

# Incidence of Pseudocyst of Pancreas in Patients Diagnosed with Pancreatitis

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## Abstract:

### ➤ Introduction:

Pancreatic pseudocysts represent a significant complication of pancreatitis, occurring as encapsulated collections of pancreatic fluid surrounded by fibrous or granulation tissue. While the incidence of pancreatitis is well-documented globally, the development of pseudocysts and their risk factors requires further investigation.

### ➤ Methods:

A prospective clinical study was conducted at Dr. D.Y. Patil University, School of Medicine, from November 2021 to November 2022. The study included 100 patients above 18 years with confirmed pancreatitis diagnosis. Initial ultrasonography was performed upon admission, with follow-up imaging scheduled after six weeks. The study analyzed demographic factors, risk factors, and clinical outcomes.

### ➤ Results:

The study revealed a 25% overall incidence of pancreatic pseudocysts, with significant gender disparity (34% in males vs. 16% in females,  $p=0.038$ ). Gallstone disease emerged as a significant risk factor ( $p=0.020$ ), particularly in males (60% incidence,  $p=0.002$ ). The highest pseudocyst development rates were observed in acute necrotizing pancreatitis (80%) and acute on chronic pancreatitis (54.5%). History of ERCP showed significant correlation with pseudocyst formation (55.6%,  $p=0.026$ ). Complications were minimal, with only 2% showing pressure effects and no mortality reported.

**Keywords:** Pancreatic Pseudocyst, Pancreatitis, Gallstone Disease, Acute Necrotizing Pancreatitis, Risk Factors, Incidence Study, Ultrasonography, Clinical Outcomes, Gender Disparity, ERCP Complications.

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## I. INTRODUCTION

Pancreatic pseudocysts represent one of the most significant local complications of pancreatitis, occurring as encapsulated collections of pancreatic fluid surrounded by fibrous or granulation tissue. These collections, which develop without an epithelial lining, pose considerable challenges in the management of pancreatitis patients and can significantly impact patient outcomes [1]. The increasing incidence of pancreatitis worldwide, attributed to various factors including alcohol consumption, gallstone disease, and metabolic disorders, has led to a corresponding rise in the occurrence of pancreatic pseudocysts [2].

The formation of pancreatic pseudocysts typically follows acute or chronic inflammatory processes affecting the pancreas. In acute pancreatitis, approximately 5-15% of patients develop pseudocysts, while in chronic pancreatitis, the incidence ranges from 20-40% [3]. These lesions develop when pancreatic inflammation leads to ductal disruption and subsequent accumulation of pancreatic secretions in peripancreatic tissues [4].

The clinical significance of pancreatic pseudocysts lies not only in their prevalence but also in their potential complications. While some pseudocysts resolve spontaneously, others may persist and grow, leading to various complications including infection, rupture, hemorrhage, and compression of adjacent structures [5]. The

risk of complications increases with pseudocyst size and duration, making early detection and appropriate management crucial [6].

Modern imaging techniques, particularly contrast-enhanced computed tomography (CECT) and magnetic resonance imaging (MRI), have revolutionized the diagnosis and monitoring of pancreatic pseudocysts [7]. These advanced imaging modalities allow for precise characterization of pseudocysts, helping clinicians distinguish them from other cystic lesions of the pancreas and guide appropriate therapeutic interventions [8].

The management of pancreatic pseudocysts has evolved significantly over the past decades, ranging from conservative observation to various interventional approaches. The choice of treatment strategy depends on multiple factors, including pseudocyst size, location, maturity, and the presence of complications [9]. Understanding the natural history and risk factors associated with pseudocyst formation is essential for optimizing patient care and preventing adverse outcomes [10].

This thesis aims to investigate the incidence of pancreatic pseudocysts among patients diagnosed with pancreatitis, analyzing various contributing factors, clinical presentations, and outcomes. The findings will contribute to the existing body of knowledge and help establish evidence-based guidelines for the management of this significant complication.

## II. METHODOLOGY

A prospective clinical study was conducted at Dr. D.Y. Patil University, School of Medicine, Nerul, Navi Mumbai, in the Department of General Surgery between November 2021 and November 2022. The study aimed to investigate the incidence of pancreatic pseudocysts in patients diagnosed with pancreatitis at this tertiary care center in the metropolitan city.

The study population consisted of 100 patients who met the inclusion criteria of being above 18 years of age and having a confirmed diagnosis of pancreatitis (both clinical and radiological). All participants were required to provide written informed consent and agree to follow-up care. Patients under 18 years of age and those unwilling to participate in follow-up were excluded from the study.

The methodology involved initial documentation of pancreatitis through ultrasonography of the abdomen upon admission, regardless of the patient's gender or comorbidities. Participants were scheduled for follow-up appointments at least six weeks after their initial pancreatitis diagnosis, at which time a repeat abdominal ultrasound was performed. The study protocol received approval from the Institutional Ethics Committee prior to commencement, and informed consent was obtained in English, Hindi, or Marathi, according to patient preference.

