Amoxycillin in the treatment of gonorrhoea

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With increasing resistance of the gonococcus to benzyl penicillin, and with the greater availability of the broad-spectrum penicillin ampicillin, this antibiotic administered orally is being increasingly used in the treatment of gonorrhoea. In some areas single doses of as much as 3-5 g. ampicillin plus 1 g. probenecid are recommended as necessary, e.g. in the U.S.A. and in the Far East, where single doses of as much as 3-5 g. without probenecid have resulted in 29-5 per cent. of failures (Kvale, Keys, Johnson, and Holmes, 1971). In other areas highly acceptable results have been reported with only 2 g. plus probenecid, e.g. in Norway (Gundersen, Ødegaard, and Gjessing, 1969) and in the United Kingdom outside London (Cobbold, Rees, Parker, Woodcock, John, Latto, Redmond, and Willcox, 1973).

In an endeavour to increase serum concentrations of ampicillin, many new semi-synthetic orally administered antibiotic compounds have been developed which hydrolyse on absorption to form ampicillin in the body, but these have the efficacy only of the equivalent amount of ampicillin into which they hydrolyse.

Recent research from Beecham Laboratories, however, has introduced a new semi-synthetic penicillin—α-amino-p-hydroxy-benzylpenicillin (amoxycillin). A test of this new antibiotic, which has a spectrum of activity similar to ampicillin, for its efficacy in the treatment of gonorrhoea is the subject of this paper.

Amoxycillin has been shown to be better absorbed than ampicillin and to produce considerably higher serum and urine levels (Acred, Hunter, and Mizen, 1971; Croydon and Sutherland, 1971; Geddes, Williams, Kosmidis, Goodall, and Andrews, 1971). Absorption is little influenced by the presence of food, and over 70 per cent. of the oral dose is recoverable from the urine in the first 6 hours after administration.

This report concerns the use of amoxycillin given orally in the treatment of 281 male patients with acute uncomplicated gonorrhoea, and the results are compared with those obtained by similar means and under like conditions with eight other antibiotics given in 1,287 other cases. Multiple dose regimes using orally administered antibiotics are not favoured by venereologists, because patients with sexually-transmitted diseases are frequently unreliable in taking their medication at the times and in the doses requested, tend to discontinue therapy once their symptoms have abated, and may use any medicine left over for later self-treatment or for the treatment of others. For these reasons treatment has been given by either single or double doses.

Case management

Single doses of 0-5-2 g. amoxycillin alone were given to 76 patients, similar doses plus 1 g. probenecid taken together were given to 132 patients, and two doses of amoxycillin at an interval of approximately 5 hours were given to 73 patients.

In all cases the diagnosis was made by Gram-stained smear before treatment and cultures before and after treatment were also used in about one-fifth of the patients. Serological tests for syphilis were also made before treatment in all cases. The initial dose of white capsules, each of 500 mg., was given in the clinic under supervision of the physician, and the patient was instructed to attend after 2 or 3 days when the urethral tests were repeated.

The patients were then told to return after 1 and 3 weeks and then at approximately 8 and 12 weeks after treatment. It was planned that at least one microscopical examination of the prostatic fluid should be made during surveillance.

Single doses of amoxycillin without probenecid

OVERALL FOLLOW-UP AND RESULTS

By no means all patients attended at the times requested although sufficient time has elapsed for all to have been able to attend for 3 months. The follow-up achieved and the results for the 76 patients...
given single doses of amoxycillin without probenecid are shown in Table I.

Of the 76 patients treated, 67 (88.2 per cent.) were followed. The status at the last visit was satisfactory in 36; fourteen were subsequently re-treated for non-gonococcal infection, seven for re-infection with gonorrhoea, and ten who denied further sexual exposure (14.9 per cent. of those followed) were judged to be treatment failures. All these failures were noted within 3 months but had they been observed later than this they would automatically have been classified as re-infections.

Apart from possible help from antibiotic sensitivity studies made before treatment and in all suspected treatment failures, no satisfactory criteria exist to distinguish relapse from re-infection, as a history of further sexual exposure or otherwise is not conclusive. Some authors (e.g. Curtis and Wilkinson, 1958), basing their opinion on sensitivity findings, have suggested that all recurrences occurring within 1 week may be regarded as treatment failures and that those encountered after this time may be regarded as re-infections regardless of the presence or absence of a history of further sexual intercourse. The author has preferred 2 weeks, the usually accepted upper limit for the incubation period in the male, as more realistic. If the latter time period is used, there were nine recurrences within 2 weeks (13.4 per cent. of those followed).

