

# Study Protocol

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

### ABSTRACT:

**Background:** The pancreas is a hidden organ and was one of the last organs in the abdomen to be analyzed by anatomists, physiologists, physicians, and surgeons. Pancreatic lesions may ~~range from~~ 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~~ 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~~ patients will undergo plain and contrast enhanced CT scan. Results will be judged, based on the observations and finding 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~~ We expect to explore on the common etiological factors, gender and age distribution of various pancreatic diseases. Correlation between ~~grade of~~ grade of acute pancreatitis according to modified CT severity index and clinical outcome of patients. In case of chronic 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 found. CECT imaging with its postprocessing techniques represents the image of choice for diagnosis and predicting pancreatic masses.

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

### INTRODUCTION:

The pancreas is a hidden organ and was one of the last organs in the abdomen to be analyzed by anatomists, physiologists, physicians, and surgeons.<sup>1</sup> 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.<sup>2</sup> 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 [human's](#) pancreas in 1642.<sup>1</sup> The histological structure of the pancreas was first described in 1869 by Langerhans and subsequently by Heidenhain.<sup>3</sup>

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 change induced by the pathologic process in the surrounding organs.<sup>4,5</sup>

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.<sup>4,6</sup> Bowel gas remains the single most important obstacle for obtaining excellent ultrasound studies.<sup>6</sup> 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.<sup>4,5</sup>

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.<sup>5</sup> Computed tomography is the non-invasive modality. It makes the use of computed processed combination of many x-ray measurements taken from different angles. It is also known as COMPUTED AXIAL TOMOGRAPHY.<sup>5,7</sup> 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.<sup>7</sup> Subsequently improvements in scanner technology and use of bolus injection of intra-venous contrast material enabled imaging of normal [pancreatic](#) parenchyma, Pancreatic duct and [peripancreatic](#) vascular structures.<sup>4,5,7</sup> CT has become the method of choice for evaluating the pancreas, detecting pancreatic lesions, assessing its severity, and determining its etiology.<sup>5,7,8</sup>

Imaging in [pancreatic](#) lesion is challenging as pancreas are located retroperitoneally and with close proximity to bowel and major blood vessels.<sup>9,10</sup> Pancreatic lesions include the spectrum of disease ranging from inflammation and its complication to [malignancy](#).<sup>[11,12]</sup> Pancreatic lesions are associated with high morbidity and comorbidity.<sup>11</sup> 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.<sup>5,7</sup> ~~CT~~ [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.<sup>4,5,7</sup>

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.<sup>13</sup> Ultrasound has limitation in evaluating [pancreas](#) as most

of times it is obscured by bowel gases.<sup>6,13</sup> 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 ~~m~~Magnetic resonance imaging.<sup>5,7</sup>

Radiological evaluation with CT scan is has become very essential for diagnosing the pancreatic lesions and planning their proper treatment. So CT become the method of choice in evaluating the ~~p~~Pancreas, in detecting a ~~p~~Pancreatic lesion, assessing its extent, defining its etiology and planning proper treatment.<sup>4,5,7</sup>

As CT scan is highly reliable, can be easily performed. It has advantage of accuracy and accessibility.<sup>5</sup> So present study is done to evaluate role of ~~c~~Computed tomography in various ~~p~~Pancreatic lesions include the spectrum of disease ranging from inflammation and its complication to malignancy, their characteristic appearance, clinical, biochemical and histopathological correlations.<sup>9-12</sup> 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~~-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~~on CT scan and correlation ~~with biochemical~~with biochemical tests and/or histopathological correlation.

**~~Rationale~~-Rationale:** CT scan is highly reliable, can be easily ~~performed~~performed. It has advantage of accuracy and ~~accessibility~~accessibility. CT scan has primary role in evaluation of pancreatitis trauma and malignancy. It detects with not only parenchymal abnormalities but also extra pancreatic spread of disease. In pancreatic neoplasm MDCT accurately depict 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) came to department of ~~r~~Radiodiagnosis, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha.