## III. RESULTS

Table 1: Demographic and Basic Characteristics (N=100)

Characteristic		Value
Mean Age (SD)		47.91 (13.469)
Sex Distribution	Males	50 (50%)
	Females	50 (50%)
Pseudocyst Development	Overall Incidence	25 (25%)
	Males with Pseudocyst	17/50 (34%)
	Females with Pseudocyst	8/50 (16%)
Statistical Significance		p=0.038

Table 2: Risk Factors and Pseudocyst Development

Risk Factor	Total Cases	Pseudocyst Development	P-value
Alcohol Intake	46	12 (26.1%)	0.817
Males with Alcohol	34	11/34 (32.4%)	0.72
Females with Alcohol	12	1/12 (8.3%)	0.406
Gallstone Disease	56	19 (33.9%)	0.020
Males with Gallstones	20	12/20 (60%)	0.002
Females with Gallstones	36	7/36 (19.4%)	0.287
History of ERCP	9	5 (55.6%)	0.026
Both Alcohol & Gallstones	16	7 (43.8%)	0.059

Table 3: Distribution by Diagnosis and Pseudocyst Development

Diagnosis	Total Cases	Pseudocyst Cases	Percentage
Acute Pancreatitis	77	12	15.6%
Acute on Chronic Pancreatitis	11	6	54.5%
Acute Necrotising Pancreatitis	5	4	80%
Pancreatitis Secondary to Cholelithiasis	6	3	50%

<b>Pancreatitis Secondary to ERCP</b>	1	0	0%
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Table 4: Complications and Interventions

Parameter		Number	Percentage
Complications	No Complications	98	98%
	Pressure Effects	2	2%
Interventions Required		0	0%
Mortality		0	0%

#### IV. DISCUSSION

Pseudocyst of the pancreas is a common complication following pancreatitis. Pancreatitis is an inflammatory condition of the pancreas, and during the acute phase of the disease there is extravasation of fluid. This can occur from the pancreas and the visceral peritoneum. Pancreatitis can damage the pancreatic ducts, leading to extravasation of pancreatic secretions rich in enzymes. In necrotising pancreatitis sloughing off of pancreatic necrosus, are some of the common causes leading to peripancreatic fluid collections.

These fluid collections are called as acute pancreatic fluid collections which usually resolve.

However fluid collections that don't resolve with time by at least 4 weeks, are usually encapsulated by fibrous tissue and are called pseudocysts of the pancreas. Those with necrotic material within are called as walled off necrosis. However the exact pathophysiology of its development is not very clearly understood.

The incidence of pancreatitis and the etiologies are well studied worldwide, but the incidence of complications like the pseudocyst formation is not well established. The present study was conducted in the Department of General Surgery at Dr. D. Y. Hospital Navi Mumbai from November 2021 to October 2022. A total of 100 cases were studied.

In study done by Kim KO et al.<sup>11</sup>, pancreatic pseudocyst developed in 14.6% of acute pancreatitis and in 41.8% of acute-on-chronic pancreatitis ( $P = 0.00$ ). In the present study we found the incidence of pseudocyst to be higher with acute necrotising pancreatitis, (80%), acute on chronic pancreatitis (80%)

Acute pancreatitis (15%) in a meta-analysis study by Lerch MM et al.<sup>12</sup>, prevalence of pancreatic pseudocysts in acute pancreatitis has been reported to range from 6% to 18.5%.

In a study Imrie CW et al.<sup>13</sup>, Pseudocysts developed in 86 patients consequent to an episode of acute pancreatitis in which a biliary cause for the preceding acute pancreatitis was found in 27, and an alcoholic cause for 59 patients.

In a study by Maringhini A et al.<sup>14</sup>, who studied pancreatic fluid collections from 83 patients (8.9%): 48 of whom developed pseudocysts (5.1%). Both were less frequent after biliary pancreatitis ( $P < 0.0001$ ) In the present

study we found the incidence of pseudocyst to be higher in patients with gallstone disease.

#### V. CONCLUSION

This prospective clinical study of 100 pancreatitis patients revealed several significant findings regarding pancreatic pseudocyst development. The overall incidence of pseudocysts was 25%, with a notably higher occurrence in males (34%) compared to females (16%). Gallstone disease emerged as a significant risk factor, particularly in males where 60% of those with gallstones developed pseudocysts ( $p=0.002$ ). The study found varying incidence rates across different types of pancreatitis, with acute necrotizing pancreatitis showing the highest rate at 80%, followed by acute on chronic pancreatitis at 54.5%, while acute pancreatitis had a lower rate of 15.6%. History of ERCP was also identified as a significant risk factor ( $p=0.026$ ). The study observed minimal complications, with only 2% of cases showing pressure effects, and notably reported no mortality or need for interventions. These findings suggest the importance of careful monitoring of patients with identified risk factors, particularly those with gallstone disease or presenting with acute necrotizing pancreatitis.

#### ➤ Declarations:

##### • Availability of Data and Materials

The datasets analyzed during the current study are available from the corresponding author on reasonable request

#### ACKNOWLEDGEMENTS

The authors would like to thank DY Patil school of medicine for allowing to conduct this study at their institute.

- **Funding:** None.
- **Ethics Declarations:** Ethics approval and consent to participate.

