

Study Protocol

Evaluation of Pancreatic Lesions by Computed Tomography Scan: A Study Protocol

ABSTRACT:

Background: The Pancreas was considered a hidden organ due to its retroperitoneal location and was one of the last organs in the abdomen to be analyzed by anatomists, physiologists, physicians, and surgeons. Pancreatic lesions may range from mild inflammation to malignancy. Ultrasound was the first cross-sectional technique that permitted direct imaging of the pancreas. It permitted precise visualization of Pancreatic parenchyma, Pancreatic ducts and bile ducts. This study aims to evaluate various pancreatic lesions using CT scan and assess their correlation with histopathological findings.

Methodology: This **will be** an observational study conducted at department of radiodiagnosis, AVBRH, Wardha. Total 180 patients with pancreatic disease confirmed by clinical, laboratory and ultrasonography **will be** enrolled in the study. All 180 patients **will undergo** plain and contrast enhanced CT scan. Results will be judged, based on the observations and findings on CT scan, biochemical and histopathological reports whenever possible. Modified CT Severity Index / Mortelet Modified CTSI Scoring **will be** used to assess severity of acute pancreatitis and acute exacerbation of chronic pancreatitis.

Results: We expect to explore the common etiological factors, gender and age distribution of various pancreatic diseases. Correlation between grade of acute pancreatitis according to modified CT severity index and clinical outcome of patients **will be** evaluated.

Conclusion: CECT is excellent diagnostic modality to stage severity of inflammatory process and staging of neoplastic lesions. Severity grading in acute exacerbation of chronic pancreatitis **will be** meticulously observed and significant conclusive findings **will be** seen. CECT imaging with its postprocessing techniques represents the imaging technique of choice for diagnosis and evaluation of pancreatic masses.

Keywords: Pancreatitis, Pancreas , Computed Tomography, CT severity Index, Scoring.

INTRODUCTION:

The Pancreas was considered a hidden organ and was one of the last organs in the abdomen to be analyzed by anatomists, physiologists, physicians, and surgeons.¹ The Pancreas has its first mention in literature around 200 B.C., when it was referred to as the 'finger of the liver' in the Talmud. The pancreas was given its name by Rufus of Ephesus, a Greek anatomist. The term 'Pancreas' is derived from a Greek word which means 'whole flesh' possibly because of its fleshy consistency.² Galen proposed that it had the role in supporting and protecting blood vessels. The pancreas was considered as a cushion for the stomach by Vesalius. It was Wirsung who first demonstrated the ducts in humans pancreas in 1642.¹ The histological structure of the pancreas was first described in 1869 by Langerhans and subsequently by Heidenhain.³

In 1967, Josef Rosch published an article in American Journal of Roentgenology in which he mentioned that the Pancreas was a difficult organ to image Roentgenologically since it is small and situated deep in the retroperitoneal space. The Roentgenologic diagnosis of Pancreatic disease relies on the changes induced by the pathologic process in the surrounding organs.^{4,5}

Ultrasound was the first cross-sectional technique that permitted direct imaging of the pancreas. It permitted precise visualization of Pancreatic parenchyma, Pancreatic ducts and bile ducts.^{4,6} Bowel gas remains the single most important obstacle for obtaining excellent ultrasound studies.⁶ Even with a meticulous scanning technique, the Pancreas cannot be visualized in 10% of the patients. CT scan is then extremely beneficial in such patients.^{4,5}

CT of the Pancreas began in the late 1970's with simultaneous publication by authors like Kreel, Stephens et al and Haaga et al in 1976.⁵ Computed tomography is the non-invasive modality. It makes use of computer processed combination of many x-ray measurements taken from different angles. It is also known as COMPUTED AXIAL TOMOGRAPHY.^{5,7} Initially only pancreatic masses or contour abnormalities could be detected. Helical CT scanners introduced in late 1980 allowed much faster accession of data with a slice thickness of 1-2mm and three dimensional imaging.⁷ Subsequently improvements in scanner technology and use of bolus injection of intravenous contrast material enabled imaging of normal Pancreatic parenchyma, Pancreatic duct and Peripancreatic vascular structures.^{4,5,7} CT has become the method of choice for evaluating the pancreas, detecting pancreatic lesions, assessing severity of disease process and determining etiology.^{5,7,8}

Imaging in Pancreatic lesions is challenging as pancreas is located retroperitoneally and in close proximity to bowel and major blood vessels.^{9,10} Pancreatic lesions include the spectrum of diseases ranging from inflammation and its complication to malignancy.^[11,12] Pancreatic lesions are associated with high morbidity and comorbidity.¹¹ Multi-detector computed tomography scan is modality of choice for detecting pancreatic pathology. It is highly sensitive in detecting necrosis, pancreatitis, peripancreatic fluid collections, calcification, neoplasm, pancreatic enlargement, atrophy and cystic lesions of Pancreas. CT has been shown to be the best imaging modality, being more sensitive than ultrasound for detection of pancreatic injury.^{5,7} CT scan has made it possible to identify and detect various benign and malignant Pancreatic lesions. In neoplastic conditions, CT scan can give an idea about extent of disease, tissue component, accurately depict tumor morphology, ductal anatomy and its relationship with the surrounding organs. CT scan is also widely used in the preoperative staging of Pancreatic neoplasm and also allows accurate post treatment follow up.^{4,5,7}

