EQUIPMENT REVIEW

The use of the Rapignost strip for estimating urinary amylase levels

SUMMARY

The Rapignost-Amylase urinary test strip (Behringwerke Laboratories) provides an estimation of urine amylase which takes a few minutes and is easy to perform. During a period of 9 months, 84 patients had their urine tested with this strip by casualty officers in the Accident and Emergency Department of St George’s Hospital, London. In addition, urine amylase, and plasma amylase and creatinine were measured in the chemical pathology laboratory. In all but one instance, the result of the strip test agreed with the laboratory result. The Rapignost strip should prove useful in screening for acute pancreatitis in situations where there is likely to be a delay in obtaining a laboratory amylase result.

INTRODUCTION

The clinical manifestations of acute pancreatitis are not specific, and measurement of plasma amylase is usually performed to provide biochemical evidence for the condition, so that appropriate management may be instituted. Solomon (1978) states that 95% of patients with acute pancreatitis have an increased plasma amylase from 2–12 hours after its onset, and that the plasma amylase returns to normal within 3 or 4 days. Conditions such as intestinal obstruction, ruptured ectopic pregnancy, perforated peptic ulcer, acute cholecystitis and dissecting aortic aneurysm may produce a similar clinical picture with an increased plasma amylase (Abruzzo et al., 1958; Brooks, 1972; Kelley, 1957) but it does not usually rise above twice the upper limit of normal. It is characteristically higher in acute pancreatitis.

Laboratory measurement of plasma amylase is not immediately available in all situations, and a rapid and reliable bedside test for urine amylase would be a useful alternative. In patients with acute pancreatitis whose renal function is not grossly impaired, the urine amylase is usually greatly increased and does not return to normal for 7 to 10 days after the plasma amylase has become normal (Solomon, 1978). This feature is advantageous if a patient presents some days after the onset of pain. Although the causes of hyperamylasaemia mentioned above are also sometimes associated with increased urine amylase, the increase in pancreatitis is usually very much greater, reflecting as it does both the increase in plasma amylase and the increase in its urinary
METHODS

At the start of the study, the Rapignost strips were calibrated in terms of amylase iu/l by testing a series of urine specimens of known amylase levels, and determining at which concentrations the strips just registered '+ +'. At this stage a number of different observers were invited to view the colour changes to check the agreement between them.

From April to December 1984, all casualty officers at St George's Hospital were asked to follow a set procedure when they attended patients who presented with abdominal pain. All patients in whom a diagnosis of acute pancreatitis was considered were asked to provide a urine specimen to be tested by the casualty officer with the Rapignost strip and then sent to chemical pathology, together with a plasma specimen for amylase and creatinine measurement. In practice about half the suitable patients had their urine tested, because some were unable to pass urine at the time, and some casualty officers forgot about the study.

During the first half of the study, the strip test was performed according to the manufacturer's instructions. One hundred microlitres of urine were pipetted onto the application zone with a tuberculin syringe. After the diffusion front had passed completely through the detection zone, but not less than 2 minutes from the time of application, the purple colour produced by the breakdown of a carboxymethyl starch compound was graded as negative, '+ ' or ' + + ' by comparison with the coloured chart supplied with the strips. The volume applied was increased to 150 µl for the second half of the study, because some urines had taken several minutes to pass through the detection zone. This problem did not recur.

Urine and plasma amylase assays were performed by the chemical pathology laboratory on the Technicon RA-1000 random access analyser using Boehringer reagents (Boehringer, Mannheim). Amylase activity was measured by monitoring the hydrolysis of a chromogenic substrate, p-nitrophenylmaltoheptaoside. The analyser has been calibrated to produce results in the same range as the widely used Phadebas method (Pharmacia, Milton Keynes). The laboratory's upper reference limits for plasma and urine amylase are 300 and 2000 iu/l respectively. Plasma creatinine was also measured, using a kinetic Jaffé method on the RA-1000, to establish whether any patients with pancreatitis had an inappropriately low urine amylase due to impaired renal function. The upper reference limit for creatinine is 110 µmol/l.

The diagnoses of all the patients who were admitted were confirmed from examination of their notes and of the results of subsequent investigations, which included laparotomies in several of the patients who were not thought to have acute pancreatitis.
RESULTS

Calibration of the strips was achieved by testing urines of known amylase concentration. A negative strip reading was found to correspond with a laboratory result of less than 2700 iu/1. A reading of ‘+’ was recorded for results between 2700 and 10,000 iu/1. A reading of ‘++’ was recorded for results above 10,000 iu/1. When the same urines were tested by several different casualty officers, there were no differences between their gradings of the colour changes.

