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**Prediction of Post-ERCP Pancreatitis
by 4-Hour Post-ERCP Serum Amylase
and Lipase Levels**

by

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Major in Medicine

Department of Medical Sciences

The Graduate School, Ajou University

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**A Dissertation Submitted to The Graduate School of
Ajou University in Partial Fulfillment of the Requirements
for the Degree of Master of Medicine**

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Major in Medicine

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**This certifies that the dissertation
of Yeon Kyung Lee is approved.**

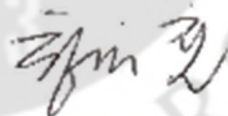
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- Abstract -

**Prediction of Post-ERCP Pancreatitis by 4-Hour Post-ERCP Serum
Amylase and Lipase Levels**

Background & Aims : Acute pancreatitis is the most common, serious complication of endoscopic retrograde cholangiopancreatography (ERCP). Early prediction of post-ERCP pancreatitis (PEP) could enable earlier safe discharge of patients on the same day after ERCP. This study investigated a predictive cut-off value of 4-hour post-ERCP serum amylase and lipase levels for PEP.

Methods : We retrospectively evaluated patients who underwent ERCP procedures and testing for serum amylase and lipase 4-hours after ERCP and the next morning at Ajou Medical Center from January 2012 to August 2013. We studied; patient demographics, procedure reasons, pancreatogram performance, and serum amylase and lipase levels.

Results : PEP occurred in 16 (3.1%) patients after 516 ERCP procedures. Its severity was mild in 4 (25%), moderate in 9 (56.3%), and severe in 3 (18.8%). Mean 4-hour amylase level was significantly higher in patients with PEP; than in those without (965 U/L vs. 158 U/L, $P = .001$). No statistically significant differences occurred in age, sex, and procedure reasons between both groups. Sensitivity, specificity and negative predictive value (NPV) of 4-hour post-ERCP amylase level with a cut-off value of 2.5x upper limit of reference (ULR) (290 U/L) were 39.1%, 98.5% and 97.2%, respectively; with a cut-off value of 8x ULR (480 U/L), they were 60.0%, 97.5% and 99.6%. The patient group undergoing pancreatogram had a high incidence of PEP; but no significant difference in 4-hour post-ERCP serum amylase and lipase, compared with its counterpart.

Conclusions : Four-hour post-ERCP serum amylase and lipase levels with cut-off values of 2.5x and 8x ULR are proven useful predictive values for earlier safe discharge of patients on the same day after ERCP.

Keywords: Acute Pancreatitis; Endoscopic Retrograde Cholangiopancreatography; Hyperamylasemia

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I . Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a useful procedure for diagnosing and choosing therapy for a variety of biliary and pancreatic disorders, which together have a prevalence of ~2% 9%. (Thomas and Sengupta, 2001; Ito et al., 2007) However, acute pancreatitis is the most common complication associated with ERCP and endoscopic sphincterotomy. (Testoni and Bagnolo, 2001) Because most ERCP procedures are performed on an outpatient basis, early evaluation could allow for the safe discharge of the majority of patients, who will go on to develop only mild symptoms that will be self-limiting. (Sultan and Baillie, 2002) In addition, determining early which patients are at risk for complications would enable timely coordination of overnight admissions and prompt initiation of appropriate supportive therapies for those patients and safe discharge for others. (Sutton et al., 2011)

In trying to identify predictors of post-ERCP pancreatitis (PEP), several parameters can be organized into 3 test categories: 1) pancreatic enzymes, 2) markers of proteolytic activation, and 3) markers of systemic inflammation. (Sultan and Baillie, 2002) Among them, serum amylase and lipase levels are regarded as the most useful markers for early diagnosis of pancreatitis. Although hyperamylasemia is a common and often benign phenomenon that follows ERCP, it has been consistently shown to be associated with PEP. (Sutton et al., 2011) Post-ERCP hyperamylasemia is known to peak between 90 minutes and 4 hours; therefore, it is hypothesized that 4-hour amylase level would be best able to predict subsequent pancreatitis. (Thomas and Sengupta, 2001)

As in many other countries, ERCP has become a common procedure performed in Korea. However, no study has been undertaken that tried to predict PEP. The aim of our study was to establish a cut-off value for 4-hour post-ERCP serum amylase and serum lipase levels in order to early diagnose PEP.

