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National Osteoporosis Foundation of South Africa. Use of generic alendronate in treatment of osteoporosis. S Afr Med J [Internet].2006 Aug[cited 2007 Jan 9];9(8):696-7. Available from: <http://blues.sabinet.co.za/WebZ/Authorize?>

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Obstructive Sleep Apnoea: Bangladesh Perspective

Majumder KA

Introduction:

Sleep medicine is a medical superspeciality devoted to the diagnosis and therapy of sleep disturbance and disorders. From the middle of 20th century research has provided increasing knowledge and answered many questions about sleep awake functioning. Disorders and disturbances of sleep are widespread and can have significant consequences for affected individuals as well as economic and other consequences for the society. sleep deprivation has also been a significant factor in dramatic accidents. The first sleep clinic in United states were established in 1970s.

The International Classification of Sleep Disorders (ICSD):

The concept of sleep medicine belongs to the second half of the 20th century. Due to the rapidly increasing knowledge about sleep, including the growth of the research field chronobiology from about 1960 and the discoveries of REM sleep (1952–53) and sleep apnea (first described in the medical literature in 1965), the medical importance of sleep was recognized.

The World Federation of Sleep Research & Sleep Medicine Societies (WFSRSMS) was founded in 1987. The European Sleep Research Society (ESRS) is a member of the WFSRSMS. The Assembly of National Sleep Societies (ANSS), which includes both medical and scientific organizations from 26 countries as of 2007, is a formal body of the ESRS. The American Academy of Sleep Medicine (AASM), founded in 1978, administered the certification process and sleep medicine examination for doctors.

Elites of Bangladesh having opportunities to get treatment from abroad were availing treatment by surgery or CPEP machines for long time but our common population is not aware of the treatment opportunities for sleep disorders. Above all our repertory physicians and Otolaryngologists were providing limited treatment for sleep apnea. Association of Surgeons for Sleep Apnoea, Bangladesh was established in 2014. Since then we were organizing International conference of Association of Surgeons for Sleep Apnoea,

Bangladesh, with Scientific sessions, live surgery workshop and Rallies.

Sleep apnea is a disorder in which breathing is repeatedly interrupted during sleep. The word “apnea” literally means “without breath”. An apnea is defined as a complete cessation of breathing that lasts 10 seconds or greater. There are two principal types of sleep apnea, “obstructive sleep apnea (OSA),” and “central sleep apnea” (CSA). Complex sleep apnea is a combination of obstructive sleep apnea and central sleep apnea. Obstructive sleep apnea is an increasingly well-recognized disease characterized by periodic collapse of the upper airway during sleep. This leads to either complete or partial obstruction of the airway, resulting in apneas, hypopneas, or both. This disorder causes daytime somnolence, neurocognitive defects, and depression. It affects almost every system in the body, resulting in an increased incidence of hypertension, cardiovascular disease, stroke, pulmonary hypertension, cardiac arrhythmias, and altered immune function. It also increases the risk of having an accident, presumably as a result of associated somnolence. Like obstructive sleep apnea, central sleep apnea is more common in males and people over the age of 65. However, unlike obstructive sleep apnea, central sleep apnea is often associated with serious illness, such as heart disease, stroke, neurological disease, or spinal or brainstem injury.

By far the most common is obstructive sleep apnea, comprising 90 to 96% of apneas diagnosed on overnight sleep study (polysomnography). OSA results from repetitive collapse of the upper airway. Central sleep apnea is due to decreased output from ventilatory control centres in the brain. In clinical practice, the most frequently used measurement of OSA is the Apnoea Hypopnea Index (AHI) derived from an overnight sleep study. It is the number of apneas (complete cessation of airflow) plus hypopneas, (50% reduction in airflow associated with oxygen desaturation and/ or arousal from sleep), divided by the number of hours of recorded sleep. An AHI of 5 or greater indicates the presence of OSA,

and more than 30 indicates a severe degree of OSA. Obstructive Sleep Apnoea occurs in an estimated 24% of middle-aged males and 9% of middle-aged females as defined by an AHI >5 on sleep study.

Pathophysiology:

Daytime sleepiness is a characteristic feature of OSA and can be assessed using the Epworth Sleepiness Scale (ESS). There are 8 questions in the scale, which ask a patient how likely they are to doze off in certain situations. A score greater than 10 out of a possible 24, indicates subjective daytime sleepiness. Obstructive Sleep Apnoea occurs as a result of collapse of the upper airway. The upper airway between the back of the nose and the top of the larynx is supported only by muscle tone. With sleep onset, this muscle tone is reduced and the airway narrows. The airspeed through this narrowed upper airway increases and results in vibration of the upper airway, with snoring. The airway may become so narrow that it collapses, usually on inspiration, resulting in an Apnoea or hypopnea. Since air can no longer enter the lungs, the oxygen level in the blood falls, and carbon dioxide levels rise. These changes are sensed by receptors in the carotid artery in the neck and also in the brain, and stimulate increased respiratory effort via the abdominal and chest wall muscles.^{12,13} These efforts are futile against the occluded upper airway. The fall in oxygen levels, the rise in carbon dioxide levels and increased respiratory effort may precipitate an arousal from sleep. Muscle tone then returns to the upper airway which allows breathing to recommence. Surges of sympathetic nerve activity occur during the period of apnea which may contribute to the cardiovascular consequences of OSA. The duration of this obstruction may last up to a minute and occasionally longer, and may occur hundreds of times during the night. The repeated fragmentation results in poor sleep quality and excessive daytime sleepiness.

Symptoms and Complications of OSA Repeated fragmentation of sleep from OSA results in poor quality of sleep, and symptoms of sleep deprivation. Apart from daytime sleepiness, which does not necessarily relate to the severity of the OSA, there are a wide range of health concerns. Cognitive function can be significantly impaired resulting in difficulty concentrating, depression, learning and memory difficulties, personality changes, and hyperactivity in children. Morning headaches, decreased libido and

impotence in men can result from OSA, which can also increase driving risk and impair work performance. OSA has been linked to several cardiovascular complications. OSA is an independent risk factor for the development of hypertension and insulin resistance, and is associated with heart attack, cardiac arrhythmia, and stroke. Bed partners are also significantly affected, with their own sleep being disrupted, even as they sleep, resulting in symptoms of sleep deprivation. Licensing authorities have strict guidelines on how sleepiness and driving risk should be addressed.

Risk Factors for OSA: There are a number of recognized risk factors for OSA. These include: Male gender, increasing age, Body Mass Index >30, Neck circumference > 42 cm, enlarged tonsils, Alcohol, Smoking, Post-menopause, Sleeping tablets.

Investigation of OSA:

In view of the high prevalence of OSA, and the potentially serious consequences of untreated OSA, investigation is essential in order to determine the most effective treatment. Investigation should be considered if the patient presents with persistent snoring, and at least one other associated symptom. Most commonly this will be excessive daytime sleepiness, but may include any of the symptoms mentioned above. Investigations can be divided into four categories: Level 1-Full monitored overnight polysomnography undertaken in a specialist unit with overnight observation. Involving both respiratory, limb and EEG leads. Level 2.- Full overnight polysomnography, without overnight observation. This might be in a specialist unit, or at home. Level 3-Monitoring of respiratory parameters and oximetry with pulse rate, and usually undertaken in the home. Level 4-Pulse oximetry, measuring oxygen desaturation and pulse rate only. Usually undertaken in the home. Level 1 studies have always been considered to be the 'gold standard' investigation for sleep disorders.

Treatments of OSA:

There are of four broad categories of effective treatments for OSA.

1. **Lifestyle:** Lifestyle changes can be very effective in mitigating the symptoms of sleep apnea.

Weight loss is most important in all those who are overweight. However approximately 25% of those suffering from OSA are not overweight but

may exhibit some craniofacial characteristics such as micro- or retrognathia. Alcohol in the evening should be reduced to <2 units. Both alcohol and sleeping tablets relax the pharyngeal muscles allowing the pharyngeal walls to collapse more easily.

Smoking results in irritation and swelling of the pharyngeal space, increasing the likelihood of snoring and OSA. Snoring and OSA is almost always worse when lying on the back. Sewing a pocket into the back of the pajamas to hold a tennis ball or golf ball will ensure that lying on the back is impossible.

2. Continuous Positive Air Pressure (CPAP): This is the “gold standard” treatment for OSA. Delivered via a nasal or oronasal mask, pressurized air is used to splint open the floppy upper airway. It is a cumbersome, but extremely effective therapy. As many as 70% of patients can tolerate therapy long term. CPAP can improve quality of life, cognitive function, reduce driving risk, hypertension and cardiovascular risk, particularly in symptomatic patients with severe disease.
3. Mandibular Advancement Splints (MAS): This works by holding the mandible forward. Since the tongue is attached to the mandible, the tongue is held forward preventing it from falling backwards and causing obstruction. There are a number of devices which are generally effective for snoring, mild and even moderate OSA. They are most effective in patients with mild OSA which is worst in the supine position in non-obese patients. Patients who may be suitable for treatment with a MAS should be referred to a dentist who has an interest in this area. It is very important that the device is properly manufactured and customized for each patient. A number of cheaper appliances are available

for purchase over the counter or from the internet. These cannot be recommended.

4. Surgery: Whilst this used to be a very popular treatment for OSA, Uvulopalatopharyngoplasty (UPPP) may improve snoring and sometimes cure OSA, particularly more severe disease. Surgery can be used to correct obstructions in the airways. This surgery removes tissue from the rear of the mouth and top of the throat. The tissues removed include parts of the uvula (the flap of tissue that hangs down at the back of the mouth), the soft palate, and the pharynx. Tonsils and adenoids are usually removed in this operation. This operation significantly improves sleep apnea in slightly more than half of all cases. Tonsillectomy is most effective when the patient has large tonsils. Nasal surgery can be used to relieve obstruction. More extensive procedures are available for selected cases where craniofacial abnormalities are impinging on the upper airway.

The most common surgery is called UPPP, Uvulopalatopharyngoplasty. Reconstructive surgery is possible for those whose OSA is due to constriction of the airway by lower jaw deformities. Genioplasty, which is a procedure that plastic surgeons usually perform to reshape a patient's chin to improve his or her appearance, is now being done to reshape the upper airway in patients with OSA.

When other forms of treatment are not successful, obstructive sleep apnea may be treated by tracheostomy.

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Comparing the Efficacy and Safety of Linezolid versus Amoxicillin-Clavulanic Acid in the Management of Moderate to Severe Diabetic Foot Infections

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Abstract:

Background: Diabetic foot infections (DFIs) represent a major global health challenge, frequently leading to hospitalization, lower extremity amputation, and significant mortality. The choice of empirical antibiotic therapy is complicated by the polymicrobial nature of DFIs and the rising prevalence of multidrug-resistant organisms, particularly methicillin-resistant *Staphylococcus aureus* (MRSA). This study aimed to compare the clinical and microbiological efficacy of Linezolid, a potent anti-Gram-positive agent, with Amoxicillin-Clavulanic Acid, a broad-spectrum antibiotic, in treating moderate to severe DFIs.

