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Original Article

Surgery Section

# Outcomes of Post-pancreatic Enzyme Replacement Therapy in Patients of Pancreatic Exocrine Insufficiency: A Prospective Observational Study

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## ABSTRACT

**Introduction:** Exocrine pancreatic insufficiency is a significant clinical condition with underlying multifactorial aetiologies. Pancreatic Enzyme Replacement Therapy (PERT) is helpful in improving certain clinical conditions such as chronic pancreatitis, exocrine pancreatic insufficiency and others.

**Aim:** To analyse post-PERT outcomes in exocrine pancreatic insufficiency.

**Materials and Methods:** The present prospective observational study was conducted in the Department of Surgery at Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India from July 2023 to May 2025. Patients of >18 years, diagnosed with exocrine pancreatic insufficiency with acute exacerbation via clinical assessment and Modified Computed Tomography Severity Index (MCTSI) score were included. Quality of Life (QoL) was recorded along with VAS for pain and weight when on medication. The PERT was initiated 3 times/day for 15 days. The patients were evaluated for symptomatic and QoL improvements based on weight, pain scale at baseline, day 7 and day 15.

**Results:** A total of 53 patients were enrolled in the study. The mean age of the study cohort was 36±10.187 years with 52.8% patients between 31 to 40 years and predominantly males. The results showed statistically significant improvement in pre- versus post-treatment in QoL (32.92±11.662 vs 52.58±12.073), vomiting (22/41.5% vs 6/11.3%), pain (53/100% vs 19/35.8%), sticky stools (33/62.3% vs 11/20.8%) and bloating sensation (30/56.6% vs 13/24.5%).

**Conclusion:** The PERT can effectively improve the symptoms in patients of exocrine pancreatic insufficiency.


**Keywords:** Acute pancreatitis, Alcohol consumption, Impaired pancreatic function, Quality of Life

## INTRODUCTION

The pancreas is one of the essential organs of the human body, and it plays a significant role in metabolism and nutritional absorption. The production of pancreatic enzymes is hampered when the pancreatic cells are damaged, which in turn causes exocrine pancreatic insufficiency [1]. It is characterised by the deficiency of the exocrine pancreatic enzymes, observed clinically by severe malnutrition, weight loss, maldigestion and steatorrhea [2]. It includes clinical symptoms such as steatorrhea, diarrhoea and other symptoms associated with fat maldigestion [3]. The islets of Langerhans in pancreas are formed of five types of cells viz., alpha, beta, delta, epsilon and upsilon cells. These cells are found to be involved in the synthesis of glucagon, insulin, somatostatin, ghrelin, and pancreatic polypeptide hormones, respectively [4]. The exact prevalence of exocrine pancreatic insufficiency is not exactly defined. However, it is observed in 60 to 90% of chronic pancreatitis patients within 10 to 12 years of the diagnosis of the disease [5]. In cases of acute pancreatitis, exocrine pancreatic insufficiency was found in 62% patients. This was found to be higher among the patients with alcohol consumption and patients undergoing bariatric surgery [6]. Exocrine pancreatic insufficiency has been associated with the emergence of various co-morbid conditions which impacts the patients' health adversely and negatively impacts the disease prognosis [7]. Hence, there is a need for proper treatment to prevent the complications associated with the disease.

The PERT mainly supplements pancreatic enzymes among patients diagnosed with exocrine pancreatic insufficiency. It was also found to be effective in reducing gastrointestinal symptoms and to help improve gastrointestinal dysregulation and nutrient absorption, thereby preventing malnutrition [8]. Evidence-based research suggests that PERT improves the survival and QoL. The doses in PERT is based on patients' symptomatic response and clinical improvement [9]. PERT is a well-tolerated treatment modality and has minimal side effects. However, the efficacy and the outcomes have not been studied in India. Hence, this study was designed to analyse the outcomes of post-PERT in patients with pancreatic exocrine insufficiency.

## MATERIALS AND METHODS

The present prospective observational study was conducted in the Department of Surgery at Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India, from July 2023 to May 2025. Ethical clearance was obtained from the Institutional Ethics Committee with reference number DMIHER (DU)/IEC/2023/965 Purposive sampling was used for participant selection.