II. Materials and Methods

We carried out a retrospective study on diagnostic or therapeutic ERCP procedures performed at Ajou Medical Center in Suwon, Korea, between January 2012 and August 2013. During this period, 516 ERCP procedures were performed for various indications, and the age of the patients ranged from 14 to 93 years. All procedures were conducted under sedation, using an Olympus side-viewing Video Duodenoscope. Prophylactic antibiotics were routinely administered in the form of a single dose of a second- or third-generation cephalosporin. Most ERCP procedures were planned as one-day procedures unless patient factors dictated otherwise. Exclusion criteria included lack of post-procedure serum amylase and lipase level testing and pre-existing pancreatitis.

Patient data were collected retrospectively. Demographics, reason for procedure (diagnostic or therapeutic), details of the procedure, final diagnosis, and complications were recorded. Each patient had blood taken 4- hours after ERCP, when serum amylase and lipase were measured. All patients were admitted overnight and observed for the development of signs or symptoms.

The study defined pancreatitis as abdominal pain persisting for at least 24 hours associated with an amylase level of at least 2.5 times the upper limit of reference (ULR). Pancreatitis severity was defined as follows: mild pancreatitis required hospitalization for less than 3 nights; moderate pancreatitis required hospitalization for 4-9 nights; and severe pancreatitis required hospitalization for 10 or more nights, necessitated intensive care unit (ICU) admission, or led to the development of local or systemic complications.

Data were entered into a Microsoft Excel spreadsheet and analyzed using Statistical Package for the Social Sciences (SPSS) software version 18.0.0. The Mann Whitney test was used for all statistical testing involving amylase levels. The Fisher's exact test and the linear-by-linear association Chi-square test were used for the contingency tables. A likelihood ratio was computed in order to test the strength of a given diagnostic test. For example, a likelihood ratio for a positive test estimated the odds that a patient who tested positive (e.g. for hyperamylasemia) actually had the disease (pancreatitis). Likelihood ratios were calculated using the following formula: $\text{sensitivity} / (1 - \text{specificity})$.

We selected optimal cut-off values for the serum amylase and lipase levels as predictors of

PEP based on their sensitivity, specificity, and NPV. Cut-off values for our study needed to be useful for ruling out PEP and for ensuring safe discharge on the same day as ERCP. Nevertheless, in spite of low sensitivity and positive predictive value (PPV), we emphasized relatively higher specificity and NPV in selecting our cutoffs.



III. Results

From January 2012 to August 2013, a total of 516 ERCP procedures were performed on 426 patients. Of these, 180 (42.2%) patients were women and 246 (57.8%) patients were men. Their mean age was 62.3 years old (range = 14-93). Of the 516 ERCP procedures studied, 374 were therapeutic (72.5%) and 142 were diagnostic (27.5%). The most common final diagnosis was common bile duct and intrahepatic stones (53.3%) .

Table 1. Patient characteristics

Number of patients	426
Number of procedures	516
Gender:	
-Female	180 (42.2%)
-Male	246 (57.8%)
Age (Mean, years)	62.3 (14 93)
Reason for ERCP	
-Therapeutic	374 (72.5%)
-Diagnostic	142 (27.5%)
Final diagnosis	
Gall-stone disease	
-Gall bladder stone with suspicious common bile duct stones	16 (3.1%)
Common bile duct and intrahepatic stones	275 (53.3%)
-Malignancy biliary stricture	117 (22.7%)
-Benign biliary stricture	27 (5.2%)
-Nonspecific finding	16 (3.1%)
-Other	65 (12.6%)

PEP occurred in 16 (3.1%) patients. Its severity was mild in 4 (25%), moderate in 9 (56.3%), and severe in 3 (18.8%). One patient who developed severe pancreatitis died due to septic shock. He had been treated with major surgery for a hepatobiliary tract malignancy just before ERCP and had experienced a long period of fasting. Except for this one, the rest of the patients recovered with hospitalization. Of the 16 post-ERCP patients who developed pancreatitis, 6 (37.5%) received a pancreatogram and 10 (62.5%) did not.