Methods: In a prospective, open-label, randomized controlled trial conducted from 2021 to 2023, 300 patients with moderate to severe DFIs were enrolled. Participants were randomized in trial, to receive either Linezolid (600 mg IV/PO q12h) or Amoxicillin-Clavulanic Acid (1.2 g IV q8h or 625 mg PO q8h) for 7-14 days. The primary outcome was clinical cure rate at the test-of-cure visit (14 days after treatment completion). Secondary outcomes included microbiological eradication, incidence of adverse events, and duration of hospital stay.

Results: Linezolid demonstrated a significantly higher clinical cure rate compared to Amoxicillin-Clavulanic Acid (85.3% vs. 73.3%, $p=0.01$). Microbiological eradication was also superior in the Linezolid group (80.0% vs. 66.7%, $p=0.02$). Subgroup analysis revealed Linezolid's pronounced efficacy against MRSA (90% vs. 25%, $p<0.001$), whereas Amoxicillin-Clavulanic Acid was more effective against Gram-negative pathogens (82% vs. 48%, $p=0.003$). The overall incidence of adverse events was comparable between groups (22% for Linezolid vs. 18% for Amoxicillin-Clavulanic Acid, $p=0.40$).

Conclusion: Linezolid is a superior therapeutic option for DFIs where Gram-positive bacteria, especially MRSA, are suspected or confirmed. Amoxicillin-Clavulanic Acid remains a valuable agent for polymicrobial infections with significant Gram-negative involvement. Tailoring empirical antibiotic therapy based on local antimicrobial resistance patterns and individual patient risk factors is crucial for optimizing outcomes in DFI management.

Introduction:

Diabetes mellitus has reached epidemic proportions globally, with its complications posing a severe burden on healthcare systems, particularly in developing nations like Bangladesh. Among the most

debilitating and costly of these complications are diabetic foot ulcers (DFUs), which affect 15–25% of diabetic individuals during their lifetime¹. A critical progression of DFUs is diabetic foot infection (DFI), which significantly increases the risk of

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hospitalization, lower extremity amputation, and mortality².

The pathophysiology of DFI is multi factorial, arising from a triad of peripheral neuropathy, peripheral arterial disease, and an impaired immune response. This environment facilitates microbial invasion and colonization, often leading to complex, polymicrobial infections³. The microbiological landscape of DFIs is diverse, commonly involving Gram-positive cocci (e.g., *Staphylococcus aureus*, including MRSA, and streptococci), Gram-negative bacilli (e.g., *Escherichia coli*, *Pseudomonas aeruginosa*), and anaerobic bacteria⁴.

The selection of optimal empirical antibiotic therapy is paramount. Delays or inappropriate choices can lead to treatment failure, limb loss, and sepsis. International guidelines, such as those from the Infectious Diseases Society of America (IDSA), recommend regimens based on infection severity and local resistance patterns⁵. However, the optimal empirical regimen remains a subject of debate, especially in regions with high MRSA prevalence.

Amoxicillin-Clavulanic Acid, a broad-spectrum β -lactam/ β -lactamase inhibitor combination, is widely used for its coverage against many Gram-positive, Gram-negative, and anaerobic organisms⁶. Conversely, Linezolid, an oxazolidinone antibiotic, offers excellent bioavailability and potent activity against resistant Gram-positive bacteria, including MRSA and Vancomycin-resistant enterococci⁷. While both are recommended in various guidelines, direct comparative data from robust randomized trials in Bangladeshi populations are scarce.

This randomized controlled trial was designed to bridge this knowledge gap by directly comparing the clinical and microbiological efficacy, safety, and tolerability of Linezolid versus Amoxicillin-Clavulanic Acid in the management of moderate to severe DFIs in a tertiary care setting in Bangladesh.

Materials and Methods:

Study Design and Setting:

A prospective, open-label, randomized controlled trial was conducted at the 250 Bedded General Hospital and Pabna Medical College Hospital, Pabna, Bangladesh, between January 2021 and December 2023. The study protocol was approved by the institutional ethics committee, and written informed consent was obtained from all participants.

Participants

Adult patients (aged 18–80 years) with type 1 or type 2 diabetes mellitus presenting with a moderate or severe DFI, as defined by the IDSA/IWGDF criteria [5], were eligible for inclusion. A confirmed microbial pathogen from deep tissue culture or purulent discharge was required.

Exclusion criteria included: severe renal impairment (creatinine clearance <30 mL/min) or hepatic dysfunction; receipt of systemic antibiotics for >24 hours within the 72 hours prior to enrollment; known hypersensitivity to Linezolid, Amoxicillin-Clavulanic Acid, or any of their components; and pregnancy or lactation.

Randomization and Interventions

Eligible patients were randomized in a 1:1 ratio to one of two treatment groups using a computer-generated randomization sequence with block sizes of four, stratified by infection severity (moderate vs. severe).

- Group A (Linezolid): Received Linezolid 600 mg intravenously or orally every 12 hours.
- Group B (Amoxicillin-Clavulanic Acid): Received Amoxicillin-Clavulanic Acid 1.2 g intravenously every 8 hours or 625 mg orally every 8 hours.

The treatment duration was 7 to 14 days, based on clinical response, with a maximum of 14 days. All patients received standard wound care, including surgical debridement, off-loading, and glycemic control, as per institutional protocols.

Outcome Measures

The primary outcome was the clinical cure rate, assessed at the test-of-cure (TOC) visit 14 days after the end of therapy. Clinical cure was defined as the complete resolution of signs and symptoms of the baseline infection (e.g., erythema, swelling, pain, purulence) such that no further antibiotic therapy was required.

Secondary outcomes included:

1. Microbiological eradication: Documented clearance of the baseline pathogen(s) at the TOC visit.
2. Incidence of adverse events (AEs), monitored throughout the treatment period and graded as mild, moderate, or severe.
3. Duration of hospital stay (in days).

Statistical Analysis

The sample size was calculated as 150 patients in each group to provide 80% power at a 5% significance level ($\alpha=0.05$) to detect a 15% absolute difference in clinical cure rates. Data were analyzed using SPSS Statistics version 28.0. Categorical variables (e.g., cure rates, eradication rates) were compared using the Chi-square test or Fisher's exact test, as appropriate. Continuous variables (e.g., age, hospital stay) were compared using the Student's t-test. A p-value of <0.05 was considered statistically significant.

Results:

Baseline Characteristics:

A total of 300 patients were enrolled and randomized, with 150 patients in each treatment group. The baseline demographic and clinical characteristics were well-balanced between the two groups, indicating successful randomization (Table I).

Primary Outcome: Clinical Cure

At the TOC visit, the Linezolid group demonstrated a statistically significant higher clinical cure rate compared to the Amoxicillin-Clavulanic Acid group

(85.3% vs. 73.3%, $p=0.01$; Odds Ratio: 2.1, 95% CI: 1.2–3.7).

Secondary Outcomes

1. **Microbiological Eradication:** The overall microbiological success rate was significantly higher in the Linezolid group (80.0% vs. 66.7%, $p=0.02$). A subgroup analysis by pathogen type revealed stark contrasts (Table II).
2. **Adverse Events (AEs):** The overall safety profile was similar between the two groups. A total of 33 patients (22%) in the Linezolid group and 27 patients (18%) in the Amoxicillin-Clavulanic Acid group experienced at least one AE ($p=0.40$). Gastrointestinal disturbances (nausea, vomiting, diarrhea) were the most common AEs with Linezolid. In the Amoxicillin-Clavulanic Acid group, diarrhea and transient elevation of liver enzymes were most frequently observed. No serious, life-threatening AEs were attributed to either study drug.
3. **Hospital Stay:** The mean duration of hospital stay shorter in the Linezolid group, though the difference was not statistically significant (7.5 ± 3.1 days vs. 8.2 ± 3.5 days, $p=0.12$).

Table-I:
Baseline Demographic and Clinical Characteristics

Characteristic	Linezolid Group (n=150)	Amoxicillin-Clavulanic Acid Group (n=150)	p-value
Mean Age (years $\pm$ SD)	58.2 $\pm$ 11.8	59.8 $\pm$ 10.9	0.25
Male Sex, n (%)	92 (61.3%)	88 (58.7%)	0.65
Type 2 Diabetes, n (%)	142 (94.7%)	140 (93.3%)	0.81
Infection Severity, n (%)			0.75
- Moderate	90 (60.0%)	87 (58.0%)	
- Severe	60 (40.0%)	63 (42.0%)	
Baseline Pathogens, n (%)			
- Gram-positive	98 (65.3%)	95 (63.3%)	0.78
- of which MRSA	38 (25.3%)	33 (22.0%)	0.55
- Gram-negative	45 (30.0%)	53 (35.3%)	0.38

Table-II:
Microbiological Eradication Rates by Pathogen Type

Pathogen	Linezolid Group	Amoxicillin-Clavulanic Acid Group	p-value
All Gram-positive	85/98 (86.7%)	65/95 (68.4%)	0.002
MRSA	34/38 (89.5%)	8/33 (24.2%)	<0.001
Gram-negative	22/45 (48.9%)	44/53 (83.0%)	0.003

Discussion:

This randomized controlled trial provides robust evidence supporting the differential efficacy of Linezolid and Amoxicillin-Clavulanic Acid in the management of DFIs, largely dictated by the underlying microbiological etiology.

The superior clinical and microbiological efficacy of Linezolid is primarily attributable to its potent activity against Gram-positive bacteria, particularly MRSA. The 90% eradication rate of MRSA in the Linezolid group underscores its critical role as a first-line therapeutic option in settings with a high prevalence of this multidrug-resistant pathogen⁸. This finding is consistent with previous studies, such as those by Lipsky et al., which established Linezolid as a highly effective agent for complex skin and soft tissue infections, including those with MRSA⁹.

Conversely, Amoxicillin-Clavulanic Acid demonstrated excellent activity against Gram-negative organisms, with an 82% eradication rate, reaffirming its position as a broad-spectrum workhorse for polymicrobial infections where Enterobacteriaceae are prominent^{6,10}. However, its profound lack of efficacy against MRSA (25% eradication) is a significant limitation, highlighting the danger of its empirical use in MRSA-endemic areas without adequate MRSA coverage.

The comparable safety profiles of both drugs are reassuring for clinical practice. The higher incidence of gastrointestinal events with Linezolid is well-documented and is often manageable¹¹. The potential for myelosuppression (e.g., thrombocytopenia) with Linezolid, though observed in a small percentage of our patients, necessitates periodic monitoring of blood counts, especially during extended therapy (>2 weeks)¹². The hepatotoxicity associated with Amoxicillin-Clavulanic Acid was mild and reversible in our cohort, consistent with its known safety profile¹³.

