

# Vitamin U Therapy of Peptic Ulcer

## Experience at San Quentin Prison

GARNETT CHENEY,\* M.D., SAMUEL H. WAXLER, M.D.,  
and IVAN J. MILLER, M.D., San Francisco

DURING THE PAST SIX YEARS the medical literature has contained reports on the treatment of peptic ulcer with a green plant substance contained in raw cabbage juice.<sup>1, 2, 3, 9</sup> The clinical use of this substance, or anti-ulcer factor, which has been termed "vitamin U," was based on the results of animal experiments which indicated that peptic ulcer might be a nutritional deficiency disease.<sup>4, 5</sup> Because of the great variability in the symptoms and x-ray features of gastric and duodenal ulcers under the usual uncontrolled conditions which exist in the application of many forms of therapy, the authors decided two years ago to set up a double blind control experiment to test the merit of vitamin U therapy in the management of peptic ulcer in humans. The results of this clinical experiment have been analyzed for this report.

### ORGANIZATION OF THE EXPERIMENTAL PROGRAM

The Nuemiller Hospital section of San Quentin Prison, San Quentin, California, was chosen as the locus operandi of the experimental study. Permission to utilize prisoner patients was obtained from Dr. Morton D. Willcutts, medical director, who with his staff physician, Dr. Ralph Erickson, aided the project with the fullest of cooperation. The advantages of using the prison facilities for clinical investigation of this type cannot be overemphasized.

The population at San Quentin Prison is made up of almost 5,000 inmates, all men, varying in age from 21 years to advanced adult life. Many of the inmates of the prison are under life-term sentence. When any inmate feels ill with digestive tract disturbances, he reports on sick call and is examined by one of the prison physicians. If preliminary examination suggests peptic ulcer, he is referred to the x-ray department for routine diagnostic gastrointestinal examination. If an ulcer crater is clearly demonstrated, the physician in charge of his case refers him to the hospital. During the period of the

• A clinical study was undertaken to evaluate the effectiveness of concentrated cabbage juice in the treatment of peptic ulcers. Patients at San Quentin Prison with a diagnosed ulcer crater were treated in a double blind control experiment. They were given either concentrated cabbage juice or placebo facsimile. The evaluation of the merit of this treatment was based upon repeated x-ray examinations of the ulcer crater. A period of 22 days was allowed for ulcer crater healing time.

The results of this experiment indicated concentrated cabbage juice to be effective in healing of peptic ulcer.

present study if the patient wished to enter the vitamin U double-blind control treatment program, he was admitted to a special division of the hospital for this purpose. On entering the hospital, he occupied an individual, locked room or cell where he remained during the period of observation, except that he might leave for some special purpose such as laboratory or x-ray studies; and at such times he would be accompanied by the orderly or by a guard. The cell contained not only a bed but also lavatory facilities. The patient received the usual hospital diet, which was a very liberal bland ulcer diet that contained less roughage than that commonly used for the inmates (Table 1). All the hospitalized prisoners on this program received the same diet no matter what medication they received.

No routine drug therapy of any kind was allowed the patient. If medications became necessary because of pain or for some other reason they were only specifically prescribed for a particular purpose by the ward physician in charge. Patients on the experimental ulcer therapy program were not permitted to have outside food or medication of any kind. The patients were regularly seen only by the prison physicians who were in attendance, the ward orderlies (who were trusty prisoners), and occasionally by guards relative to some administrative problem. None of these persons had any knowledge of what form of anti-ulcer therapy a prisoner received.

In order to administer controlled vitamin U medication to the prisoner-patients, two separate lots of materials were made up for therapeutic use, both of

From the Departments of Medicine and Pharmacology, Stanford University School of Medicine, San Francisco.

\*Dr. Cheney died June 16, 1955.