**Inclusion and Exclusion criteria:** Consenting patients diagnosed with acute or chronic pancreatitis who were ≥18 years of age were included in the study. The patients <18 years, other pancreatic pathologies, such as pancreatic malignancy and pancreatic cyst, contraindicated contrast Computed Tomography (CT) scan, intellectual disability, pregnant/lactating mothers, and those not willing to complete the follow-up were excluded. Out of the total 54 patients, one patient was excluded from this study due to the unrelated death and remaining 53 patients were included in the study cohort.

### Study Procedure

A brief history and the clinical assessment of the patient were recorded in a predefined questionnaire. The medical history included all clinical parameters, such as steatorrhea, abdominal pain, sticky stools, and bloating. The severity of the pain has been assessed with

the help of the visual analogue scale. They were then subjected to a contrast CT scan to identify acute pancreatitis, and grading was based on the Modified CT Severity Index (MCTSI) severity index. The severity index ranged from 0 to 10, as shown in [Table/Fig-1] [10].

| Prognostic indicators | Points |
|---|---|
| **Pancreatic inflammation** | |
| Normal pancreas | 0 |
| Intrinsic pancreatic abnormalities with or without inflammatory changes in peripancreatic fat. | 2 |
| Pancreatic or peripancreatic fluid collection or peripancreatic fat necrosis. | 4 |
| **Pancreatic necrosis** | |
| None | 0 |
| ≤30% | 2 |
| ≥30% | 4 |
| **Extra pancreatic complications** | |
| One or more of the following:<br>Pleural effusion, ascites, vascular complications, parenchymal complications or gastrointestinal tract involvement. | 2 |

**[Table/Fig-1]:** MCTSI score (The MCTSI score was calculated by summing these values and acute pancreatitis was then categorized as: Mild Pancreatitis MCTSI score 0-3; Moderate Pancreatitis MCTSI score 4-6; Severe Pancreatitis MCTSI score [10].

Then, the patients were subjected to the World Health Organisation (WHO) QoL Questionnaire [11]. The patients were further initiated on PERT with a dose range of 10000 IU to 25000 IU/three times per day for 15 days as per the requirement. The treatment was given with the meal or immediately after the meal. Parameters assessed were abdominal pain, sticky stools, and bloating sensations. The patients were evaluated before and after PERT for the symptoms of pancreatic insufficiency, and the WHO-QoL questionnaire were assessed post-completion of the therapy at baseline-day 0, day 7 and day 15. The patients were counselled regarding the need for regular medication.

## STATISTICAL ANALYSIS

Student's t-test was used for independent samples (mean values) and Chi-square test was used to assess the difference between the groups with a p-value <0.05 considered significant. The IBM Statistical Package for the Social Sciences (SPSS) version 25 was used for all the statistical analyses.

## RESULTS

Majority of the patients of the study cohort were between 31 and 40 years of age, 28 (52.8%). The study group comprised of 48 (90.6) males and 5 (9.4). Majority of the patients belong to Socioeconomic class v 22 (41.5) males [Table/Fig-2].

| Parameters | Categories | Value Mean±SD/n (%) |
|---|---|---|
| **Age (years)** | Mean age | 36±10.187 |
| | 18-30 | 12 (22.6) |
| | 31-40 | 28 (52.8) |
| | 41-50 | 7 (13.2) |
| | 51-60 | 5 (9.4) |
| | >60 | 1 (1.9) |
| **Gender** | Male | 48 (90.6) |
| | Female | 5 (9.4) |
| **Alcohol** | Present | 44 (83) |
| | Class I | 2 (3.8) |
| | Class II | 5 (9.4) |
| | Class III | 8 (15.1) |
| | Class IV | 16 (30.2) |
| | Class V | 22 (41.5) |

**[Table/Fig-2]:** Demographic profile of the patients.

All the study participants experienced pain before the initiation of the treatment, which was reduced significantly to only 19 (35.8) patients [Table/Fig-3].

| Symptoms | Pretreatment | Post-treatment | p-value |
|---|---|---|---|
| Vomiting | 22 (41.5) | 6 (11.3) | <0.001 |
| Sticky stools | 33 (62.3) | 11 (20.8) | 0.001 |
| Bloating | 30 (56.6) | 13 (24.5) | 0.001 |
| Pain | 53 (100) | 19 (35.8) | <0.001 |

**[Table/Fig-3]:** Comparison of clinical symptoms pretreatment and resolution post-treatment.

All three groups of VAS scores were significantly improved after the patients were subjected to the treatment, with a similar trend observed in QoL [Table/Fig-4,5].