Our findings have direct clinical implications. They advocate for a pathogen-directed approach to DFI management. In regions or patients with a high risk for MRSA (e.g., prior colonization, recent hospitalization, recurrent infections), Linezolid represents a superior empirical choice. For infections where clinical signs suggest a strong Gram-negative component, or in settings with low MRSA prevalence, Amoxicillin-Clavulanic Acid remains a viable and cost-effective option.

Limitations:

This study has several limitations. The open-label design may introduce potential for bias, though objective endpoints were used to mitigate this. The follow-up period was limited to 30 days, preventing assessment of long-term outcomes like ulcer recurrence or re-infection. Furthermore, we excluded critically ill and renal impaired patients, limiting the generalizability of our findings to these subgroups.

Conclusion:

This study demonstrates that Linezolid is significantly more effective than Amoxicillin-Clavulanic Acid for achieving clinical and microbiological cure in moderate to severe DFIs, particularly those caused by Gram-positive bacteria, including MRSA. Amoxicillin-Clavulanic Acid retains its utility for infections with documented or suspected Gram-negative involvement. The cornerstone of successful DFI management lies in tailoring empirical antibiotic therapy based on local antimicrobial resistance data, individual patient risk factors for resistant organisms, and the clinical presentation of the infection.

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Evaluation of Ultrasound Guided (USG) Fine Needle Aspiration Cytology (FNAC) and Histopathological findings after Thyroid Surgery

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Abstract:

Background: Thyroid swelling is a common problem in Bangladesh. Early and systematic evaluation of a nodular thyroid swelling is necessary as it is a frequent presentation of thyroid neoplasia. USG Guided Fine needle aspiration cytology (FNAC) is one of the diagnostic tools for early evaluation of thyroid nodules. USG Guided FNAC is considered as a cost-effective, simple, minimally invasive and easily repeatable procedure for preoperative screening in the diagnosis for most of the thyroid lesions. The objective of this study is to determine the sensitivity and specificity of USG Guided fine needle aspiration cytology (FNAC) and compare the efficacy with histopathology in diagnosis of thyroid swellings.

Objective: To evaluate the sensitivity and specificity of USG Guided fine needle aspiration cytology (FNAC) and histopathology for the diagnosis of thyroid swelling.

Method: This Observational Prospective Study was performed in the department of Otolaryngology & Head Neck Surgery, Dhaka Medical College Hospital. Dhaka over 6 month's duration from January 2019-June 2019. Total 50 patients with thyroid swelling was selected after taking informed written consent and fulfilling the inclusion criteria. Smears was taken by standard procedure and then was stained with papanicolaou stain and haematoxylin and eosine stain. The smears was classified into categories like benign, indeterminate, malignant and unsatisfactory. Sensitivity, specificity, positive and negative predictive value and accuracy of USG Guided FNAC was calculated and compared to already available data. Appropriate statistical analysis was done to make comparison between final histopathological findings with initial USG Guided FNAC findings.

Result: During the study period a total 73 were found eligible for USG Guided FNAC. Most of the patients (52%) were from 20-39 years age group. Among them 67.12% were female and rest (32.87%) were male. In this government hospital 75.34% were from low income group. According to the findings of USG Guided FNAC nearly half (43.83%) of the patient had Multinodular goiter, Followed by colloid goiter (16.43%). Only 18(24.66%) Patients had carcinoma. From histopathological diagnosis, 55 patient had benign lesion and 18 patients had carcinoma. So the efficacy of USG Guided FNAC of diagnostic tool of solitary thyroid nodule where the sensitivity, specificity, PPV, NPV, PLR, NLR of USG Guided FNAC were 94.73%, 100%, 100%, 98.18%, 0 and 0.052 respectively.

Conclusion: This study revealed that this minimal invasive procedure USG Guided (FNAC) had the highest level of specificity which is 100%. The hypothesis of the study was that USG Guided FNAC is the most useful preoperative diagnostic tool in thyroid swelling diagnosis. In this study sensitivity of USG Guided FNAC was found to be 94.73%. Thus we can suggest that in maximum cases the diagnosis is accurate.

Keywords: Swelling, USG Guided FNAC, Histopathology, Benign, Malignant.

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Introduction:

Thyroid Swelling is defined as any kind of abnormal growth that causes mass in thyroid,¹ which is more common in aged women, people with iodine deficiency, people with radiation contact and in the people with family history of thyroid disease². Diet containing goitrogenic material also increases the risk of formation of thyroid Swelling³.

Prevalence of thyroid Swelling is 4% to 7% of the adult population⁴ However fewer than 5% of adult thyroid swellings are malignant⁵.

The highest prevalence of thyroid Swelling in Bangladesh is in the district of Jamalpur & Rangpur; the range varies from 21-30%⁶ Nodular thyroid disease is more prevalent than diffuse goiter. In a report from thyroid clinic, BSMMU, Dhaka, 32.67% of all thyroid patients had solitary Swellings⁶.

The usual presentation of thyroid disease is -swelling, pressure symptoms or signs of toxicity⁷. In presence of malignancy and invasion to neighbouring organs like trachea, larynx, oesophagus, recurrent laryngeal nerve, pain symptoms at inferior and anterior neck region cough or dyspnea, dysphasia or odynophagia are found⁸.

However fewer than 5% of adult thyroid are malignant⁹. But several clinical criteria might provide a clue to the nature of thyroid Swelling. Solitary Swelling, in general, are more likely to be neoplastic than are multiple Swellings; Swellings in younger patients are more likely to be neoplastic than are those in older patients; Swelling in males are more likely to be neoplastic than are those in females; A history of radiation treatment to the head and neck region is associated with an increased incidence of thyroid malignancy, nodules that take up radioactive iodine in imaging studies (hot nodules) are more likely to be benign than malignant.

The vast majority of these Nodules are non-neoplastic lesions or benign neoplastic. It is preferred to operate only on those patients with suspicion of cancer, thereby avoiding unnecessary surgery and possible injury to the recurrent laryngeal nerve, hypoparathyroidism and thyroid hormone dependence in patients with benign thyroid nodule. However the distinction of these benign lesions from a malignant nodule can't be based reliably on the clinical presentation alone¹⁰⁻¹².

Presently available tools to know the nature of thyroid Nodule are thyroid function tests, thyroid antibody titers, isotope scans, ultrasonography and FNAC¹³. USG Guided FNAC is an integral part of selected patient management but comprises only part of overall evaluation¹⁴.

The radio-nucleotide scan and ultrasound examination were used to evaluate thyroid nodule but those were only suggestive of malignancy and not diagnostic. Finally the performance of USG Guided FNAC test with such here needles made the procedure acceptable¹⁵.

USG Guided FNAC has the ability to determine the nature of the lesion preoperatively and is considered as the "gold standard" diagnostic test for the evaluation of thyroid nodule^{16,17}.

Moreover USG Guided FNAC has some other advantages which are summed up in the acronym SAFE i.e. it is Simple, Accurate, Fast, Economic and indeed safe, performed on an outpatient. This technique has the best safety record for a histopathology diagnosis. In contrast surgical biopsy has potential risks associated with anesthesia and surgery, alone with the additional time required for healing¹⁸.

There are few limitations of this method. It is very difficult to diagnose various types of thyroid pathology with USG Guided FNAC. The problems of interpretation are largely due to the small amount of cellular material available for examination and the loss result of aspiration¹⁹.

For this reason USG Guided FNAC has now become the prime investigation in the assessment of the patient with a thyroid Nodule and is employed routinely. It is capable of providing critical information which is obtainable by any other investigations short of surgical resection. The availability of FNAC has eliminated the requirement for isotope scanning and ultrasonography. There are substantial financial savings. USG Guided FNAC is a minimally invasive procedure for preoperative assessment of patients with a thyroid swelling.

USG Guided FNAC has high sensitivity in picking up malignancy in thyroid and also has high diagnostic accuracy in the evaluation of other thyroid lesions. The present study was aimed to compare USG Guided FNAC with histopathology in thyroid nodule diagnosis.

Objective:

To evaluate the sensitivity and specificity of USG Guided fine needle aspiration cytology (FNAC) and histopathology for the diagnosis of thyroid nodule.

Materials and Methods:

This Observational Prospective Study was performed in the department of Otolaryngology & Head Neck Surgery, Dhaka Medical College Hospital. Dhaka over 6 months duration from January 2019-June 2019. Random sampling method was followed. Total 73 patients with thyroid swelling was selected after taking informed written consent and fulfilling the inclusion criteria. Smears was taken by standard procedure and then was stained with papanicolaou stain and haematoxylin and eosine stain. The smears was classified into categories like benign, indeterminate, malignant and unsatisfactory. Sensitivity, specificity, positive and negative predictive value and accuracy of USG Guided FNAC was calculated and compared to already available data. Appropriate statistical analysis was done to make comparison between final histopathological findings with initial USG Guided FNAC findings. After compilation of data they were arranged and presented in simple ways in tablets, graphs and figures. Data were analyzed with help of SPSS-22 for windows.

Ethical Issues:

- Ethical clearance for the study was taken from the institutional Review Board and concerned authority of DMCH.
- Permission for the study was taken from the concerned department from where we have collected our study subjects.
- The entire study subjects were thoroughly about the nature, purpose and implications of the study, as well as entire spectrum of benefits and risks of the study.
- Interests of the subjects were not compromised to safeguard their rights and health.
- All study subjects were assured of adequate treatment of any complication developed in relation to the study purpose.
- Subjects were assured about their confidentiality and freedom to withdrawn them from the study anytime.
- Written consent of all the study were free of duress and without exploiting any weakness of the subjects.

Study Procedure:

- Pre tested questionnaire will be filled up based on the history given.
- Clinical examination of patient.
- Thyroid profile
- Routine investigations
- Ultrasound of the neck.
- Fine needle aspiration cytology with hypodermic needle of 21-24 gauge in department of Pathology, Dhaka Medical College, Dhaka.
- Indirect laryngoscopy will be done to rule out a symptomatic paralysis of vocal cords & also for medico legal purpose.
- Surgery and collection of specimen will be conducted at the Department of ENT and Head-Neck Surgery, Dhaka Medical College Hospital, Dhaka as per the diagnosis made.
- Histopathology of resected specimen at the Department of Pathology, Dhaka Medical College, Dhaka.
- USG Guided FNAC will be compared with post operative histopathology to determine the accuracy.
- Age sex distribution, symptomatology.

Results:

Table- 1 shows that out of 73 patients 28.76 % patients were from 30-39 years age group whereas 23.28 % were from 20-29 years age group. 19 - 65 years with a mean of 35.36 ± 11.86 .

