Prospective audit of mucosal biopsy specimens of the gastrointestinal tract

P M Stephenson, P J Gallagher

Abstract

Aims—To determine why mucosal biopsy specimens of the gastrointestinal tract were taken and whether they were justified on clinical or pathological grounds.

Methods—A prospective audit of 190 consecutive biopsy specimens received in a university hospital histology department over six weeks.

Results—The 31 separate presenting symptoms included diarrhoea (34%), abdominal pain (16%) and rectal bleeding (15%). In 41% (78/190) the histology was normal, 28% (53/190) showed inflammatory changes and 11% (21/190) carcinoma. A clear justification for the procedure was identified in over 90% (171/190) of patients. In 36% (68/190) there was a change in patient management on receipt of biopsy reports and further investigations were ordered in 29% (55/190). The mean time taken to report biopsy specimens was 4.7 working days and there was no difference between the reporting time of a pathologist compared with a consultant or a trainee.

Conclusions—There is no evidence that mucosal biopsy specimens are taken unnecessarily.

Keywords: Audit, mucosal biopsy specimens, patient management.

For the past 10 years, mucosal biopsy specimens of the gastrointestinal tract have made up about 15% of our surgical histology workload and in absolute numbers have increased each year. Further increases are likely as general practitioners expect increased access to endoscopic services and the numbers of colonoscopies rises to levels recommended by specialist advisory groups. Pathologists are rightly concerned about the accuracy and consistency with which these biopsy specimens are reported, but we are more concerned about the clinical value of the biopsy itself. Before this study began we had the impression that many were histologically normal and sometimes questioned their value, both in terms of patient management and the proper use of laboratory services. After a short pilot investigation we designed a prospective clinico-pathological study to test our hypothesis that a significant number of mucosal biopsy specimens are unnecessary or, at least, contribute little to patient management.

Methods

All mucosal biopsy specimens from the gastrointestinal tract received in the Southampton University Hospital histopathology laboratory over a consecutive six week period were studied. Oral, dental, pharyngeal, and perianal biopsy specimens were excluded.

Eighty items of clinical or pathological information were recorded for each case, coded on a proforma, transferred onto tape, and analysed using spss-x. The analyses were mainly descriptive using frequency tables and histograms; some cross tabulations were also performed and some new summary variables were created to express detailed data more intelligibly.

The information from the histology request cards and the biopsy reports was largely factual and could be transferred into numerical data with little difficulty. All histology was reviewed and where necessary discussed with the pathologist who originally reported the case. The clinical records were examined no less than four weeks after the biopsy. The information extracted included details of major symptoms, their severity and duration, past illnesses, treatment at the time of biopsy, and further investigations ordered after the biopsy report was received. Changes in drug treatment and patterns of investigation and management that were related to the receipt of the biopsy report were graded using the guidelines summarised in table 1. A combination of histological and clinical information was used to define justifications for the biopsy procedure. In a small number of cases these were discussed with the responsible clinicians.

Results

The median age of the 190 patients studied was 58 years (range eight to 95 years) and the sex ratio was exactly equal. The biopsies were performed at five separate hospitals and only one health centre. Patients were seen by 29 different accredited specialists; two gastroenterologists accounted for 35% of all cases.

Table 1 Definitions used to assess changes in treatment or management

<table>
<thead>
<tr>
<th>Degree of change</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change</td>
<td>Same drugs Same treatment plan Continued investigation of current problem following unhelpful biopsy report</td>
</tr>
<tr>
<td>Minor change</td>
<td>Changes in dose of same drug Different class of drug but treatment based on same diagnosis as before biopsy Variation in treatment but based on same diagnosis as before biopsy report, but excluding invasive or operative procedures</td>
</tr>
<tr>
<td>Major change</td>
<td>Invasive procedure on operation after receipt of biopsy report Any drug or treatment change based on a new or different diagnosis</td>
</tr>
</tbody>
</table>

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Seven specialists submitted one biopsy specimen only. Over the six weeks of the study the biopsy specimens were examined by five consultants and nine trainee pathologists.

