

Comparison of Internal Mammary Artery Ligation and Sham Operation for Angina Pectoris*

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LIGATION of the internal mammary arteries as therapy for angina pectoris has received wide attention.¹⁻⁹ This report describes an evaluation of the treatment of angina pectoris by ligation of the internal mammary arteries compared with a sham procedure.

METHOD

This has been carried out in the following manner:

(1) Two cardiologists selected patients who presented an adequate and uniform history classic for angina pectoris.

(2) Each patient had, either at rest or on exercise, a distinctly abnormal electrocardiogram.

(3) Before operation each patient was exercised to the point of angina under observation, and electrocardiograms were then obtained.

(4) The patients were operated on under local anesthesia. The surgeon, by random sampling, selected those in whom bilateral internal mammary artery and vein ligation (second interspace) was to be carried out and those in whom a sham procedure was to be performed. The sham procedure consisted of a similar skin incision with exposure of the internal mammary vessels, but without ligation.

(5) Neither the cardiologists nor the patient knew which operative procedure had been performed.

(6) Before and after the operation, the patients maintained personal "logs" describing their daily use of nitroglycerin, the characteristics of their pain and their tolerance to work. They were asked to grade in per cent their change following the operation.

(7) On the day following surgery, the patients were exercised to angina (when possible) and electrocardiograms were recorded. This was repeated frequently during the first week following surgery and at intervals up to one year. The cardiologists attempted to quantitate the patient's tolerance to effort and evaluate the degree of abnormality in the exercise electrocardiogram.

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RESULTS

Eighteen carefully selected patients comprised this group. A total of 156 exercise electrocardiograms were obtained. In attempting to evaluate these eighteen patients it was apparent that the two yardsticks, (1) the patient's appraisal of his work capacity, and (2) the changes in the electrocardiogram after exercise, were unrelated. The subjective sensation, angina, was materially lessened in all of the patients immediately following the operation and this improvement was maintained in fifteen of the patients (Chart I). Three patients who were temporarily improved retained this benefit for two days, two weeks and one month, respectively. In the fifteen patients who had sustained benefit (that is, lessened angina) following the surgery, a distinctly abnormal or "positive" electrocardiographic response to exercise could be provoked in thirteen of the fifteen. The degree of exercise necessary to produce a significant change was similar to that required before

Cured (90-100%)	4, 10, 11, 12,* 14*
Definite benefit (50-90%)	2, 3,* 6, 8, 9,* 13,* 15, 17, 18
Improved but disappointed (25-50%)	7
Improved for two weeks, now same or worse	1, 5, 16

CHART I. Patients' opinion of surgical benefit. The numbers (1 through 18) refer to the individual patients as they occurred in the series, grouped according to their own evaluation of their benefit, expressed as percentage. Those numbers followed by an asterisk indicate a patient on whom the sham operation was performed.

operation. In the three patients noting temporary relief, the rest and exercise tracings were unchanged.

Daily "logs" in the fifteen patients indicated a decreased need for nitroglycerin and an increased tolerance to exercise.

Finally, after the cardiologist had reached the aforementioned conclusion, namely, that fifteen of the eighteen patients noted a sustained decreased need for nitroglycerin and an increased freedom from angina after the operation and that the "positive" exercise electrocardiogram could continue to be provoked in thirteen of the fifteen improved patients, the surgeon then released code numbers for the "sham" operations. These were patients 3, 9, 12, 13 and 14. They had all noted material improvement following the operation (Chart I) and a significant improvement in their ability to work. Need for nitroglycerin was uniformly decreased.

The entire group of eighteen patients maintained a written record of the character of discomfort, work capacity and weekly use of nitroglycerin.

RECORDS OF PATIENTS WHO UNDERWENT SHAM OPERATION

The five patients who had sham operations maintained the following records (or were directly quoted in the physician's records).

Sham No. 12 (total follow up eight months).

Questionnaire: "Have you noticed any change following surgery? If so, how soon did it occur? In what exact way are you better? Worse? Are you 100 per cent, 75 per cent, 25 per cent, etc. better? Same?"

Answer: "Yes. Practically immediately I felt better. I felt I could take a deep breath and I have taken about ten nitroglycerins since surgery. These pains were light and brought on by walking. I figure I'm about 95 per cent better. I was taking five nitros a day before surgery. In the first five weeks following, I have taken a total of twelve."

