

Comprehensive Outpatient Care in Rheumatoid Arthritis

A Controlled Study

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Patients with classical or definite rheumatoid arthritis by American Rheumatism Association (ARA) criteria (peripheral type, functional classes 2 and 3 and anatomical stages 2 and 4), were randomly assigned to treatment and control groups in a study of effectiveness of multidisciplinary clinic and home care. Comprehensive care was supplied by staff of the Arthritis Outpatient Clinic of University Hospitals of Cleveland and by staff of the Visiting Nurse Association of Cleveland. Services were coordinated through regularly held staff conferences. An independent clinical investigation team evaluated changes in function and disease activity. Treatment was beneficial in the following terms: fewer deteriorations in activities of daily living, more numerous improvements and fewer deteriorations in economic dependence, and more improvements and fewer deteriorations in clinical manifestations of disease activity. Of methodologic importance was the demonstration of the feasibility of controlled testing of long-term program effectiveness.

Though efforts to rehabilitate patients with rheumatoid arthritis have been described for hospital and institutional settings, these efforts have too seldom been continued into the unstructured home environment and have seldom focused on ambulatory patients.¹⁻⁹ There have, furthermore, been few or no previously published controlled studies of rehabilitation in rheumatoid arthritis, and the limited development of home health services, in which the public health nurse plays a major role, may be attributed in part to the absence of convincing information on the actual value of such services. This

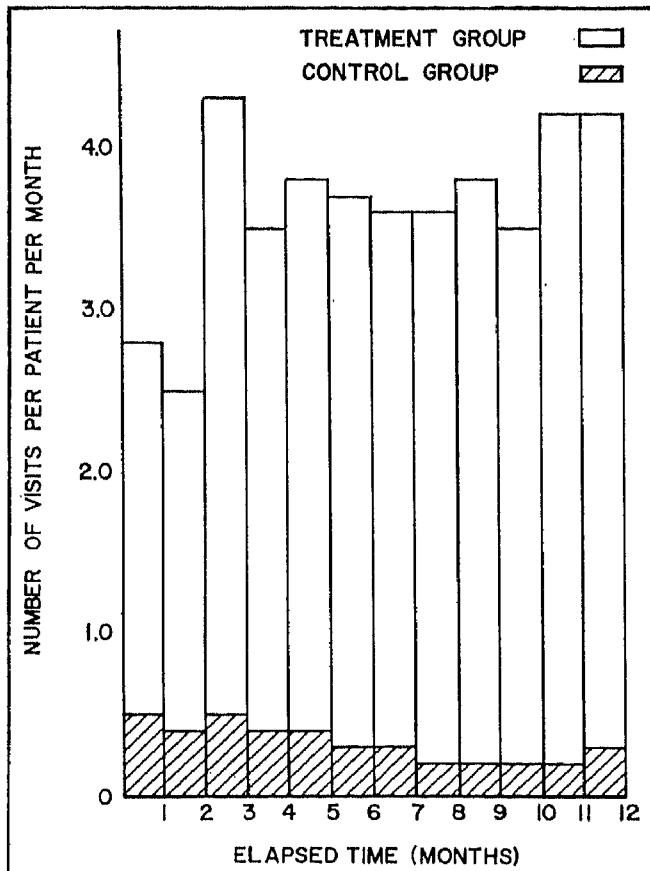
report presents results from a controlled study of coordinated rehabilitation of ambulatory patients with rheumatoid arthritis. The study was designed to test the following hypothesis: Patients with chronic rheumatoid arthritis will more often maintain current levels or achieve higher levels of physical, psychological, and social function with the aid of a coordinated management program which extends into the home and which is closely supervised by a physician working with a public health nurse than without such a program.

The need to evaluate the effect of such coordinated care and the lack of controlled studies led three organizations to cooperate in this study. The three organizations were the Arthritis Outpatient Clinic of University Hospitals of Cleveland, the Visiting Nurse Association of Cleveland, and the clinical investigation team of the Interdisciplinary Program in Aging Research at Case Western Reserve University School of Medicine. The directors of the arthritis clinic and the Visiting Nurse Association had long recognized the need for continuing rehabilitation efforts into the home and for evaluating their effectiveness in such service. The investigating team had more than ten years' experience in studying the natural history of chronic diseases and had developed methods for the epidemiologic and experimental study of aging and chronic illness. These skills and motivations led to the cooperative venture reported here.