This study was conducted according to the principles expressed in the Declaration of Helsinki and approved by DY Patil School of Medicine Navi Mumbai India—Ethical Review Board (Study Number: 2021152). Return informed consent was taken from all patients, consent form attached in manuscript.

- **Consent for Publication:** Applicable.
- **Competing Interests:** The authors declare that they have no competing interests.

**AUTHORS CONTRIBUTION**

Dr zulekha Bhimani -**Corresponding Author** collected Data and did analysis of the results, coordinated with technician to prevent any sample loss.

Dr P.S. Eswar –**Primary Author** divided patient based on the inclusion and exclusion criteria

Dr Pedneker- professor at DY Patil school of medicine supervised the whole study, to prevent any errors

Dr. Mehnish Malik- Made Mastercharts and collected all the intraoperative pictures

Dr Nidhi Shah- coordinated with Path lab for stone analysis and reporting

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**Institutional Ethics Committee (IEC)**  
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Date: Monday, 8 November, 2021

To,

**Dr. P. S. ESWAR**  
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Sir/Madam,

The Institutional Ethics Committee for Biomedical and Health research (IECBH) of Dr D Y Patil Medical College & Hospital, Navi Mumbai has reviewed and discussed your application to conduct the study titled **"INCIDENCE OF PSUEDOCYST OF PANCREAS IN PATIENTS DIAGNOSED WITH PANCREATITIS"** on 6/26/2021. Your research involves risk category **"Minimal risk"** as per the 'National Ethical Guidelines for Biomedical & Health Research involving Human Participants, ICMR, 2017' (ICMR\_Ethical\_Guidelines\_2017.pdf), and your project was processed as "" review by the IECBH.

The following documents were reviewed by the IECBH:

Document	Reviewed
1. Covering letter of submission	Yes
2. Synopsis of protocol/study/dissertation/thesis	Yes
3. Participant Information Sheet (PIS) in English, Hindi and Marathi	Yes
4. Informed Consent Form (ICF) in English, Hindi and Marathi	Yes
5. Case Record Form (CRF) / Study proforma / Questionnaire(s)	Yes
6. Other	None

None of the study team members including principal investigator were a part of the voting procedure.

**DECISION**

- The IEC hereby approves the study to be conducted in its presented form subject to:
  1. All clinical studies are recommended to be registered on the "Clinical Trials Registry - India (CTRI)" at "http://ctri.nic.in" before commencement of study subjects (first patient in (FP)).
  2. All applicable mandatory regulatory and other permissions to be obtained prior to commencement of the study.
  3. The study team members should be trained on the protocol & protocol related procedures and the Good Clinical Practices (GCP) Guidelines prior to commencing the study.
  4. Participating subjects should not be put to additional financial burden due to participation in the study.
  5. Monitor all enrolled patients for adverse events (AE) and serious adverse events (SAE).
  6. The study conduct should comply with the provisions of 'New Drugs & Clinical Trial Rules, 2019', and the 'National Ethical Guidelines for Biomedical & Health Research involving Human Participants, ICMR, 2017'.

1



**Institutional Ethics Committee (IEC)**  
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- The validity of this approval is for the duration of the study period.
- The IEC is required to be informed about the following:
  1. All updates on safety related information.
  2. Any SAE occurring during the study to be communicated within 24 hours of information to the IEC and the sponsor (if applicable).
  3. Progress of the study to be reported annually to the IEC.
  4. Any amendments/changes in the protocol and/or patient information / informed consent document.
  5. To provide a copy of the final report after completion of the study.

Thank you

**Dr. Vaishali Thakare**  
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Chairperson / Secretary  
Institutional Ethics Committee for Biomedical  
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### PATIENT CONSENT FORM

I \_\_\_\_\_ have read the information in this form (or it has been read to me). I was free to ask any question and they have been answered. I am over years of age and exercising my free power of choice, hereby give my consent to be included as a participant.

1. I have read and understood this consent form and the information provided to me.
2. I have read the consent document explained to me.
3. I have been explained about the nature of the study.
4. My rights and responsibilities have been explained to me by the investigator .
5. I agree not to restrict the use of any data or results that arise from this study, provided such a use is only for scientific purpose.
6. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.
7. I am aware of the fact that I can opt out of the study at anytime without having to give any reason and this will not affect my future treatment in the hospital.
8. I am also aware that the investigators may terminate my participation in the study at any time for any reason without my consent.
9. I hereby give permission to the investigator to release the information obtained from the result of participation in this study to the ethics committee. I understand that they inspect my original records.
10. My identity will be kept confidential if my data is publically presented.
11. I have had my questions answered to my satisfaction.
12. I have decided to be in the research study.

I am aware, that if I had any questions during this study, I should contact at one of the addresses listed above . By signing this consent form, I attest the information given in this document. I will be given a copy of this consent document.

88

**Participants initials: - \_\_\_\_\_**

**Name and signature/thumb impression of participant (or legal representative if participant incompetent):**

\_\_\_\_\_  
**(NAME)**

\_\_\_\_\_  
**(SIGNATURE)**

**Date: \_ / \_ / \_ \_ \_ \_**

**Time: \_\_\_\_\_**