

Diagnosing acute pancreatitis in children: what is the diagnostic yield and concordance for serum pancreatic enzymes and imaging within 96 h of presentation?

M. J. Coffey¹, S. Nightingale^{2,3}, C. Y. Ooi^{1,4}

¹*School of Women's and Children's Health, Faculty of Medicine, University of New South Wales, Sydney, Australia*

²*Department of Gastroenterology, John Hunter Children's Hospital, Newcastle, Australia*

³*Discipline of Paediatrics and Child Health, School of Medicine and Public Health, University of Newcastle, Newcastle, Australia*

⁴*Department of Gastroenterology, Sydney Children's Hospital Randwick, Sydney, Australia*

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Introduction

The diagnosis of acute pancreatitis (AP) in children requires a high index of clinical suspicion. A recent consensus statement by The International Study Group of Paediatric Pancreatitis: In Search for a Cure (INSPPIRE) consortium recommended the use of the adult diagnostic criteria i.e. the diagnosis of AP requires 2 of the 3 criteria: (1) abdominal pain not due to other causes, (2) elevated serum lipase or amylase >3 times the upper limit of the normal reference range (xULN), and/or (3) imaging evidence of pancreatitis [1, 2]. Nonetheless, there are limitations associated with each criterion in children and, to our knowledge, a systematic evaluation of the laboratory and imaging criteria have not been performed.

Although abdominal pain is the most common presentation, up to one third of patients may not report abdominal pain and radiation of pain to the back occurs in <5% [3, 4, 5, 6]. Pre-verbal children in particular may present with non-specific symptoms [7]. The clinical suspicion of AP is usually supported by the finding of

increases in serum amylase and/or lipase levels. Serum lipase is considered superior to serum amylase and in a recent paediatric study [7], elevated serum lipase, amylase and 'lipase and/or amylase' performed with sensitivities of 77%, 52% and 81% respectively. Regarding imaging, the two most commonly used modalities for the diagnosis of AP are abdominal ultrasonography (US) and computed tomography (CT). Due to its wide availability and reluctance in subjecting children to ionizing radiation, US has been the imaging modality of choice, with 56-84% of children undergoing US upon presentation [7, 8]. However, US has been reported to only identify morphologic changes of AP in about one third to one half of cases [3, 6, 7, 9]. Approximately one third of children with AP undergo CT [8], which show pancreatic changes in only 60-75% of cases [6, 7, 10, 11].

We retrospectively examined the contribution of both serum pancreatic enzymes and imaging to the diagnosis of AP in a cohort of children who already fulfilled the diagnostic criteria for AP. More specifically, we evaluated within 96 h of presentation: (1) the overall diagnostic yield of serum lipase, serum amylase, US and CT for AP; (2) the diagnostic yield when single *vs.* various combinations of tests were performed; and (3) the agreement between serum pancreatic enzyme(s) and imaging.

Methods

Study population. A retrospective review (January 2000 to July 2011) was performed in all patients admitted to the Sydney Children's Hospital Randwick (SCH) and John Hunter Children's Hospital (JHCH). Both hospitals are tertiary referral hospitals for their respective regions in the state of New South Wales, Australia. This study was approved by the human research ethics boards of both participating institutions: South Eastern Sydney Human Research Ethics Committee (10/188) and Hunter New England Human Research Ethics Committee (11/02/16/5.07).

Patients <18 years old at the time of presentation were eligible for inclusion if they had a diagnosis of AP or acute recurrent pancreatitis (ARP). Acute pancreatitis was defined as abdominal pain not due to other causes, *plus* either elevated serum lipase or amylase >3 x ULN and/or imaging evidence of pancreatitis (e.g. pancreatic

interstitial oedema, pancreatic or peripancreatic necrosis, peripancreatic inflammation, acute peripancreatic fluid collections, pancreatic haemorrhage, pancreatic abscess and pancreatic pseudocyst) [1, 2]. Complete resolution of pain *and* at least one month pain free interval between episodes was required to be considered ARP. Each documented episode of ARP was analysed as a separate AP episode. Patients presenting with pain and elevation of serum pancreatic enzyme levels secondary to pseudocyst(s) rather than acute pancreatitis were excluded.