Coordinated care between clinic and home was accomplished by integrating comprehensive multidisciplinary care supplied in the hospital clinic with care supervised in the home by a public health nurse. Care was integrated through regularly scheduled conferences. Effectiveness of the management program was measured in physical, psychological,

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Home visits by nurses during one year in study of comprehensive care for rheumatoid arthritis.

and social areas. The results presented here are limited to those which deal with the effectiveness of the program in terms of changes in walking, stair climbing, activities of daily living, house confinement, and socioeconomic dependence, as well as in terms of changes in the Lansbury index.

Experimental Care Variable

The care variable described here involved more than the activities of a single doctor or nurse. It comprised a comprehensive treatment program organized and coordinated through the joint efforts of community organizations and professional disciplines with specific skills and goals.

The arthritis clinic of University Hospitals of Cleveland provides multidisciplinary medical care with emphasis on rheumatology. Staff of the clinic includes physician-specialists (rheumatologists, internists, orthopedists), resident physicians, nurse, practical nurse, physical therapist, social worker, occupational therapist, podiatrist, dietitian, laboratory technician, aide, orderly, secretary, and volunteer. Consultations in other medical specialty areas are obtained by referrals to the specialty clinics.

The Visiting Nurse Association of Cleveland is a voluntary community agency offering care and rehabilitation services to the sick and family health counselling. Care plans and goals are related to the

family and home environment with consideration for social, cultural, and economic factors that influence health. Nurses have the benefit of a staff education program which includes the services of physical therapist, physician, psychiatrist, social worker, and nutritionist. For this study, 16 nurses of the Visiting Nurse Association were assigned to patients in the treatment group. Nurses helped with exercises, treatments, activities of daily living, health promotion, planning, coordination, and psychological therapy.

Patient needs were assessed in the clinic by clinic staff and in the home by visiting nurses. Goals were set and management plans were coordinated through regularly scheduled, patient-centered conferences which were attended by clinic staff and visiting nurses. Information was exchanged about patient's disease activity, patient resources, changing needs, adequacy of follow-through, and socio-psychologic family interactions. Staff judgements about effectiveness of treatment led to modifications of goals and management plans. These changes were made in the scheduled conferences and by unscheduled phone and written communications, when necessary.

During the one-year interval of study, 98 regularly scheduled intake and quarterly follow-up multidisciplinary conferences were held concerning the 20 patients in the treatment group, while no such conferences were held for control patients. During this interval, visiting nurses made 864 visits to the 20 patients in the treatment group, visiting 13 of them during at least 11 months of the study. Of the remaining seven treatment patients, five were visited for eight to ten months; and two were visited for three and four months, respectively. In the control group, 17 patients had no nurse visits during the year. The remaining three had been referred for visiting nurse care by other than study procedures and had a total of 73 visits by nurses. The difference between nurse visits to the treatment and control groups is shown graphically in the Figure.

Selection of Study Patients and Randomization

The study sample consisted of 40 patients with classical or definite rheumatoid arthritis by American Rheumatism Association (ARA) criteria, of peripheral-type only.⁴ Selection occurred before patients were assigned at random to treatment and control groups, and the following selection criteria were used. The sample was limited to people between 16 and 75 years of age who had attended the clinic regularly and who lived within the area served by the Visiting Nurse Association. Patients selected had had rheumatoid arthritis continuously for at least one year and were limited in normal activities, namely, class 2 or 3 by ARA functional criteria and stage 2, 3, or 4 by ARA anatomic classification.⁵ Because of a known tendency toward spontaneous remissions in early stages and in order to narrow the variable spectrum of disease, patients with early disease were excluded. At the time of a

physician's prestudy review, at least four joints had to be involved with swelling, tenderness, or pain on motion, or some combination of these; and at least two of the involved joints had to be other than hands and wrists. Most of the patients had additional joints involved. Conditions which, by ARA criteria, excluded the diagnosis of rheumatoid arthritis were also eliminated from this study.