**STUDY DESIGN:-**prospective observational study.

**STUDY ~~PLACE~~-PLACE:** - Patients came to department of ~~r~~Radio-diagnosis, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha. Both inpatient department (IPD) and outpatient's department (OPD)-patients were included.

**DURATION OF STUDY:-**Study will be conducted during period from July 2018 to Junely 2020

#### **STUDY POPULATION:-**

The study conducted on patients of either sex referred to department of ~~r~~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 pPatients who presented with symptoms related to pancreatic disease referred to department of rRadiodiagnosis, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital (AVBRH), 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~~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 pPatients were randomly selected that fulfilled the inclusion criteria that came to department of rRadiodiagnosis, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha.

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

### **SELECTION CRITERIA:-**

### **INCLUSION CRITERIA:-**

- 1) Patients presented with complaints related to pancreas and clinically diagnosed.
- 2) Patients undergone ultrasonography with high suspicious of pancreatic pathology.
- 3) Patients with deranged biochemical tests for pancreas.

### **EXCLUSION CRITERIA**

- 1) Postoperative patients.
- 2) Pregnant females presenting with complaints of pancreatic lesion
- 3) Patients allergic to contrast media
- 4) 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 developed and used for data collection. Patient were informed and explained about the study. Written informed consent had been taken prior to procedures as per attached proforma.

- Clinical and consequential data were documented by a predesigned proforma.
- Patient will be kept nil per os 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~~ 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 oral and intravenous contrast will be given to the patient and then 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 section will be done in cranio-caudal direction from the level of xiphisternum to pubis symphysis
- Axial sections will be taken of slice thickness of 5mm and then reconstructed to thickness of 1.5mm
- Results will be judged, based on the observations and finding 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.
- The observations will be graphically depicted and with the help of tables and graphs and conclusions is 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 <sup>13</sup> 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~~ 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:**

In this study we expect to find out the common etiological factor 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 disease 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~~ severity index. Problems of pancreatic disease are evident from GBD Studies <sup>14-16</sup>. Studies on related aspects of pancreatic disease were reported by Gawande-Kirnake <sup>17</sup> and Kambale et. al. <sup>18</sup>. Studies on use of Computed tomography were reported <sup>19-21</sup>. 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~~ will be observing clinical outcome of it. It also helps in staging of pancreatic neoplasm and preoperative planning for resection. Various biochemical tumor markers are increased in cases of pancreatic neoplasm.<sup>22-30</sup>

### 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 found. CECT imaging with its postprocessing techniques represents the image of choice for diagnosis and predicting pancreatic masses. It is a standard investigation to identify and quantify distribution of various pancreatic lesions and also evaluates activeness and progression of disease. It helps in accurate diagnosis and characterization of lesion and in proper treatment of patients.