When the Rapignost test was performed on urine samples from the 84 patients, the results were in good agreement with the laboratory amylase values. There were no incorrect positive results, although one patient had a urine amylase of 14,830 iu/1 and was graded ‘+’ where ‘++’ would have been expected. There was only one incorrect negative result, recorded in a patient with pancreatitis whose laboratory urine amylase result was 3955 iu/1.

Twelve patients’ urines gave positive results with the strip test (Table 1). The four patients who scored ‘++’ and four of the patients who scored ‘+’ had acute pancreatitis. The remaining four patients graded ‘+’ had a diagnosis other than acute pancreatitis; one had a strangulated femoral hernia and three had cholecystitis. These four patients subsequently underwent surgery which confirmed their diagnoses. None of the patients in this group had increased plasma creatinine levels.

<table>
<thead>
<tr>
<th>Rapignost strip result</th>
<th>Lab amylase urine iu/l</th>
<th>Lab amylase plasma iu/l</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ +</td>
<td>52052</td>
<td>10345</td>
<td>Acute pancreatitis</td>
</tr>
<tr>
<td>+ +</td>
<td>38698</td>
<td>2672</td>
<td>Acute pancreatitis</td>
</tr>
<tr>
<td>+ +</td>
<td>26950</td>
<td>5690</td>
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<tr>
<td>+ +</td>
<td>21760</td>
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<tr>
<td>+</td>
<td>8915</td>
<td>8370</td>
<td>Acute pancreatitis</td>
</tr>
<tr>
<td>+</td>
<td>5985</td>
<td>179</td>
<td>Strang. fem. hernia</td>
</tr>
<tr>
<td>+</td>
<td>5945</td>
<td>468</td>
<td>Recent pancreatitis</td>
</tr>
<tr>
<td>+</td>
<td>4295</td>
<td>537</td>
<td>Cholecystitis</td>
</tr>
<tr>
<td>+</td>
<td>3370</td>
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</tr>
<tr>
<td>+</td>
<td>3358</td>
<td>864</td>
<td>Acute pancreatitis</td>
</tr>
<tr>
<td>+</td>
<td>2710</td>
<td>244</td>
<td>Cholecystitis</td>
</tr>
</tbody>
</table>

The remaining 71 patients who had laboratory urine amylase results below 2700 iu/1 had negative strip tests. One of these had a plasma amylase of 879 iu/1 although his urine amylase was only 691 iu/1. There was no evidence of impaired renal function, as judged by his plasma creatinine result of 77 μmol/1. He was an alcoholic who had previously had acute pancreatitis and this attack of pain was considered, but not proved, to be due to a further attack. None of the other patients in this group had acute pancreatitis, and none had significant increases in plasma amylase or creatinine.
DISCUSSION

The results obtained by the Rapignost strip were correct in 83 out of 84 tests by a variety of operators in a busy department. This suggests that the strip is sufficiently robust and reliable for practical application, although firm conclusions cannot be drawn because there were only 12 positive results.

This study demonstrated that a negative Rapignost result is unlikely in a patient with acute pancreatitis and that, although positive results did not confirm the diagnosis, they were associated with conditions serious enough to require admission to hospital.

It is interesting that a patient with a diagnosis of recent acute pancreatitis complained of abdominal pain of sudden onset 3 days earlier and had a moderately increased plasma amylase (468 iu/1) by the time he presented, but a urine amylase of 5945 iu/1, which was detected by the strip. This is consistent with the longer persistence of an increased urine amylase in acute pancreatitis (Solomon, 1978).

In a recent study, Holdsworth et al. (1984) tested the Rapignost strip on 61 patients with acute abdominal pain. They reported that eight of their patients who had positive Rapignost urine tests were ‘false positives’, because they had a normal plasma amylase. They did not, however, measure urine amylase in their laboratory. In the light of our findings these patients may well have had increases in urine amylase for reasons other than acute pancreatitis.

CONCLUSIONS

As there were only 12 positive strip results in this study, conclusions must still be guarded. However, the Rapignost strip is a promising addition to the range of tests available in an accident and emergency department, or in general practice. It should aid the diagnosis of acute pancreatitis, and may help to avoid unnecessary laparotomies.

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REFERENCES


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