REFERENCES


Clinical Evaluation of a New Laxative

By

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Almost always, when the physician prescribes a certain type drug, he is offered a choice. In the case of the laxatives, this opportunity for selection is almost overwhelming. Perhaps it is partly because of their number, plus the tendency to regard laxatives as, at best, homely necessities, that explains why these drugs are seldom subjected to critical appraisal. Yet an agent so widely and frequently used as a laxative seems to warrant careful study, and selection by criteria more exacting than advertising claims. "When the physician is urged to use this agent, he should have available such evidence as will satisfy his questions concerning safety and efficacy" (1).

Definite standards for the "Laboratory and Clinical Appraisal of New Drugs" have been suggested by the A. M. A. Council on Pharmacy and Chemistry (1). The studies of a new laxative reported here were set up along those lines. In the selection of patients, and in judging effectiveness of the product, an attempt was made to apply objective, as well as subjective, criteria. In the clinical toxicity study, detailed laboratory tests were performed by disinterested hospital personnel. Control observations were made whenever possible either by before-and-after-treatment tests, or by comparison with previously used laxatives. The patients were carefully followed throughout treatment, which in most cases extended over several months. Whenever possible, the data collected were subjected to statistical analysis.

The drug investigated was 'Eskalose', a wafer-form bulk laxative employing a new hydrophilic substance, sodium carboxymethylcellulose, as the active component. The chemical itself had been subjected to extensive and thorough experimental investigation, (2) with results that indicated its safety for clinical trial. This colloid appeared, from laboratory data, (3) to have excellent hydrophilic properties and extreme solubility, claimed to minimize the possibility of side reactions such as impaction. Offered in the wafer form, the preparation was suggested as a desirable substitute for hydrophilic granules routinely prescribed in this clinic as part of the regimen for control of functional constipation.

Tests for Safety

Twenty-one cooperative subjects were chosen for study. About half the group showed minor gastrointestinal disorders, while the others appeared to have no intestinal abnormality. The diagnoses were confirmed by X-ray and sigmoidoscopic examination.

In complete laboratory examination of these patients before the institution of treatment, results all fell within the normal range. The tests were repeated in 17 patients (four did not return for the final check-up) after four to nine months on 'Eskalose.'

Although these results (see Table I.) showed no deviations that could be considered significant physiologically, as a final check the numerical data from the tests was subjected to statistical analysis (see Table II.).

* This work was initiated with the aid of the John S. Sharpe Research Foundation of The Bryn Mawr Hospital.

To our surprise, this showed up three differences that, mathematically, might be considered significant: an increase in the number of red cells per cu. mm., a lesser increase in hemoglobin values, and a slight rise in the blood ascorbic acid. Obviously, these favorable changes must be credited to a general improvement of the patient's under treatment, rather than to any effect of 'Eskalose.'

Since no unfavorable change of any kind was revealed by either medical or mathematical study of the results, it is concluded that 'Eskalose' has no dele-

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**TABLE I**

<table>
<thead>
<tr>
<th>Name</th>
<th>Sex</th>
<th>Age</th>
<th>Diagnosis</th>
<th>Date of Entry</th>
<th>Change</th>
<th>Date of Discharge</th>
<th>Change</th>
<th>Hemoglobin</th>
<th>Widal</th>
<th>Ascorbic Acid</th>
<th>Result</th>
<th>Comment</th>
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<tr>
<td>A.A.</td>
<td>50 F</td>
<td>25</td>
<td>Diarrhea</td>
<td>1947-09-27</td>
<td>No</td>
<td>1947-10-03</td>
<td>Yes</td>
<td>72</td>
<td>0</td>
<td>0.7</td>
<td>Normal</td>
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<tr>
<td>F.B.</td>
<td>25 M</td>
<td>60</td>
<td>Multiple Ulcers</td>
<td>1947-09-27</td>
<td>Yes</td>
<td>1947-10-03</td>
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</tr>
<tr>
<td>C.G.</td>
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<td>60</td>
<td>Gastric Ulcer</td>
<td>1947-09-27</td>
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<td>D.H.</td>
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<td>70</td>
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<td>1947-10-03</td>
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<td>E.I.</td>
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<td>60</td>
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<td>70</td>
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<tr>
<td>K.N.</td>
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<td>Haemorrhoid</td>
<td>1947-09-27</td>
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<tr>
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*Note: Magnifying Glass if Necessary*