Table 2. Incidence of post-ERCP pancreatitis

	Pancreatogram (+)	Pancreatogram (-)	Total
Mild (%)	2 (33.3%)	2 (20%)	4 (25%)
Moderate (%)	3 (50%)	6 (60%)	9 (56.3%)
Severe (%)	1 (16.7%)	2 (20%)	3 (18.7%)
	6 (37.5%)	10 (62.5%)	16 (100%)

No statistically significant differences were seen in age ($P = .137$), sex ($P = .122$), and procedure reasons ($P = .819$) between the pancreatogram and non-pancreatogram groups. Some studies have shown the effects of age and female sex as relevant factors in the development of PEP. In contrast, our study found a significant correlation between developing PEP and undergoing pancreatogram ($P = .003$) as well as elevated 4-hour post-ERCP serum amylase ($P = .001$) and lipase levels ($P = .003$). However, without considering other factors that raise the risk of PEP, we cannot be sure that a pancreatogram is significantly correlated with the occurrence of PEP.

Table 3. Patient characteristics of those who had post-ERCP pancreatitis versus those who did not

	Post-ERCP pancreatitis

	Yes (n=16)	No (n=500)	P-value
Age (years)	51.06±20.9	63.75±33.89	0.137
Male sex	6 (37.5%)	285 (57.0%)	0.122
Therapeutic purpose	12 (75%)	362 (72.4%)	0.819
Pancreatogram (+)	6 (37.5%)	62 (12.4%)	0.003
4-hour amylase (U/L)	965.75 ± 775.13	158.49 ± 273.13	0.001
4-hour lipase (U/L)	2018.94 ± 2038.27	222.74 ± 826.53	0.003

Not all patients with 4-hour post-ERCP hyperamylasemia developed PEP. Four patients had PEP, though accompanied by relatively low serum amylase levels (< 2.5 ULR). Sixty patients with hyperamylasemia (> 2.5 ULR) did not have PEP.

Table 4. Serum 4-hour post-ERCP amylase levels of patients who developed post-ERCP pancreatitis versus those who did not

Amylase level	Post-ERCP pancreatitis		Total
	Yes	No	
> 2.5 ULR	12 (75%)	60 (12%)	72 (14%)
> 2 - 2.5 ULR	1 (6.25%)	15 (3%)	16 (3.1%)
> 1.5 - 2 ULR	1 (6.25%)	40 (8%)	41 (7.9%)
≤ 1.5 ULR	2 (12.5%)	385 (77%)	387 (75%)
Total	16	500	516

The receiver-operator characteristic curve for 4-hour post-ERCP serum amylase level as a predictor of PEP is shown in Figure 1. Area under the curve was 0.919 ($P < .001$), demonstrating good test performance. The sensitivity, specificity, and NPV for amylase levels that were 1.5x ULR were 27.3%, 99.2%, and 93.6%; for 2x ULR, they were 27.2%, 98.5%, and 95.2%; and for 2.5x ULR, they were 39.1%, 98.5%, and 97.2%.

Table 5. Cutoff 4-hour post-ERCP amylase levels for predicting pancreatitis

Cut-off value	Positive predictive value	Negative predictive value	Sensitivity	Specificity	Likelihood ratio
Amylase > 2.5xULR	56.2%	97.2%	39.1%	98.5%	27.6
Amylase > 2x ULR	56.2%	95.2%	27.2%	98.5%	18.5
Amylase > 1.5xULR	75.0%	93.6%	27.3%	99.2%	32.4