**Histopathology**

There were 73 (38.4%) rectal, 38 (20%) gastric and 38 (20%) colonic, 24 (12.6%) small intestinal, and 17 (9%) oesophageal biopsy specimens; 47% (89/190) of all patients had had a previous histology report issued by the department.

There were 49 different histopathological diagnoses. In 41% (78/190) the histology was normal, carcinoma was diagnosed in 11% (21/190) and inflammation or inflammatory bowel disease in 26% (50/190). Of the biopsy reports, 42% (80/190) had no histological detail apart from a diagnosis. In the others, 33 different features were described as present or absent. On review, there were no major disagreements with the original diagnosis and minor disagreements in only two of the 190 cases.

The average time between the arrival of the specimen in the laboratory and the dispatch of the signed report was 4.7 working days (SD 1-9, range one to 14 working days); 29% (55/190) of reports took more than one working week. Of the urgent requests, 30% (57/190) were dispatched within three and 80% (152/190) within four working days. There was no correlation between either the site of the biopsy or the pathological diagnosis and the total reporting time. Reports produced jointly by a consultant and a member of the junior staff were issued in almost exactly the same time as those by a consultant alone (table 2).

### Table 2

<table>
<thead>
<tr>
<th>Reporting time (in working days)</th>
<th>Consultant alone (%)</th>
<th>Consultant plus junior (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td>22-7</td>
<td>26-8</td>
</tr>
<tr>
<td>4-6</td>
<td>57-7</td>
<td>61-0</td>
</tr>
<tr>
<td>7-9</td>
<td>18-6</td>
<td>11-0</td>
</tr>
<tr>
<td>10+</td>
<td>1-0</td>
<td>1-2</td>
</tr>
</tbody>
</table>

No significant differences were found for the reporting times of the two categories.

### Table 3

<table>
<thead>
<tr>
<th>Histological diagnosis</th>
<th>No change (%)</th>
<th>Minor change (%)</th>
<th>Major change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal histology</td>
<td>82-9</td>
<td>12-2</td>
<td>4-9</td>
</tr>
<tr>
<td>Inflammation</td>
<td>42-3</td>
<td>11-5</td>
<td>46-2</td>
</tr>
<tr>
<td>Other diagnosis</td>
<td>56-7</td>
<td>13-3</td>
<td>30-0</td>
</tr>
</tbody>
</table>

### Table 4

<table>
<thead>
<tr>
<th>Clinical or histological justification</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firm histological diagnosis</td>
<td>26</td>
</tr>
<tr>
<td>Important diagnosis excluded (for example, malignancy or IBD)</td>
<td>68</td>
</tr>
<tr>
<td>Subsequent change in management</td>
<td>27</td>
</tr>
<tr>
<td>Assess progress of disease</td>
<td>11</td>
</tr>
<tr>
<td>Confirm previous diagnosis</td>
<td>11</td>
</tr>
<tr>
<td>Further line of investigation</td>
<td>11</td>
</tr>
<tr>
<td>No obvious justification</td>
<td>10</td>
</tr>
</tbody>
</table>

Note: the total number of case records suitable for evaluation was 129. There were two separate justifications in 55 and three in 12 patients. IBD = inflammatory bowel disease.

### Discussion

There has been a noticeable increase in the complexity of the work performed in histopathology laboratories in the past 10 to 15 years. In Britain the greater workload arises from increased numbers of specimens being taken from outpatients rather than from hospital patients, and from increased numbers of comparatively straightforward specimens, such as skin biopsy specimens, being taken by general practitioners. Purchasers of health care are expressing doubt about the value of these biopsy specimens although pathologists have emphasised that in a small percentage unexpected and important diagnoses are made.

A recent external audit of our department showed that the full cost of a biopsy with a single haematoyxlin and eosin slide was £21, giving an annual cost of £35 000 for gastrointestinal biopsy specimens. This prospective study has shown that over 90% of these biopsy specimens could be justified on one or more clinical grounds, despite the fact that 41% were histologically normal and a specific pathological diagnosis was made in only a quarter of cases. We were surprised that in 36% of patients there was a change in clinical management when the biopsy report was available and in nearly 30% further investigations were then requested.