Demographic, clinical, laboratory and radiographic data were collected from medical records of patients with a confirmed diagnosis of AP. Laboratory and radiographic data within 96 h of initial hospital presentation were analysed. For the overall diagnostic test yield and concordance analysis, the following considerations were made: (i) If multiple lipase or amylase results were recorded, then the peak value (within 96 h of initial presentation) for each parameter was analysed; (ii) If one patient had two US or CT investigations recorded and these tests had different results, then a positive result took preference over a negative result. Unavailable data for a given parameter was recorded as missing.

To further evaluate the diagnostic yield according to whether they were performed as a single test or combination of tests, as well as to describe the trends and frequency of tests performed, information on tests performed were determined according to the following time frames from presentation: 0-24 h (24 h), 24-48 h (48 h), 48-72 h (72 h), and 72-96 h (96 h). Within each time period every patient was categorized into one of 16 testing categories, namely L, A, U, C, LA, LU, LC, AU, AC, UC, LAU, LAC, LUC, AUC, LAUC or no testing, with L as lipase, A as amylase, U as ultrasound and C as computed tomography. If a patient presented via a referring hospital, data was included and analysed from the time of initial presentation. Patients in this study have been previously reported in a different context [12, 13].

Statistical analysis. The agreement between serum pancreatic enzymes and imaging modalities was evaluated by calculating observed agreement and Cohen's kappa coefficient (κ) [14]. Observed agreement was calculated as the number of

patients with the same diagnostic finding divided by the total number of patients. Kappa values ranged from -1 (complete disagreement) to 1 (perfect agreement), and interpreted by the degree of agreement: $\kappa < 0$ is none, $\kappa=0.01-0.20$ is poor, $\kappa=0.21-0.40$ is fair, $\kappa=0.41-0.60$ is moderate, $\kappa=0.61-0.80$ is good and $\kappa=0.81-1.00$ is excellent [15, 16, 17].

Descriptive analysis was utilized to describe the frequencies of test combinations within each 24 h period from presentation. Each patient was recorded as having none, one, two, three or all four tests (lipase, amylase, US and CT) performed within each time period (24 h, 48 h, 72 h, 96 h), with each category/combination of testing being mutually exclusive. Diagnostic criteria were satisfied if at least one test within the specified combination was positive (given all patients had abdominal pain). The diagnostic yield for each combination of testing (over 96 h from presentation) was calculated.

Results

Study population. A total of 131 AP episodes from 125 patients were identified from the two institutions. Of these, 28 cases (21%) did not have an US or CT performed within 96 h of presentation and were excluded from further analysis, leaving 103 episodes. Fifty-nine of these cases (57%) were from SCH and 44 (43%) were from JHCH.

The demographic data for the cases included in the analysis are summarized in Table 1. The median age (IQR) of all included AP episodes was 12.1 (9.5-15.1) years with a range of 0.9-17.9 years. Males represented 52% (54/103) of the cohort. The mean weight- for-age z-score (SD) for children during AP episodes was 0.10 (1.5) with a range of -6.07 to 3.14.

Table 1

Episode and patient characteristics

Characteristic	Values
Included episodes, <i>n</i>	103
Serum pancreatic enzymes measured, <i>n</i> (%)	
Lipase	100 (97)
Amylase	80 (78)

Imaging studies performed, <i>n</i> (%)	
Ultrasonography	77 (75)
Computed tomography	42 (41)
Patient age, years, median (IQR)	12,1 (9,5–15,1)
Male gender, <i>n</i> (%)	54 (52)
Weight <i>z</i> -score, mean (SD)	0,10 (1,53)

Yield of serum pancreatic enzymes and imaging in the diagnosis of AP. Lipase, amylase, US and CT within 96 h of initial presentation were performed in 97% (100/103), 78% (80/103), 75% (77/103) and 41% (42/103) of the 103 cases, respectively. Lipase, amylase, US and CT were consistent with a diagnosis of AP in 93% (93/100), 54% (43/ 80), 27% (21/77) and 67% (28/42) of cases respectively (Table 2).