RESULTS RELATED TO DOSAGE

The results obtained with single oral doses of amoxycillin without probenecid are related to dosage in Table II.

Single doses of 0.5 g. were inadequate, resulting in 18.2 per cent. of failures based on all recurrences within 2 weeks and also based on history. When 1 g. was given and failures were calculated by each method the rate was 12.5 and 16.7 per cent. respectively.

When doses of 2 g. were given, there were two recurrences (9.5 per cent.) as judged by both methods of assessment.

COMPARISON WITH OTHER SINGLE-DOSE TREATMENTS

In Table III (overleaf) a comparison is made with some other single-dose oral regimes which have been used in the same clinic.

The results obtained with amoxycillin were very similar to those previously reported with ampicillin.

Single doses of amoxycillin with probenecid

OVER-ALL FOLLOW-UP AND RESULTS

Serum levels of the penicillins and of some of the cephalosporins can be enhanced by the simultaneous

<table>
<thead>
<tr>
<th>Duration of follow-up (days)</th>
<th>No. followed</th>
<th>Results</th>
<th>No.</th>
<th>Per cent.</th>
<th>No.</th>
<th>Per cent.</th>
<th>No.</th>
<th>Per cent.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Satisfactory</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>76</td>
<td>-</td>
<td>14</td>
<td>36</td>
<td>7</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>1</td>
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<td>3</td>
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<td></td>
</tr>
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<td>15-21</td>
<td>35</td>
<td>4</td>
<td>2</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22-28</td>
<td>26</td>
<td>2</td>
<td>2</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2 mths</td>
<td>22</td>
<td>1</td>
<td>2</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-3 mths</td>
<td>18</td>
<td>6</td>
<td>4</td>
<td></td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 3 mths</td>
<td>10</td>
<td>6</td>
<td>4</td>
<td></td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
<td>36</td>
<td>14</td>
<td>7</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Single dose (g)</th>
<th>No. treated</th>
<th>No. followed</th>
<th>Recurrence</th>
<th>Within 1 wk</th>
<th>No.</th>
<th>Per cent.</th>
<th>No.</th>
<th>Per cent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>27</td>
<td>22</td>
<td>3</td>
<td>13.6</td>
<td>4</td>
<td>18.2</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td>1.0</td>
<td>25</td>
<td>24</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>12.5</td>
<td>4</td>
<td>16.7</td>
</tr>
<tr>
<td>2.0</td>
<td>24</td>
<td>21</td>
<td>1</td>
<td>4.8</td>
<td>2</td>
<td>9.5</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td>Total</td>
<td>76</td>
<td>67</td>
<td>4</td>
<td>60</td>
<td>9</td>
<td>13.4</td>
<td>10</td>
<td>14.9</td>
</tr>
</tbody>
</table>
or prior use of probenecid. The follow-up and over-all results obtained with amoxycillin plus probenecid are shown in Table IV. As in the previous series more than 3 months have been allowed to elapse before making the assessment.

Of 132 patients treated, 119 (90·1 per cent.) were followed. The status of 85 was satisfactory at the last visit and twelve were treated for non-gonococcal urethritis. According to the presence or absence of a history of further sexual exposure, there were eleven re-infections and a further eleven (9·2 per cent. of those followed) treatment failures.