CT scan is popular for diagnosing the pancreatic pathology due its availability and easy interpretation of CT images by radiologist. CT has the benefit of high accuracy over ultrasound in pancreatic lesions.¹³ Ultrasound has limitation in evaluating Pancreas as most of times it is obscured by bowel gases.^{6,13} CT scan can easily detect the pancreatic and extra pancreatic spread of disease. CT scan has benefit of comparative low cost, less time consumption, and detection of concretions over Magnetic resonance imaging.^{5,7}

Radiological evaluation with CT scan has become very essential for diagnosing the pancreatic lesions and planning their proper treatment. So CT becomes the method of choice in evaluating the Pancreas, in detecting a Pancreatic lesion, assessing its extent, defining its etiology and planning proper treatment.^{4,5,7}

CT scan is highly reliable and can be easily performed. It has the advantage of accuracy and accessibility.⁵ So present study is done to evaluate role of Computed tomography in various Pancreatic lesions including the spectrum of diseases ranging from inflammation and its complication to malignancy, their characteristic appearance, clinical, biochemical and histopathological correlations.⁹⁻¹² In almost all the studies acute exacerbation of chronic pancreatitis is not separately mentioned and is included in chronic pancreatitis. In present study, we have tried to describe the cases of acute exacerbation of chronic pancreatitis separately.

Study objectives :

1. To evaluate various pancreatic lesions on CT scan.
2. To evaluate various pancreatic lesions on CT scan their characteristics appearance and clinical correlation.
3. To differentiate various pancreatic lesions on CT scan and correlation with biochemical tests and/or histopathological correlation.

Rationale : CT scan is highly reliable, can be easily performed. It has advantage of accuracy and accessibility. CT scan has primary role in evaluation of pancreatitis, trauma and malignancy. It detects not only parenchymal abnormalities but also extra pancreatic spread of disease. In pancreatic neoplasm MDCT accurately depicts tumor morphology, ductal anatomy and its relationship with surrounding organs.

MATERIAL AND METHODOLOGY

This is observational study which included the patients from July 2018 to June 2020 presenting to the department of Radiodiagnosis, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha.

STUDY DESIGN:- Prospective observational study.

STUDY PLACE:- Patients came to department of Radio-diagnosis, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha. Both IPD and OPD patients were included.

DURATION OF STUDY:- Study will be conducted from July 2018 to July 2020

STUDY POPULATION:-

The study was conducted on patients of either sex referred to department of Radiodiagnosis, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha after taking a written informed consent that fulfilled the inclusion criteria.

SAMPLE SIZE: -

A total of 180 Patients who presented with symptoms related to pancreatic disease referred to department of Radiodiagnosis, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha were taken for study.

SAMPLE SIZE CALCULATION:-

The incidence of pancreatic lesions in AVBRH is 0.35 per thousand

So by formula

$$n = (z\alpha/2)^2 \times p \times (1-p) / d^2$$

$z\alpha/2$ = level of significance at 5% i.e 95% confidence interval=1.96

p = Incidence (0.35)

d= allowable error, 20% of p

=20% of p

=20% of 0.35=0.07

$$n = (1.96)^2 \times 0.35 \times (1-0.35) / (0.07)^2$$

n =178.36 (approximately 180)

n =180

SAMPLING METHODS:-

180 patients were randomly selected who fulfilled the inclusion criteria and presented to the department of Radiodiagnosis, Jawaharlal Nehru Medical College and Acharya Vinobha Bhave Rural Hospital, Sawangi, Wardha.

STUDY PERIOD:- July 2018 to June 2020 (24 Months)

SELECTION CRITERIA:-

INCLUSION CRITERIA:-

1. Patients presenting with complaints related to pancreas and clinically diagnosed.
2. Patients who underwent ultrasonography with high *suspicious* of pancreatic pathology.
3. Patients with deranged biochemical tests for pancreas.

EXCLUSION CRITERIA

- Postoperative patients.
- Pregnant females presenting with complaints of pancreatic lesion
- Patients allergic to contrast media
- Patients not willing to participate.

STUDY EQUIPMENTS:

Siemens Somatom 16 Slice Computed Tomography (CT) Scan Machine.

