude.The fathers scored between 5 and 7, with an average of 6.45 (SD ±0.512), indicating a positive attitude. Mark Whatley's study found that the average score on the Attitudes toward Parenthood Scale was 6.36 (SD + 0.65), with a range of 3.89 to 7[13].

The self-esteem of them was measured using Rosenberg's self-esteem scale. A total self-esteem score is calculated by summing all responses, with higher scores indicating higher levels of self-esteem[6]. The range of scores is 25 to 38,with a mean score of 32.36±2.955. Fathers' Self-esteem information is inadequate and previous studies mostly described the self-esteem of adolescents. According to a study of adolescents' self-esteem, the average score was 38.49±6.55[14].

There was no relationship between parenting attitude and self-esteem in this study. It holds up the generality of fatherhood which demonstrates that a father's self-esteem does not usually influence his parenting style. This study's findings contradict prior research by Yamawaki, Nelson and Omori, among Japanese college students, which found a substantial relationship between parenting style and self-esteem[15].

The fathers were largely from nuclear families (95.2 %) and worked 8.56±1.868 hours a day on average, whereas Hawkins reported that the mean work hours of the fathers in his study were nearly 7 hours[12]. Based on their sociodemographic traits, fathers' views on parenting were evaluated as well. The results showed that the fathers' attitudes toward parenting were unaffected by their religious beliefs and family factors such as family type and total number of family members. According to the study's findings of Celik, parents' child-rearing attitude ratings show statistically significant disparities in terms of family living arrangements[16]. In comparison to parents in nuclear families, parents in extended families are more disciplined, less overprotective, and less democratic-egalitarian in their attitudes. The projected results are similar to the aforementioned result when considering large families who predominantly live in rural areas. However, a larger sample with a more diverse variety of cultural origins may produce some important results regarding differences in religion or culture. It makes room for further investigation of the views of parents across many cultures and religions.

Furthermore, this study only used self-report measures; other source categories may be explored in subsequent research. This study explored parenting style to determine whether self-esteem and parenting style were related. In general, attitudes regarding parenting were good, irrespective of the individual fathers' self-esteem within this study population. Moreover, it was found that men who had good self-esteem and a positive parenting style also took a more active role in raising their kids.

This study has certain limitations that might be investigated in future research. The first has to do with the cross-sectional design of the study. Future studies that employ a longitudinal design will be better able to identify the causal links between fathers' activities and self-esteem as well as the direction of those associations. Second, even though this study discovered significant and pertinent associations between fathers' parenting attitudes and self-esteem, it cannot completely rule out the chance that other factors could be at work. Subsequent investigations ought to examine the role of additional plausible factors, like structural and personality characteristics, which may impact the consequences of parenting philosophy.

The study's findings provide crucial directions for father-focused therapies. To help them adjust, fathers should take part in parenting education programs that enhance their parenting skills and self-awareness. The design, development, implementation, and evaluation of fathers' involvement in the home environment are all impacted by the study's conclusions. Educational strategies should be applied to increase everyone's awareness and understanding of the concept of self-esteem, the impact of parenting styles, and the dangers of poor self-esteem. Initiatives for education that focus on resource connections, public awareness, and training may all be successful.

Conclusion:

This study sheds light on the significant role of fathers' self-esteem in shaping their parenting attitudes, particularly during the adolescent years. The findings highlight that fathers' parenthood is unaffected by their self-esteem. This does not

underscore the importance of addressing fathers' self-esteem in parenting interventions and support programs aimed at enhancing family dynamics and adolescent well-being. Fathers with higher educational backgrounds and those whose spouses were well-educated showed greater enthusiasm for raising their children. Therefore, activating fathers' parenting concerns through education was an ideal place to start. The study may lack diversity in terms of participant demographics, such as socioeconomic status, co-parenting dynamics, ethnicity, or cultural background, which potentially impacts the generalizability of the findings to a broader population. Reliance on self-reported measures of both self-esteem and parenting attitudes may introduce bias by providing socially desirable responses. Moving forward, further research in this area could explore building up self-esteem and parenting attitudes among fathers, ultimately contributing to the development of more supportive and nurturing family environments for adolescents.

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Conflict of interest:
No conflict of interest.

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Authors'Contributions:
Rahman MS, Khan MRM, conceived and designed the study, analyzed the data, and interpreted the results. Zaber M and Hoshen MM wrote up the draft manuscript. Rahman MS involved in the manuscript review and editing. All authors read and approved the final manuscript.