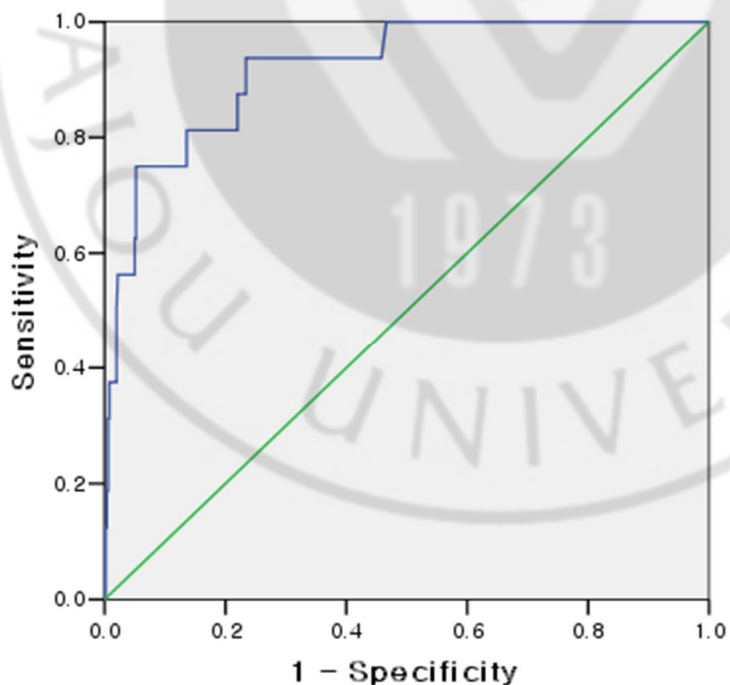


Figure 1. Receiver-operator characteristic curve for 4-hour post-ERCP amylase levels

as a predictor of post-ERCP pancreatitis. Area under the curve = 0.919 ($P < .001$)

As mentioned earlier, having a pancreatogram and a 4-hour post-ERCP serum amylase test were good predictors of PEP. For patients who received a pancreatogram, amylase levels of 2.5x ULR had a sensitivity of 25%, a specificity of 92.2%, and an NPV of 95.2% for PEP. For patients who did not receive a pancreatogram, amylase levels of 2.5x ULR had a sensitivity of 42.1%, a specificity of 99.5%, and an NPV of 97.5% for PEP.

Table 6. Cutoff 4-hour post-ERCP amylase levels for predicting pancreatitis in patients who had a pancreatogram (n = 68)

Cut-off value	Positive predictive value	Negative predictive value	Sensitivity	Specificity	Likelihood ratio
Amylase>2.5x ULR	16.7%	95.2%	25.0%	92.2%	3.2
Amylase>2x ULR	16.7%	91.9%	16.7%	91.9%	2.1
Amylase >1.5x ULR	66.7%	88.7%	36.4%	96.5%	10.4

Table 7. Cutoff 4-hour post-ERCP amylase levels for predicting pancreatitis in patients who did not have a pancreatogram (n = 448)

Cut-off value	Positive predictive value	Negative predictive value	Sensitivity	Specificity	Likelihood ratio
Amylase>2.5xULR	80.0%	97.5%	42.1%	99.5%	45.2
Amylase > 2x ULR	80.0%	95.7%	29.6%	99.5%	62.4
Amylase>1.5xULR	80.0%	94.3%	24.2%	94.2%	50.3

Not only 4-hour post-ERCP serum amylase levels, but also serum lipase levels were a

predictor of PEP. The receiver-operator characteristic curve for 4-hour post-ERCP serum lipase level as a predictor of PEP is shown in Figure 2. Area under the curve was 0.933 ($P < .001$), demonstrating good test performance. The sensitivity, specificity, and NPV for lipase level of 2x ULR were 29.4%, 98.8%, and 95.2%; for 4x ULR, they were 41.2%, 98.2%, and 98.0%; and for 8x ULR, they were 60.0%, 97.5%, and 99.6%.

Table 8. Cutoff 4-hour post-ERCP lipase levels for predicting pancreatitis

Cut-off value	Positive predictive value	Negative predictive value	Sensitivity	Specificity	Likelihood ratio
Lipase > 8x ULR	18.8%	99.6%	60.0%	97.5%	24
Lipase > 4x ULR	43.8%	98.0%	41.2%	98.2%	22.9
Lipase > 2x ULR	62.5%	95.2%	29.4%	98.8%	24.5