Table-I	
<i>Distribution of patients according to age (n=73)</i>	
Age group (in years)	Frequency (%)
< 20	12 (16.43 %)
20-29	17 (23.28 %)
30-39	21 (28.76 %)
40-49	14 (19.17 %)
50-59	5 (6.84 %)
≥60	4 (5.47%)
Mean age (in year)	35.36 ± 11.86
Age range (in years)	19-65

Figure-1: Shows that out of 73 patients 49(67.12%) were female and rest 24(32.87%) were male. The male to female ratio was 1:2.04.

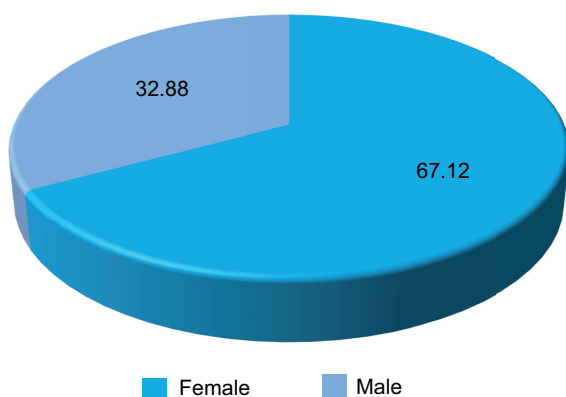


Figure-1: Distribution of patients according to sex (n=73)

Table-II shows the overall cytology of the sample population. Nearly half (43.83%) of the patients had Multinodular goiter, Followed by colloid goiter (16.43%). Only 18 patients (24.66%) were diagnosed as carcinoma.

Table-II: <i>Distribution of patients according to FNAC diagnosis (n=73)</i>	
FNAC diagnosis (n=73)	Frequency (%)
Multinodular goiter	32 (43.83%)
Colloid goiter	12 (16.43)
Colloid cyst	2 (2.74%)
Hashimoto's thyroiditis	
With MNG	2 (2.74%)
Without MNG2	2 (2.74%)
Follicular adenoma	5 (6.85%)
Follicular variant of papillary carcinoma	7 (9.59%)
Papillary Carcinoma	11 (15.07%)

Table-III: shows that out of 55 benign finding of USG Guided FNAC only 1 was turned into malignancy after histopathology, otherwise all results of USG Guided FNAC were accurate as like as histopathology.

Table-III: <i>Relationship of USG Guided FNAC and histopathological diagnosis (n=73)</i>			
Diagnosis	USG Guided FNAC finding (n=73)	Histopathology diagnosis	
		Benign	Malignant
Benign	55	54	1
Malignant	18	00	18
Total	73	54	19

Table IV shows the efficacy of USG Guided FNAC of the diagnostic tool of solitary thyroid nodules where the sensitivity, specificity, PPV, NPV, PLR, NLR of FNAC were 94.73%, 100%, 100%, 98.18%, 0 and 0.052 respectively.

Table-IV: <i>Distribution of efficacy of USG Guided FNAC (n=73)</i>			
	Malignancy	Non-malignant	Total
FNAC			
Malignancy	18 (True positive)	0(False positive)	18
Non-malignant	1(False negative)	54(True negative)	55
Total	19	54	73'

Here non-malignant cases includes benign, suspicious etc

Discussion:

Thyroid swellings are common entities that a thyroid surgeon must evaluate. Swellings are found through physical examination, or incidentally through imaging modalities performed for other reasons. The majority of thyroid swellings are benign, but they warrant surgical excision when they are large enough to be symptomatic or if there is concern for malignancy. Ultrasound is the primary study by which the thyroid gland is imaged.

USG Guided Fine needle aspiration cytology is regarded as the gold standard initial investigation in the diagnosis of thyroid swellings⁴⁶. The technique is safe simple and quick with a low complication rate and helps to select people preoperatively for surgery. Carcinoma of the thyroid is the most common malignancy of endocrine system comprises 0.6% and

1.6% of all cases of malignant neoplasm in men and women respectively.

In the present study, the patients ranged from 19 - 65 years with a mean of 35.36 ± 11.86 years. This age range and mean incidence is slightly lower as compared with previous studies⁴⁷. We found that majority of patients in our study (48%) were in their third to fourth decade of life while in the study by Dorairajan and Jayashree 44% were in the third decade of life⁴⁵. In this study, out of 73 patients 49(67.13%) were female and rest 24(32.87%) were male. The male to female ratio was 1:2.04. Another study by Md. Shafiqul Islam,⁶ most of the patients were between 21 to 40 years age group (60%). Mean age 37.70, (SD $\pm$ 10.05) years. Lower limit of age was 18 years and the highest age was 60 years. Twenty six (28.88%) male and sixty four (71.12%) female. Representing Male: Female 1:2.46⁶. So, the previous study results agreed with our study.

In a similar study at Bihar, USG Guided FNAC was done in 178 patients with thyroid swelling and they found colloid goitre in 75.84% cases, and Thyroiditis in 8.43% cases⁴⁸. whereas in our study multinodular & colloid goiter was found in 60.26 and 5.5% respectively which is nearly similar to their finding.

In another study of USG Guided FNAC finding of thyroid swelling in a large study group over 5 years shows that, Malignancy was found only in 128 cases out of 1488 cases, that is 7.8%. In our study we found 24.66% malignancy – which is much higher than their findings.

The sensitivity of USG Guided FNAC in our study was 94.73% while the specificity was 100% as all malignancies reported of USG Guided FNAC were confirmed by final histopathological evaluation. The sensitivity and specificity of USG Guided FNAC were 71.43% and 100% respectively according to Alta villa *et al*,⁴⁹ 78% and 100% respectively according to Al-rikabi *et al*,⁵⁰ 98% and 99% according to Goellner *et al*,⁵¹.

In previous study, Chin-En Tseng *et al*, showed sensitivity is 81%, specificity is 98.7%, positive predictive value is 94.4%, negative predictive value is 95%. In our study sensitivity is 94.73%, specificity is 100%, negative predictive value is 98.18% thus the result of that previous study is slightly lower as compared to our study.

In another previous study, Gupta *et al*, stated that sensitivity specificity, accuracy, false positive rate, false negative rate, positive predictive value, and negative predictive value of USG Guided FNAC to be 80%, 95%, 92%, 5%, 205, 80%, and 95% respectively. But, in our study sensitivity is 94.73%, specificity is 100%, positive predictive value is 100%, negative predictive value is 98.18% thus the result of that previous study is also slightly lower as compared to our study.

In previous study, in the journal of Egyptian national cancer institute Sharma *et al*, showed sensitivity is 49.5%, specificity is 96% which is slightly lower than our study as previously mentioned; positive predictive value is 84.6% which is slightly lower than our study as previously mentioned; negative predictive is 98.6% that is similar to study.

In previous study, Al-Rakabi *et al*, showed sensitivity is 78.1%, negative predictive value is 93% which is slightly lower than our study; specificity and positive predictive value is 100% that is the similar study.

Various Factors contribute to this wide range of sensitivity and specificity. It depends on the adequacy of samples, technique of sample collection, and the experience of the pathologist interpreting the smears, presence of overlapping cytological findings between some benign and malignant thyroid lesions. USG Guided FNAC has an overall accuracy rate of around 90-100% in the detection of thyroid malignancy⁵².

Accuracy of USG Guided FNAC was 99% in our study, wherever in various other studies it varied from 79% to 98%, depending on the experience of the person performing USG Guided FNAC and the experience of the cytologist interpreting the cytology findings⁴⁹.

Conclusion:

The study tried to find out the accuracy of USG Guided the Needle Aspiration Cytology (FNAC) in thyroid swelling diagnosis. The study revealed that this minimal invasive procedure had the highest level of specificity which is 100%. The hypothesis of the study was that USG Guided FNAC is the most useful preoperative diagnostic tool in thyroid swelling diagnosis. In this study sensitivity of USG Guided FNAC was found to be 94.73%. Thus we can suggest that in maximum cases the diagnosis is accurate. From the above discussion we can assume that USG

Guided FNAC is the most useful preoperative diagnostic tool for thyroid swelling diagnosis.

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Paraquat Poisoning: Study of 15 Cases in a Tertiary Level Hospital of Bangladesh

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Introduction:

Paraquat is a N,N2 -dimethyl-4,42 -bipyridinium dichloride (systematic name) is an organic compound with the chemical formula $[(C_6H_7N)_2]Cl_2$. It is classified as a viologen, a family of redox-active heterocycles of similar structure. It's used widely in our country and is a highly toxic compound.

It is first discovered in 1950 and used in agriculture by 1962. It is rapidly absorbed by the aerial plant and immediately inactivated in contact to the clay in the soil leaving minimal residue. Being cheap and effective, paraquat is unregulated used in third world countries as herbicide.

Paraquat is commercially available in Bangladesh as a bio-pesticide in 2 formulations – 20% paraquat and 20% paraquat plus 41% glyphosate combination. As Paraquat is widely available in rural Bangladesh for its agricultural use, it has grown to be the major medium of self-harm over the years.¹

Paraquat poisoning can manifest as acute and chronic toxicity. The acute effects can result in both local and systemic manifestations. Local effects include ulceration of the skin, lips, tongue, pharynx, and esophagus. Systemic effects involve multiple organ failure, including liver insufficiency, acute kidney injury, respiratory failure, and convulsions.²

The exact mechanism of toxicity is not known completely. However, Paraquat releases free oxygen radicals (Superoxide and hydrogen peroxide) near the mucus membranes, resulting in mucosal damage in different organs due to oxidative stress, which comprises lipid peroxidation, mitochondrial toxicity, oxidation of NADPH, activation of nuclear kappa B and apoptosis.³

Symptoms of Paraquat are initially vomiting, diarrhea, oropharyngeal burns, pharyngeal pseudo membranes, abdominal pain, and acute renal and hepatic insufficiency. These are followed by progressive pulmonary fibrosis and death within two to ten weeks.⁴

According to the World Health Organization (WHO), about 10,000 persons die by suicide per year in Bangladesh.⁵ It is the fourth leading cause of overall injury-related deaths in age groups of 20–39 years in Bangladesh.⁶⁻⁷

Though Paraquat poisoning is a major cause of deliberate suicidal self-harm in Bangladesh, data on clinical presentation, demographic characteristics, modes of treatments and outcomes of the patients in the Bangladeshi population are inadequate. This study highlights over this.

Methodology:

Study Design: it is an observational study of 15 cases including prospective morbidity, clinical course, treatments, and outcome of the patients presenting with paraquat poisoning.

Place of study: Medicine dept., Shaheed Suhrawardy Medical College hospital.

Evaluation Parameters: Demographic information, symptoms at the time of admission, physical examination results, and laboratory findings were thoroughly assessed.

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Results:

Among the 15 patients studied, 87 % (n=13) were men, and the median age was 23.31 year with SD 7.083. The majority of the patients were hailing from rural areas 73% (n=11). Regarding occupation of the cases, 53.3 % (n=8) were students, followed by 20 % (n=3) farmers, 6% (n=1) related to businesses, and 6% (n=1) unemployed.