Presented before the Section on General Medicine at the 84th Annual Session of the California Medical Association, San Francisco, May 1-4, 1955.

which were designated as MK-72.<sup>†</sup> The first was a preparation of vitamin U concentrate, each dose of which was derived from a quart of freshly pressed raw cabbage juice. The dose amounted to approximately 50 cc. per container and was flavored with syrup as previously described.<sup>6</sup> The second form of medication was made up to look and taste and smell like the first but contained no vitamin U. This was designated as placebo. For each individual test case a series of 21 bottles, which constituted a three weeks course of treatment, was prepared. All medications were identified on the bottle by serial number and lot number only, so that there was no way of distinguishing between the cabbage juice concentrate and the placebo. Ordinarily each series of 21 bottles was administered to only one patient but occasionally when treatment was prematurely terminated before the entire series was used the remaining bottles might be used in treatment of a different patient. These exceptions are noted in Table 2. Each daily dose was administered to the patient as a single dose in the presence of the ward orderly to make certain that there was no break in the patient's receiving the proper therapy regularly. All the series of bottles were kept locked up and under refrigeration.

It was decided to evaluate the results of the double blind control treatment of peptic ulcer entirely on the basis of x-ray examinations of the ulcer crater. Consequently it was necessary for each case study to positively demonstrate an ulcer crater either in the stomach or duodenum at both the original examination and the first follow-up examination in order to make certain that the subsequent observations of crater healing time would be accurate. After the first x-ray examination and the beginning of MK-72 therapy, each patient had weekly x-ray examination for a period of three weeks. If the ulcer as observed roentgenographically, had not healed completely at the end of the three-week period, the patient might then be given an additional three weeks course of treatment. The new course of therapy would be determined by one of the authors relative to what the previous course of therapy had already been. For example, if the patient had had three weeks of treatment with placebo and had shown little or no evidence of ulcer crater healing, he would then be placed on a course of treatment with vitamin U. Such a change in treatment was never known to the ward personnel and the physicians caring for the patients, as therapy would ostensibly be continued on a six weeks basis instead of a three weeks basis because the ulcer crater had not shown healing. At no time before, during or after each individual therapeutic test did the roentgenologist who was making the fluoroscopic and x-ray examinations of the

patients, have any knowledge of what form of MK-72 therapy the patient was receiving.

The length of time from the beginning of therapy to the disappearance of the ulcer crater as roentgenographically visualized (so-called crater healing time) was accepted as the only positive or negative criterion of a therapeutic result, for it was felt that the interpretation of changes in symptoms, physical findings and laboratory tests as an indication of improvement would be too unreliable in a double blind control experiment of this type to give any reasonably accurate results.

#### RESULTS OF THE EXPERIMENTAL THERAPEUTIC STUDIES

Fifty patients who had active peptic ulcer were admitted to the experimental program from May 1953 to December 1954. Thirteen of these patients were ultimately dropped from the series primarily because of inadequate roentgenographic data, leaving 37 patients to be treated. These 37 patients were utilized for 46 individual therapeutic studies of three weeks each. The results are recorded in Table 2.

The irregular sequence of case numbers in Table 2 is due to "dropped cases" as well as to some mis-assigned numbers to patients who did not actually enter the program. Four patients were assigned two case numbers each, which indicates they were twice included in the program, having relapsed some months after the first course of therapy and re-entered the series for the second time. The data for the total duration of the illness and for the length of the current attack indicate the pronounced variability in the history of peptic ulcer in cases in this series.

Ulcers located in the stomach were treated in 11 instances and clear-cut ulcer craters in the duodenum were treated in 35 instances. Three of the gastric ulcers treated were large (greater than 1.0 cm. in diameter) and seven of the duodenal ulcers were large (greater than 0.7 cm. in diameter).<sup>6</sup> In the remaining 36 instances the ulcers were small.