Data Availability:
The corresponding author can be contacted with any questions about the availability of the study's supporting data, which are available upon reasonable request.

Ethical 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 following the relevant guidelines and regulations.

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Original Article ***Open Access***

Morphological Changes of Placenta in Preeclampsia and Eclampsia Syndrome & its Correlation with the Outcome of Pregnancy

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Abstract

Background: Preeclampsia and eclampsia syndrome are late-pregnancy symptoms that include both nonconvulsive and convulsive periods. **Objectives:** This study aimed to see the morphological changes of the placenta in the pregnant women having preeclampsia and eclampsia syndrome & coordinate the placental changes with the outcome of pregnancy. **Methods:** The study was conducted among 138 clinically diagnosed pregnant women (from mild PE, severe PE, eclampsia group) having preeclampsia and eclampsia syndrome. The placentas of all cases were obtained after delivery and assessed for morphological changes. Relevant data, including morphological changes of placenta (weight, volume, diameter) and pregnancy outcome (neonatal birth weight, maturity, Apgar score, and stillbirth), were observed and evaluated. **Results:** This study revealed mean placental weight, mean placental volume, mean placental diameter, and mean placental thickness were 426.55±54.1 g, 418.9±61.9 ml, 15.00±1.50cm, and 2.25±0.44 cm respectively in mild PE. In the severe PE group, these were 397.75±63.58 g, 386.2±63.8 ml, 13.98±1.46 cm, and 2.06±0.42 cm, respectively. On the other hand, the parameters were 354.24±77.74 g, 344.7±76.3 ml, 13.25±1.74 cm, and 1.95±0.48 cm, respectively in the eclampsia group. A statistically significant difference was found among three groups regarding pregnancy outcome (neonatal birth weight, maturity, stillbirth, etc.). A significant positive correlation was calculated between the neonatal birth weight and placental macroscopic parameters in severe PE and eclampsia groups. In the present study, the severe PE group showed a statistically significant positive correlation of Apgar score with placental weight (r=+0.283, p=0.024), placental diameter (r=+0.259, p=0.040) and placental volume (r=+0.194, p=0.127). All three groups exhibited a statistically negative correlation of prematurity with placental macroscopic parameters. In severe PE group, statistically significant negative correlation of stillbirth with placental macroscopic parameters [weight (r=-0.248, p=0.050), volume (r=-0.283, p=0.025) and diameter (r=-0.324, p=0.010)] were observed. **Conclusion:** The placental morphological changes occurred in preeclampsia and eclampsia syndrome can affect the pregnancy outcome.

Keywords: Placenta, Morphological Changes, Pregnancy Outcome.

Introduction:

Pregnancy is a healthy & welcoming process. A placenta is vital for the maintenance of a normal pregnancy. Fetal growth and well-being depend on the functional and structural components of the placenta[1].

Preeclampsia and eclampsia syndrome are late-pregnancy symptoms that include both nonconvulsive and convulsive periods[2]. Preeclampsia and eclampsia syndrome causes diminished blood flow in the uteroplacental vessels.

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Finally, this creates decreased oxygen and nutrition supply to the fetus, leading to reduced growth and maturation of the fetus. Moreover, reduction of weight, volume, diameter, thickness etc. also occur in placenta[3]. The neonatal outcome is different from the normal pregnancy. It includes- stillbirth, low birth weight, asphyxia, and prematurity[4].

Many studies provide good evidence for the occurrence of distinctive structural and morphological abnormalities in the placenta complicated by preeclampsia and eclampsia syndrome. But most of these studies have not commented on the relation of placental morphological parameters (weight, volume, diameter) with fetal outcome.

So the present study has been undertaken to assess the correlation between placental morphological changes and fetal outcome. The morphological changes of placenta can be evaluated by using ultrasonogram during antenatal period. Therefore, complete pathologic evaluation of the placenta provides valuable information for maternal and perinatal care for the obstetrician, neonatologist, and pediatrician.