Table 2

Diagnostic yield and concordance of serum pancreatic enzymes and imaging

Test modalities	Concordance data			Observed agreement	κ (95% CI)	
2A. Serum Enzymes and Imaging						
Lipase or Amylase	vs.	US or CT	Lipase or Amylase	US or CT Positive Negative	40%	-0.083 (-0.712 to 0.006)
			(n = 103) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	40 (39%) 5 (5%)	57 (55%) 1 (1%)	
Lipase or Amylase	vs.	US	Lipase or Amylase	US Positive Negative	24%	-0.070 (-0.162 to 0.021)
			(n = 77) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	18 (23%) 3 (4%)	55 (71%) 1 (1%)	
Lipase or Amylase	vs.	CT	Lipase or Amylase	CT Positive Negative	62%	-0.091 (-0.208 to 0.026)
			(n = 42) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	26 (62%) 2 (5%)	14 (33%) 0 (0%)	
2B. Serum Lipase and Imaging						
Lipase	vs.	US or CT	Lipase	US or CT Positive Negative	39%	-0.072 (-0.167 to 0.022)
			(n = 100) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	37 (37%) 5 (5%)	56 (56%) 2 (2%)	
Lipase	vs.	US	Lipase	US Positive Negative	26%	-0.037 (-0.162 to 0.021)
			(n = 74) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	17 (23%) 2 (3%)	53 (72%) 2 (3%)	
Lipase	vs.	CT	Lipase	CT Positive Negative	60%	-0.139 (-0.277 to 0.001)
			(n = 40) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	24 (60%) 3 (8%)	13 (33%) 0 (0%)	
2C. Serum Amylase and Imaging						
Amylase	vs.	US or CT	Amylase	US or CT Positive Negative	63%	0.251 (0.041 to 0.462)
			(n = 80) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	26 (33%) 13 (16%)	17 (21%) 24 (30%)	
Amylase	vs.	US	Amylase	US Positive Negative	64%	0.283 (0.056 to 0.511)
			(n = 59) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	13 (22%) 5 (8%)	16 (27%) 25 (42%)	
Amylase	vs.	CT	Amylase	CT Positive Negative	59%	0.063 (-0.275 to 0.401)
			(n = 34) $\geq 3 \times \text{ULN}$ $< 3 \times \text{ULN}$	16 (47%) 8 (24%)	6 (18%) 4 (12%)	

Overall diagnostic yield of lipase, amylase, US and CT is 93%, 54%, 27% and 67% respectively. This is calculated by the sum of positive results for each test, i.e. lipase has 93 (37 + 56) positive results out of 100 tests (2B). Observed agreement represents the frequency with which both serum pancreatic enzymes and imaging agreed – i.e. for 'lipase or amylase' and 'US or CT' the observed agreement of 40% is the total of 39% positive agreement and 1% negative agreement. Concordance data presents the distribution of cases with enzyme(s) above and below the cut-off of $3 \times \text{ULN}$ (rows) and with positive and negative imaging findings (columns). Kappa value (κ) interpretation of agreement: $\kappa \leq 0$ is none, $\kappa = 0.01-0.20$ is poor, $\kappa = 0.21-0.40$ is fair, $\kappa = 0.41-0.60$ is moderate, $\kappa = 0.61-0.80$ is good and $\kappa = 0.81-1.00$ is excellent. The following considerations were made: (i) If multiple lipase or amylase results were recorded, then the peak value (within 96 h) for each parameter was analysed; (ii) If one patient had two US or CT investigations recorded and these tests had different results, then a positive result took preference over a negative result. Note: one patient (1%) was diagnosed with AP based on elevated amylase after the first 96 h from presentation.

κ , Cohen's kappa statistic; CI, confidence interval; CT, computed tomography; n, number of tests performed; ULN, upper limit of normal; US, ultrasound.

Chronology, frequency and yield of diagnostic tests when performed as single vs. combination of tests. The chronology and frequency of testing according to the combination of tests performed for each patient is presented in Table 3. The highest frequency of testing was within the first 24 h of presentation with 94% (97/103) of patients having at least 1 test performed. Lipase was the most common single test performed, while LA and LAU were the two most commonly performed test combinations within the first 24 h of presentation (n=22). The diagnostic yield when a combination of tests consisting of at least one blood and one imaging test was superior to any single test or combination of two blood tests (i.e. lipase and amylase) (83-100% vs 19-56% respectively).

Concordance between serum pancreatic enzymes and imaging findings.