Sham No. 13 (total follow up six weeks).

Office Note (two weeks postoperative): "Has no anginal pains since leaving the hospital and has felt well."

Office Note (four weeks postoperative): "Feels much better. Much calmer today. No anginal pain or other pain since last visit."

Office Note (six weeks postoperative): "Had brief, slight episode of burning-type pain in the area of the incision yesterday while walking. Did not stop walking and pain disappeared within a few minutes. Has had no other pain. The patient is optimistic and says he feels much better."

Office Note (next day): "Patient dropped dead today following moderate exertion."

Sham No. 14 (total follow up three months).

Same questionnaire as Sham No. 12.

Answer: "I can do anything except real hard lifting. I am running farm equipment and using maybe one nitro a week. I used to need fifteen a day. Believe I'm cured."

Sham No. 3 (total follow up seven months).

Doctor's Note: "Internal mammary procedure this a.m. Is feeling well and happy with results. States he has lost the heavy feeling in 'pit of stomach' and could feel the difference the moment the arteries were tied off."

Doctor's Note (five days later): "No chest trouble even with exercise."

Doctor's Note (five weeks later): "Since surgery has been feeling very well and is operating heavy machinery. Could not work before. Believes he has improved very much after surgery."

Doctor's Note (twelve weeks later): "Working every day, need about two nitro a day, but can do about anything."

Sham No. 9 (follow up six months).

Same questionnaire as Sham No. 12 and 14.

Answer: "The pressure has come off my chest. I still have angina if I push myself (yesterday, raking). Hiking over your wooden steps doesn't bother me now."

RECORDS OF PATIENTS WHO UNDERWENT LIGATION

As a balance, it is useful to cite some answers from the ligated patients.

Ligated No. 6.

Reply to Questionnaire: "I have noticed relief from these pains within a day after surgery. I can now do my normal walking or exercise with less effort than before. I have not found it necessary to use nitroglycerin since surgery."

Ligated No. 11.

Reply to Questionnaire: "I have felt some better since the day of surgery and have been better day by day since. It takes more emotion or hurrying to bring on the trouble. Before surgery, I was taking from thirty-six to forty nitro tablets per week so I feel I have been helped quite a lot. Now I take none to three a week."

EXERCISE ELECTROCARDIOGRAMS

A total of 156 exercise electrocardiograms were obtained from these eighteen patients. In the majority, the wooden steps suggested by Master were used. On occasion, if the patient had extremely easily provoked angina, the

patient was walked on the level until angina resulted. Our definition of a "positive" response differs from Master's in that we do not believe that a 0.5 mm. depression of the RS-T segment is necessarily significant, but consider a late terminal dipping of the RS-T segment a distinct warning. Several examples of a typical "positive" response to exercise by our definition are illustrated in Figure 1.

Analysis of the 156 exercise tracings indicates that in general the change in the electrocardiogram can be dependably produced day after day with the same amount of exercise. Exceptions occur and infrequently a resting and exercise tracing will be abnormal one day and normal on the subsequent day. As a general statement, however, the tracing was reliably altered by standard exertion.

A further observation is that the degree of abnormality in the exercise tracing is not quantitatively related to the degree of angina. True effort and emotional chest pressure, amazingly sensitive in its provocation, may occur with a minimally changed electrocardiogram, while another patient may be unaware of chest discomfort, yet have a 3 or 4 mm. depression of the RS-T segment in leads V_3 , V_5 and V_6 on exercise.

Of the five patients subjected to the sham procedure, all improved subjectively in terms of tolerance to exercise, lessened need for nitroglycerin and sense of well-being, and constitute, although a very small group, an important and unique group. Any proponent of either medical or surgical therapy for angina who cites as a criterion an improvement in the patient's work capacity, will need to remember and explain away the marked response in the five patients who underwent the sham operation.