### TABLE III Comparison with other antibiotics given in single oral doses

<table>
<thead>
<tr>
<th>Authors</th>
<th>Date</th>
<th>Antibiotic</th>
<th>Dose (g.)</th>
<th>No. treated</th>
<th>No. followed</th>
<th>Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unpublished</td>
<td></td>
<td>Limecycline</td>
<td>0·8-1·2</td>
<td>75</td>
<td>66</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Demethylchlortetracycline</td>
<td>0·9-1·2</td>
<td>82</td>
<td>76</td>
<td>12</td>
</tr>
<tr>
<td>Willcox</td>
<td>1967</td>
<td>Amoxicillin</td>
<td>0·5-1·0</td>
<td>200</td>
<td>174</td>
<td>26</td>
</tr>
<tr>
<td>Present study</td>
<td>1972</td>
<td>Amoxicillin</td>
<td>0·5-2·0</td>
<td>76</td>
<td>67</td>
<td>10</td>
</tr>
<tr>
<td>Willcox</td>
<td>1956</td>
<td>Spiramycin*</td>
<td>2·0-4·0</td>
<td>54</td>
<td>47</td>
<td>6</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td>Doxycycline</td>
<td>0·9</td>
<td>32</td>
<td>25</td>
<td>3</td>
</tr>
<tr>
<td>Cobbold, Morrison, and Willcox</td>
<td>1968</td>
<td>Rifampicin</td>
<td>0·9</td>
<td>103</td>
<td>89</td>
<td>10</td>
</tr>
</tbody>
</table>

*There were no failures in 25 followed who were given 3-4 g.

### RESULTS RELATED TO DOSAGE

The results obtained with single oral doses of amoxycillin plus probenecid are related to dosage in Table V.

Although better results were obtained when probenecid was used, the differences previously observed in relation to dosage were less striking. Among 95 patients followed after treatment with 1-2 g. plus probenecid there were seven failures (7·3 per cent.) based on all recurrences within 2 weeks and eight (8·4 per cent.) based on a denial of further sexual intercourse.

### TABLE IV Follow-up and results with single doses of amoxycillin with 1·0 gm. probenecid

<table>
<thead>
<tr>
<th>Duration of follow-up (days)</th>
<th>No. followed</th>
<th>Satisfactory</th>
<th>Nongonococcal urethritis</th>
<th>Re-infection</th>
<th>Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>132</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>1-3</td>
<td>119</td>
<td>14</td>
<td>—</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td>4-7</td>
<td>103</td>
<td>17</td>
<td>—</td>
<td>—</td>
<td>3</td>
</tr>
<tr>
<td>8-14</td>
<td>83</td>
<td>12</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>15-21</td>
<td>64</td>
<td>7</td>
<td>—</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td>22-28</td>
<td>55</td>
<td>11</td>
<td>1</td>
<td>3</td>
<td>—</td>
</tr>
<tr>
<td>1-2 mths</td>
<td>40</td>
<td>9</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2-3 mths</td>
<td>25</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Over 3 mths</td>
<td>14</td>
<td>11</td>
<td>2</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>119</td>
<td>85</td>
<td>12</td>
<td>11</td>
<td>11</td>
</tr>
</tbody>
</table>

### TABLE V Results with amoxycillin plus 1 g. probenecid related to dosage

<table>
<thead>
<tr>
<th>Single dose (g.)</th>
<th>No. treated</th>
<th>No. followed</th>
<th>Recurrence</th>
<th>Failure based on history</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Within 1 wk</td>
<td>Within 2 wk</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No.</td>
<td>Per cent.</td>
</tr>
<tr>
<td>0·5</td>
<td>26</td>
<td>24</td>
<td>1</td>
<td>4·5</td>
</tr>
<tr>
<td>1·0</td>
<td>28</td>
<td>25</td>
<td>1</td>
<td>4·0</td>
</tr>
<tr>
<td>2·0</td>
<td>78</td>
<td>70</td>
<td>4</td>
<td>5·7</td>
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<tr>
<td>Total</td>
<td>132</td>
<td>119</td>
<td>5</td>
<td>4·2</td>
</tr>
</tbody>
</table>
COMPARISON WITH OTHER SINGLE-DOSE TREATMENTS GIVEN IN CONJUNCTION WITH PROBENECID

The results obtained with single doses of 2 g. amoxycillin plus 1 g. probenecid were similar to those recently obtained in the same clinic with the same dose of ampicillin plus probenecid (Willcox, Woodcock, Latto, John, Redmond, Parker, Rees, and Cobbold, 1973), and both were much better than those obtained with a larger dose of the orally administered cephalosporin-cephalexin plus probenecid (Table VI).

Double dose regimes

OVERALL RESULTS

73 patients were treated with two oral doses of amoxycillin at an interval of approximately 5 hours: 26 with a total of 1 g., 24 with a total of 2 g., and 23 with a total of 3 g. Not enough time has so far elapsed since then to have enabled all the treated patients to have been followed for 3 months, although all could have been observed for 2 weeks. The results so far are shown in Table VII.