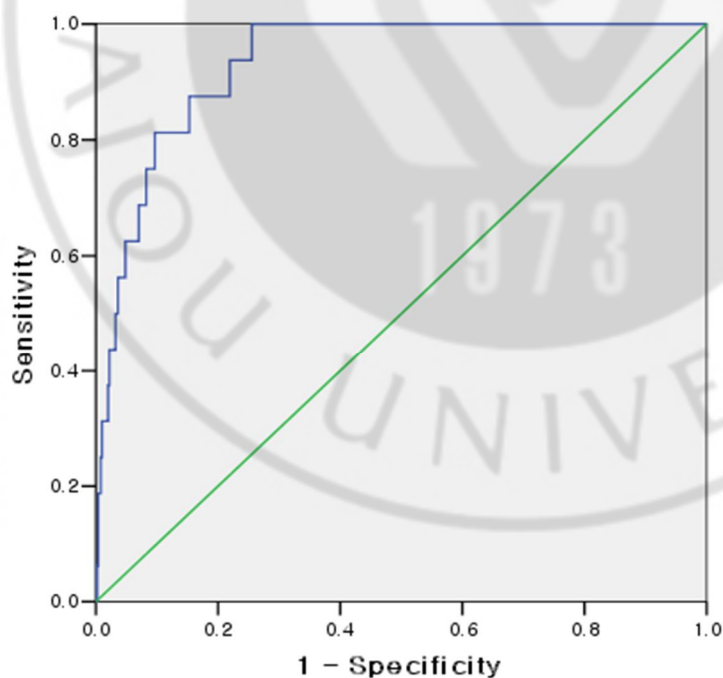


Figure 2. Receiver-operator characteristic curve for 4-hour post-ERCP lipase levels as a

predictor of post-ERCP pancreatitis. Area under the curve=0.933 ($P < .001$)

Otherwise, having a pancreatogram and a 4-hour post-ERCP serum lipase test did not have a significant relationship to developing PEP. (All patients who had both PEP and received a pancreatogram had 4-hour post-ERCP hyperlipasemia $< 4x$ ULR.)



IV. Conclusions

Various studies have been done in order to predict PEP and identify risk factors. Although previous studies have suggested that early hyperamylasemia can be a predictor of PEP, each of them reported different test timings, predictive values, and cut-off values. Also, most previous studies showed that a pancreatogram increases the risk of PEP.

Our study demonstrated that hyperamylasemia 4- hours after ERCP is strongly associated with PEP; and that patients who received a pancreatogram were at higher risk for PEP than those who did not have a pancreatogram. We also found that hyperlipasemia 4- hours post-ERCP can be a predictive factor for PEP.

The optimal timing for measuring post-ERCP amylase and lipase levels has been controversial, so many studies were designed to determine this timing. In the absence of pancreatitis, serum amylase levels peak at 90 minutes to 4 hours after ERCP; and return to normal levels within 48 hours. (Sultan and Baillie, 2002) However, the degree of serum amylase elevation is more marked when PEP occurs. Thus, in addition to timing post-ERCP amylase tests, the degree of serum amylase elevation has also been studied as a predictor of PEP. Early studies documented 2-hour post-ERCP hyperamylasemia. (LaFerla et al., 1986; Gottlieb et al., 1996) To apply a cut-off value for serum pancreas enzyme levels for predicting PEP, we also must consider its practical usefulness. Relatively lower risk patients can be discharged earlier; in other patients, early treatment for PEP must be started. Recently, laboratory techniques have made great progress and test results are now available ever more rapidly. In other studies, 2-, 4-, 8-, and 24-hour post-ERCP hyperamylasemia levels were considered for their predictive value for PEP; however, 8- and 24-hour serum amylase level has the limitation of frequent same-day discharge after ERCP.

Testoni et al. (Testoni et al., 1999) conducted a study in which serum amylase activity was measured in a prospective series of 409 consecutive patients after they were treated with ERCP. They found that the sensitivity of amylase measurement for detecting PEP was highest 8 hours after ERCP, though; in practice, the 4-hour post-ERCP assessment was more reliable and cost-effective for predicting PEP.

In another study, the authors indicated that pain at 24 hours after ERCP associated with

amylase levels greater than 5x ULR was the most reliable indicator of PEP. (Testoni and Bagnolo, 2001) However, here too, it had less meaning considering the practice of same-day discharge and early management of PEP.

Thomas and Sengupta (Thomas and Sengupta, 2001) demonstrated that 4-hour post-ERCP hyperamylasemia is a reliable predictor of the risk of PEP and useful for excluding pancreatitis at the cut-off level of 1.5x normal, so safe discharge of ERCP day patients could be planned. They suggested an algorithm for patient management following ERCP. Gottlieb et al. developed an algorithm allowing for the discharge of patients whose amylase level is less than 2.4x ULR and lipase level is less than 4.2x ULR. (Gottlieb et al., 1996)