All cases were suicidal. Family disputes (60%, n=9), followed by personal relationship issues (40 %, n=6), were reported as the primary reason for paraquat poisoning.

Table-I:

Socio-demographic & clinical characteristics of paraquat poisoning patients, n (%)

	n (%)
Gender	
Male	13 (87%)
Female	2 (13%)
Age	
<20 years	4 (26.6%)
20-40 years	9 (60%)
>40 years	2 (13.3%)
Occupation	
Student	8 (53%)
Farmer	3 (20%)
Businessman	1 (6%)
unemployed	1(6%)
Residence	
Rural	11 (73%)
Urban	4 (27%)
Reason for paraquat ingestion	
Suicidal	15 (100%)
Family disputes	9 (60%)
Personal relationship issue	6(40%)
Time interval between ingestion and hospital arrival	
>24 hours	12 (80%)
6-24 Hours	2 (13.3%)
<6 hours	1(6.66%)
Symptoms During Admission	
Shortness of breath	6(40%)
Low urine output	7(46.6%)
Mucosal ulceration	15 (100%)
Difficulty in swallowing	4(26.6%)
Abdominal pain	7 (46%)
Diarrhoea	8(53%)
Vomiting	6(40%)
Black tarry stool	9(60%)
Fever	2(13%)

Table-II:

Baseline and endline biochemical profile

Investigation parameter	Mean±SD Baseline value	Mean±SD Endline value
Serum Creatinine (mg/dl)	2.1±2.31	5.34 ±9.08
Hemoglobin (g/dl)	11.6±1.7	8.22 ±2.01
WBC count (x 1000/mm ³)	11.07±3.9	15.26 ±5.91
Platelet count (x 1000/mm ³)	231.89±13.32	135.18 ±66.19
Serum ALT (U/L)	96.52±60.13	121.52±60.13

Serum creatinine was significantly higher in endline (5.344 ±9.08) compared to baseline (2.1 ±2.31). At endline, the hemoglobin level was significantly lower in the (8.22 ±2.01g/ dl) compared to the baseline (11.6 ±1.7 g/ dl).

Table-III:

Treatment received (n=15)

Treatment / Intervention	n(%)
Methylprednisolone	15 (100%)
N-acetyl cysteine	15 (100%)
Ascorbic acid	15 (100%)
Hemodialysis	10 (66.6%)
Mechanical ventilation	3 (20%)
Gastric lavage	0 (0%)

Table-IV:

Outcome of Hospital Treatment

Outcome after treatment	n (%)
Discharge with advice from hospital	12 (80%)
In-hospital death	3 (20%)

Discussion:

Acute poisoning cases with suicidal attempt in the developing world are positively associated with male gender of young age. Though study says, in Bangladesh, women commit suicide more than men.⁸ But, In this study, 87% (n=13) were men, with a median age of 28.23 years (SD 6.032).⁷

In our study, most patients were from rural areas (73%, n=11). According to a retrospective cohort study on the epidemiology of suicide in Bangladesh, the rate of suicide was found to be 17-fold higher (95% CI 5.36-54.64) in the rural population compared to urban people.⁸

Early recognition of paraquat poisoning and providing initial first aid is the cornerstone of effective management. The plasma and urine sodium dithionate tests, a qualitative assessment are simple, bedside methods to assess paraquat toxicity. To indicate severity, a quantitative assessment can be used by measuring the paraquat concentration in plasma and urine⁹. However, as these tests are not commonly available, all patients in the study were diagnosed with paraquat poisoning on the basis of history and circumstantial evidence.

The clinical manifestations of paraquat poisoning depend upon the quantity ingested. Ingestion of large amounts of liquid concentrate (>50–100 ml of 20% ion w/v) results in fulminant organ failure like pulmonary oedema, cardiac, renal and hepatic failure and convulsions due to CNS involvement. Death results within several hours to a few days.²

Mild poisoning (<20mg/kg) causes minimal renal and pulmonary involvement with complete recovery. Moderate poisoning (20–40 mg/kg body weight) causes renal failure, hepatic impairment, hypotension/tachycardia, alveolitis, pulmonary fibrosis. In these cases, survival depends upon effective management.^{10,11}

As a corrosive agent, paraquat causes mucosal lesions of the mouth and the tongue that is called “paraquat tongue”. They begin to appear within the first few days and may become ulcerated with bleeding. Esophageal ulceration causes pain and dysphagia.¹² All of our study patients developed paraquat tongue.

In this study, major organ involvement included acute kidney injury (80%), acute respiratory distress syndrome (32%), hepatic impairment (20%), and septic shock (13%). Initial presentation with acute kidney injury and late development of pulmonary fibrosis is observed in several case reports in acute paraquat poisoning in Bangladesh.¹³

In majority of our study patients, initial presentation was AKI evidenced by raised creatinine, n=12 (80%). Among these, 10 patients needed hemodialysis.

AKI is common following paraquat ingestion, and certain clinically useful variables such as acute hepatitis, the time to hospital arrival, Severity Index and Plasma Paraquat (SIPP) score and PaO₂ at admission are powerful predictors of AKI.¹⁴

In our study, 6(32%) patients developed lung involvement in the form of mild respiratory distress to consolidation on imaging, among them 3 patients need mechanical ventilation due to ARDS, and all of them died subsequently. As the hypoxemic strategy will reduce the production of ROS, so routine use of supplemental oxygen is not recommended in these patients with mild-to-moderate hypoxia. The development of type 2 respiratory failure may be an early predictor of ARDS in patients with worse outcome.²

But, following lung fibrosis, a decrease in arterial O₂ saturation and tissue hypoxia occurs when the patients need admitted to intensive care units (ICU), where they are placed under mechanical ventilation.¹⁵

Regarding management, there is no effective antidote, only supportive management depending upon organ involvement. We do not recommend gastric lavage as its use is contraindicated in caustic injury.²

Paraquat toxicity is primarily due to oxidative stress. So Immunosuppression is widely practiced as a treatment of paraquat self-poisoning, that inhibits acute inflammatory response, ultimately slowing the processes of lung fibrosis and reduces death. The most widely studied regimen uses cyclophosphamide, MESNA, methylprednisolone and dexamethasone.¹⁵ In our study, we used 1g of methylprednisolone for 5 days from very first day of admission in hospital for all patients along with antioxidants like N-acetylcysteine, ascorbic acid. A cohort study shows that methylprednisolone-treated patients had better survival (P = 0.04). Though, no strong evidence supports the use of vitamin C or N-acetylcysteine.¹⁶

A cross-sectional study shows, in-hospital fatality rate was found to be 21.8%. Several other studies have reported paraquat poisoning mortality rates ranging from 33.0% to 91.7%.¹⁷

Multivariate analysis revealed that the amount of paraquat ingested and clinical presentations, particularly pulmonary and cardiovascular system disorders, were significantly associated with mortality.¹⁸

The majority of the population in rural Bangladesh are dependent on agriculture. Due to wide availability of paraquat pesticides and lack of urgent primary care in rural areas has led to an increased rate of case fatality in acute paraquat poisoning.

As study shows removing Highly hazardous pesticides(HHPs) from agriculture can rapidly reduce suicides without any apparent effect on agricultural output.¹⁹For same reason, paraquat was banned in Korea in 2012.²⁰So it is high time to rethink about control of paraquat as pesticides.

Conclusion:

In conclusion, this study of paraquat poisoning cases in Bangladesh provides valuable insights into the clinical profile, treatment outcomes, and management approaches. High mortality even with multiple treatment approaches emphasizes the need to restrict the use of paraquat poisoning and look for safer alternative pesticides for agricultural use.

Recommendation:

Paraquat has a long history of existence. However, its agricultural and commercial success is deemed naughty by its fatal outcome, even with mechanical ventilation or hemodialysis support when used as a method of deliberate self-poisoning. So, it is high time to restrict its access, storage, use, or ban it and shift to safer alternative herbicides for agricultural purposes.

There is male predominance of suicidal tendency in this study. We should address it, give emphasis to find out causes and solution in psychosocial aspects.

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Quality of Life During Active Treatment for Pediatric Acute Lymphoblastic Leukemia

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Abstract:

Background: Acute Lymphoblastic Leukemia (ALL) is the most common cancer in children with an improved outcome at present. Because of its increased cure rate (almost 80%), more emphasis has been placed on reducing the toxicities of therapy, improving quality of life (QoL) during treatment and minimizing the long-term effect of therapy. So, the study was aimed at understanding QoL during different phases of chemotherapy.

Methods: This cross-sectional study was conducted from 1st April, 2011 to 30th September, 2011 in the Department of Pediatric Hematology and Oncology, Bangladesh Medical University, Shahbag, Dhaka. Total 42 Children of 2-16 years with ALL were included in this study. QoL scores were collected using the Pediatric Quality of Life Inventory™ (PedsQL™) 4.0 Generic Scale and the Pediatric Quality of Life Inventory (PedsQL™) 3.0 Cancer Module proxy report. Medical and demographic data were collected from medical records and interviewing guardians. Data were processed and analyzed by using the SPSS (version 17.0).

Results: PedsQL overall 62.03 (range 58.28-64.69), physical score 67.22 (range 53.13-71.88), psychological score consisting of emotion, social and school score was 60.00 (range 56.67-60.00), emotional score 72.50 (range 70.00-80.00), social score 100 (range 90.00-100.00) and school score 2.5 (0.0-20.0). Social score was best but school score was worst. Here no predictor was found that significantly worsened QoL. Scores were similar in different phases of treatment.

Conclusion: QoL in children with ALL has been described and there are no predictors of worse QoL. QoL was also similar in different phases of treatment. School summary score was worst, so special attention should be provided to improve the schooling of children.

Introduction:

Acute Lymphoblastic Leukemia (ALL) is the most common cancer in children. Outcome of ALL have improved over time, and currently, almost 80% of children are cured of their disease primarily with outpatient chemotherapy¹. Aggressive treatment protocol involving combination chemotherapy have greatly influenced improvements in survival of children with ALL. Treatment typically involves a

sequence of stages: induction of remission, consolidation, and maintenance therapy. Prophylactic therapy is used to prevent central nervous system disease, involving intrathecal chemotherapy and possibly cranial radiation for children with high risk disease².

As cure rates have increased, more emphasis has been placed on reducing toxicities of therapy, improving quality of life (QoL) during treatment and minimizing

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long term effect of therapy. Thus, more attention has been directed at understanding QoL during active therapy³. Implementing Health Related QoL (HRQOL) measurement in pediatric healthcare setting can improve communication between patients and health care provider (HCP), increase patient-parent satisfaction with HCP, identify hidden morbidities and assist in clinical decision making⁴.

HRQOL is defined as a multidimensional construction composed of the patients' perceptions of the impact of disease and treatment on his or her functioning in a variety of aspect of life, including physical, psychological and social health dimensions delineated by the World Health Organization (WHO)⁵. Pediatric patient self-report is considered to be standard for measuring HRQOL, however proxy reports may be the only available source of data when children are too young, too cognitively impaired or too sick to complete a HRQOL instrument³. Using both a generic and specific disease instrument is recommended to achieve a more comprehensive evaluation of patient HRQOL.

