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A PROSPECTIVE OBSERVATIONAL STUDY ON CHANGES IN RENAL FUNCTION PARAMETERS AMONG PATIENTS RECEIVING PROTON PUMP INHIBITORS IN A TERTIARY CARE HOSPITAL

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ABSTRACT: Background: Proton pump inhibitors (PPIs) are widely prescribed for acid-related disorders. Emerging evidence suggests potential renal adverse effects with prolonged use. **Objectives:** To evaluate changes in renal function parameters among patients receiving prolonged PPI therapy and to assess comparative trends and pharmacoeconomic aspects. **Methods:** A prospective observational study was conducted over six months at a tertiary care hospital. Adult patients receiving continuous PPI therapy were included. Serum creatinine and blood urea nitrogen (BUN) were assessed at baseline, 3 months, and 6 months. Data were analyzed using repeated-measures ANOVA. **Results:** Of 400 enrolled patients, 360 completed the 6-month follow-up. Mean BUN increased from 20.03 ± 6.30 mg/dL to 27.99 ± 6.39 mg/dL ($p < 0.001$). Mean serum creatinine increased from 0.83 ± 0.23 mg/dL to 1.50 ± 0.12 mg/dL ($p < 0.001$). A clinically significant rise in serum creatinine (≥ 0.3 mg/dL) was observed in some patients. Descriptive trends suggested higher absolute changes among patients receiving pantoprazole, likely reflecting prescribing predominance. Omeprazole demonstrated lower treatment cost. **Conclusion:** Prolonged PPI therapy was associated with significant changes in renal function parameters. Periodic monitoring and rational prescribing are recommended.

INTRODUCTION: Proton pump inhibitors (PPIs) are among the most commonly prescribed medications for the management of acid-related gastrointestinal disorders such as gastroesophageal reflux disease, peptic ulcer disease, and stress ulcer prophylaxis. Their efficacy and favorable short-term safety profile have contributed to widespread and often prolonged use.

Recent literature has raised concerns regarding potential adverse effects associated with long-term PPI therapy, including renal complications such as acute interstitial nephritis, acute kidney injury, and chronic kidney disease. Observational studies have suggested a possible association between prolonged PPI exposure and deterioration of renal function. Despite increasing global evidence, real-world data from Indian tertiary care settings remain limited. This study was undertaken to evaluate changes in renal function parameters among patients receiving prolonged PPI therapy.

Objectives:

1. To evaluate changes in serum creatinine and blood urea nitrogen (BUN) over 6 months.

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- To assess trends among commonly prescribed PPIs.
- To evaluate pharmacoeconomic aspects.

MATERIALS AND METHODS:

Study Design and Setting: A prospective observational study was conducted over six months at ACS Medical College and Hospital, Chennai, Tamil Nadu, India.

Study Population:

Inclusion Criteria:

- Adults aged ≥ 18 years.
- Receiving continuous PPI therapy for at least 6 months.

(Continuous therapy was defined as daily use of standard-dose PPI (e.g., pantoprazole 40 mg once daily or equivalent) for a minimum duration of 6 months without interruption exceeding 7 days. Adherence was assessed using prescription records and patient self-report.)

Exclusion Criteria:

- ❖ Baseline renal impairment (serum creatinine >1.5 mg/dL).
- ❖ Pregnancy.
- ❖ Acute illness affecting renal function.
- ❖ Incomplete follow-up.

Baseline renal status was verified using laboratory values within 2 weeks prior to enrollment.

Data Collection: Data collected included demographic details, type of PPI prescribed, duration of therapy, and renal function parameters.

Renal function was assessed using serum creatinine and blood urea nitrogen (BUN). Estimated glomerular filtration rate (eGFR) could not be calculated due to incomplete demographic data; this is acknowledged as a limitation.

All laboratory measurements were performed using a standardized automated biochemistry analyzer

with routine calibration and quality control procedures. All samples were processed in the same laboratory to ensure consistency. All laboratory values were verified for accuracy and consistency.