A shorter initial follow-up was obtained in this series than in the two single-dose series. Of the 73 patients treated, 53 (72.6 per cent.) were followed. The status was satisfactory at the last visit in 36, six were re-treated for non-gonococcal infection and seven for re-infection with gonorrhoea (rectal infections in three cases), and judging by a denial of further sexual intercourse there were four failures (7.5 per cent. of those followed).

If the five recurrences within 2 weeks are considered to be failures regardless of history, the failure rate was 6.8 per cent. It is likely that, had the initial follow-up been better, the results would also have been better.

RESULTS RELATED TO DOSAGE (Table VIII, overleaf)

Of the fifty patients receiving a total of 1 to 2 g. in two doses, 37 were followed; there were four failures based on a denial of further sexual intercourse (10.8 per cent.) and five recurrences within 2 weeks (13.5 per cent.), whereas there were no recurrences during this time in the smaller series of 23 patients who were given 3 g.

COMPARISON WITH OTHER DOUBLE-DOSE SCHEDULES

The results are compared with those obtained with two double doses of other antibiotics in Table IX (overleaf).

TABLE VI Results compared with those of single doses of ampicillin and cephalaxin plus probenecid

<table>
<thead>
<tr>
<th>Schedule</th>
<th>No. treated</th>
<th>No. followed</th>
<th>Recurrence</th>
<th></th>
<th></th>
<th>Failure based on history (within 3 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Within 1 wk</td>
<td>Within 2 wks</td>
<td>No.</td>
<td>Per cent.</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>78</td>
<td>70</td>
<td>4</td>
<td>5.7</td>
<td>6</td>
<td>8.6</td>
</tr>
<tr>
<td>2 g. plus probenecid 1 g.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ampicillin 2 g. plus probenecid 1 g.</td>
<td>114</td>
<td>94</td>
<td>5</td>
<td>5.3</td>
<td>6</td>
<td>6.4</td>
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<td>Cephalexin 3 g.* plus probenecid 1 g.</td>
<td>87</td>
<td>66</td>
<td>12</td>
<td>18.2</td>
<td>13</td>
<td>19.8</td>
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</table>

*See Willcox and Woodcock (1970)

TABLE VII Follow-up of patients receiving two doses of amoxycillin

<table>
<thead>
<tr>
<th>Duration of follow-up (days)</th>
<th>No. followed</th>
<th>Results</th>
<th>Satisfactory</th>
<th>Nongonococcal urethritis</th>
<th>Re-infection</th>
<th>Failure based on history</th>
</tr>
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<tr>
<td>0</td>
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<td>4-7</td>
<td>45</td>
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<td>4</td>
<td>1</td>
<td>1</td>
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<tr>
<td>8-14</td>
<td>38</td>
<td></td>
<td>7</td>
<td>2</td>
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<tr>
<td>15-21</td>
<td>27</td>
<td></td>
<td>3</td>
<td>2</td>
<td>1</td>
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</tr>
<tr>
<td>22-28</td>
<td>21</td>
<td></td>
<td>4</td>
<td>1</td>
<td>1</td>
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<tr>
<td>1-2 mths</td>
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<td>7</td>
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<td>1</td>
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</tr>
<tr>
<td>2-3 mths</td>
<td>8</td>
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<td>1</td>
<td></td>
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<tr>
<td>Over 3 mths</td>
<td>8</td>
<td></td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>36</td>
<td>6</td>
<td></td>
<td>7</td>
<td>4</td>
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</tbody>
</table>

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TABLE VIII Results related to dosage in patients given double doses of amoxycillin

<table>
<thead>
<tr>
<th>Dosage (g.)</th>
<th>No. treated</th>
<th>No. followed</th>
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<td></td>
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</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>53</td>
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</table>