### References:

1. Busnardo AC, DiDio LJ, Tidrick RT, Thomford NR. History of the pancreas. The American journal of surgery. 1983 Nov 1;146(5):539-50..
2. Isenmann R, Beger H. Natural history of acute pancreatitis and the role of infection. Baillieres Best Pract Res Clin Gastroenterol ~~1999;13:291~~ 1999; 13:291–301.
3. Motta PM, Macchiarelli G, Nottola SA, Correr S. Histology of the exocrine pancreas. Microscopy Research and Technique 1997; 37:384–398.
4. Freeny PC. Radiology of the pancreas: two decades of progress in imaging and intervention. American Journal of Roentgenology. 1988 May 1;150(5):975-81.
5. Haaga JR, Dogra V, Forsting M, Gilkeson R, Kwon Ha H, Sundaram M. CT and MR imaging of the whole body, 5th ed. Philadelphia: Elsevier; 2003.p.1599–1667.
6. Rumack C, Wilson S, Charboneau W. Diagnostic ultrasound. 3rd ed. ~~Missouri: Mosby~~ Missouri: Mosby; 2005.p. 213-239.
7. Chaudhary V, Bano S. Imaging of the pancreas: recent advances. Indian journal of endocrinology and metabolism. 2011 Jul;15(Suppl1):S25.
8. Banks PA. Practice guidelines in acute pancreatitis. Am J Gastroenterol. 1996; 92:377-386.
9. Moo TA, Zarnegar R, Brunaud L. Pancreas: Embryology, Anatomy, and Physiology. In Endocrine Surgery 2009 (pp. 459-469). Springer, ~~London.~~ London.
10. Magee DJ, Burdick JS. Anatomy, histology, embryology and development anomalies of the pancreas. In: Feldman M, Friedman LS, Sleisenger MH, editors. Gastrointestinal and Liver Diseases: Pathophysiology, Diagnosis and Management. 7th ed. Philadelphia: W.B. Saunders Co; 2002. p. 859-870.
11. Nealon WH. Surgical Diseases of the Pancreas. 3rd Edition. Ann Surg. 2001 April; 233(4): 595–596.

12. Vaughn DD, Jabra AA, Fishman EK. Pancreatic disease in children and young adults: evaluation with CT. *Radiographics*. 1998 Sep;18(5):1171-87.
13. Mortelet KJ, Wiesner W, Intriere L, Shankar S, Zou KH, Kalantari BN, et al. A Modified CT Severity Index for Evaluating Acute Pancreatitis: Improved Correlation with Patient Outcome. *Am J Roentgenol*. 2004 Nov 1;183(5):1261-5.
14. James, Spencer L, Chris D Castle, Zachary V Dingels, Jack T Fox, Erin B Hamilton, Zichen Liu, Nicholas L S Roberts, et al. "Global Injury Morbidity and Mortality from 1990 to 2017: Results from the Global Burden of Disease Study 2017." *Injury Prevention* 26, no. Supp 1 (October 2020): i96-114. <https://doi.org/10.1136/injuryprev-2019-043494>.
15. Murray, Christopher J L, Cristiana Abbafati, Kaja M Abbas, Mohammad Abbasi, Mohsen Abbasi-Kangevari, Foad Abd-Allah, Mohammad Abdollahi, et al. "Five Insights from the Global Burden of Disease Study 2019." *The Lancet* 396, no. 10258 (October 2020): 1135-59. [https://doi.org/10.1016/S0140-6736\(20\)31404-5](https://doi.org/10.1016/S0140-6736(20)31404-5).
16. Murray, Christopher J L, Aleksandr Y Aravkin, Peng Zheng, Cristiana Abbafati, Kaja M Abbas, Mohsen Abbasi-Kangevari, Foad Abd-Allah, et al. "Global Burden of 87 Risk Factors in 204 Countries and Territories, 1990-2019: A Systematic Analysis for the Global Burden of Disease Study 2019." *The Lancet* 396, no. 10258 (October 2020): 1223-49. [https://doi.org/10.1016/S0140-6736\(20\)30752-2](https://doi.org/10.1016/S0140-6736(20)30752-2).
17. Gawande, A., and V. Kirnake. "Cardiac Involvement in Acute Pancreatitis and Its Effect on Morbidity and Mortality." *Journal of Datta Meghe Institute of Medical Sciences University* 14, no. 3 (2019): 125-29. [https://doi.org/10.4103/jdmimsu.jdmimsu\\_226\\_19](https://doi.org/10.4103/jdmimsu.jdmimsu_226_19).
18. Kamble, T., A. Husain, and A. Dafal. "Recurrent Hemosuccus Pancreaticus Treated by Endovascular Intervention Alone: A Rare Case Report." *Journal of Datta Meghe Institute of Medical Sciences University* 14, no. 4 (2019): 414-16. [https://doi.org/10.4103/jdmimsu.jdmimsu\\_185\\_19](https://doi.org/10.4103/jdmimsu.jdmimsu_185_19).
19. Pattabiraman, S., S.V. Phatak, P.A. Patwa, and G. Marfani. "Bilateral Sporadic Renal Angiomyolipoma. Ultrasonography and Computed Tomography Imaging." *Journal of Datta Meghe Institute of Medical Sciences University* 15, no. 1 (2020): 134-35. [https://doi.org/10.4103/jdmimsu.jdmimsu\\_199\\_19](https://doi.org/10.4103/jdmimsu.jdmimsu_199_19).
20. Gupta, P.P., A.M. Dhok, S.T. Shaikh, A.S. Patil, D. Gupta, and N.N. Jagdhane. "Computed Tomography Evaluation of Craniovertebral Junction in Asymptomatic Central Rural Indian Population." *Journal of Neurosciences in Rural Practice* 11, no. 3 (2020): 442-47. <https://doi.org/10.1055/s-0040-1712719>.
21. Pote, M., S. Phatak, and P. Thakare. "Computed Tomographic Evaluation of Intracerebral Hemorrhage." *Journal of Datta Meghe Institute of Medical Sciences University* 14, no. 3 (2019): 179-82. [https://doi.org/10.4103/jdmimsu.jdmimsu\\_75\\_19](https://doi.org/10.4103/jdmimsu.jdmimsu_75_19).
22. James SL, Castle CD, Dingels ZV, Fox JT, Hamilton EB, Liu Z, Roberts NL, Sylte DO, Henry NJ, LeGrand KE, Abdelalim A. Global injury morbidity and mortality from 1990 to 2017: results from the Global Burden of Disease Study 2017. *Injury Prevention*. 2020 Oct 1;26(Supp 1):i96-114.
23. Agrawal A, Cincu R, Goel A. Current concepts and controversies in the management of non-functioning giant pituitary macroadenomas. *Clinical neurology and neurosurgery*. 2007 Oct 1;109(8):645-50.