COMMENTS

The question which must be answered, of course, is did these patients actually have angina or was their limitation simply an emotional overlay. No final answer is reliably possible. When a clinician places a label of "angina" on a patient, he does so by eliciting a story which sufficiently fits the clinician's own personal definition. There is no scientific quantitation for angina. The value of the clinician's opinion is conditioned by his training and experience. We have attempted to validate the "angina" in this series by selecting patients from whom a reproducible history of discomfort on effort could be elicited separately by two cardiologists

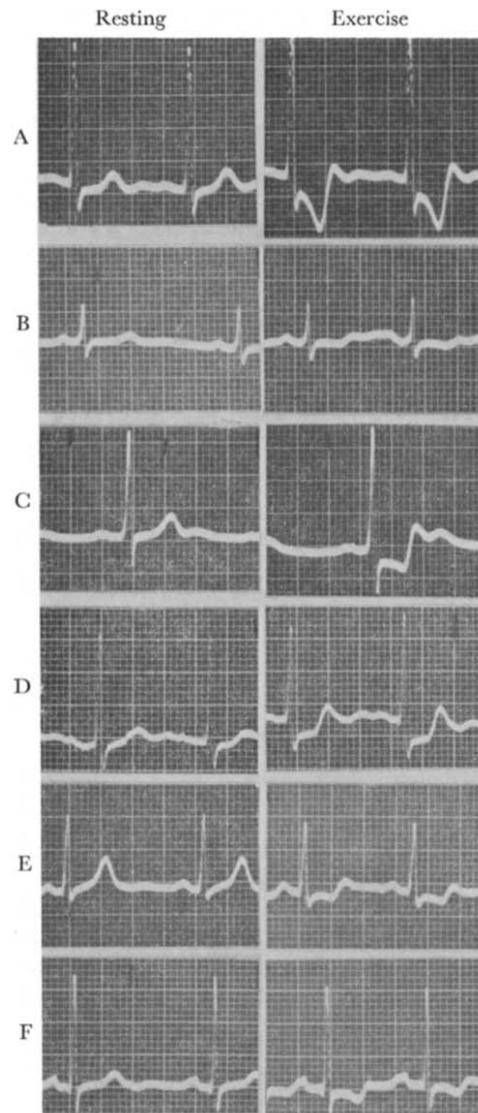


FIG. 1. Examples of exercise electrocardiographic response. Lead V_3 in six patients (A through F). Resting complex at left, exercise complex at right. The patients all had clinical angina. According to our criteria, all exercise responses are "positive" except patient B, whom we consider "borderline."

and further, by selecting patients with marked RS-T and T wave changes on exercise.

Angina is a sensation experienced by the patient and the degree of his experience is not simply a measure of the amount of coronary disease, but of a patient's threshold for pain. Any attempted therapy for coronary atherosclerosis which assumes the patient's degree of angina or his feeling of well-being as a reliable index of improvement must first take account of the physician's (or surgeon's) personality, the

effect of group therapy and the natural course of angina. The frightened, poorly informed man with angina, winding himself tighter and tighter, sensitizing himself to every twinge of chest discomfort, who then comes into the environment of a great medical center and a powerful positive personality and sees and hears the results to be anticipated from the suggested therapy is not the same total patient who leaves the institution with the trademark scar. The additional effect of bed rest, sedation and anesthesia (local or general) must also be weighed. It is also difficult for a patient's actual care to remain constant over a period of so-called controlled observation. Variables of digitalization, weight gain, weight loss and change in dietary habits are also involved.

The traditional relationship of angina and emotion is well accepted. A thoughtful appraisal of this group of patients makes one conclude that true angina was present in the entire group and that under the strong psychotherapy of surgery there occurred a rearrangement of the provoking myocardial metabolites, or a lessened sensory pathway or a lessened cerebral awareness.

Remembering these variables, and from a study of these eighteen patients, it is our conclusion that if internal mammary artery ligation is truly offering protection to the patient, some supporting data other than patient-reported improvement must be offered. Decreased angina in itself is an unreliable measurement. Patients who underwent a sham operation experienced the same relief. The electrocardiogram after exercise is not improved by the ligation of the internal mammary arteries, even if the patient notes an almost total remission of pain.

The benefits described by the five patients who underwent a sham operation should be remembered by all proponents of therapy for angina, either medical or surgical, who cite as

their index of proof that the patient was relieved or had a decreased need for nitroglycerin.

SUMMARY

A sham operation was compared to ligation of the internal mammary arteries in patients with angina pectoris. Patient improvement was identical. The exercise electrocardiogram was not altered by either procedure.

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