Serum pancreatic enzymes ('lipase or amylase') vs. imaging ('US or CT'). The concordance between serum pancreatic enzymes and imaging modalities are presented in Table 2. The observed agreement between 'lipase or amylase' and 'US or CT' was 40% (41/103) (Table 2A). A diagnosis of AP within 96 h of presentation was agreed upon by both serum pancreatic enzymes and imaging in 39% (40/103) of cases. Both bloods and imaging missed AP in the remaining 1% (1/103); in this instance, the diagnosis of AP was made after 96 h based on abdominal pain and elevated amylase on day six of admission. In 5% (5/103) of cases, AP was found on imaging but not reflected by serum pancreatic enzymes levels (i.e. positive imaging findings but enzyme(s) <3 x ULN). In contrast, imaging was normal despite elevated serum lipase or amylase in 55% (57/103) of cases. The κ statistic for 'lipase or amylase' vs. 'US or CT' was -0.083, suggesting no agreement.

Serum pancreatic enzymes ('lipase or amylase') vs. US. Ultrasonography was performed in 77 patients (75%). 'Lipase or amylase' agreed with US in 25% (19/77) of cases, with a κ of -0.070 (no agreement) (Table 2A). More specifically, in 71% (55/77) of cases, US was normal despite the presence of AP. US was positive for AP in 3 (4%) cases with normal serum pancreatic enzymes.

Serum pancreatic enzymes ('lipase or amylase') vs. CT. Computed tomography was performed in 42 patients (41%). 'Lipase or amylase' concurred with CT in 62%

(26/42) of cases, with the corresponding κ of -0.091, suggesting no agreement (Table 2A). 33% (14/42) of subjects with a negative CT for AP had a 'lipase or amylase' >3 x ULN. CT was positive for AP in 2 (5%) cases that were associated with 'lipase or amylase' levels <3 x ULN.

Lipase vs. imaging ('US or CT'). The observed agreement between lipase and 'US or CT' was 39% and the κ was -0.072 (no agreement) (Table 2B). Although the observed agreement improved to 60% when lipase was compared against CT only, the level of agreement according to κ statistics remained unchanged. In 2% (2/100) of cases, both serum lipase and imaging (only US performed) results were negative; diagnosis in these 2 cases were made by abdominal pain and elevated amylase on day two and six of admission.

Amylase vs. imaging ('US or CT'). The observed agreement between amylase and 'US or CT' was 63% and the κ was 0.251, suggesting a fair agreement (Table 2C). This level of agreement is similar with the concordance between amylase and US (observed agreement 64%; κ of 0.283) but not so between amylase and CT (observed agreement 59%; κ of 0.063). Serum amylase levels were <3 x ULN in 46% (37/80) of cases, and of these cases, US was positive in 17% (5/30) and CT was positive in 67% (8/12).

Discussion

In this study, we report the diagnostic yield and concordance, within 96 h of presentation, between the various diagnostic measures of serum lipase, serum amylase, US and CT in a cohort of children and adolescents diagnosed with acute pancreatitis using consensus criteria. The overall diagnostic yields, in descending order, were 93% (93/100), 67% (28/42), 54% (43/80) and 27% (21/77) for serum lipase, CT, serum amylase and US respectively. The superiority of lipase over amylase, and CT over US are consistent with previous reports [8]. The concern about radiation likely accounted for CT being the least frequently performed test. Nevertheless, the diagnostic yield was higher compared to amylase and US. A previous study found that CT aided the diagnosis of AP in approximately 60% of cases [7]. Both amylase and US were performed with approximately the same frequency

but the diagnostic yield of amylase was twice that of US.

In general, the diagnostic yield for different combinations of tests was greater than for tests done in isolation. The exception was combination of lipase and amylase, which provided a similar yield to lipase alone. This suggests a role for using combinations of the two different modalities of testing (i.e. blood and imaging tests) in the diagnosis of AP in children. In addition, the "child-friendly" combination of serum lipase and/or amylase in combination with US appears to provide a satisfactory diagnostic yield without subjecting children to unnecessary radiation. Furthermore, a combination of 3 or 4 tests appeared to have a higher diagnostic yield than a combination of 2 tests. These findings anecdotally suggest an improvement in diagnostic yield with an increasing number of testing modalities is performed. In regards to the chronology of testing, the majority of tests were performed within the first 24 and 48 h of presentation (Table 3). Not surprisingly, any combination of tests involving CT was the least performed in contrast to "child-friendly" options of LA and LAU.