24. Chole RH, Gondivkar SM, Gadbail AR, Balsaraf S, Chaudhary S, Dhore SV, Ghonmode S, Balwani S, Mankar M, Tiwari M, Parikh RV. Review of drug treatment of oral submucous fibrosis. *Oral oncology*. 2012 May 1;48(5):393-8.
25. Korde SD, Basak A, Chaudhary M, Goyal M, Vagga A. Enhanced nitrosative and oxidative stress with decreased total antioxidant capacity in patients with oral precancer and oral squamous cell carcinoma. *Oncology*. 2011;80(5-6):382-9.
26. Kumar A, Chery L, Biswas C, Dubhashi N, Dutta P, Dua VK, Kacchap M, Kakati S, Khandeparkar A, Kour D, Mahajan SN. Malaria in South Asia: prevalence and control. *Acta tropica*. 2012 Mar 1;121(3):246-55.
27. Chole RH, Patil RN, Basak A, Palandurkar K, Bhowate R. Estimation of serum malondialdehyde in oral cancer and precancer and its association with healthy individuals, gender, alcohol, and tobacco abuse. *Journal of cancer research and therapeutics*. 2010 Oct 1;6(4):487.
28. Pradhan S, Madke B, Kabra P, Singh AL. Anti-inflammatory and immunomodulatory effects of antibiotics and their use in dermatology. *Indian journal of dermatology*. 2016 Sep;61(5):469.
29. Acharya S, Shukla S, Mahajan SN, Diwan SK. Acute dengue myositis with rhabdomyolysis and acute renal failure. *Annals of Indian Academy of Neurology*. 2010 Jul;13(3):221.
30. Gadbail AR, Chaudhary M, Patil S, Gawande M. Actual Proliferating Index and p53 protein expression as prognostic marker in odontogenic cysts. *Oral Diseases*. 2009 Oct;15(7):490-8.