Patients eligible for the study were hospitalized for two or three days of prestudy evaluations. One of each pair of consecutively evaluated patients was then randomly assigned to the treatment group and the other to the control group. Randomization was accomplished with the aid of sealed envelopes, containing "treatment-control" sequences prepared with the aid of tables of random numbers. Each envelope was opened by an investigator who had no contact with the patients. No envelope was opened until a pair of eligible patients had completed the prestudy evaluations.

Measures

Patients were identified according to ARA criteria as having either definite or classical rheumatoid arthritis and as being in either anatomical stage 2, 3, or 4 of disease.^{4,5} For the purposes of this report, the following measures defined prestudy disease activity, as well as disability and dependence levels.⁶⁻¹⁰ These were also the measures used to evaluate the effectiveness of the treatment program.

Lansbury's corrected, combined systemic and articular indexes served as a clinical measure of rheumatoid activity.⁶ This six-item comprehensive index summarized measurements of stiffness, fatigue, pain (in terms of aspirin need), muscle weakness (in terms of grip strength), erythrocyte sedimentation rate, and total joint inflammation.

Walking was observed and classified according to the following five-grade scale⁷; walking by self, with mechanical aid, with personal assistance, with both mechanical and personal assistance, and not walking at all. Patients were considered to be walking by themselves if they received no assistance and no supervision or if they used, at most, a cane. Mechanical aids included the use of a quad cane, two canes, crutches, walker, or brace. The index of independence in activities of daily living, an ordered seven-grade scale ranging from a high of A to a low of G was used to rate functional performance in activities of daily living.⁸ Ratings were based on detailed evaluation by both history and observation of independence or dependence in bathing, dressing, going to toilet, transferring, continence, and feeding. Ratings in walking and in activities of daily living were based on the most dependent levels (nonhospital) which were present in the two-week period preceding the time of evaluation.

House-confinement was measured in terms of the number of days on which the patient had been outside of his residence during the two-week period preceding the date of evaluation. Patients were classified as "outside three or more times" during the

Table 1.—Treatment and Control Patients Compared Upon Entering Study*

| Patient Characteristics | Treatment Group | Control Group |
|--|-----------------|---------------|
| Mean age in years | 51.7 | 53.3 |
| SD | 6.9 | 12 |
| Number of men | 7 | 5 |
| of women | 13 | 15 |
| Number of whites | 5 | 8 |
| of nonwhites | 15 | 12 |
| Number married or widowed | 10 | 14 |
| Divorced, separated, or never married | 10 | 6 |
| Number in economic dependence class 1 or 2 | 9 | 10 |
| in class 3, 4, or 5 | 11 | 10 |
| Number in Hollingshead social class 2, 3, or 4 | 6 | 8 |
| in class 5 | 14 | 12 |
| Number with definite ARA rheumatoid arthritis | 1 | 3 |
| with classical ARA rheumatoid arthritis | 19 | 17 |
| Number in ARA anatomical stage 2 | 4 | 6 |
| in stage 3 or 4 | 16 | 14 |
| Mean Lansbury index score in units | 82.8 | 81.3 |
| SD | 27.8 | 28.6 |
| Mean Raven intellect test score in units | 23 | 22.2 |
| SD | 7.6 | 5.3 |
| Number walking without personal aid | 12 | 13 |
| Walking with personal aid | 8 | 7 |
| Number independent in activities of daily living | 12 | 11 |
| Dependent | 8 | 9 |
| Number not confined to residence | 12 | 15 |
| Confined | 8 | 5 |
| Mean walking time in seconds | 27.3 | 20.8 |
| SD | 21.7 | 20.1 |
| Mean stair-climbing time in seconds | 19 | 9.1 |
| SD | 25 | 4.6 |

*Measures used to characterize patients are defined in the text. By statistical test, the treatment and control groups were not remarkably different ($P > 0.10$ for all differences).

two weeks or "outside 0 to 2 times." Time to walk 50 feet and climb eight steps was measured in seconds and in standard settings.⁹

The index of independence in socioeconomic function, an ordered five-class scale from a high of I to a low of V, served as a measure of socioeconomic dependence.¹⁰ Grading was based on detailed evaluation of four profiled indicators of patient resources, needs, and productivity. The four indicators were employment status, residence ownership, degree of assistance provided within the residence, and economic support from charitable agencies.