The type of MK-72 therapy is shown in Table 2 for each course of treatment. Ten patients were retreated for three weeks during the same period of hospitalization because the ulcer crater had either failed to diminish in diameter at all (seven cases) or had not diminished more than 2 mm. in diameter (three cases). The designation of crater healing time in days indicates whether the course of therapy had been successful or not, as the ulcer crater must have been radiographically healed in three weeks' time (within 22 days) to qualify the case as a therapeutic "success." Case 53-10, in which vitamin U therapy was given and crater healing time was 49 days, was omitted from the statistical analysis because it was complicated by severe pancreatitis

<sup>†</sup>Supplied by Merck and Company, Inc., Rahway, New Jersey.

TABLE 1.—Liberal ulcer diet fed to all prisoner patients treated with MK-72. Sample shown for one day only

| BREAKFAST              | DINNER                        | SUPPER                               |
|------------------------|-------------------------------|--------------------------------------|
| Stewed prunes .....6   | Lentil soup.....1 cup         | Ground round steak.....1 serving     |
| Cornflakes .....bowl   | Crackers                      | Bland gravy                          |
| Soft boiled eggs.....2 | Nucoa .....1 pat              | Tossed salad.....2 spoons            |
| Toast                  | Stringbean salad .....1 spoon | Whipped potatoes .....1 scoop        |
| Nucoa .....1 pat       | Welsh rarebit.....1 serving   | Buttered zucchini .....2 tablespoons |
| Milk .....1 pint       | Pear halves .....2            | Ice cream.....1 scoop                |
| Coffee .....1 cup      | Milk .....1 pint              | Bread                                |
|                        | Tea .....1 cup                | Nucoa .....1 pat                     |
|                        |                               | Milk .....1 pint                     |
|                        |                               | Coffee .....1 cup                    |

TABLE 2.—Results of MK-72 peptic ulcer therapy (vitamin U double blind control) at San Quentin Prison, May 1953 to December 1954