METHODOLOGY OF STUDY:

- The pre-tested, semi structured questionnaire was developed and used for data collection. Patients were informed and explained about the study. Written informed consent was taken prior to procedures as per attached proforma.
- Clinical and consequential data were documented in a predesigned proforma.
- Patient **will be** kept nil per oral for 6 to 8 hours.
- Serum creatinine **will be** done.
- Patient **will be** placed on gantry table in supine position with both hands above the head.
- A scanogram **will be** taken in inspiration / expiration.
- Initially a non-contrast CT scan **will be** taken. (*only oral contrast is given, most commonly used here will be positive contrast Urografin*)
- Then the *intravenous contrast will be* given to the patient and contrast enhanced CT scan **will be** taken (commonly used intravenous contrast in AVBRH **will be** positive contrast Omnipaque or Ultravist (300mg iodine), both 2ml per kg of body weight and given at the rate of 2.8ml/sec at 280 psi)
- *Pancreatic Parenchymal phase will be taken at delay of 50 second after contrast injection, portal venous phase at 70 second delay and delayed phase at 6-10 mins.*
- *Then the lateral decubitus view with patient lying on his right side will be taken.*
- Acquisition of axial sections **will be** done in cranio-caudal direction from the level of xiphisternum to *pubis* symphysis
- Axial sections **will be** taken with slice thickness of 5mm and then reconstructed to thickness of 1.5mm
- Results **will be** judged, based on the observations and *findings* on CT scan, biochemical and histopathological reports whenever possible.
- Modified CT Severity Index / Mortele Modified CTSI Scoring **will be** used to assess severity of acute pancreatitis and acute exacerbation of chronic pancreatitis.
- The observations **will be** graphically depicted and with the help of tables and graphs and conclusions **will be** drawn on the basis of observations and discussion.
- The data obtained **will be** compiled in tabular form and analyzed and suitable statistical tests applied for results.

SCANNING PARAMETERS USED:-

- Position: Supine
- Scanner settings: KV(p): 80 – 120; mAs: 80-160 for non-contrast scan and 180-280 for contrast enhanced CT
- Matrix size: 512x512
- Image order- cranio-caudal
- Pitch-1.25
- Superior extent: xiphisternum
- Inferior extent: *pubis* symphysis

TOOLS FOR ASSESSMENT OF SEVERITY

“Modified CTSI”¹³ Scores are generated by estimating pancreatic inflammation and necrosis to give a score out of 10. Pancreatic inflammation

- Score 0: normal pancreas
- Score 2: intrinsic pancreatic abnormalities with or without inflammatory changes in peripancreatic fat
- Score 4: pancreatic or peripancreatic fluid collection or peripancreatic fat necrosis

Pancreatic necrosis

- Score 0: none
- Score 2: 30% or less
- Score 4: more than 30%

Extra pancreatic complications

- Score 2: one or *more of* ascites , pleural effusion, parenchymal complications ,vascular complications or gastrointestinal involvement.

Total score

Total points are given out of 10 to determine the grade of pancreatitis:

- 0-2: Mild Acute Pancreatitis
- 4-6: Moderate Acute Pancreatitis
- 8-10: Severe Acute Pancreatitis

EXPECTED RESULTS: (*Need to reconsider this section as results are already available*)

In this study we expected to find out the common etiological factors, age group and symptoms of pancreatic pathologies. We **also intend to find** common computed tomographic findings of various pancreatic pathologies. We **expect** positive correlation between modified CTSI and clinical outcome of patients. We **expect** high sensitivity of CECT in diagnosis of benign and malignant pancreatic neoplasm. In case of pancreatic trauma we **intend to** grade them according to AAST scale and correlate it with clinical outcome.

DISCUSSION:

Pancreatic diseases are associated with high mortality. Computed tomography is imaging modality of choice for diagnosing pancreatic pathology. It has high accuracy in detecting pancreatic lesions and their nature. It also helps in grading of acute pancreatitis and revealing its prognosis by modified computed tomography severity index. Problems of pancreatic disease are evident from GBD Studies¹⁴⁻¹⁶. Studies on related aspects of pancreatic disease were reported by Gawande-Kirnake¹⁷ and Kambale et. al.¹⁸. Studies on use of Computed tomography were reported¹⁹⁻²¹. In many studies there is positive correlation between modified CTSI and clinical outcome in terms of infection, hospital stay and need for intervention. In cases of chronic pancreatitis, duct dilatation, pancreatic calcifications and parenchymal atrophy are visible on CT scan, thus helping in easy and rapid diagnosis. Serum amylase and serum lipase are increased in the cases of acute pancreatitis but in chronic pancreatitis there can be serum amylase and lipase insufficiency. We **will be** discussing acute exacerbation of chronic pancreatitis as separate entity with imaging changes. We **will be** applying modified CTSI to acute exacerbation of chronic pancreatitis and **will be** observing clinical outcome of it. It also helps in staging of pancreatic neoplasm and preoperative planning for resection. Various biochemical tumors markers are increased in cases of pancreatic neoplasm.²²⁻³⁰

CONCLUSION:

CECT is excellent diagnostic modality to stage severity of inflammatory process and staging of neoplastic lesions. Severity grading in acute exacerbation of chronic pancreatitis **will be** meticulously observed and significant conclusive findings **will be** seen. CECT imaging with its postprocessing techniques represents the imaging of choice for diagnosis and evaluation of pancreatic masses. It is a standard investigation to identify and quantify distribution of various pancreatic lesions and also evaluates progression of disease. It helps in accurate diagnosis and characterization of lesion and in proper treatment of patients.

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