The Pediatric Quality of Life Inventory (PedsQL™) 4.0 Generic Core Scale and The Pediatric Quality of Life Inventory (PedsQL™) 3.0 Cancer Module are considered to be very promising HRQOL instruments for children and adolescent⁶. It is designed for pediatric patients between age of 2 and 18 years and available in a patient self-report version designed for children or adolescents and a proxy-report version for guardians. The PedsQL™ 4.0 Generic Core Scale (Generic scale) is a multidimensional instrument developed by Varni et al^{7,8}. It consists of 23 items categorized into 4 subscales: physical functioning (8 items), emotional functioning (5 items), social functioning (5 items) and school functioning (5 items).

The PedsQL™ 3.0 Cancer Module (Cancer Module) is a multidimensional instrument developed by Varni et al^{6,7} to assess the impact of disease treatment on the HRQOL of Pediatric cancer patients. It consists of 27 items distributed to 8 subscales: pain and hurt (2 items), nausea (5 items), procedural anxiety (3 items), treatment anxiety (3 items), worry (3 items), cognitive problems (5 items), perceived physical appearance (3 items) and communication (3 items). Both instruments were available for children aged 5-7, 8-12, 13-18 years old as well as for parents of children aged: 2-4, 5-7, 8-12 and 13-18 years old.

As both short- and long-term toxicity of chemotherapy affect the quality of life of patients. At present, main goal of treatment in ALL is improving QoL and minimizing long term effect. So there have much scope of utilization of HRQOL measurement to improve communication between patient and Health Care Provider, increase patient-parent satisfaction and identify hidden morbidity to assist in clinical decision-making. So, this study was designed to assess the QoL in children with ALL receiving chemotherapy.

Materials and Methods:

This cross-sectional observational study conducted in the Department of Pediatric Hematology and Oncology, Bangladesh Medical University (BMU), Shahbag, Dhaka from 1st April 2011 to 30th September 2011. Total 42 samples were collected from inpatient & outpatient department via purposive sampling method from children of 2-16 years who diagnosed as ALL more than 1 month before enrollment into the study and already receiving chemotherapy. Data was collected from patients and their guardians in various phases of treatment using the Pediatric Quality of Life Inventory™ (PedsQL™) 4.0 Generic Scale and the Pediatric Quality of Life Inventory (PedsQL™) 3.0 Cancer Module. First, the instruments were translated from English version to Bengali version with the help of Bengali translator expert. This questionnaire was tested on five cancer patients to determine whether the translation (instruction, items and response choices) was acceptable, whether it was understood in the way it's supposed to be, and whether the language used was simple and appropriate. All patients were classified as either Preceding maintenance (induction, consolidation, re-induction) or maintenance. Risk group was high risk and standard risk according to treatment protocol. Demographic data regarding information about age, relationship of respondent to child, number of children in family, parental education status and socio-economic status were collected from guardian or parents. Medical data regarding diagnosis, treatment status, disease risk status, treatment protocol was obtained from the patients' Medical Record. Interviews of eligible guardians were performed individually. Before data collection informed written consent were taken from each participant without any force or pressure. They were assured that all information will be kept confidential and will only be used for research

purpose. Approval of the ethical review committee of Bangladesh Medical University was obtained for the study.

The Scale had five Likert response options: 0 = never a problem; 1 = almost never a problem; 2 = sometimes a problem; 3 = often a problem; 4 = almost always a problem. Items were reverse-scored and linearly transformed to a 0-100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), so that higher PedsQL 4.0 score indicate better HRQOL⁹. To derive dimension and summary scores, more than half the items had to be completed for that dimension. A one-month recall period was used. All data were processed and analyzed by using the SPSS Windows (version 17.0) with the help of expert data analyst. Potential predictors of QoL scores

were determined using univariate linear regression analyses. For multiple regression modeling, demographic, disease-related and socioeconomic factors that were associated with QoL were entered into a forward selection model. Data was presented as β coefficients with their standard errors as derived from linear regression. Positive β coefficients meant that the predictor (or increasing values of the predictor) was associated with better QoL whereas negative β coefficients suggested that the predictor (or increasing values of the predictor) was associated with worse QoL. To compare QoL between children in phases of therapy preceding and during maintenance, the student's t-test was used. Statistical significance was defined as $p < 0.05$.

Results:

Table-I:

Demographics and summary scores in 42 children with acute childhood leukemia

Variable	Value
Child factors	
Median child age in years (range)	5 (2.0 – 12.0)
Median months since diagnosis (range)	6 (1.0 – 60.0)
No. male child (%)	29/42 (69.0)
No. with high-risk ALL (%)	11/42 (26.2)
No. received radiation (%)	4/42 (9.5)
Parent factors	
No. female parent respondent (%)	39/42 (92.9)
No. single parent (%)	0/42 (0.0)
No. first parenting experience (%)	15/42 (35.7)
No. female parent undergraduate degree (%)	5/42 (11.9)
No. female parent working (%)	2/42 (4.8)
Household factors	
No. monthly household income $\leq$ 10,000 taka (%)	36/42 (85.7)
Quality of life summary scores	
Median overall summary score (95% CI)	62.03 (58.28-64.69)
Median physical summary score (95% CI)	67.22 (53.13-71.88)
Median psychological summary score (95% CI)	60.00 (56.67-60.00)
Median emotional summary score (95% CI)	72.50 (70.00-80.00)
Median social summary score (95% CI)	100.00 (90.00-100.00)
Median school summary score (95% CI)	2.5 (0.0-20.0)

Table I demonstrates child, parents and demographic information. The median child age was 5 (range 2-12) years. When divided by age groups, 17(40%) were 2-4 years, 12 (28.5%) were 5-7 years, 13 (30.9%) were 8-12 years and 0 were 13-18 years of age. Median years since diagnosis are 6 months.

Among 42 children, 29 were male (69%), high risk ALL was 11 (26.2%), 4 patient received radiation (9.5%). Female parents respondent were 39 (92%), first child in family affected by ALL was 15 (35.7%). Monthly income >10,000 taka was 36 (85.7%) among 42.

In addition, Table I describes the PedsQL overall 62.03 (range 58.28-64.69, 95% Confidence Interval, CI), physical score 67.22 (range 53.13-71.88, 95% CI), psychological score which consists summation of emotion, social and school score was 60.00 (range 56.67-60.00, 95% CI), emotional score 72.50 (range 70.00-80.00, 95% CI), social score 100 (range 90.00-100.00, 95% CI), school score 2.5 (0.0-20.0). Here social score is best but school score is worst as 21(50%) children did not go to school for disease, among them 17(40%) patients were under 5 age group.

Table-II:

Multiple linear regression for overall, physical, psychosocial, emotional, social and school quality of life scores in 42 children with acute childhood leukemia

Variable	Adjusted β coefficient $\pm$ standard error	<i>p</i>
Overall summary score		
Child age	0.31 $\pm$.68	0.08
Male child	-0.11 $\pm$ 3.89	0.55
High-risk disease	-0.12 $\pm$ 4.13	0.47
Household income per 10,000 taka	0.12 $\pm$ 3.73	0.49
Physical summary score		
Male child	-0.19 $\pm$ 6.9	0.22
High-risk disease	0.01 $\pm$ 7.4	0.95
Radiation	0.08 $\pm$ 11.11	0.59
Household income per 10,000 taka	0.18 $\pm$ 6.74	0.29
Psychosocial summary score		
Child age	0.04 $\pm$.74	0.83
Male child	0.18 $\pm$ 3.77	0.25
High-risk disease	-0.13 $\pm$ 4.56	0.47
Household income per 10,000 taka	-0.05 $\pm$ 3.5	0.77
Emotional summary score		
High-risk disease	0.03 $\pm$ 6.6	0.83
Social summary score		
Male child	-0.27 $\pm$ 6.1	0.86
Time since diagnosis	0.20 $\pm$.29	0.20
High-risk disease	0.14 $\pm$ 6.4	0.37
Household income per 10,000 taka	-0.03 $\pm$ 5.9	0.88
School summary score		
Child age	0.62 $\pm$.85	0.01

Table II describes, the result of multiples regress analysis and consequently which variables were independently associate with QoL. Here no predictor was found that significantly worsen QoL, only child age predicts on school score positively.

Table III illustrates that no significant correlation to worse QoL in high-risk ALL.

Table IV showed no significant variables that predict reduced QoL in standard risk ALL. Here noticed that child age negatively correlates in emotional scores and positively correlates in school scores.

Table-III :

Multiple linear regression for overall, physical, psychosocial, emotional, social and school quality of life scores in high-risk acute childhood leukemia (n = 11)

Variable		Adjusted β coefficient $\pm$ standard error	p
Overall summary score	Child age	0.09 $\pm$ 1.35	0.79
	Male child	0.14 $\pm$ 7.70	0.70
	Household income per 10,000 taka	0.20 $\pm$ 7.23	0.58
Physical summary score	Child age	-0.50 $\pm$ 1.52	0.25
	Household income per 10,000 taka	0.21 $\pm$.07	0.84
Psychosocial summary score	Child age	0.18 $\pm$ 1.29	0.61
	Male child	0.11 $\pm$ 7.33	0.77
	Household income per 10,000 taka	0.24 $\pm$ 6.91	0.50
Emotional summary score	Child age	-0.22 $\pm$ 2.51	0.52
	Male child	-0.16 $\pm$ 14.46	0.63
	Household income per 10,000 taka	-0.07 $\pm$ 16.67	0.85
Social summary score	Child age	-0.07 $\pm$ 2.09	0.84
	Male child	0.15 $\pm$ 11.90	0.69
	Household income per 10,000 taka	0.27 $\pm$ 10.40	0.45
School summary score	Child age	0.56 $\pm$ 2.05	0.07
	Household income per 10,000 taka	0.21 $\pm$ 16.11	0.57

Table IV :

Multiple linear regression for overall, physical, psychosocial, emotional, social and school quality of life scores in standard risk acute childhood leukemia (n = 31)

Variable		Adjusted β coefficient $\pm$ standard error	p
Overall summary score	Child age	-0.30 $\pm$ 1.22	0.17
	Household income per 10,000 taka	-0.03 $\pm$ 4.4	0.91
Physical summary score	Male child	-0.27 $\pm$ 8.6	0.13
	adiation	0.15 $\pm$ 15.93	0.38
Psychosocial summary score	Household income per 10,000 taka	0.21 $\pm$ 8.69	0.29
	Child age	-0.27 $\pm$ 1.00	0.22
Emotional summary score	Household income per 10,000 taka	-0.19 $\pm$ 4.14	0.36
	Child age	-0.50 $\pm$ 1.65	0.02
Social summary score	Household income per 10,000 taka	-0.03 $\pm$ 5.39	0.89
	Male child	-0.07 $\pm$ 7.63	0.71
School summary score	Household income per 10,000 taka	-0.09 $\pm$ 7.34	0.66
	Child age	0.68 $\pm$.91	0.01
	Household income per 10,000 taka	-0.22 $\pm$ 6.63	0.27