There have been few comparable studies in the past. A retrospective audit of the clinical indications for over 1500 upper gastrointestinal endoscopies in patients over 65 years of age suggested that 72% were appropriate, 11% equivocal and 17% unjustified. Over one third of the inappropriate endoscopies were for evaluation of peptic symptoms without a full trial of medical treatment. A more recent pro-

### CLINICAL FEATURES

Patients presented with 31 different symptoms, most commonly diarrhoea (34%) (64/190), abdominal pain (16%) (30/190) and rectal bleeding (16%) (30/190). In 37% a clinical diagnosis had been made before the biopsy. In 67% (127/190) the biopsy was taken in an outpatient clinic, 24% (46/190) on a ward, 8% (15/190) in theatre, and 1% (two of 190) in general practice.

There was a change in patient management of some kind on receipt of 36% (68/190) of biopsy reports (table 3) and 55% (37/68) of these changes involved drug treatment. Further investigations were ordered on receipt of 29% (55/190) of reports, chiefly barium enema (40%) (76/190) and colonoscopy (29%) (55/190). There was no change in management in 82% (156/190) of patients with normal biopsy reports. A firm decision to proceed to surgery was made in 9% (17/190) of patients at the time the biopsy was taken. A further 5% (10/190) of patients were booked for operation when the biopsy result was obtained.

The case records of 129 of the 190 patients were studied. Others were missing or follow up information had not been entered in appropriate or sufficient detail. In all but 10 there was a plausible justification for the biopsy (table 4).

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**Note:** The full text is a summary of a detailed study on the audit of gastrointestinal biopsy specimens, including histological justifications, changes in patient management, and clinical features. The study highlights the importance of histological diagnosis in clinical practice and the need for appropriate and justified biopsy requests.
spective study of 107 consecutive patients with dyspepsia suggested that endoscopy was unhelpful unless biopsy specimens were taken routinely. Without histology the specificity of endoscopy in the diagnosis of chronic gastritis was less than 60%. It has also been suggested that young patients with dyspepsia can be safely managed without a preliminary gastroscopy.9

For two separate reasons we found it more difficult to identify unnecessary large intestinal biopsy specimens. Firstly, there is a growing range of clinicopathological indications for flexible colonoscopy, some centres even advocating periodic colonoscopy as a method of screening for large bowel carcinoma.10 Secondly, there are a number of specific disorders which require histology for diagnosis, and the smallest suspicion of these may be construed as a proper indication for colonoscopy and biopsy. These include amyloidosis and microscopic and collagenous colitis.1112 Furthermore, inflammatory bowel disease can only be accurately diagnosed by examining multiple sections of large intestinal biopsy specimens1314 and even macroscopically normal bowel can show dysplasia.1516

Our review of the microscopic features showed no serious disagreement with the original histological diagnosis. This is perhaps exceptional as we know that minor errors occur in up to 3-4% of our routine reports17 and that after clinicopathological consultation up to 40% of gastrointestinal histology reports require some modification.18 A mean reporting time of nearly five days appears excessively long, particularly as mucosal biopsy specimens are relatively easy to process and can often be reported with a single slide containing several strips of sections. Biopsy specimens which clinicians marked urgent were reported much more quickly. The figures shown in table 4 demonstrate that the delay cannot be attributed to the involvement of junior staff in the examination of biopsy specimens. This is a common explanation for slow reporting in teaching hospitals and one that we have identified by auditing our own reports.14 Our histopathology laboratory attracts both favourable and unfavourable comments from its users. Slow reporting of mucosal biopsy specimens has not been identified as a particular problem perhaps because two thirds of biopsy specimens were taken from outpatients who are unlikely to return to clinic within a week. All small biopsy specimens should be reported within two to three days, but a variety of constraints can make this target unrealistic. Laboratories may need to allocate a priority to certain groups of biopsy specimens. Our results suggest that non-urgent mucosal biopsy specimens need no special treatment but that in clinicopathological terms there is ample justification for these procedures.

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