Patients were also described in terms of age, sex, race, marital status, social position, and intellectual function. Hollingshead's two-factor index defined social position as a function of education and occupation.¹¹ Intellectual function was measured with the aid of Raven's coloured progressive matrices.¹²

Tests of significance used to calculate probability included the chi-square test and the test of difference in means. Where the number of observations in any cell of a four-cell table was less than five, Fisher's direct method was used to calculate probability.

Patient Population Description

At the time of entry into the study, the randomly selected treatment and control groups did not differ significantly in age, sex, race, marital status, socioeconomic dependence, social position, ARA diagnostic class, anatomical stage of disease, Lansbury index score, intellectual function, walking status, status in activities of daily living, degree of house-confinement, speed of walking, or speed of stair climbing (Table 1).

The average age of study patients was 52½ years.

Table 2.—Persons With Changes in Activities of Daily Living

| Study Group† | Deterioration in Activities* | | Total |
|-----------------|------------------------------|--------|-------|
| | Present | Absent | |
| Treatment group | 1 | 19 | 20 |
| Control group | 7 | 13 | 20 |
| Total | 8 | 32 | 40 |

*Deterioration is defined as decrease to a grade lower than B according to the index of independence in activities of daily living, described in the text.

†Detailed descriptions of the treatment variable and experiment design are presented in the text.

Table 3.—Persons With Changes in Economic Dependence

| Study Group† | Level of Economic Dependence* | | | Total |
|-----------------|-------------------------------|-----------|--------------|-------|
| | Improved | No Change | Deteriorated | |
| Treatment group | 5 | 14 | 1 | 20 |
| Control group | 1 | 14 | 5 | 20 |
| Total | 6 | 28 | 6 | 40 |

*Economic dependence was measured according to the index of socioeconomic function, a five-class scale described in the text.

†Detailed descriptions of the treatment variable and experiment design are presented in the text.

Table 4.—Persons With Changes in Lansbury's Six-Item Index

| Study Group† | Deterioration in Lansbury Index* | | Total |
|-----------------|----------------------------------|--------|-------|
| | Present | Absent | |
| Treatment group | 8 | 12 | 20 |
| Control group | 14 | 6 | 20 |
| Total | 22 | 18 | 40 |

*Deterioration is defined as an increase of five or more units according to Lansbury's index of disease activity, described in the text.

†Detailed descriptions of the treatment variable and experimental design are presented in the text.

Table 5.—Persons With Changes in Lansbury's Five-Item Index

| Study Group† | Improvement in Lansbury Index* | | Total |
|-----------------|--------------------------------|--------|-------|
| | Present | Absent | |
| Treatment group | 15 | 5 | 20 |
| Control group | 8 | 12 | 20 |
| Total | 23 | 17 | 40 |

*Improvement is defined as a decrease of five or more units according to Lansbury's index of disease activity, described in the text.

†Detailed descriptions of the treatment variable and experimental design are presented in the text.

The youngest was 27 years old: the eldest was 73 years old: and 90% were between 40 and 69 years of age. Men numbered 12 and women 28. There were 13 whites and 27 nonwhites. Of the forty, 24 were married and living with spouse or widowed. The remainder were divorced, separated, or had never been married. Patients were of below-average social class as evidenced by the following facts. Seventy five percent lived in residences which they did not own, 13% received financial aid from charitable agencies, 40% had completed no more than eight grades of schooling, 85% were unemployed, and 45% were unskilled.

Illness and disability status were characterized in the following terms (Table 1): Patients were, in general, severely handicapped as indicated by ARA criteria, with 10 in anatomical stage II and 30 in stages III or IV. Thirty-six patients had classical rheumatoid arthritis (seven of 11 standard ARA criteria), and four had definite rheumatoid arthri-

tis (five of 11 criteria). Patients averaged 82 units by the Lansbury index, a composite measure of stiffness, fatigue, pain, muscle weakness, erythrocyte sedimentation rate, and overall joint inflammation. The extent of disability was indicated by the findings that 38% required personal assistance in walking, 33% had been outside of their residence two or fewer times during a two-week reference interval, and 43% received personal assistance in at least one of the six primary functions (bathing, dressing, toileting, transferring, continence, or feeding) measured by the index of activities of daily living.