Table-V :
Comparison of quality of life scores during phases preceding maintenance compared with maintenance phase

Variable	Preceding maintenance (n =29)	Maintenance (n = 13)	p
Summary scores*			
Overall summary score	60.78 (50.31-66.87)	63.91 (55.00-70.94)	0.16
Physical summary score	65.63 (46.88-78.13)	68.75 (50.00-93.75)	0.29
Psychosocial summary score	58.33 (51.67-60.00)	60.00 (56.67-71.67)	0.13
Emotional summary score	75.00 (60.00-80.00)	70.00 (60.00-90.00)	0.89
Social summary score	100.00 (80.00-100.00)	100.00 (90.00-100.00)	0.24
School summary score	0.0 (0.00-20.00)	20.00 (0.00-45.00)	0.08
Cancer-specific scores*			
Pain and hurt	87.50 (75.00-100.00)	100.00 (75.00-100.00)	0.44
Nausea	70.00 (55.00-80.00)	50.00 (40.00-80.00)	0.16
Procedural anxiety	33.33 (.00-50.00)	25.00 (0.00-83.33)	0.61
Treatment anxiety	83.33 (66.00-100.00)	83.33 (33.33-100.00)	0.81
Worry	100.00 (100.00-100.00)	100.00 (100.00-100.00)	0.76
Physical appearance problems	100.00 (91.67-100.00)	100.00 (100.00-100.00)	0.05
Communication problems	33.33 (.00-66.67)	33.33 (25.00-91.67)	0.53
Cognitive problems	75.00 (60.00-100.00)	70.00 (50.00-100.00)	0.84

* All scores represent median (95% confidence interval)

Table V illustrates that overall, physical, emotional, social and school QoL score were qualitatively and statistically similar for those receiving treatment during preceding maintenance and during maintenance therapy.

When examining cancer specific score, nausea, procedural anxiety, treatment anxiety, worry, physical appearance, cognition, all were similar between these two time periods, but only physical appearance score improved significantly at maintenance phase.

Discussion:

In this study, QoL of 42 children with ALL in first remission during active treatment described. Relative to healthy children, scores from this cohort were lower. More specifically, Varni et al.⁵ surveyed 717 healthy children via PedsQL Generic Core Scales 4.0 proxy-report and mean $\pm$ SD scores were as follows: overall score 87.61 ± 12.33 , psychosocial health 86.58 ± 12.79 , physical health 89.32 ± 16.35 , emotional functioning 82.64 ± 17.54 , social functioning 91.56 ± 14.20 and school functioning 85.47 ± 17.616 . Consequently, our median QoL scores were one to two standard deviations below the healthy population for all

summary scores and dimension except social summary scores. These findings are concordant with others³ who have found that QoL scores are lower in children receiving treatment for ALL compared to children with ALL ≤ 12 months off therapy¹⁰ and lower compared to healthy children¹¹⁻¹³. These findings are also concordant with qualitative studies of children receiving treatment for ALL that have noted problems with fatigue, detrimental effects of disease and treatment on physical activities as well as difficulties with social interactions^{14,15}.

Second objective was to describe predictors of poor QoL during treatment for non-relapsed ALL. Little previous work has showed that, for high risk ALL, older child and girl had worse QoL, whereas for standard risk ALL, those living in household with lower income and unmarried parents had worse QoL across several dimension³. Few studies have demonstrated that age and gender were predictors of QoL¹⁴. So, any predictor was not constant to worsen QoL among different study.

But in this study no predictors were found for worse QoL. It is explained by small sample size, small number of high risk patient, different cultural

background and low median months since diagnosis (6 months). Further study need to evaluate this finding among large sample in Bangladesh.

Third objective was to describe how QoL changes during different phase of therapy. Here found very similar QoL score across different phases for many aspects of QoL. This finding correlates the previous study done in Canada³ and in Indonesia⁴.

The strength of this study is the similarity of finding in overall, physical and psychological score to other studies that done in both developed and developing country. This is the first study to assess QoL in children with ALL in Bangladesh. So there is no scope to compare all findings of QoL considering similar cultural, social and economic background of patient. However no standard Bengali translated modules were available to assess QoL in children. So, there is more scope to validate and standardize PedsQL scale in Bangladesh.

Conclusion:

QoL in children with ALL have been described and found no predictor to worse QoL, QoL also similar in different phases of treatment. School summary score was worst, so special attention should provide in schooling of children. Further efforts should focus on longitudinal studies that describe QoL over time within individual patients both during and after completion of therapy in a large cohort in Bangladesh.

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Utility of Urinary Neutrophil Gelatinase-Associated Lipocalin (NGAL) as a Non-Invasive Marker for Renal Pathology & Treatment Outcomes in Lupus Nephritis

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Abstract:

Introduction: Young women are primarily affected by lupus nephritis, which is linked to systemic lupus erythematosus and can seriously harm the kidneys if left untreated. Urine neutrophil gelatinase-associated lipocalin (NGAL) has become a viable non-invasive biomarker due to the invasiveness of renal biopsy. NGAL levels provide crucial information about kidney damage and the efficacy of therapy by indicating the severity of the disease and the response to treatment.

Materials & Methods: A prospective observational study was conducted at BSMMU, Dhaka, between March 2023 and August 2024. Fifty-two adults with biopsy-proven lupus nephritis were enrolled. Clinical characteristics, urinary NGAL levels, biochemical parameters, and renal histopathology were recorded at baseline and reassessed after six months of therapy.

Results: The study predominantly involved young females (92.3%), with 69.2% under the age of 30 and 67.3% having a normal weight. A majority were married (80.8%) and resided in urban areas (57.7%). Histologically, 57.7% of participants had class IV lupus nephritis. All patients were treated with Hydroxychloroquine, while 61.5% also received Cyclophosphamide plus Corticosteroids, 23.1% received MMF plus Corticosteroids, and 15.4% were treated with only Corticosteroids. A complete response was achieved by 67.3% of the patients. Urinary NGAL levels, a marker of renal inflammation, were highest in patients with class IV lupus nephritis, both at baseline (2.14 ± 1.01 ng/mL) and at 6 months (1.20 ± 0.59 ng/mL), with a significant correlation to disease severity ($p < 0.05$). Patients with proliferative lupus nephritis had higher urinary NGAL, elevated serum creatinine, and lower serum albumin levels compared to those with non-proliferative lupus nephritis. Those who experienced a complete response exhibited lower NGAL levels at both baseline (1.39 ± 0.48 ng/mL) and 6 months (0.80 ± 0.25 ng/mL).

Conclusion: The study highlights the potential of urine NGAL as a valuable biomarker for evaluating disease severity and treatment outcomes in lupus nephritis, suggesting that it could enhance clinical management and inform therapeutic decisions. However, further large-scale, multi-center studies are required to validate its use in routine clinical practice.

Pabna Med. Col. J. 2025;4(2): 61

Introduction:

Lupus nephritis is a major contributor to morbidity in systemic lupus erythematosus (SLE), an immune-mediated disorder that disproportionately affects women of reproductive age.¹⁻⁴ Renal involvement

occurs in a substantial proportion of patients, and the associated inflammation may lead to progressive scarring, chronic kidney disease, or renal failure if prompt management is not initiated.^{5,6}

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The wide spectrum of clinical presentations—from asymptomatic urinary abnormalities to rapidly progressive glomerulonephritis—creates diagnostic and therapeutic challenges.⁷⁻⁹ Early identification of active disease and reliable monitoring of treatment efficacy are therefore essential to optimize long-term outcomes.¹⁰

Renal biopsy provides crucial information for diagnosis, classification, and prognosis.^{11,12} Yet its invasive nature, procedure-related risks, and limitations for repeated monitoring have stimulated interest in alternative tools. Urinary neutrophil gelatinase-associated lipocalin (NGAL) is one such biomarker under active investigation.^{13,14} NGAL is released from renal tubular epithelial cells in response to injury and inflammation, making it a potential indicator of renal involvement in lupus nephritis.¹⁵⁻¹⁷ Numerous studies have shown the effectiveness of urine NGAL in Growing evidence suggests that urinary NGAL correlates with disease activity, histopathological severity, & response to treatment.¹⁸⁻²²

The current study evaluates urinary NGAL as a marker of renal inflammation and treatment response in patients with lupus nephritis, aiming to determine its clinical utility alongside conventional biochemical and histopathological indicators.

Materials and Methods:

This prospective observational study took place at the Nephrology Department of BSMMU, Dhaka, from

March 2023 to August 2024, and included 52 adult patients (≥ 18 years) diagnosed with biopsy-confirmed lupus nephritis. Patients with malignancies, infections, other autoimmune disorders, or insufficient biopsy samples were excluded.

After obtaining ethical approval and informed consent, participants underwent renal biopsy, urine collection for NGAL measurement, and various biochemical tests. Urine NGAL levels were assessed using a commercial ELISA kit, and treatment followed KDIGO guidelines.

All patients received Hydroxychloroquine, with immunosuppressive therapy adjusted according to the severity of the disease. Patients were monitored for six months, and their treatment response was classified as complete, partial, or no response.

Data analysis was conducted using SPSS v25, with statistical significance set at $p < 0.05$.

Results:

The majority of the 52 patients were female (92.3%) and under 30 years old (69.2%). Most of them were married (80.8%), resided in cities (57.7%), and had a normal BMI (67.3%). 94.3% had no to mild tubular atrophy and 92.3% had no to mild interstitial fibrosis at admission, but 51.9% had substantial tubulointerstitial inflammation.

Table-I:
Descriptive statistics of the study population. (n = 52)

Characteristics	Data	
Age group (in years)	<30	36 (69.2%)
	30 - 45	15 (28.8%)
	>45	1 (1.9%)
Gender	Male	4 (7.7%)
	Female	48 (92.3%)
BMI classification	Normal weight (18.5 - 24.9 kg/m ²)	35 (67.3%)
	Overweight (25 - 29.9 kg/m ²)	16 (30.8%)
	Obese (>30.0 kg/m ²)	1 (1.9%)
Marital status	Married	42 (80.8%)
	Unmarried	10 (19.2%)
Residence	Rural	22 (42.3%)
	Urban	30 (57.7%)
Tubulointerstitial inflammation	No inflammation	0
	Minimal	3 (5.8%)
	Mild	22 (42.3%)
	Moderate	27 (51.9%)
	Severe	0
Tubular atrophy	No to mild	49 (94.3%)
	Moderate to severe	3 (5.8%)
Interstitial fibrosis	No to mild	48 (92.3%)
	Moderate to severe	4 (7.7%)

Data presented as n (%).