Our data demonstrate that 4-hour post-ERCP hyperlipseamia is a reliable predictor of the risk of PEP, although other studies have questioned its usefulness. Panteghini et al demonstrated that serum lipase level increased faster than levels of other measured enzymes and that the average peak in lipase level was the highest in PEP. (Panteghini et al., 1991) Doppl et al concluded that serum lipase measurement is the most sensitive diagnostic test for PEP. (Doppl et al., 1996) A large retrospective study performed in Japan demonstrated that serum lipase was a more effective marker than amylase for predicting PEP. (Nishino and Toki)

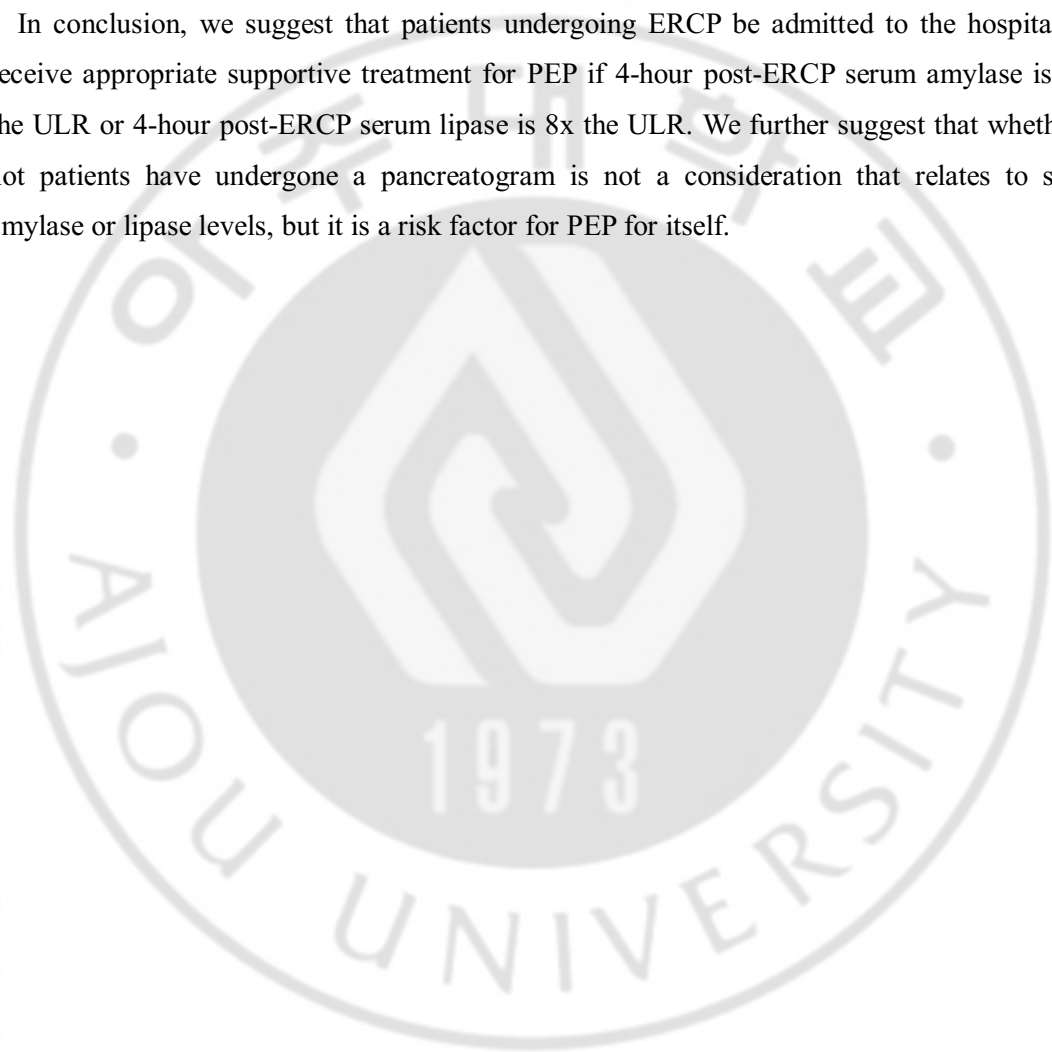
Based on our study data, pancreatogram might be an additional risk factor for PEP. Our study had several limitations. For example, it did not include the fact that difficulty in cannulating the bile duct is a risk factor for PEP, as many studies determined. It was also influenced by the technique of the endoscopist. (Nishino and Toki; Freeman et al., 1996)