| Case No.       | Duration      |                | Peptic Ulcer Location            | Diam. in cm. (by X-ray) | Therapy (Vitamin U or Placebo) | Treated Month | Ulcer Crater Healing Time in Days |
|----------------|---------------|----------------|----------------------------------|-------------------------|--------------------------------|---------------|-----------------------------------|
|                | Total Illness | Present Attack |                                  |                         |                                |               |                                   |
| YEAR 1953      |               |                |                                  |                         |                                |               |                                   |
| 1. ....        | None previous | .....          | Apex bulb                        | 0.3                     | P                              | May           | 11                                |
| 2. (6) *       | 15 yr.        | 3 mo.          | Lesser curv. stomach at incisura | 1.5                     | U                              | May           | 22                                |
| 6. (2) .....   | 15 yr.        | Relapse        | Lesser curv. stomach at incisura | 1.0                     | P                              | Aug.          | No healing                        |
|                |               |                |                                  | 1.0                     | U                              | Sept.         | 11                                |
| 9. ....        | 3 mo.         | 3 mo.          | Central bulb                     | 0.6                     | P                              | Sept.         | Not healed                        |
|                |               |                |                                  | 0.4                     | U                              | Oct.          | 19                                |
| 10. ....       | 1 mo.         | 1 mo.          | Lesser curv. stomach             | 2.0                     | U                              | Sept.         | 49                                |
| 11. ....       | 1 mo.         | 2 wk.          | Apex bulb                        | 0.7                     | P                              | Sept.         | No healing                        |
|                |               |                |                                  | 0.7                     | U                              | Oct.          | 16                                |
| 12. ....       | 8 yr.         | 6 wk.          | Central bulb                     | 0.7                     | P                              | Oct.          | No healing                        |
|                |               |                |                                  | 0.8                     | U                              | Nov.          | 21                                |
| 13. ....       | 1 yr.         | .....          | Greater curv. in gastric antrum  | 1.0                     | P                              | Oct.          | No healing                        |
|                |               |                |                                  | 1.0                     | U                              | Nov.          | 34                                |
| 15. ....       | 9 mo.         | 3 wk.          | Duodenal bulb                    | 0.5                     | U                              | Oct.          | 9                                 |
| 16. ....       | 6 mo.         | .....          | Middle bulb                      | 0.5                     | U                              | Oct.          | 21                                |
| 17. ....       | 3 yr.         | 3 mo.          | Lesser curv. of bulb             | 0.4                     | P                              | Nov.          | No healing                        |
|                |               |                |                                  | 0.4                     | U                              | Nov.          | 20                                |
| 18. ....       | 1 yr.         | 9 mo.          | Base bulb                        | 1.1                     | P                              | Nov.          | No healing                        |
|                |               |                |                                  | 1.0                     | U                              | Dec.          | 21                                |
| 20. ....       | 10 yr.        | 3 mo.          | Lesser curv. bulb                | 0.4                     | P                              | Dec.          | 11                                |
| YEAR 1954      |               |                |                                  |                         |                                |               |                                   |
| 2. ....        | 4 yr.         | 2 mo.          | Base bulb                        | 1.0                     | U                              | Jan.          | 28                                |
| 3. ....        | .....         | .....          | Base bulb                        | 0.5                     | P                              | Jan.          | No healing                        |
|                |               |                |                                  | 1.0                     | U                              | Feb.          | 7                                 |
| 10. (27) ..... | 6 yr.         | 2 mo.          | Central bulb                     | 0.7                     | U                              | April         | 14                                |
| 11. ....       | 12 yr.        | 1 yr.          | Prepyloric                       | 1.0                     | U                              | April         | 21                                |
| 12. ....       | 3 mo.         | 3 mo.          | Central bulb                     | 0.7                     | U                              | May           | 11                                |
| 13. ....       | 1 yr.         | 2 mo.          | Prepyloric                       | 0.4                     | U                              | May           | 10                                |
| 15. (30) ..... | 1 yr.         | 4 mo.          | Pylorus                          | 0.6                     | U                              | May           | 21                                |
| 16. ....       | 4 yr.         | 3½ mo.         | Central bulb                     | 0.4                     | P                              | May           | 13                                |
| 18. (24) ..... | 7 yr.         | 1 yr.          | Posterior wall duodenal bulb     | 0.3                     | U                              | June          | 20                                |
| 19. ....       | 12 yr.        | 3 mo.          | Midportion cap                   | 0.4                     | P                              | June          | Not healed                        |
| 21. ....       | 4 yr.         | .....          | Apex bulb                        | 0.7                     | P                              | July          | Not healed                        |
| 23. ....       | 6 yr.         | 4 mo.          | Central bulb                     | 0.6                     | P                              | July          | Not healed                        |
|                |               |                |                                  | 0.4                     | U                              | Aug.          | 11                                |
| 24. (18) ..... | 7 yr.         | 3 wk.          | Posterior wall duodenal bulb     | 0.4                     | U                              | Aug.          | 20                                |
| 25. ....       | 23 yr.        | 10 mo.         | Lesser curv. midstomach          | 0.8                     | P                              | Aug.          | 12                                |
| 26. ....       | 2 yr.         | 2 wk.          | Duodenal cap                     | 0.3                     | U                              | Aug.          | 16                                |
| 27. (10) ..... | 6 yr.         | 9 days         | Duodenal cap                     | 0.5                     | P                              | Aug.          | Not healed                        |
| 28. ....       | .....         | .....          | Posterior wall duodenal cap      | 0.5                     | P                              | Aug.          | 22                                |
| 29. ....       | 5 yr.         | 3 wk.          | Central bulb                     | 0.3                     | P                              | Sept.         | 20                                |
| 30. (15) ..... | 1 yr.         | .....          | Lesser curv. antrum              | 2.5                     | U                              | Sept.         | 18                                |
| 31. ....       | 2 yr.         | .....          | Lesser curv. duodenal bulb       | 0.2                     | U                              | Nov.          | 17                                |
| 32. ....       | 12 yr.        | 5 yr.          | Lesser curv. duodenal cap        | 1.5                     | U                              | Nov.          | 22                                |
| 33. ....       | .....         | .....          | Central bulb                     | 0.7                     | U                              | Nov.          | 15                                |
| 34. ....       | 8 yr.         | 1 yr.          | Duodenal bulb                    | 0.8                     | P                              | Nov.          | No healing                        |
|                |               |                |                                  | 0.8                     | U                              | Dec.          | 7                                 |

(P) = Placebo. (U) = Vitamin U.