Results

Deteriorations in activities of daily living and in walking were compared between the treatment and control groups as a measure of the effectiveness of the treatment program. Deterioration in activities of daily living was more frequent in the control group (Table 2). With the use of Fisher's direct method to calculate probability, $P < 0.05$; and there is, thus, a strong probability that the care program influenced outcome favorably in terms of activities of daily living. A similarly favorable outcome in walking was not demonstrated by the measure used. It should be noted that, in tabulations of data concerning effectiveness, the one control patient who died was regularly classed with those having an unfavorable outcome.

More patients in the treatment group improved and fewer deteriorated in terms of the index of socioeconomic functioning, a measure of overall socioeconomic dependence (Table 3). By this measure, 14 patients in the treatment group and 14 in the control group were at the same level of socioeconomic dependence at one year as at the start of the study. The remaining 12 patients had changed, and the change was in favor of the treatment program in ten of the 12. Thus, among the six in the treatment group who changed, five improved and only one deteriorated; and among six in the control group who changed, five deteriorated and only one improved ($P=0.08$ for those showing a change). A probability of 0.08 can be considered to be fairly strong evidence of a beneficial treatment effect, since only one other distribution of patients (ie, 6:0:0:6) among the small number who showed change would result in any smaller probability. In this group, return to gainful employment was the most common improvement which contributed to the difference in favor of the treatment group.

Effectiveness of the coordinated program was also demonstrated in terms of a standardized clinical measure of disease activity, namely, the six-item Lansbury index (Table 4). Deterioration of five index units or more occurred more frequently in the control group ($P=0.06$). Since an adequate intake of prescribed medication was stressed in the treatment program, the treatment group ingested more salicylates. The resulting increased salicylate com-

ponent of the six-item Lansbury score, thereby, tended to offset the lower total score which would be expected in the event of improvement and decreased the six-item index's sensitivity as a measure of effectiveness. In accordance, thus, with modifications permitted in use of the index, five-item Lansbury index scores were calculated for all patients, excluding the salicylate item from the score.⁶ By this means, effectiveness of the coordinate program was demonstrated more strongly than by use of six-item scoring (Table 5). Five-item scoring revealed more frequent improvements (five index units or more) in the treatment group than in the control group with a statistical probability of less than 0.025. Five-item scoring revealed improvements of ten index units or more in 12 treatment and six control patients ($P=0.06$). It is, thus, highly likely that the care program was beneficial in terms of Lansbury's measure of clinical manifestations of disease.

Effectiveness of the program was also evaluated in terms of changes in degree of house-confinement, time to walk 50 feet, and time to climb eight steps. By statistical test, beneficial treatment effects were not demonstrated on any of these measures.

As indicated earlier, the experimental care variable in this study embodied a program of several disciplines with specific skills working with community organizations toward a defined goal. Through combined efforts, they set into action a train of events which was attributable to the coordinated and supervised multidisciplinary effort. The broad spectrum of the program was illustrated by differences in hospitalizations between the treatment and control groups, as well as by differences in the number of clinic appointments kept, the use of ancillary services, and the more adequate use of salicylate medication.

During the year of study, patients in the treatment group were hospitalized for a total of 341 days, while those in the control group were hospitalized for 140 days ($P < 0.0001$). Patients in the treatment group made 240 clinic appointments and kept 201 of them, while those in the control group made 192 appointments and kept 154 ($P < 0.03$ for the differences in appointments made and kept). Out-patient physical therapy visits numbered 161 in the treatment group and 66 in the control group ($P < 0.0001$), while the respective numbers of orthopedic consultations were 29 and 7 ($P < 0.001$). During the study, salicylate dosages were increased in 11 treatment patients and in two control patients ($P < 0.01$). Correspondingly, blood salicylate levels at the time of the one-year study examination and two hours after salicylate ingestion revealed ten patients in the treatment group and five in the control group with salicylate levels of 15 mg/100 ml or greater.

Significant differences were not demonstrated in occupational therapy visits between the treatment and control groups, nor in social service, podiatry, or eye clinic visits; however, significant differences

might be missed in studies of small sample size. Differences were similarly not demonstrated in the use of hand splints nor in the administered amounts of prednisone, other steroids, chloroquine phosphate, indomethacin, or phenylbutazone.