Other risk factors for PEP that were studied, such as age, sex and therapeutic purpose, were not shown to be related to PEP. Recently, a study was done to identify risk factors for PEP. This study identified risk factors for PEP as female sex, previous pancreatitis, previous PEP, sphincter of Oddi dysfunction (SOD), intraductal papillary mucinous neoplasm (IPMN), difficult cannulation, endoscopic sphincterotomy (EST), precut sphincterotomy and painful pancreatic duct injection, conflicting with our study results. (Ding et al., 2014)

Here we retrospectively evaluated the relationship between changes in serum pancreatic enzyme levels and PEP in a relatively large series of patients. The incidence of PEP was 3.1% (16 cases in 516 procedures). The 4-hour post-ERCP serum amylase and lipase levels with cut-off values of 2.5x and 8x ULR (NPV, 97.2%, and 99.6%, respectively) have so far proven to be useful predictive values for earlier safe patient discharge on the same day after ERCP. The

patient group that received a pancreatogram had a higher incidence of PEP, but no significant differences in 4-hour post-ERCP serum amylase and lipase levels, compared with the non-pancreatogram group. The results of our study demonstrated that serum lipase was a more effective marker than amylase for predicting PEP, based on sensitivity, specificity and area under the ROC curves. A further prospective study needs to be performed to identify the superiority of serum lipase over amylase for predicting of PEP.

In conclusion, we suggest that patients undergoing ERCP be admitted to the hospital and receive appropriate supportive treatment for PEP if 4-hour post-ERCP serum amylase is 2.5x the ULR or 4-hour post-ERCP serum lipase is 8x the ULR. We further suggest that whether or not patients have undergone a pancreatogram is not a consideration that relates to serum amylase or lipase levels, but it is a risk factor for PEP for itself.



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4시간 후 혈청 아밀라아제와 리파아제 농도를 이용한 내시경

역행성 췌담도 조영술 이후 췌장염 발생의 예측

목적 : 급성 췌장염은 내시경 역행성 췌담도 조영술 이후 흔하게 발생하지만, 치명적일 수 있는 합병증이다. 시술 당일에 안전하게 퇴원 할 수 있기 위해서는 이러한 합병증을 예측할 수 있는 방법이 필요하다. 우리는 시술 4시간 후의 혈청 아밀라아제와 리파아제 농도를 측정하여 급성 췌장염 발생을 예측할 수 있는 절단값을 구하였다.

방법 : 2012년 1월부터 2013년 8월까지, 아주대학교 병원에서 내시경 역행성 췌담도 조영술을 시행한 환자들을 대상으로, 후향적 연구를 진행하였다. 총 516건의 시술에 대해 분석하였다.

결과 : 내시경 역행성 췌담도 조영술 이후 급성 췌장염은 전체 516건의 시술 중 3.1%에서 발생하였다. 그 중증도를 살펴보면, 경증 25%, 중등증 56.3%, 그리고 중증 18.5% 의 분포를 보였다. 시술 4시간 후 혈청 아밀라아제 농도는 급성 췌장염이 발생한 환자에게서 평균적으로 유의하게 높았으며, 민감도, 특이도와 음성 예측도 값이 각각 39.1%, 98.5%, 97.2%를 보이는 농도가 가장 급성 췌장염의 발생을 잘 예측할 수 있는 절단값이었으며 정상의 2.5배였다. 또한 혈청 리파아제 농도도 급성 췌장염이 발생한 환자에게서 평균적으로 유의하게 높았으며, 민감도, 특이도와 음성 예측도 값이 각각 60.0%, 97.5%, 99.6%를 보이는 정상의 8배에

해당하는 농도가 급성 췌장염의 발생을 가장 잘 예측할 수 있는 절단값이었다.

고찰 : 내시경 역행성 췌담도 조영술 시행 4시간 후 혈청 아밀라아제와 리파아제 농도를 측정하여, 각각 정상치의 2.5배와 8배가 급성 췌장염의 발생을 잘 예측할 수 있는 절단값이었다. 이러한 값을 이용하여, 시술 후 환자의 안전한 퇴원 혹은 급성 췌장염에 대한 빠른 치료가 가능할 수 있다.

핵심어 : 급성췌장염, 내시경 역행성 췌담도 조영술, 고아밀라아제혈증

