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Original Research Article

Comparative role of tumor marker CA 242 and CA 19.9 in various pancreatic lesions

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ABSTRACT

Background: The pancreas has important endocrine and exocrine function and diseases of it causes significant morbidity and mortality. Diseases of the pancreas thus remain a continuing source of frustration in modern medicine. Clinical parameters have their limitations in diagnosing such lesions. Radiological evaluation also helps in diagnosing these lesions but to a certain extent. A good tumor marker is the answer to these problems. There are two tumor markers CA 242 and CA 19.9 which will not only help in early diagnosis of various pancreatic lesions, but also in differentiating them into neoplastic & non-neoplastic lesions.

Materials and Methods: 100 patients of various pancreatic lesions were evaluated prospectively having USG confirmed pancreatic lesions, unexplained pancreatitis, pancreatic mass or pancreatic cystic lesion or worrisome clinical, imaging (CECT/USG) or laboratory findings.

Results: Serum tumor marker CA 242 is more specific (100%) than CA 19.9(75%) and CA 19.9(71.9%) is more sensitive than CA 242(70.1%) in patients of various pancreatic lesions. While combined serum tumor marker CA 19.9 and CA 242 was more sensitive (70.5%) and specific (100%) than CA 19.9 and CA 242 alone.

Conclusion: For detection of various pancreatic lesions by serum tumor marker CA 19.9 and CA 242, the sensitivity, specificity and positive predictive value increases if markers are used in combination (serum tumor marker CA 19.9 and CA 242).

1. Introduction

The pancreas has important endocrine and exocrine function and diseases of it causes significant morbidity and mortality. Despite the physiological importance of the organ, the retroperitoneal location of the gland and the vague signs and symptoms associated with injury to gland allow diseases to progress relatively unnoticed for extended period of time. Diseases of the pancreas thus remain a continuing source of frustration in modern medicine.[1]

Acute pancreatitis is the most common pancreatic disease while pancreatic cancer is the most lethal disease.[2] Pancreatitis, which was first reported in 17^{th} century, now affects nearly 0.15% of the world population with high morbidity. 55% patients die within 20 years of diagnosis.[3]

Pancreatic cancer is the fourth leading cause of cancer related deaths with an estimated 227,000 deaths reported globally every year.[4] 05-year survival rate of pancreatic cancer is less than 5% due to the diagnosis of the disease at an advanced stage.[5,6]

Alcohol, tobacco and genetic factors have been identified for aggravating pancreatitis. The incidences of pancreatitis are rising in India and are not restricted to one region

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only. The disease should be understood well to reduce their burden on individuals and their families.[2] The alcoholic abuse identified as a cause of acute pancreatitis at a median age of around 40 years compared with median age of biliary etiology around 53 years.[7]

Alcohol is considered the most common cause of pancreatitis followed by genetic or environmental factors. Similarly, the risk of Pancreatitis was observed to be higher among smokers in comparison to non-smokers but could not be attributed as the cause of pancreatitis.[7] Heredity is also a causative factor of Pancreatitis and such patients could be placed among high risk of developing pancreatic cancer, ranging from 40-55%. The disease is more common among male and affects middle aged individuals the most.[8]

Incidence is higher in elderly population (more than 50% in 65–75 years). The incidence is highest among North-eastern Indian regions.[9] Most pancreatic cancers (>85%) are adenocarcinoma.[10]

This study will be useful in giving some leads on the pancreatic cancer possible causes and thereby help in formulating strategies for reducing the burden of this disease.

Clinical parameters have their limitations in diagnosing such lesions. Radiological evaluation also helps in diagnosing these lesions but to a certain extent. A good tumor marker is the answer to these problems. There are two tumor markers which will not only help in early diagnosis of various pancreatic lesions, but also in differentiating them into neoplastic & non-neoplastic lesions.

CA242 is a tumor marker commonly tested along with CEA for detecting various pancreatic lesions while CA 19.9 tumor marker is used primarily in the management of various pancreatic lesions.

2. Aims and Objectives

1. To study the value of tumor marker CA 19.9 & CA 242 in various pancreatic lesions.
2. To compare the values of CA 242 and CA 19.9 in various pancreatic lesions, both non-neoplastic and neoplastic as well as predicting about the prognosis of various neoplastic lesions.