Table 3

Chronology, frequency and yield (in bold) of diagnostic testing

#	Test (s)	24 h	48 h	72 h	96 h	Total	
		<i>n</i>	<i>n</i>	<i>n</i>	<i>n</i>	<i>n</i>	Dx %
1	L	9	14	16	6	45	25 56
	C	-	2	-	-	2	1 50
	A	3	3	1	6	13	6 46
	U	4	8	1	3	16	3 19
2	AU	1	-	-	-	1	1 100
	LU	14	1	-	2	17	16 94
	LC	8	3	-	1	12	10 83
	LA	22	38	37	15	112	60 54
	AC	-	-	-	-	-	- -
	UC	-	-	-	-	-	- -
3	AUC	2	-	-	-	2	2 100
	LUC	-	1	-	-	1	1 100
	LAC	9	7	2	3	21	20 95
	LAU	22	12	6	-	40	37 93
4	LAUC	3	1	-	-	4	4 100

Number of patients tested	97	90	63	36	286	186	65
Number of patients not tested	6	13	40	67	126		
Total number of patients	103	103	103	103	412		

Note. The frequency of testing during each 24 h period divided between 16 potential combinations of blood and imaging tests. Each category within each time period is mutually exclusive, thus total number of patients tested plus those not tested equals 103. Furthermore, if a patient had a lipase and US performed, they were classified into the LU category only, not in the L and U categories. The total number (over 96 h) of each combination of testing performed, along with their diagnostic yield is presented. Diagnostic criteria were satisfied if at least one of the tests within the combination was positive, i.e. for LAU, only one test would need to be positive to fulfil the diagnostic criteria.

A, amylase; C, computed tomography; Dx, number of subjects who fulfil the diagnostic criteria; L, lipase; *n*, number of test(s) performed; U, ultrasonography; %, percentage of subjects who met the diagnostic criteria based on the combination of testing on a given day.

Overall, the concordances between the various diagnostic tests were none to fair. Collectively, the observed agreement between 'lipase or amylase' and 'US or CT' was 40% with an agreement level of "none" (κ of -0.083). In more than half (55%) of the cases, a diagnosis was based on elevated serum pancreatic enzymes ($>3 \times \text{ULN}$) alone vs. in 5% of cases where the diagnosis was based on imaging findings alone. A diagnosis of AP was agreed upon by both serum pancreatic enzymes and imaging in 39% (40/103) of cases. When individual diagnostic measures were compared against one another, there was no agreement, with the exception of the concordance between amylase and US (fair agreement). It is likely that this exception is due to the fact that both amylase and US agree in missing a large number of cases of AP. There may be several explanations for these observations. Elevations in amylase are not specific for AP and may be elevated due to a variety of other conditions [8]. Serum lipase is purportedly more specific to AP due to fewer alternative sources of lipase and more sensitive due to the longer half-life compared to serum amylase (lipase $t_{1/2}=6.9-13.7$ h vs. amylase $t_{1/2}=2-2.2$ h) [18]. US maybe unreliable as its diagnostic accuracy, is operator-dependent and may be limited by obscured views of the pancreas due to overlying intestinal gas.

Several additional important observations and insights can be derived from this study. The diagnosis of AP in children can be difficult and easily missed. Normal imaging or serum pancreatic enzyme levels $<3 \times \text{ULN}$ may occur in spite of AP. Based on this study, the finding of one or two negative diagnostic tests for AP, especially if the initial test(s) performed may have compromised diagnostic performance in favour of being "child-friendly", should not deter clinicians from

performing additional and preferably higher yield tests if the suspicion for AP remains high. This is particularly so if only low yield tests such as serum amylase or US have been performed. An improvement in diagnostic yield was observed when a combination of at least one blood and one imaging test is performed. In addition, the low concordance rates observed in our study suggests that the finding of a negative test result should not deter clinicians from making a diagnosis of AP if another test is consistent with AP. The current paediatric and adult consensus statements recommend that if the diagnosis of AP is established by abdominal pain and elevations in the serum pancreatic enzyme activities, imaging is not usually required for the diagnosis in the emergency department or on admission to hospital [1, 2]. Our findings of no to fair relationships between serum pancreatic enzymes and imaging modalities provide support for this notion. Nevertheless, imaging remains important in the identification of specific aetiology such as structural anomaly or biliary obstruction due to stones or sludge, as well as complication(s) of AP [13]. Furthermore, in our study, imaging test(s) increased the combined diagnostic yield and 5% (5/103) of AP cases were diagnosed on positive imaging findings alone. This further supports the decision to consider imaging tests in patients with serum enzyme(s) $<3 \times \text{ULN}$, especially if the index of suspicion for AP remains high.

