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## RESEARCH ARTICLE

# DRUG INDUCED PANCREATITIS SECONDARY TO ORLISTAT: A CASE REPORT AND LITERATURE REVIEW

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### ABSTRACT

**Background:** Two percent of all pancreatitis is accounted by Drug induced pancreatitis. It is a diagnosis of exclusion, a patient can be diagnosed with Drug induced pancreatitis only after alcohol use, and cholelithiasis are excluded. The diagnosis can be made by establishing a temporal link between the drugs and the development of pancreatitis in the patient who does not have any other factors that can contribute to the development of pancreatitis. **Case report:** Here we present a case of 18 years old female who presented to the emergency room with acute onset severe pain abdomen 7 days after being started on Tablet Orlistat for the treatment of obesity. The patient does not give any history of alcohol consumption habits. Diagnosis of pancreatitis was established by elevated levels of amylase and lipase and CT abdomen showed a bulky pancreas with peri pancreatic fluid with no evidence of gallbladder and hepatobiliary abnormality. **Conclusion:** Tablet Orlistat is being extensively used for the treatment of obesity. Few studies have shown that Orlistat can trigger Drug induced pancreatitis in certain patients, so it should be prescribed cautiously, especially in patients at high risk of pancreatic injury.

## INTRODUCTION

Acute pancreatitis can be a potentially life threatening condition which is a major cause of worldwide morbidity; mortality rate being 10%. There are various etiological factors causing pancreatitis such as hypertriglyceridemia, gall stones, alcohol consumption, infection, autoimmune causes, malignancy, trauma etc, drugs are responsible for about 2% of the cases (Conti Bellocchi, 2015). In most cases of drug induced pancreatitis, the severity of acute pancreatitis may vary from mild to moderate however the fatality may increase in certain drugs. The mainstay of management of such cases is withdrawal of the causative agent and supportive management (Jones, 2015; Chaudhuri, 2013). Drug induced pancreatitis can be established in patient who does not have any other factors that can contribute to the development of pancreatitis. To diagnose drug induced pancreatitis, criteria includes patient taking the prescribed medication & new onset of pancreatitis (6). Orlistat is a gastric & pancreatic lipase inhibitor used for management of obesity. It acts by binding to gastric & pancreatic lipase and inactivating them. It reduces the absorption of monoglycerides and free fatty acids by inhibiting the hydrolysis of triglycerides. Tablet Orlistat is licensed to be used in obese people with body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> or  $\geq 27$  kg/m<sup>2</sup> with risk factors such as hypertension, dislipidemia or diabetes (1,7). 60mg of Tablet Orlistat has been approved by FDA as an over the counter drug (Anderson, 2007). Some studies have reported that Orlistat can trigger pancreatitis in some patients.

It was stated by the Joint Non Prescription Drugs Advisory Committee & Endocrinology & Metabolic Drug Committee meeting in Maryland in 2006 that 99 raw reports of acute pancreatitis cases had been reported for orlistat but it was said that placebo controlled trials of orlistat in patient treated for 2 years showed no increase in incidence of pancreatitis & it was discussed that orlistat as a new drug application for which it can become a non prescription drug had it been applied for (Napier, 2006; Chaudhuri, 2013).

## CASE REPORT

A 18 years old female presented to Emergency Department with acute onset of pain abdomen since previous night, associated with four episodes of vomiting and nausea. She also complained of fever since four days associated with generalised weakness. Patient gives medical history of taking tablet Orlistat since one week for obesity. No history of abdominal trauma or road traffic accident. Patient denied history of alcohol consumption, nor any significant family history. Physical examination revealed patient was obese with Body Mass Index of 32kg/ m<sup>2</sup>. On clinical examination, patient was haemodynamically stable with normal vital parameters of Blood Pressure 130/90 mm of Hg, Heart Rate 78 bpm, Respiratory Rate 18 cpm and Saturation 99% at room air, Temperature 97.6 °F. Systemic examination revealed Epigastric tenderness without signs of peritonitis. Other systemic examinations were normal.

Table 1.

| Sl. No. | LABORATORY DATA           | CASE 1<br>(2006)<br>(Napier, 2006) | CASE 2<br>(2010)<br>(Ahmad, 2010) | CASE 3<br>(2010)<br>(Ahmad,<br>2012) | CASE 4<br>(2012)<br>(Şimşekzahide,<br>2012) | CASE 5<br>(2013)<br>(Chaudhuri,<br>2013) | CASE 6<br>(2022) | REFERENCE<br>RANGE |
|---------|---------------------------|------------------------------------|-----------------------------------|--------------------------------------|---------------------------------------------|------------------------------------------|------------------|--------------------|
| 1       | Serum Amylase (U/L)       | 136                                | 1070                              | 371                                  | 467                                         | 850                                      | 988              | 0-100              |
| 3       | Serum Creatinine (µmol/L) | N/M                                | 51                                | 60                                   | Normal                                      | Normal                                   | 56.7             | 60-100             |
| 4       | Serum Urea (mmol/L)       | N/M                                | 5.1                               | 3.8                                  | Normal                                      | Normal                                   | 3.57             | 2.5-7.5            |
| 5       | Adjusted Calcium (mmol/L) | 2.4                                | 2.04                              | 2.12                                 | 2.15                                        | N/M                                      | 2.0              | 2.1-2.6            |
| 6       | Albumin (g/L)             | N/M                                | 39                                | 45                                   | N/M                                         | N/M                                      | 28               | 36-52              |
| 7       | AST (U/L)                 | N/M                                | 94                                | 78                                   | 52                                          | N/M                                      | 298              | 0-40               |
| 8       | ALT (U/L)                 | N/M                                | 101                               | 58                                   | 69                                          | N/M                                      | 164              | 0-50               |
| 9       | ALP (U/L)                 | N/M                                | 113                               | 58                                   | Normal                                      | 350                                      | 75               | 25-110             |
| 10      | WBC (x10 <sup>9</sup> /L) | 20.0                               | 15.8                              | 11.9                                 | 14.8                                        | 14.0                                     | 3.5              | 4.5-11             |

N/M – Not Mentioned, Normal- Values not provided but mentioned normal in respective case reports.