<table>
<thead>
<tr>
<th>Authors</th>
<th>Date</th>
<th>Antibiotic</th>
<th>Total dose (g.)</th>
<th>No. treated</th>
<th>No. followed</th>
<th>Percentage of those followed</th>
</tr>
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<tbody>
<tr>
<td>Willcox and Woodcock</td>
<td>1970</td>
<td>Cephalexin</td>
<td>4-0</td>
<td>102</td>
<td>82</td>
<td>14-6</td>
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<tr>
<td>Willcox</td>
<td>1965</td>
<td>Ampicillin</td>
<td>2-0</td>
<td>153</td>
<td>127</td>
<td>11-8</td>
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<tr>
<td>Present study</td>
<td>1972</td>
<td>Amoxycillin</td>
<td>1-0–2-0</td>
<td>50</td>
<td>37</td>
<td>10-8</td>
</tr>
<tr>
<td>Willcox</td>
<td>1971</td>
<td>Triple tetracycline</td>
<td>2-4</td>
<td>100</td>
<td>89</td>
<td>9-0</td>
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<tr>
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<td>1969</td>
<td>Demethylchlor tetracycline</td>
<td>2-4</td>
<td>107</td>
<td>93</td>
<td>4-3</td>
</tr>
</tbody>
</table>

The results obtained with amoxycillin were again similar to those achieved with similar doses of ampicillin.

Side-effects
Patients with a history of possible penicillin sensitivity were excluded from the trial, except one who was treated without further trouble. Of the remainder, one patient experienced difficulty in swallowing the tablets, one developed some irritant papules which were thought to be mosquito bites, and one complained of itchy palms 2 days later and was treated with antihistamines at another clinic.

Summary and conclusions
(1) A pilot study has been undertaken in London of a new semisynthetic penicillin, amoxycillin, in the treatment of acute gonorrhoea in males. Altogether 281 cases have been treated, 76 with single oral doses of 0-5–2 g. alone, 132 with these doses given simultaneously with 1 g. probenecid, and 73 with two doses (total 1–3 g.) given at an interval of 5 hours.
(2) Single doses of 2 g. resulted in a failure rate of 9-5 per cent. of those followed. Smaller doses proved less satisfactory. Overall the results were very similar to those obtained with ampicillin.
(3) Single doses of 2 g. with probenecid resulted in a 10 per cent. failure rate in those followed, again similar to that achieved in similar circumstances with ampicillin and superior to that previously obtained with cephalixin and probenecid.
(4) Using double doses of amoxycillin, a total of 3 g. gave the best results in the small series described.
(5) Very few side-effects were reported and these were trivial. Amoxycillin would seem to be a satisfactory alternative to ampicillin in the treatment of gonorrhoea and to merit further trials using larger dosages (e.g. 3 to 3-5 g.) than those employed in this pilot study.

Grateful acknowledgments are expressed to Beecham Laboratories, Ltd., for providing the amoxycillin used in this study.

References
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L'amoxycilline dans le traitement de la gonococcie

SOMMAIRE

(1) On a entrepris à Londres une étude pilote sur une nouvelle pénicilline semi-synthétique, l'amoxycilline, dans le traitement de la gonococcie aiguë masculine. 281 cas ont été traités, 76 avec une dose orale unique de 0,5 à 2 g., sans adjonction d'un autre produit, 132 avec ces mêmes doses associées à 1 g. de probénécide, et 73 avec deux doses (1 à 3 g. au total) données avec un intervalle de 5 heures.

(2) Avec des doses uniques de 2 g., il y eut 9,5 pour cent d'échecs parmi les cas suivis. Les doses inférieures se montrèrent moins satisfaisantes. Dans l'ensemble, les résultats ont été très similaires à ceux de l'ampicilline.

(3) Avec des doses uniques de 2 g. associées au probénécide, il y eut 10 pour cent d'échecs parmi les cas suivis; ceci est également semblable à ce que l'on obtient dans des circonstances similaires avec l'ampicilline et supérieur à ce qui avait été obtenu auparavant avec céphalexine + probénécide.

(4) En employant des doses doubles d'amoxycillin, un total de 3 g. a donné les meilleurs résultats dans la petite série observée.

(5) Très peu d'effets secondaires furent signalés et ceux-ci furent banaux. L'amoxycilline semble être une alternative satisfaite à l'ampicilline dans le traitement de la gonococcie et semble mériter des essais complémentaires avec des posologies plus élevées (c.à.d. 3 à 3,5 g.) que celles employées dans cette étude pilote.