Materials and Methods:

Study procedure:

This cross-sectional observational study was performed over a period of 2 years from July 2019 to June 2021 in the Department of Pathology, BIRDEM General Hospital, Dhaka. The study was approved by the Institutional Review Board (IRB) of BIRDEM General Hospital, Dhaka. After approval, we recruited 138 clinically diagnosed cases of pregnant women with preeclampsia and eclampsia syndrome by inclusion and exclusion criteria. The pregnant women who had blood pressure at or above 140/90 mmHg on at least two occasions 6 hours apart after 20 weeks of gestation, with or without edema, proteinuria and convulsion were included in this study. These cases are further divided as mild preeclampsia and severe preeclampsia as per criteria set up by American Society of Gynaecology and Obstretics. Preeclampsia becomes eclampsia as it becomes complicated by convulsions and/or coma[5]. Among all the cases, relevant history with attention to age, gravida, other clinical information (anaemia, BP, oedema, H/O previous childbirth, past illness), were taken. All informations were recorded systematically in a prepared proforma. Ethical considerations were strictly followed throughout the study, ensuring informed consent was obtained from all participants, and participant confidentiality was maintained.

Experimental procedure and data analysis:

Immediately after delivery, neonatal birth weight, prematurity, stillbirth, presence of fetal distress (assessed by Apgar score) were recorded as parameters of the outcome of pregnancy.

Soon after the delivery, the placenta was collected in a clean tray. Then the placental membranes were trimmed off and the umbilical cord was cut to a length of 2.5 cm. After that placenta was washed in tap water, blood clots were removed and mopped with cotton. Then placental weight, volume, diameter were measured.

To determine the significance of results among groups, we used analysis of variance (ANOVA) and Chi square tests in Statistical Package for Social Sciences version 20.0 for Windows. Pearson's correlation coefficient test and Spearman's rank correlation coefficient test were done to see the morphological variables and pregnancy outcome. Statistical significance was set as $p \leq 0.001$

Results:

A total number of 138 cases were selected for the study. Out of 138 cases, there were 42 cases of mild preeclampsia (mild PE), 63 were of severe preeclampsia (severe PE), and 33 were of eclampsia. This study found placental weight, volume and diameter significantly reduced according to the severity of diseaseamong the three groups (Table 1).

Table 1 Gross morphological findings of the placenta in preeclampsia and eclampsia syndrome (n=138)

Morphological changes	Normal Term placenta	Mild PE (n=42)	Severe PE (n=63)	Eclampsia (n=33)	p value*
Placental weight (g) Range (Min – Max)	450-600 Ŧ	397.75±63.58	397.75±63.58	354.24±77.74	<0.001s
Placental volume (ml) Range (Min – Max)	Average 500 Ŧ	386.2±63.8	386.2±63.8	344.7±76.3	<0.001s
Placental diameter (cm) Range (Min – Max)	15-20 Ŧ	15.00±1.50	13.98±1.46	13.25±1.74	<0.001s

*Anova test was carried out to measure the level of significance.

S = Significant

Ŧ :(Konar, 2018)

Immediately after delivery Apgar score and weight of the newborn were taken. Among 138 cases, difference regarding birth weight, prematurity and stillbirth were found as statistically significant among the three groups. Regarding the Apgar score, it range from 0 to 10 as minimum normal score is 7. So newborn were divided into two groups. A low Apgar score (score<7) was mainly observed in the severe PE and eclampsia group. The data showed no statistically significant difference among all groups (Table-2)

Table-2: The outcome of pregnancyin preeclampsia and eclampsia syndrome (n=138)

Outcome of pregnancy	Normal ** term newborn	Mild PE (n=42)	Severe PE (n=63)	Eclampsia (n=33)	p value*
Baby weight (kg)	2.5-4.0	2.12±0.57	1.82±0.57	1.52±0.47	<0.001s
Apgar score					
<7	7 & above	28(66.7%)	49(77.8%)	28(84.8%)	0.170ns
≥7		14(33.3%)	14(22.2%)	5(15.2%)	
Total		42(100.0%)	63(100.0%)	33(100.0%)	
Prematurity	Born at 37 to 42 completed weeks	6(14.3%)	25(39.7%)	10(30.3%)	0.020s2
Stillbirth	-	0(0.0%)	12(19.0%)	18(54.5%)	<0.001s

Figures within parentheses indicated in percentage and expressed as Mean±SD

*Chi-square test was carried out to measure the level of significance.

S= significant; ns = not significant,

** : (Mollah and Nahar, 2020)

Table-3: Correlation of neonatal birth weight with morphological changes of placenta according to the severity of preeclampsia and eclampsia syndrome (n=138)

Morphological changes	Mild PE (n=42)		Severe PE (n=63)		Eclampsia (n=33)	
	r value	p value	r value	p value	r value	p value
Placental weight	-0.067	0.673	+ 0.422*	0.001	+ 0.560*	0.001
Placental volume	+0.011	0.944	+ 0.458*	0.000	+ 0.539*	0.001
Placental diameter	+0.155	0.328	+ 0.398*	0.001	+ 0.545*	0.001

Pearson's correlation coefficient test was done.