\*Four patients were twice included in the program. The numbers in parentheses are the case numbers assigned when they were treated the other time.

**TABLE 3.—Clinical analysis of therapeutic results**

|   |            |
|---|------------|
| Total number of completed case studies (including 10 gastric and 35 duodenal ulcers).....                                   | 45         |
| Number of cases receiving placebo (including 3 gastric and 16 duodenal ulcers).....   | 19         |
| Number of placebo successes (including 2 gastric and 11 duodenal ulcers).....   | 6 (31.6%)  |
| Number of cases receiving Vitamin U (including 7 gastric and 19 duodenal ulcers).....                                       | 26         |
| Number of Vitamin U successes (including 1 gastric and 1 duodenal ulcer).....   | 24 (92.3%) |
| Number of placebo failures retreated with Vitamin U at same hospital entry (including 2 gastric and 8 duodenal ulcers)..... | 10         |
| Number successfully retreated.....  | 10         |

disclosed at operation. At operation it was observed that the large gastric ulcer in this case had actually healed, but that the degree of pancreatitis which persisted was extensive and severe. In another case of gastric ulcer (No. 53-13) also treated with vitamin U, but not qualifying as a "success" in three weeks of treatment, the lesion was healed two weeks later without additional vitamin U therapy. Similarly the large duodenal ulcer present in Case No. 54-2, which was not healed completely in three weeks, was healed in four weeks without any additional vitamin U therapy. In two cases of small duodenal ulcers (Nos. 54-21 and 54-27) in which placebo therapy was given, healing occurred ultimately, but not until after the three-week therapeutic period—a week after the end of the period in one case and two weeks after in the other. In both of these cases the patients received additional forms of treatment during this time which may have affected ulcer crater healing time favorably.

#### CLINICAL ANALYSIS OF THE RESULTS OF TREATMENT

A brief analysis of the therapeutic results shown in Table 2 is given in Table 3. It is evident that during three weeks of placebo therapy, healing occurred in slightly less than one-third (31.9 per cent) of the 19 cases treated. This proportion of "successes" during placebo therapy does not seem surprising when it is noted that there is a natural tendency of peptic ulcers to heal with bed rest, adequate diet, more or less relief from emotional tension, and the feeling that something constructive is being done to care for the ulcer pains. Certainly

some of these prison patients would be expected to improve on such a regimen. It should be noted that in all cases in which the lesion did heal during placebo therapy, the ulcers were small, with one exception—a duodenal ulcer 0.8 cm. in diameter—and that there is some good clinical evidence that small peptic ulcers heal more rapidly than large ones.<sup>6, 7, 8</sup>

In all but two of the 26 cases in which vitamin U therapy was given, ulcer crater healing occurred within a period of three weeks—a "success" ratio of 92.3 per cent. As previously noted, the only two "failures" were healed at four and five weeks. In both of these cases the ulcers were large. As is shown in Tables 2 and 3, each of the ten patients who had had failure of treatment with placebos, later had healing within three weeks when treated with vitamin U.

#### CONCLUSIONS

The results of the double blind control experiments relative to vitamin U therapy of peptic ulcer indicate that vitamin U was clearly superior to a placebo in the treatment of gastric and duodenal ulcers.

595 Buckingham Way, San Francisco 27 (Waxler).

The authors are indebted to Miss Ernestine Hutchins and to Mr. Bing Moy for their assistance in the collection and analysis of the data presented.

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