Class IV lupus nephritis accounted for the majority of patients (57.7%), followed by class III (17.3%) and class II (15.4%), according to histological examination. There were no class I or VI cases found.

Multiple treatment protocols were administered to the study population (Table II). All respondents (100%) were given hydroxychloroquine, 61.5% were given cyclophosphamide plus corticosteroid, 23.1% were given MMF plus corticosteroid, and 15.4% were given corticosteroid alone. 67.3% of respondents gave a complete response, 28.8% gave a partial response, and 3.8% gave no response at all.

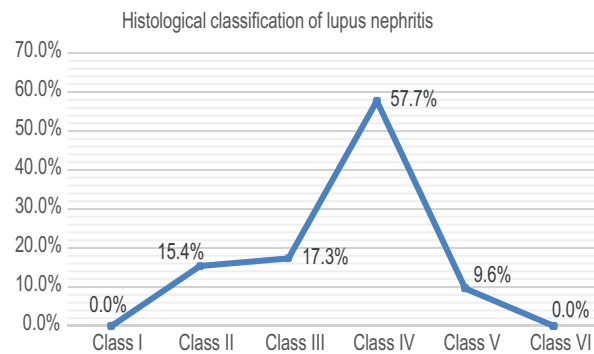


Figure 1: Distribution of study population according to histological classification of lupus nephritis. (n = 52)

Table-II:

Distribution of study population according to treatment. (n = 52)

Characteristics	Data
Treatment protocol	MMF + Corticosteroid 12 (23.1%)
	Cyclophosphamide + Corticosteroid 32 (61.5%)
	Corticosteroid (only) 8 (15.4%)
	Hydroxychloroquine 52 (100.0%)
Treatment response	Complete response 35 (67.3%)
	Partial response 15 (28.8%)
	No response 2 (3.8%)

Data presented as n (%).

At baseline (2.14 ± 1.01 ng/mL) and at 6 months (1.20 ± 0.59 ng/mL), class IV lupus nephritis had the highest urine NGAL levels, followed by class III. Histological class differences showed a substantial connection with disease severity and were statistically significant ($p < 0.05$).

Urinary NGAL levels were significantly higher in proliferative nephritis at both time points. Urinary PCR did not significantly change at any time point.

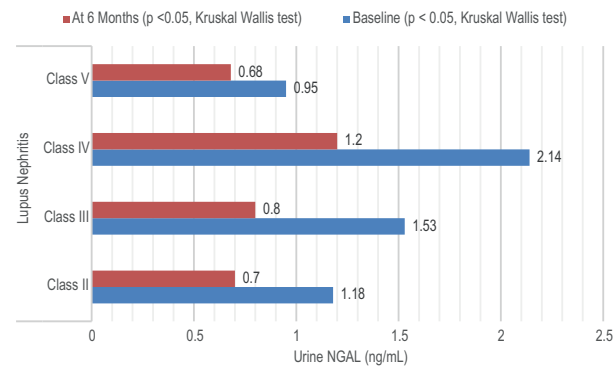


Figure 2: Urine NGAL levels at different stages of lupus nephritis.

Table-III:

Comparison of biochemical profile between proliferative and non-proliferative groups. (n = 52)

Characteristics		Lupus Nephritis		P value
		Proliferative	Non-Proliferative	
Baseline	Urine NGAL (ng/mL)	2.00 ± 0.96	1.12 ± 0.29	$< 0.05^a$
	Urinary PCR (mg/ mmol)	3.22 ± 2.08	3.07 ± 3.59	0.852^a
At 6 Months	Urine NGAL (ng/mL)	1.11 ± 0.56	0.70 ± 0.15	$< 0.05^a$
	Urinary PCR (mg/ mmol)	0.69 ± 0.94	0.21 ± 0.21	0.073^a

Data presented as mean $\pm$ SD.

^a Unpaired t-test was done. $P < 0.05$ was considered statistically significant.

Patients with moderate tubulointerstitial inflammation had the highest urine NGAL levels (2.34 ± 0.90 ng/mL), followed by mild (1.16 ± 0.14 ng/mL) and minimal (0.81 ± 0.16 ng/mL) inflammation. There were statistically significant differences between the groups ($p < 0.05$).

At baseline and six months, the proliferative group's median NGAL levels were higher than those of the non-proliferative lupus nephritis patients (Figure 3). Individuals with elevated urine NGAL levels were more prevalent in the proliferative group.

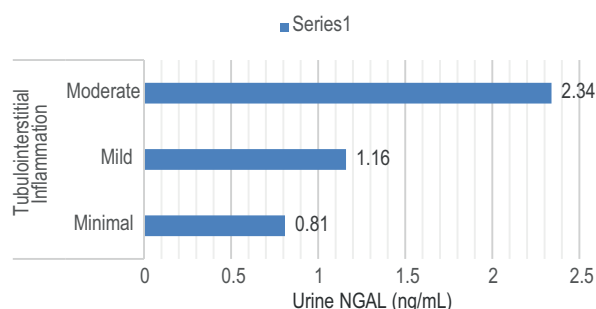


Figure 3: Urine NGAL levels at different severity groups for tubulointerstitial inflammation.

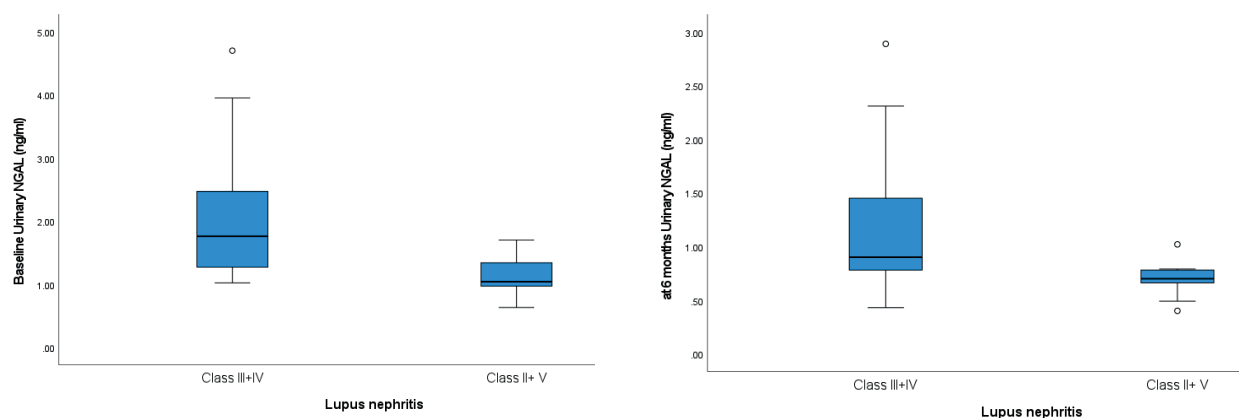


Figure 4: Box plot showing central tendency of the Urinary NGAL.

Table-IV : Relation of biochemical profile with treatment response. (n = 52)					
Characteristics		Treatment Response			P value
		Complete response (n=35)	Partial response (n=15)	Non-Response (n=2)	
Baseline	Urine NGAL (ng/mL)	1.39 ± 0.48	2.43 ± 0.99	3.80 ± 1.27	$< 0.05^b$
	Urinary PCR (mg/mmol)	3.12 ± 2.88	3.06 ± 1.38	5.10 ± 1.41	0.428^b
At 6 Months	Urine NGAL (ng/mL)	0.80 ± 0.25	1.37 ± 0.66	1.90 ± 0.57	$< 0.05^b$
	Urinary PCR (mg/mmol)	0.25 ± 0.30	0.90 ± 0.74	3.75 ± 0.21	$< 0.05^b$

Data presented as mean $\pm$ SD. ANOVA was done.

^b P value < 0.05 was considered statistically significant.

Patients exhibiting a complete treatment response demonstrated markedly reduced urine NGAL levels at both baseline (1.39 ± 0.48 ng/mL) and at 6 months (0.80 ± 0.25 ng/mL) in comparison to the partial and non-response cohorts.

Discussion:

This study assessed urinary NGAL as an indicator of renal inflammation, histopathological severity, and treatment response in lupus nephritis. The demographic distribution — with a predominance of

young females—is consistent with global epidemiological patterns of SLE.^{24–26} Similarly, the presence of overweight and obesity in a subset of participants reflects findings from earlier research suggesting that altered body composition may affect disease activity.²⁷ More than half of the cohort exhibited moderate tubulointerstitial inflammation, reinforcing prior observations that interstitial lesions strongly influence renal prognosis.^{28,29}

The low prevalence of significant tubular atrophy and fibrosis suggests limited chronic damage at presentation, possibly contributing to the favorable treatment outcomes observed.

Class IV nephritis was the dominant histological subtype, aligning with previous studies reporting its high frequency and association with aggressive clinical behavior.³⁰ The absence of class I and class VI nephritis may relate to referral patterns or patient selection characteristics.^{31,32} Treatment outcomes in the present study were comparable to those reported in the literature, with the majority achieving complete or partial response following standardized immunosuppressive regimens.^{33–37} The most notable finding was the strong correlation between urinary NGAL and markers of disease severity. Patients with class IV lupus nephritis and those categorized within the proliferative group exhibited the highest NGAL levels at baseline. These results are consistent with previous studies demonstrating that NGAL rises sharply in response to acute tubular injury and immune-mediated inflammation.^{21,38,39} The biochemical differences between proliferative and non-proliferative groups—such as elevated serum creatinine and lower serum albumin in the former—reinforce the association between NGAL and renal dysfunction.^{31,44–47}

Hypoalbuminemia in proliferative nephritis is commonly linked to heavy proteinuria and impaired renal function, although this difference diminished after treatment initiation, reflecting clinical improvement. NGAL's close relationship with tubulointerstitial inflammation is particularly important. Patients with moderate inflammation exhibited the highest levels, supporting the concept that NGAL originates from injured tubular epithelial cells. Because interstitial lesions strongly influence long-term renal prognosis, NGAL could help identify patients at higher risk.

Individuals who achieved complete therapeutic response demonstrated lower NGAL levels at both baseline and follow-up, consistent with findings from recent biomarker-based studies.^{48,49}

This suggests that NGAL may be useful both for initial risk stratification and for monitoring treatment response.

Overall, the results support urinary NGAL as a promising biomarker for disease activity, renal injury, and therapeutic response in lupus nephritis.

Conclusions:

Urinary NGAL showed strong associations with histopathological severity, biochemical markers, and clinical response in lupus nephritis. Higher baseline levels were linked to proliferative disease and greater interstitial inflammation, whereas declining levels corresponded with favorable therapeutic outcomes. Given its non-invasive nature and demonstrated sensitivity, urinary NGAL may serve as a valuable adjunct to conventional markers for disease monitoring. Further multi-center studies with larger sample sizes are needed to validate these findings and determine its optimal role in clinical practice.

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