

# USE OF PROTON PUMP INHIBITORS AND EFFECTS OF AMYLASE AND OTHER ENZYMES

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## INTRODUCTION

The main action of Proton Pump Inhibitors (PPIs) is a long-lasting reduction of gastric acid production by irreversibly blocking the  $H^+/K^+$ -ATPase enzyme of the gastric parietal cells.

## AIMS

To correlate the activities of pancreatic (p-) and total (t-) amylase in patients using PPIs, to compare the effectiveness of different PPIs and different dosage regimens of PPIs.

## METHOD

An ethical approval for the study methodology was obtained. The patients from the Endoscopy Unit at Mater Dei Hospital were invited to participate in the study and asked to fill and sign the informed consent either in Maltese or English. A patient information sheet was given to each patient. Seventy five patients were recruited, 48 patients were on PPI therapy while 27 patients acted as control. Gastric juice sample collection was carried out at the Endoscopy Unit. Once all the samples were collected, the analysis was done at the Pharmacy Department by means of the Reflotron® device. A previously designed methodology<sup>1</sup> was adopted to analyse both t- and p-amylase. A correlation of the current PPI therapy with the respective amylase activity was carried out. Comparison of gastric pH with amylase activity was carried out and the effectiveness of PPIs with the respective dosage regimen was achieved.

## RESULTS

- Cost analysis studies of the Reflotron® method previously designed by Zammit<sup>1</sup> was carried out which is shown in table 1. The cost per patient on PPI therapy (n=34) amounted to 32 Euros excluding any dilutions required.
- Fifty patients completed the study, 34 on PPI and 16 acting as control (age range 29–88 years). Out of these 16 patients, 13 never took a PPI before while 3 did take a PPI sometime before the gastroscopy.
- Omeprazole (n=29) was the most frequently prescribed PPI (Figure 1). The most common dosage regimen was 20mg twice daily (n=19).
- SPSS version 22 was used to analyse the data. The Pearson correlation coefficient showed a positive relationship between gastric pH and amylase activity ( $p < 0.05$ ). This implies that as the gastric pH becomes more alkaline, both p- and t-amylase increase significantly. The mean gastric pH was 4.95 ranging from 0.86–7.78.
- Average t-amylase was 432U/L and average p-amylase 128U/L. Independent samples t-test indicated that PPI patients have a significantly higher p- and t- amylase activity when compared to control patients (p-value for both tests  $< 0.05$ ).
- For six patients that had stopped PPI treatment at time of gastric juice sample collection, amylase activity was higher than the PPI naïve patients.

Procedure	Cost	Frequency of Consumption
Reflotron® pipette	134.10	Once
Reflotron® process	75	Each treatment patient (excluding dilution costs)
AGJ BP 2002	117.60	Every 2 weeks
Gastric Juice Buffer	26.20	Every 2 weeks
Reflotron® calibration	25	Every 3 months
Cost per test	32	Each treatment patient (excluding dilution costs)

Table 1: Reflotron method costs

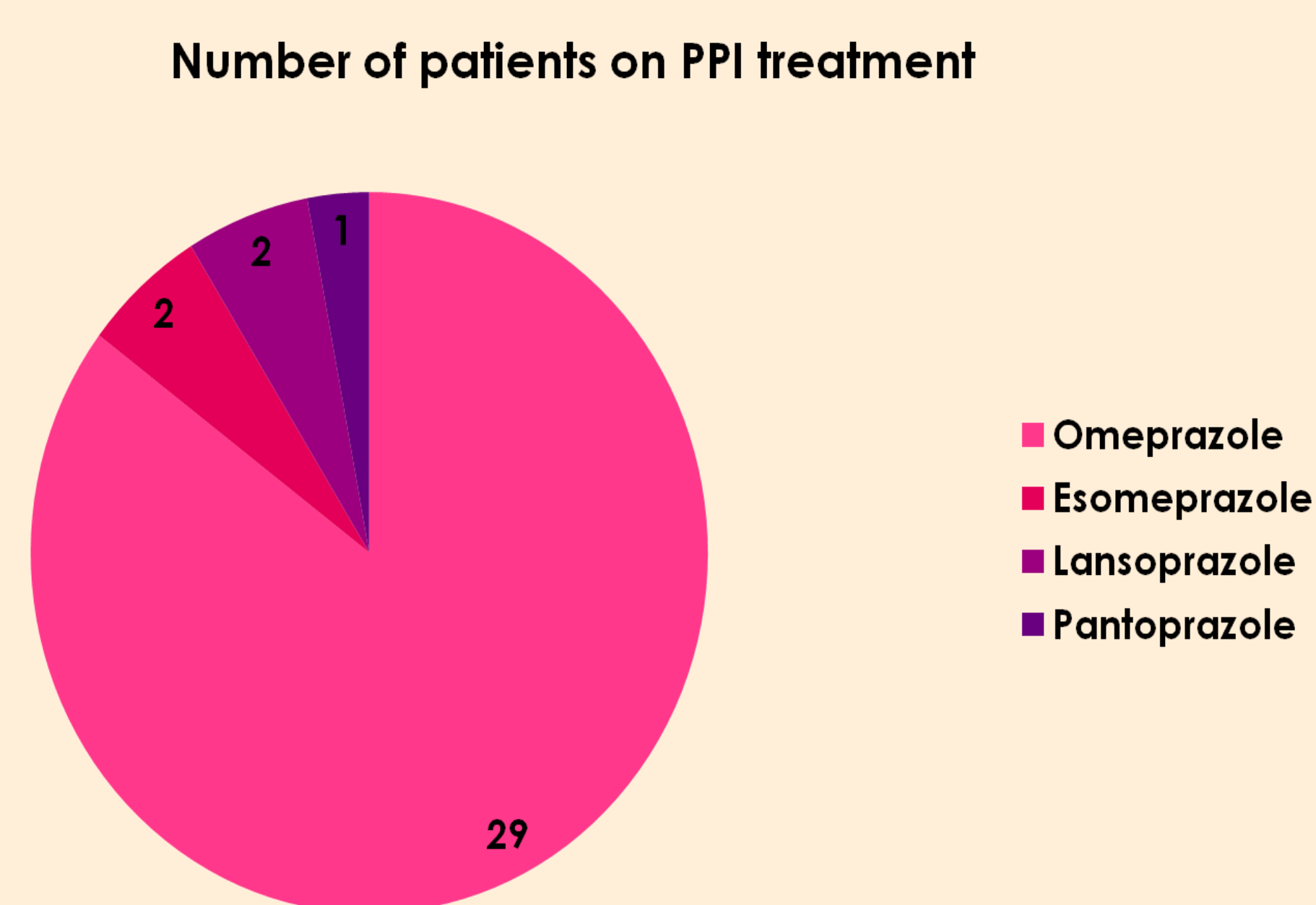


Figure 1: Pie chart showing the patient population on PPIs (n=34)

## CONCLUSION

Individualised treatment should be based on the relationship of gastric pH, amylase activity and pathology to achieve better long-term treatment and knowledge of the disease. The duration of action of different PPIs after cessation of therapy needs to be studied.

## References

<sup>1</sup>Zammit K. Determination of  $\alpha$ -amylase in gastric juice [project]. Msida (Malta): Department of Pharmacy, University of Malta; 2010.