3. Materials and Methods

3.1. Type of study

Prospective

3.2. Period of study

2 years.

3.3. Sample size

100 cases.

3.4. Inclusion criteria

1. All patients > 18 years age and with symptoms of abdominal pain.
2. Patients with USG confirmed pancreatic lesions.
3. Patients having unexplained pancreatitis, pancreatic mass or pancreatic cystic lesion or worrisome clinical, imaging (CECT/USG) or laboratory findings.

3.5. Exclusion criteria

1. Patients < 18 years of age.
2. Pregnant women.
3. Lactating mothers.
4. Patient having moderate or severe cardiac disease
   (a) Myocardial infarction.
   (b) Unstable angina pectoris.
   (c) New York heart association (NYHA) class III/IV congestive heart failure.
   (d) Uncontrolled hypertension.
   (e) Major abnormality documented by ECHO with Doppler.

3.6. Method

This test was based on two-site sandwich enzyme immunoassay principle. Tested specimen was placed into the microwells coated by specific murine monoclonal to human CA 242 and CA 19.9 antibodies. Antigen from the specimen was captured by the antibodies coated onto the microwell surface. Unbound material was removed by washing procedure. Second antibodies – murine monoclonal to human CA242 and CA 19.9, labeled with peroxidase enzyme, are then added into the microwells. After washing procedure, the remaining enz1ymatic activity bound to the microwell surface was detected and quantified by addition of chromogen- substrate mixture, stop solution and photometry at 450 nm. Optical density in the microwell was directly related to the quantity of the measured analyte in the specimen.

4. Result

In this prospective study conducted on 100 patients of various pancreatic lesions admitted to surgery department and evaluated for pathology, biochemistry and radiological investigations following observations were made.

All Neoplastic lesions were confirmed by Histopathological examination as GOLD STANDARD while inflammatory lesions were diagnosed by non-invasive Radiological techniques such as CECT/USG as biopsy is contraindicated in such cases.

Out of these 100 patients, 18 (27%) male patients from 21 – 30 year age group are more common age group from male patients. 08 (23%) female patients from 31 – 40 year age group are more common age group from female

Table 1: Age & gender distribution of the patients (n = 100)

Age (Year)	Male	Female
00 – 10	0 (00%)	0 (00%)
11 – 20	2 (03%)	2 (06%)
21 – 30	18 (27%)	3 (09%)
31 – 40	13 (20%)	8 (23%)
41 – 50	13 (20%)	5 (15%)
51 – 60	9 (14%)	6 (17%)
61 – 70	8 (12%)	5 (15%)
71 – 80	3 (04%)	3 (09%)
81 – 90	0 (00%)	2 (06%)

patients.

Table 2: Clinical presentation in patients of various pancreatic lesions (n = 100)

Clinical presentation	Number of patients (%)
No complain	1 (01%)
Pain in epigastrium/ Abdominal pain	83 (53%)
Nausea –Vomiting	31 (20%)
Weight loss	27 (17%)
Back pain	13 (08%)
Fever	1 (01%)

Table 2 shows that 83 (53%) patients presented with pain in abdomen. Nausea-vomiting was present in 31(20%) patients, Weight loss in 27 (17%) patients. Back pain in 13 (08%) patients, Fever in 1 (01%) patient. Most common clinical presentation was pain in abdomen (53%) followed by nausea and vomiting (20%). Few patients had more than one complains.

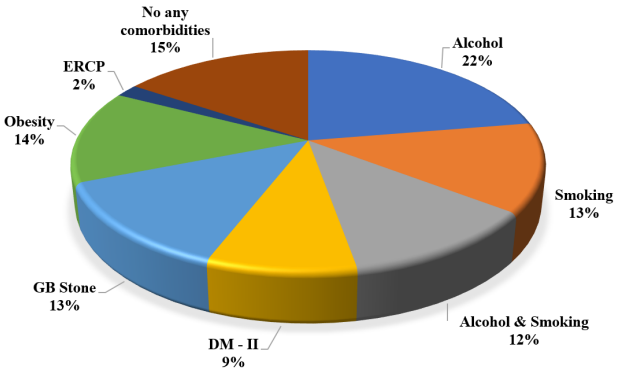

Figure 1: Comorbidties in various pancreatic lesions

Figure 1 show comorbidities in various pancreatic lesions from detailed personal history assessment led us to identification of 22% chronic alcoholic patients and 13% were chronic smoker, out of which 12% were smoker as well as chronic alcoholic.