Outcome Measures:

Primary Outcomes:

- Change in serum creatinine from baseline to 6 months.
- Change in BUN from baseline to 6 months.

Secondary Outcomes:

- Descriptive trends among different PPIs.
- Pharmacoeconomic comparison.

Statistical Analysis: Continuous variables were expressed as mean \pm standard deviation. Changes in renal parameters over time were analyzed using repeated-measures ANOVA. A p-value <0.05 was considered statistically significant.

Ethical Considerations: The study was approved by the Institutional Ethics Committee (IEC No: 386/2021/IEC/ACSMCH). Written informed consent was obtained from all participants.

RESULTS:

Participant Flow: A total of 450 patients were screened, of whom 400 were enrolled. At 3 months, 18 patients were lost to follow-up. At 6 months, an additional 22 patients were lost. A total of 360 patients completed the study.

TABLE 1: BASELINE CHARACTERISTICS

| Variable | Value |
|-------------------|---|
| Total sample size | 400 |
| Age distribution | <35 yr: 15.4%; 36–40 yr: 18.0%; 41–45 yr: 23.0%; 46–50 yr: 25.6%; 51–65 yr: 18.0% |

TABLE 2: DISTRIBUTION OF PPIs

| Proton Pump Inhibitor | Number (%) |
|-----------------------|------------|
| Pantoprazole | 334 (83.5) |
| Omeprazole | 38 (9.5) |
| Rabeprazole | 18 (4.5) |
| Esomeprazole | 10 (2.5) |

TABLE 3: CHANGES IN RENAL FUNCTION PARAMETERS

| Parameter | Baseline (Mean \pm SD) | 3 Months (Mean \pm SD) | 6 Months (Mean \pm SD) | p-value |
|--------------------------|--------------------------|--------------------------|--------------------------|----------|
| BUN (mg/dL) | 20.03 \pm 6.30 | 23.17 \pm 6.13 | 27.99 \pm 6.39 | <0.001 |
| Serum creatinine (mg/dL) | 0.83 \pm 0.23 | 1.12 \pm 0.15 | 1.50 \pm 0.12 | <0.001 |

Comparative Analysis among PPIs: Due to unequal distribution of PPIs, subgroup comparisons were limited to descriptive analysis. Patients receiving pantoprazole showed higher absolute changes in renal parameters; however, this likely reflects prescribing predominance rather than intrinsic drug-related differences.

Pharmacoeconomic Analysis: Omeprazole demonstrated the lowest cost among commonly prescribed PPIs based on average market pricing.

DISCUSSION: The present study demonstrated a statistically significant increase in renal function parameters over six months of continuous PPI therapy. These findings are consistent with previous observational studies suggesting an association between prolonged PPI use and renal function changes. The magnitude of increase in serum creatinine observed in this study is higher than typically reported in general populations. This may reflect underlying comorbidities, clinical status, or unmeasured confounding factors rather than a direct causal effect. Pantoprazole showed higher absolute changes; however, this is likely attributable to its predominant use rather than intrinsic nephrotoxicity. Although PPIs have been associated with acute interstitial nephritis, this study did not include diagnostic evaluation for such outcomes. Confounding by indication remains a key limitation, as such patients often have comorbidities that independently affect renal function.

Limitations:

- ❖ Single-center observational design.
- ❖ Absence of a non-PPI comparator group.
- ❖ Lack of adjustment for confounding variables.
- ❖ Renal assessment limited to BUN and serum creatinine.
- ❖ eGFR not calculated due to incomplete demographic data.
- ❖ Inability to establish causality.

CONCLUSION: Prolonged PPI therapy was associated with significant changes in renal function parameters. Periodic monitoring and rational prescribing are recommended, particularly for patients on long-term therapy.

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CONFLICT OF INTEREST: None declared.

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