Abdominal USG scan showed well distended normal wall thickness acalculus gallbladder with no evidence of hepatobiliary duct dilation. Laboratory Analysis showed S. Amylase -988 U/L, S. Lipase- 660 U/L, WBC counts – 3500 cells /cumm, AST- 298U/L, ALT- 164 U/L, ALP- 75 U/L, S. Calcium levels - 7.6 mg/dl. Patient was planned for Abdominal CT which demonstrated bulky pancreas with peripancreatic inflammation, mild peripancreatic fluid and No evidence of gallbladder and hepatobiliary abnormality. According to the Scoring by Modified Glasgow Score 1984 criteria, patient had score of 2 which indicates mild pancreatitis.

The patient was initiated on supportive medical therapy with Intravenous fluids and Analgesics. She was kept Nil per oral with discontinuation of Tab Orlistat. On third day, patient was symptomatically better with normal amylase and lipase values. She was discharged in stable condition and advised to adopt alternate measures for weight reduction.

## DISCUSSION AND LITERATURE REVIEW

World Health Organization (WHO) has reported in its database that acute pancreatitis has been suspected to be caused by five hundred and twenty five different drugs (Conti Bellocchi, 2015). The mechanism of different drugs causing pancreatitis is also different, some drugs may act on the hepatobiliary system while others may have direct affect on the pancreas (Napier, 2006). The diagnosis of Drug induced pancreatitis is challenging as there are no clear clinical characteristics that can differentiate drugs from the other causative factors of pancreatitis (Chaudhuri, 2013). To say that the patient has Drug induced pancreatitis, we have to establish a temporal relation between the drug and time of onset of pancreatitis, after excluding other possible etiological factors that can contribute to the development of the disease. Studies pertaining to Orlistat inducing acute pancreatitis are under reported. Napier et al reported a case of 36 years old male who developed pancreatitis within four days of starting tablet Orlistat with normal Serum amylase level. Ct scan of abdomen showed appearance of acute severe pancreatitis affecting the distal body and tail of pancreas with no evidence of gall stones. The study concluded that Orlistat can cause pancreatitis without elevating the serum amylase level, hence the diagnosis of Orlistat induced pancreatitis should be considered in patients presenting with pain abdomen after being initiated on the drug, even if the amylase level of the patient is normal (Napier, 2006).

Ahmad FA et al reported two cases, one 73 years old female with past medical history of depression and on long term treatment for it gave history of commencement of orlistat ten days before developing pain abdomen and the other 45 years old female with known history of alcohol consumption and one previous episode of known alcoholic pancreatitis and on long term medication for the same gave history of commencement of Orlistat two days before developing pain abdomen. This study recommended that Orlistat should be used cautiously in patients who are at high risk of developing pancreatitis (Ahmad, 2012).

Şimşek zahideet al, in their case report of 43 years old male with USG abdomen finding of single large gall stone with no hepatobiliary obstruction gave history of commencement of Orlistat 8 days before developing symptoms of pancreatitis. The study suggested that usually Orlistat induced pancreatitis has a comparatively milder course and that co-existing factors should also be considered in patients of Orlistat induced pancreatitis, other than obesity. Even so clinicians should prescribe Orlistat more vigilantly, especially in patients who are at high risk of developing pancreatitis (Şimşek zahide, 2012).

Choudhuri et al reported a case of 31 years old female with type 2 diabetes mellitus and hypothyroidism, who gave history of development of pain abdomen 5 weeks after starting Orlistat. The study suggested to increase the awareness of use of anti-obesity medications, more so now as there are increasing rate of obesity and sale of non-prescription anti-obesity pills. The Above table 1 represents the laboratory data of the case reports on drug induced pancreatitis secondary to Orlistat:

## CONCLUSION

Acute pancreatitis may be characterized by onset of parenchymal and peripancreatic fat necrosis which may be associated with inflammation in an individual who was previously healthy (Jones, 2015.) Due to rising incidence of obesity, use of drugs like Orlistat is also increasing markedly (Şimşekzahide, 2012). In many patients it is a possibility or probability of diagnosing drug induced pancreatitis (Conti Bellocchi, 2015). Early diagnosis facilitates the cessation of causative agent and thereby reducing the associated complications (Jones, 2015). According to proposed classification for medications associated with drug induced pancreatitis, Orlistat is not included therefore we suggest the inclusion of Orlistat in medication causing drug induced pancreatitis (Trivedi, 2005). Orlistat is being extensively used for the treatment of obesity as mentioned in our review of literature. Few studies have shown that Orlistat can trigger pancreatitis in certain patients, especially those who are at high risk, therefore it should be prescribed cautiously and over the counter sale of Tablet Orlistat should also be limited.

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