Table 3: Various lesions of pancreas (n = 100)

Lesions of Pancreas	Number of patients
Non-Malignant Lesions	
Acute Pancreatitis	55 (55%)
Chronic Pancreatitis	26 (26%)
Necrotizing Pancreatitis	02 (02%)
Malignant Lesions	
Malignant Lesion of Pancreas	14 (14%)
Other Malignant Lesions	03 (03%)

In nonmalignant lesions acute pancreatitis (55%), chronic pancreatitis (26%) and necrotizing pancreatitis (02%) lesions were evaluated. Acute pancreatitis (55%) was most common nonmalignant lesion.

In malignant lesions, pancreatic ductal adenocarcinoma was found in 14% patients and in other than pancreatic lesions, pyloric gland, gall bladder and duodenum lesions were 03%.

Table 4: CA 19.9 value range in patients of various pancreatic lesions (n = 100)

CA 19.9 (U/ml)	Number of Patients
Less Than 35	29 (29%)
36 – 70	41 (41%)
71 – 105	16 (16%)
106 -140	04 (04%)
141 – 175	02 (02%)
176 – 210	00 (00%)
211 – 240	00 (00%)
More Than 240	08 (08%)

In these study, serum tumor marker CA 19.9 various value evaluated in various pancreatic lesions. Normal serum tumor marker CA 19.9 value is less than 35 U/ml. 29 (29%) patients, out of total 100 patients was serum tumor marker CA 19.9 value less than 35 U/ml. 41 patients, out of total 100 patients was serum tumor marker value between 36 – 70 U/ml and more common. 08 patients were more than 240 U/ml serum tumor marker CA 19.9.

Table 5: CA 242 value range in patients of various pancreatic lesions (n = 100)

CA 242 U/ml	Number of Patients
Less Than 20	31 (31%)
21 – 40	40 (40%)
41 – 60	09 (09%)
61 – 80	08 (08%)
81 – 100	01 (01%)
101 – 120	02 (02%)
121 – 140	00 (00%)
141 – 160	04 (04%)
161 – 180	02 (02%)
181 – 200	00 (00%)
More Than 200	03 (03%)

In these study, serum tumor marker CA 242 various value evaluated in various pancreatic lesions. Normal serum tumor marker CA 242 value is less than 20 U/ml. 31 (31%) patients, out of total 100 patients was serum tumor marker CA 242 value less than 20 U/ml. 40 patients, out of total 100 patients were serum tumor marker value between 21 – 40 U/ml and more common. 03 patients were more than 200 U/ml serum tumor marker CA 242.

Table 6: Sensitivity, specificity and positive predictive value of serum tumor marker CA 19.9 in various pancreatic lesions (n = 100)

Test Results	Pancreatic Lesions	No Pancreatic Lesions	Total
Serum CA 19.9 Level > 35 U/ml	69	01	70
Serum CA 19.9 Level < 35 U/ml	27	03	30
Total	96	04	**100**

Table 7:

Sensitivity	Specificity	Positive Predictive value	Negative Predictive value
71.9%	75.0%	98.6%	10.0%

69 patients had true positive value means who had pancreatic lesions and tested positive. 03 patients had true negative value means who had no pancreatic lesions and tested negative. 01 patients had false positive value means who had no pancreatic lesions but tested positive. 27 patients had false negative value means who had pancreatic lesions but tested negative.

Sensitivity & specificity of serum tumor marker CA 19.9 was 71.9% & 75% respectively.

Positive predictive value & negative predictive value of serum tumor marker CA 19.9 was 98.6% & 10% respectively.

In these study, 68 patients, out of total 100 patients had true positive value means who had pancreatic lesions and tested positive. 03 patients out of total 100 patients had true negative value means who had no pancreatic lesions and tested negative. No patients had false positive value means who had no pancreatic lesions but tested positive. 29 patients out of total 100 patients had false negative value means who had pancreatic lesions but tested negative.

Sensitivity of serum tumor marker CA 242 is 70.1%. It means, ability of serum tumor marker CA 242 to identify correctly all those who have the pancreatic lesions, that is true positive.