*significant

In the current study, statistically significant positive correlation was calculated between neonatal birth weight and placental morphological parameters (weight, volume, diameter) in case of severe PE and eclampsia group (Table-3).

Table-4: Correlation of Apgar score with morphological changes of placenta according to the severity of preeclampsia and eclampsia syndrome (n=138)

Morphological changes	Mild PE (n=42)		Severe PE (n=63)		Eclampsia (n=33)	
	r value	p value	r value	p value	r value	p value
Placental weight	+0.017	0.916	+ 0.283*	0.024	-0.062	0.730
Placental volume	+0.119	0.453	+ 0.194	0.127	-0.076	0.676
Placental diameter	+0.284	0.068	+ 0.259*	0.040	+0.251	0.158

Spearman's rank correlation coefficient test was done.

*significant

In the present study, severe PE and mild PE group showed statistically positive correlation of Apgar score with placental morphological parameters (weight, volume, diameter). On the other hand, there was negative correlation of Apgar score and placental morphological parameters (weight, volume) (Table-4).

Table-5: Correlation of prematurity with morphological changes of placenta according to the severity of preeclampsia and eclampsia syndrome (n=138)

Morphological changes	Mild PE (n=42)		Severe PE (n=63)		Eclampsia (n=33)	
	r value	p value	r value	p value	r value	p value
Placental weight	-0.234	0.136	-0.052	0.686	-0.240	0.178
Placental volume	-0.202	0.199	- 0.311*	0.013	-0.267	0.132
Placental diameter	-0.077	0.628	-0.085	0.510	-0.350*	0.046

Spearman's rank correlation coefficient test was done.

*significant

All three groups (mild PE, severe PE, eclampsia) exhibited statistically negative correlation of prematurity with placental morphological parameters (weight, volume, diameter) (Table-5).

Table-6: Correlation of stillbirth with morphological changes of placenta according to the severity of preeclampsia and eclampsia syndrome (n=138)

Morphological changes	Mild PE (n=42)		Severe PE (n=63)		Eclampsia (n=33)	
	r value	p value	r value	p value	r value	p value
Placental weight	-	-	-0.248	0.050	-0.318	0.071
Placental volume	-	-	- 0.283*	0.025	-0.288	0.104
Placental diameter	-	-	- 0.324*	0.010	-0.268	0.131

Spearman's rank correlation coefficient test was done

*significant

In this study, no stillbirth was found in the mild PE group. The 12 cases and 18 cases of stillbirth were found in the severe PE and eclampsia groups, respectively. In severe PE and eclampsia group revealed statistically negative correlation of stillbirth with placental morphological parameters (weight, volume, diameter) (Table-6).

A B

Figure: Placenta of Pre eclampsia & Eclampsia Syndrome (A) Photomicrograph showing gross appearance of fetal surface of placenta (B) Photomicrograph showing gross appearance of maternal surface of placenta

Discussion:

On gross examination of the placenta, this study revealed mean placental weight was 426.55±54.1gm in mild PE, 397.75±63.58 gm in severe PE, and 354.24±77.74 gm in the eclampsia group. This difference was found statistically significant ($p<0.001$ from unpaired T-test) among the three groups. Here we can see that the weight of the placenta decreases with the increasing severity of the disease. The cause of reduction in blood flow is due to vasculopathy of spiral arteries, which in turn causes a reduction in the weight of the placenta (Bangal et al., 2012)[5]. Results from our study match with the study of Raghavendraet al. (2014), in which mean placental weight was 406.69 gm in mild PE, 374.68 gm in severe PE, and 390.33 gm in case of eclampsia[6]. They found the value was significantly reduced according to the severity of the disease[6]. A slightly higher value was noted in studies done in Iraq (395.5±50.03 gm) and India (345.96 gm to 524.24 gm) (Mousa et al., 2019 and Chhatwal et al., (2018)[1,10]. This may be because these three included all PIH cases in contrast to our study, which had only preeclampsia and eclampsia cases.