| Parameters | Pretreatment Value [N (%)] | Post-treatment Value {N (%)} |
|---|---|---|
| **VAS score** | | |
| 0-3 | 3 (5.7) | 17 (32.1) |
| 4-7 | 42 (79.2) | 36 (67.9) |
| 8-10 | 8 (15.1) | 0 (0) |
| **Weight (in kg)** | | |
| ≤50 | 2 (3.8) | 2 (3.8) |
| 51-65 | 24 (45.3) | 20 (37.7) |
| 66-75 | 23 (43.4) | 25 (47.2) |
| >75 | 4 (7.5) | 6 (11.3) |
| **QoL** | | |
| Good (≥80) | 6 (11.3) | 29 (54.7) |
| Poor | 47 (88.7) | 24 (45.3) |

**[Table/Fig-4]:** Pretreatment clinical profile of the patients.

| Variables | Pretreatment | Post-treatment | p-value |
|---|---|---|---|
| VAS score | 5.49±1.552 | 4.06±1.322 | <0.001 |
| Weight | 64.44±9.056 | 65.93±9.368 | 0.235 |
| QoL | 32.92 ±11.662 | 52.58±12.073 | <0.001 |

**[Table/Fig-5]:** Comparison of the variables before and after the treatment.

## DISCUSSION

The prevalence of exocrine pancreatic insufficiency is higher in older populations, which can be attributed to the loss of cells with advancing age [12,13]. The findings of this research showed that most patients were middle-aged. This might be attributed to acute and chronic pancreatitis, which is more common in middle-aged people [14]. This research was male-dominated, with 90.6% male participants, which is supported by research evidence stating that older males have comparatively higher risk for the development of exocrine pancreatic insufficiency than older females [15]. The predominance of male participants observed in the present study may reflect the underlying distribution of pancreatic disorders in the present study population.

Socioeconomic status was also found to affect the health, QoL and alcohol consumption, which in turn increases the risk of the development of pancreatic injuries [16-18]. Alcohol consumption is a common risk factor associated with exocrine pancreatic insufficiency. A study by Pezzilli R et al., showed that alcohol consumption is a significant risk factor for the development of acute pancreatitis and exocrine pancreatic insufficiency [17]. This can be understood through the damage caused by the alcohol to the pancreatic cells, which can further interfere with the enzyme production, which in turn worsens the symptoms of exocrine pancreatic insufficiency [19,20].

The mean weight of the study group was 64.44±9.056 kg before the initiation of the treatment, which was increased to 65.93±9.368 kg after the enzyme replacement therapy treatment, but the difference

was not statistically significant. Multiple studies have demonstrated that following PERT, patients with exocrine pancreatic insufficiency experienced weight gain as a result of improved nutritional status, while individuals who were non-compliant experienced weight loss [21,22].

Zhou Y et al., (2023) in a pancreatitis patient cohort reported that major underlying factors for a poor QoL were persistent abdominal pain, steatorrhea, bloating, diarrhoea, weight loss and malnutrition, anxiety related to food intake and social functioning. Irregular adherence to PERT was related to continued digestive symptoms, higher fatigue scores, reduced daily activity and work productivity as compared to PERT post-treatment with good adherence [22]. A similar observation was also noted in this study cohort, showing improved nutritional status, weight stabilisation, reduced Gastrointestinal (GI) symptoms and better productivity. Psychological QoL improved indirectly, which can be due to better symptom control and reduced disease-related anxiety.

Hu W et al., (2020) addressed that lower adherence to the treatment regime were also associated with higher emotional distress and social limitations; which after increased adherence to the treatment resulted in sustained disease remission or reduced flare frequency, marked improvement in physical and emotional QoL domains with better treatment satisfaction, confidence in disease control, improved daily functioning and social engagement [23]. Clinical insights can be marked with the QoL improvement in chronic pancreatitis is adherence-dependent, and linked to disease control. Improper use might not provide the expected outcomes, and increased adherence was closely associated to better physical and psychological QoL. Effective counseling and patient education are therefore critical therapeutic interventions.

### Limitation(s)

This research is a single-centre study, and has been carried out in a smaller sample size, so it may not represent the whole population. Additionally, a faecal elastase test can be added for better records of the outcomes.

## CONCLUSION(S)

The present PERT can alleviate the symptoms in patients of exocrine pancreatic insufficiency. It also benefits in improvement of the overall health significantly. PERT can be helpful in fulfilling the enzyme deficiency and help in the symptomatic resolution caused by the impaired function of the pancreas.

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