Specificity of serum tumor marker CA 242 is 100%. It means, ability of serum tumor marker CA 242 to identify correctly those who do not have the pancreatic lesions, that is true negative.

Positive predictive value of serum tumor marker CA 242 is 100%. It means, the predictive value which reflects the diagnostic power of serum tumor marker CA 242. The predictive value of positive serum tumor marker CA 242 indicates the probability that a patient with a positive serum tumor marker value of CA 242 has, in fact the pancreatic lesion.

Negative predictive value of serum tumor marker CA 242 is 9.4%. It means, the predictive value which reflects the diagnostic power of serum tumor marker CA 242. The predictive value of negative serum tumor marker CA 242 indicates the probability that a patient with a negative serum tumor marker value of CA 242 has, in fact no pancreatic lesion.

In these study, 67 patients, out of total 100 patients had true positive value means who had pancreatic lesions and tested positive. 05 patients out of total 100 patients had true negative value means who had no pancreatic lesions and tested negative. No patients had false positive valued. 28 patients out of total 100 patients had false negative value means who had pancreatic lesions but tested negative.

Sensitivity of combined serum tumor marker CA 19.9 & CA 242 is 70.5%. It means, ability of combined serum tumor marker CA 19.9 & CA 242 to identify correctly all those who have the pancreatic lesions, that is true positive.

Specificity of combined serum tumor marker CA 19.9 & CA 242 is 100%. It means, ability of combined serum tumor marker CA 19.9 & CA 242 to identify correctly those who do not have the pancreatic lesions, that is true negative.

Positive predictive value of combined serum tumor marker CA 19.9 & CA 242 is 100%. It means, the predictive value which reflects the diagnostic power of combined serum tumor marker CA 19.9 & CA 242. The predictive value of combined positive serum tumor marker CA 19.9 & CA 242 indicates the probability that a patient with a combined positive serum tumor marker CA 19.9 & CA 242 has, in fact the pancreatic lesions.

Negative predictive value of combined serum tumor marker CA 193.9 & CA 242 is 15.2%. It means, the predictive value which reflects the diagnostic power of combined serum tumor marker CA 19.9 & CA 242. The predictive value of negative combined serum tumor marker CA 19.9 & CA 242 indicates the probability that a patient with a negative combined serum tumor marker CA 19.9 & CA 242 has no pancreatic lesion.

From this study, serum tumor marker CA 242 is more specific than CA 19.9 and CA 19.9 is more sensitive than CA 242 in patients of various pancreatic lesions. While combined serum tumor marker CA 19.9 and CA 242 was more sensitive and specific than CA 19.9 and CA 242 alone.

5. Discussion

The pancreas has important endocrine and exocrine function and diseases of it causes significant morbidity and mortality.

Table 8: Sensitivity, specificity and positive predictive value of serumtumor marker CA 242 in various pancreatic lesions (n = 100)

Test Results	**Pancreatic Lesions**	**No Pancreatic Lesions**	**Total**
Serum CA 242 Level > 20 U/ml	68	00	68
Serum CA 242 Level < 20 U/ml	29	03	32
Total	97	03	100
Sensitivity	**Specificity**	**Positive Predictive value**	**Negative Predictive value**
70.1%	100%	100%	9.4%

Table 9: Sensitivity, specificity and positive predictive value of serum tumor marker CA 19.9 and CA 242 in various pancreatic lesions (n = 100)

Test Results	**Pancreatic Lesions**	**No Pancreatic Lesions**	**Total**
Serum CA 19.9 Level > 35 U/ml Serum CA 242 Level > 20 U/ml	67	00	67
Serum CA 19.9 Level < 35 U/ml Serum CA 242 Level < 20 U/ml	28	05	33
Total	95	05	100
Sensitivity	**Specificity**	**Positive Predictive value**	**Negative Predictive value**
70.5%	100%	100%	15.2%

Despite the physiological importance of the organ, the retroperitoneal location of the gland and the vague signs and symptoms associated with injury to gland allow diseases to progress relatively unnoticed for extended period of time.