Comment

Arthritis is the most common crippling disease in the United States. It afflicts about 13 million people, one fourth of whom report limitations in activities.¹⁰ Rheumatoid arthritis, one of the more severe forms, affects an estimated 3.6 million and is thus one of the major disabling diseases in the country.¹⁴ Though objective evidence is lacking, current professional opinion indicates that proper long-term management and rehabilitation can prevent seven of ten instances of severe crippling.¹³ The presence of hundreds of thousands of severely disabled reveals that this goal has not been reached.

Accumulation of knowledge about the success to be expected from various types of long-term management has been hampered by difficulties in designing and conducting controlled studies. A few of the difficulties are cited here. Many studies have included para-arthritis conditions such as fibrositis, and the resulting heterogeneity of sample obscures interpretations about the treatment of rheumatoid arthritis.¹⁵ The variable and chronic course of rheumatoid arthritis offers the investigator technical difficulties as he seeks to establish a process of long-term measurement at comparable times. Another problem is the scarcity of well-developed measures of the effectiveness of multidisciplinary rehabilitation. Not the least of the research tasks is that of providing a continuing program of comprehensive rehabilitation to an experimental group, while simultaneously withholding it from a control group.

In view of the aforementioned difficulties, the types of studies usually conducted have been descriptive studies, uncontrolled comparative studies, and controlled drug studies.^{9,10-10} In the absence of controlled studies of long-term comprehensive management, the present experiment tested the idea that long-term coordinated care between clinic and home may increase the effectiveness of service. Coordinated care is defined here as services by various professionals who communicate regularly about their observations and who integrate decisions and actions in relation to their separate goals. In the absence of communication, the various professionals may duplicate observations and may seek certain information with less skill than other specialists. They may not see enough of the whole physical, psychological, and socioeconomic picture to make the best decisions. In the absence of evaluations in the patient's natural environment, observations may be limited by the unfamiliar and restrictive environments of clinics or offices. Goals may thus be limited or unrealistic. Treatment, moreover, is not an inflexible set of actions that follows a single set of goals worked out in a clinic or office. Treatment is a dynamic process of changing goals and changing

service decisions based on feedback of information about improvement or lack of improvement and about the associated reasons.

In the present investigation, the complex service and study tasks were accomplished as a unique cooperative effort between an arthritis outpatient clinic, a community nursing agency, and a clinical research team. Comprehensive care was supplied in the clinic. Visiting nurses worked with patients in their homes, bringing to the multidisciplinary team information about family and patient responses to treatment, both of which were essential to sound planning. Since both control and treatment patients had good multidisciplinary care in the clinic, the added element in the treatment program was formal coordination of care between clinic and home. Formal coordination was accomplished through intake and regularly scheduled, quarterly conferences which were attended by all service personnel.

The attempt to provide long-term coordinated care to the treatment group and to withhold it from the control group was largely successful. This was evidenced by the fact that 98 formal conferences were held for patients in the treatment group and none for those in the control group. Visiting nurses maintained contact with 18 of 20 patients in the treatment group for at least eight of the 12 study months in contrast to a complete absence of nurse visits to 17 of 20 patients in the control group (Figure). Care in the treatment group differed from care in the control group in other ways. Thus, for example, patients in the treatment group spent significantly more time in the hospital, made more

clinic appointments, kept more of these appointments, had more physical therapy service, had more orthopedic help, and showed more increases in salicylate intake during the year of study. Such findings demonstrate the complexity of the care variable to which the study results are attributed.

The following benefits resulted from the treatment program in this study. Fewer patients in the treatment group deteriorated on a graded measure of activities of daily living (index of activities of daily living). More treatment patients improved and fewer deteriorated in economic functioning as measured by the index of socioeconomic functioning. Lastly, more patients in the treatment group improved and fewer deteriorated by the Lansbury index, a clinical measure of disease activity. The study thus gives objective evidence that certain patients with severe rheumatoid arthritis are benefited in functional and clinical areas by multidisciplinary care which is coordinated between clinic and home. Methodologically, the study demonstrates the feasibility of controlled evaluation of a long-term program of community care.

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Generic and Trade Names of Drugs

Chloroquine phosphate—*Aralen Phosphate*.

Indomethacin—*Indocin*.

Phenylbutazone—*Butazolidin*.

Prednisone—*Cotone, Delta-Dome, Deltasone, Deltra, Lisacort, Metasone, Melicorten, Paracort*.

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