In the current study, mean placental volume was 418.9±61.9 ml in mild PE, 386.2±63.8 ml in severe PE, and 344.7±76.3 ml in cases of eclampsia group. This difference was found statistically significant ($p<0.001$ from the Unpaired T-test). A study performed by Navbir et al. (2012) revealed 409.64±57.19 ml in mild PE, 371±65.74 ml in severe PE, 328.33±122.38 ml in eclampsia which was close to our study[7]. In the Indian population (Madhya Pradesh and Kottayam), studies that occurred in 2014 revealed mean placental volume was 385.89±142.70 ml and 397±59.9 ml that was a higher value than our study (Anjankar et al., 2014 and Kartha et al., 2014)[8,9]. We observed in the present study that the volume of the placenta decreases with the increasing severity of the disease. This finding is because of placental insufficiency and so affected growth.

Concerning placental diameter, this study exhibited significant differences among the three groups. The measurements are 15.00±1.50 cm for mild PE, 13.98±1.46 cm for severe PE, and 13.25±1.74 cm for eclampsia. Thus, this explains diameter is decreased according to the severity of the disease. A similar finding was observed by Chhatwal et al., 2018 that the mean placental diameter was 15.23±2.93 cm[10]. A study done by Goswami et al. in 2016 in India (Gujarat) found mean placental diameter was 14.5cm[11]. On the contrary, a slightly higher mean placental diameter was observed in the study performed in Iraq (16.83±1.74 cm) (Mousa et al., 2019)[1].

The present study noted that the mean thickness of the placenta calculated was 2.25±0.44 cm in mild PE,2.06±0.42 cm in severe PE, and 1.95±0.48 cm in cases of eclampsia. Hence, the placenta of more severe cases is thinner as compared to milder cases. Another study performed by Chhatwal et al., 2018 and Goswami et al., 2016 revealed mean placental thickness was 1.91±0.47 cm and 2.60 cm, respectively[10,11]. The variance in placental thickness measurement could be the difference in measurement methods in different studies (Chhatwal et al., 2018)[10].

Regarding pregnancy outcome, this study exhibited mean birth weight of newborns was 2.12±0.57 kg in mild PE,1.82±0.57 kg in severe PE, and 1.52±0.47 kg in cases of eclampsia. The birth weight of the newborn was significantly reduced according to the severity of the disease. A study performed in India (Karnataka) by Raghavendra et al. (2014) revealed mean birth weight of newborns was 2.54 kg in mild PE, 2.67 kg in severe PE, and 2.1 kg in cases of eclampsia[6]. On the other hand, Mousa and his colleagues performed a study in Iraq and found 3.2±0.49 kg in mild PE, 2.6±0.50 kg in severe PE, and 1.8±0.64 kg in cases of eclampsia (Mousa et al., 2019)1. Concerning these values, it is inferred that a newborn baby's weight is significantly low in PIH due to placental insufficiency.

In the current study, Apgar score ranges between 4 to 9. For working convenience, it was divided into <7 and ≥ 7 groups. In cases of mild PE, severe PE, and eclampsia, Apgar scores of <7 were reported in 66.7%, 77.8%, and 84.8% respectively. This alteration was not found statistically significant. In 2016, Kambale and his team documented about low Apgar score was 26.9% in mild PE, 46.6% in severe PE and 75% in case of eclampsia[12]. In Turkey, Yucesory and his team found low Apgar score in 17.89% cases of mild PE and 36% cases of severe PE (Yucesory et al., 2005)[13]. Maternal vasospasm leads to fetal hypoxia, which is responsible for fetal jeopardy. In our setting, the incidence is much higher than other studies. This may be linked to resource constraints that limit technological advances such as mechanical ventilator and surfactant replacement therapy needed for the care of these newborn.

The present study showed that the incidence of prematurity in mild PE, severe PE and eclampsia was 14.3%, 39.7%, and 30.3%, respectively. This variation was found statistically significant. A secondary analysis of the WHO Multicountry Survey on Maternal and Newborn Health was held on 29 countries from Africa, Asia, Latin America and the Middle East. They found 30.89% and 39.84% of preterm birth in PE and eclampsia cases respectively (Abalos et al., 2014)[14]. Bangal and his colleagues in 2012 in India (Maharastra) reported about prematurity that was 17.99% in mild PE, 47.62% in severe PE and 52.63% in case of eclampsia, which was slightly higher than our findings[15].

Regarding stillbirth, 19.0% of cases of severe PE and 54.5% cases of eclampsia exhibited stillbirth. In the case of mild PE, no stillbirth case was found in this study. These findings were also statistically significant. Results from the current study match with the study done by Kambale and his colleagues in 2016. They concluded about stillbirth in their study was 0% in mild PE, 20% in severe PE and 50% in case of eclampsia. Raghavendra et al. (2014) in India (Karnataka) reported 0.5% in mild PE, 12.5% in severe PE, and 20% in cases of eclampsia regarding stillbirth that is very close to our study[6].