This study has several limitations including its small sample size. Due to the retrospective nature of this study, patients with a missed diagnosis of AP, e.g. those with no or minimal abdominal symptoms, would not have been included in this study. A further limitation is the variability in the type and timing of tests performed in relation to onset of symptoms. The true concordance between each diagnostic test cannot be determined due to the variance in number or tests performed. This was particularly the case for analyses that involved CT, which was the least commonly performed test. The variability of the timing of diagnostic testing (within the defined time frame) may have limited the accuracy of this study; for instance, the peak rise in serum amylase may have been missed if performed late and pancreatic necrosis may not be evident on CT if it is performed early in the course of admission [19]. The diagnostic yield of CT observed in this study may have been subject to bias. Sicker

children with a more severe course of AP, and therefore more easily detectable morphologic changes, may have been more likely to be subjected to CT imaging compared to those who were not. Furthermore, it is imperative to consider the risks related to radiation from CT. Again due to the nature of this study, it was not possible to perform a more in-depth analysis looking at specific imaging findings and height of serum pancreatic enzymes. Other imaging modalities such as magnetic resonance imaging and/or cholangiopancreatography (MRI/MRCP) could not be properly assessed due to the very small numbers of children who underwent this imaging in our cohort (n=6). Data collection was also limited by the availability of medical records. There were 8 children who were referred to the study institutions after presenting initially to a referring centre, however results for these patients were taken from the time of initial presentation to ensure consistency. Large multicentre prospective studies involving subjects from different demographics and regions, performing different tests concurrently and incorporating other diagnostic tests such as serum trypsinogen and MRI/MRCP are needed.

Conclusion

In a cohort of children with AP, elevated serum lipase $>3 \times$ ULN contributed most to the diagnosis, followed by CT, amylase and US. Combinations of diagnostic tests, especially those utilizing both blood and imaging, provide the highest diagnostic yield. There was no to fair concordance between elevated serum pancreatic enzymes and abnormal imaging. Abnormal imaging contributes to diagnosis of AP when pancreatic enzymes are not elevated ($>3 \times$ ULN) in only 5% of cases. Awareness of the contributions and limitations of each diagnostic measure may help reduce the number of missed cases of AP in children.

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¹*School of Women's and Children's Health, Faculty of Medicine, University of New South Wales, Sydney, Australia*

²*Department of Gastroenterology, John Hunter Children's Hospital, Newcastle, Australia*

³*Discipline of Paediatrics and Child Health, School of Medicine and Public Health, University of Newcastle, Newcastle, Australia*

⁴*Department of Gastroenterology, Sydney Children's Hospital Randwick, Sydney, Australia*

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Key words: concordance, enzymes, imaging, children, pancreatitis, lipase

Background/objectives. There are limitations and challenges with the diagnosis of acute pancreatitis (AP) in children. We evaluated the diagnostic yield and concordance for serum pancreatic enzymes and imaging in children with AP.

Methods. A retrospective review of laboratory and radiographic results within 96 h of AP presentation (January 2000 — July 2011) was performed at two paediatric hospitals. Observed agreement and kappa statistics (κ) were determined between outcomes of bloods (lipase and/or amylase) and imaging (ultrasound (US) and/or computed tomography (CT)).

Results. A total of 103/131 (79%) AP cases had both bloods and imaging performed (within 96 h). Overall, lipase, amylase, US and CT were consistent with an AP diagnosis in 93% (93/100), 54% (43/80), 27% (21/77) and 67% (28/42) of cases respectively. The diagnostic yield for combinations of blood(s) and imaging(s) tests was higher than any single test and blood tests alone. The observed agreement between bloods 'lipase or amylase' and imaging 'US or CT,' was 40%. The κ was

0.083 suggesting no agreement. In 55% of cases, enzymes were positive whilst imaging was negative and the converse was evident in 5% of cases. There was no agreement between the various diagnostic tests, except between amylase and US, which had fair agreement.

Conclusion. Elevations in serum lipase contributed to the diagnosis more often than other tests. Combinations of blood(s) and imaging(s) tests have an increased diagnostic yield. Serum enzyme elevation and imaging changes poorly correlated. At least 5% of cases of AP may be missed if imaging is not performed.