Throughout the last decades, pancreatitis remains one of the most extensively investigated therapeutic problems with a hardly improvable course. The incidence of the first attack of pancreatitis has increased in past decades. In 80% of acute pancreatitis patients, pancreatic injury is mild or moderate and self-limiting, requiring only brief hospitalization to recover without complications. About 25% of the patients is associated with organ failure and local complications. [11]

The etiology of various pancreatic lesions is complex because many different factors have been implicated in the causation of the disease and there are some times no identifiable cause. Two factors alcohol abuse and smoking are accounting for 80-90% of cases and variety of other causes are responsible for 10-20% of case. [12]

Malignant lesion of pancreas is a lethal malignancy and fourth or fifth commonest cause of cancer mortality. Various pancreatic lesions such as pancreatitis & pancreatic carcinomas carry a grave prognosis if not diagnosed early & treatment not started early.

We compared various study of serum tumor marker CA 19.9 in various pancreatic lesions. In C. Haglund et al, 1994 [13] study, out of total 179 patients, sensitivity of serum tumor marker CA 19.9 was 83% and specificity was 81%. In these study, serum tumor marker CA 19.9 sensitivity is more than specificity. In Jiang JT et al, 2004 [14] study, out of total 200 patients, sensitivity of serum tumor marker CA 19.9 was 82% and specificity was 86.5%. In these study, serum tumor marker CA 19.9 specificity is more than sensitivity. In Int J Clin Exp Med et al, 2015 [12] study, out of total 138 patients, sensitivity of serum tumor marker CA 19.9 was 75.4% and specificity was 77.6%. In these study, serum tumor marker CA 19.9 specificity is more than sensitivity.

In present study, out of total 100 patient's sensitivity of serum tumor marker CA 19.9 was 71.9% and specificity was 75%. Serum tumor marker CA 19.9 specificity is more than sensitivity. Sensitivity and specificity were closer to the Int j clin exp med et al, 2015 [15] study.

We compared various study of serum tumor marker CA 242 in various pancreatic lesions. In C. Haglund et al, 1994 [13] study, out of total 179 patients, sensitivity of serum tumor marker CA 242 was 74% and specificity was 91%. In Jiang JT et al, 2004 [14] study, out of total 200 patients, sensitivity of serum tumor marker CA 242 was 79% and specificity was 93.5%. In Int J Clin Exp Med et al, 2015 [15] study, out of total 138 patients, sensitivity of serum tumor marker CA 242 was 67.8% and specificity was 83%. In all these three studies, serum tumor marker CA 242 specificity is more than sensitivity.

In present study, out of total 100 patient's sensitivity of serum tumor marker CA 242 was 70.1% and specificity was 100%. In present study, serum tumor marker CA 242 specificity is more than sensitivity. Sensitivity was closer to the Int J Clin Exp Med et al., 2015 [15] study and specificity was closer to the Jiang JT et al., 2004 [14] study.

6. Conclusion

The serum tumor marker CA 19.9 and CA 242 are a good indicator for the various pancreatic lesions, and they can be used as a marker to check for the diagnosis and progression of various diseases. Serum tumor marker CA 19.9 and CA 242 can be used as marker of choice in primary diagnosis

of a various pancreatic lesions when an early diagnosis is required or when an invasive methods like fine needle aspiration and or Biopsy is not possible due to patient conditions or contraindication. Serum Amylase & serum lipase are also raised in various pancreatic lesions & more commonly in acute pancreatitis.

In cases of various pancreatic lesions, serum tumor marker CA 19.9 and CA 242 value increases significantly above the standard (< 35 U/ml; < 20 U/ml respectively) reference ranges but in majority of cases the values are between range of 35 to 70 U/ml in CA 19.9 and 20 to 40 U/ml in CA 242. Serum tumor marker CA 242 is more specific than CA 19.9, while CA 19.9 is more sensitive than CA 242 when used alone. Combined serum tumor marker CA 19.9 and CA 242 are more specific than CA 19.9 or CA 242 alone.

For detection of various pancreatic lesions by serum tumor marker CA 19.9 and CA 242, the sensitivity, specificity and positive predictive value increases if markers are used in combination (serum tumor marker CA 19.9 and CA 242). Serum tumor marker is a useful tool for selection of patients for biopsy or complete excision in cases of malignant lesions, while histopathological examination can be safely avoided in pancreatitis because of contraindication.

7. Source of Funding

None.

8. Conflict of Interest

None.

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