In the current study, a significant positive correlation was calculated between neonatal birth weight and macroscopic parameters of placenta (placental weight, placental volume, placental diameter) in case of severe PE and eclampsia group [placental weight (r=+0.422, p=0.001), placental volume (r=+0.458, p=0.000) and placental diameter (r=+0.398, p=0.001) for severe PE and placental weight (r=+ 0.560, p=0.001),placental volume (r=+ 0.539, p=0.001) and placental diameter (r=+0.545, p=0.001) for eclampsia]. Thus we can see that neonatal birth weight decreases with the decreasing of macroscopic parameters of the placenta.These findings were also similar in the case of mild PE. In mild PE group, statistically negligible positive correlation with placental volume (r=+0.011, p=0.944) and placental diameter (r=+0.155, p=0.328) were found. However statistically negligible negative correlation of neonatal birth weight with placental weight (r=-0.067, p=0.673) was observed in the mild PE group. That means neonatal birth weight decreases with the increase of placental weight in the case of mild PE. This may be due to the compensatory hypertrophy of the placental mass following placental insufficiency secondary to inadequate uteroplacental blood flow as described by Fox (1975) and Wigglesworth (2000) (Pathiraja et al., 2015)[16].

In the present study, severe PE group showed statistically significant positive correlation of Apgar score with placental weight (r=+ 0.283, p=0.024),

placental diameter (r=+ 0.259, p=0.040) and placental volume (r=+ 0.194, p=0.127). In mild PE group exhibited statistically positive correlation of Apgar scores with placental weight (r=+0.017, p=0.916), placental volume (r=+0.119, p=0.453) and placental diameter (r=+0.284, p=0.068). That means Apgar score decreases with the decreasing of placental macroscopic parameters (weight, volume , diameter).

A statistically positive correlation with the placental diameter (r=+0.251, p=0.158) was also observed in eclampsia groups. On the contrary in eclampsia group revealed negligible negative correlation of Apgar score with placental weight (r=-0.062, p=0.730) and placental volume (r=-0.076, p=0.676).

All three groups (mild PE, severe PE, eclampsia) exhibited statistically negative correlation of prematurity with placental macroscopic parameters (weight, volume, diameter) [placental weight (r=-0.234, p=0.136), placental volume (r=-0.202, p=0.199), placental diameter (r=-0.077, p=0.628) for mild PE; placental weight (r=-0.052, p=0.686), placental volume (r=-0.311, p=0.013), placental diameter (r=-0.085, p=0.510) for severe PE; placental weight (r=-0.240, p=0.178), placental volume (r=-0.267, p=0.132), placental diameter (r=-0.350, p=0.046) for eclampsia group]. That means prematurity increases with the decreasing of placental macroscopic parameters (weight, volume, diameter).

In this study, no stillbirth was found in the mild PE group. The 12 cases and 18 cases of stillbirth were found in the severe PE and eclampsia groups, respectively. In severe PE group statistically significant negative correlation of stillbirth with placental macroscopic parameters [weight (r=-0.248, p=0.050), volume(r=- 0.283, p=0.025), diameter(r=-0.324,p=0.010)] were observed. In eclampsia group statistically negative correlation of stillbirth with placental weight (r=-0.318, p=0.071), placental volume (r=-0.288, p=0.104) and placental diameter (r=-0.268, p=0.131) were found. This indicates stillbirth increases with the decreasing of placental macroscopic parameters (weight, volume, diameter).

Various workers on this subject have not commented on the relation of placental macroscopic parameters (weight, volume, diameter) with fetal outcome. So the comparative study among different studies was not possible regarding the correlation between placenta macroscopic parameters and fetal outcome.

Conclusion:
We conclude that morphological changes of placenta occurred in preeclampsia and eclampsia syndrome can affect the outcome of pregnancy. These information may also help us in managing the mother and baby by analyzing the placental parameter antenatally in an ultrasonogram to anticipate the outcome of pregnancy.

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Authors' Contributions:
Rahman F conceived and designed the study. Rahman F, Haque SM, Rahman N, Ahmad M and Rahman FN analyzed the data, and interpreted the results, wrote up the draft manuscript, involved inthe 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.

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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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