Appendixes

Appendix A.— Length of Stay and Outcome: Myocardial Infarction

Myocardial infarction (MI) is the clinical condition that has received the most attention from researchers with respect to how much hospital care is required for treatment. Prolonged bed rest was the hallmark of the treatment of acute MI patients until the 1960's. Lewis (109), for example, recommended 8 weeks of bed rest in 1937. White (179) recommended 1 month of bed rest in **1945.** These recommendations were based in part on fears that inadequate bed rest would lead to cardiac rupture or ventricular aneurysm formation (112,123). A few dissenting voices were heard (70,43). In 1947, Asher (8) wrote colorfully of the dangers of too much time spent in bed:

> Look at a patient lying long in bed. What a pathetic picture he makes! The blood clotting in his veins, the lime draining from his bones, the scybala stacking up in his colon, the flesh rotting from his seat, the urine leaking from his distended bladder, and the spirit evaporating from his soul.

He thought the traditional 6 weeks of bed rest following a MI was unsupported by good evidence of efficacy. Levine and others (10,107,108) recommended that MI patients be placed in a sitting position as soon as possible, believing that greater rest was afforded to the heart in this position.

In 1950, Irvin and Burgess (90) discussed the disadvantages of bed rest, including poor circulation to the basilar part of the lungs, worsened congestive failure, increased thrombophlebitis and pulmonary embolism, negative nitrogen balance, and negative psychologic sequellae. They recommended a period of 2 weeks bed rest and 4 weeks hospitalization for MI patients. Brummer and his colleagues (27) reported on 258 consecutive MI patients whom they treated with an average of 16 days bed rest and 23 days hospitalization. They reported two cases of sudden death during the ambulation period in the hospital, both occurring in patients who had been kept in bed longer than usual, presumably to treat complications. They also noted one patient with sudden death and 21 with recurrent MI during the first month after discharge. Although this incidence of recurrent infarction seemed to the authors to be higher than they expected, they concluded that on the whole early ambulation should be prescribed for MI patients.

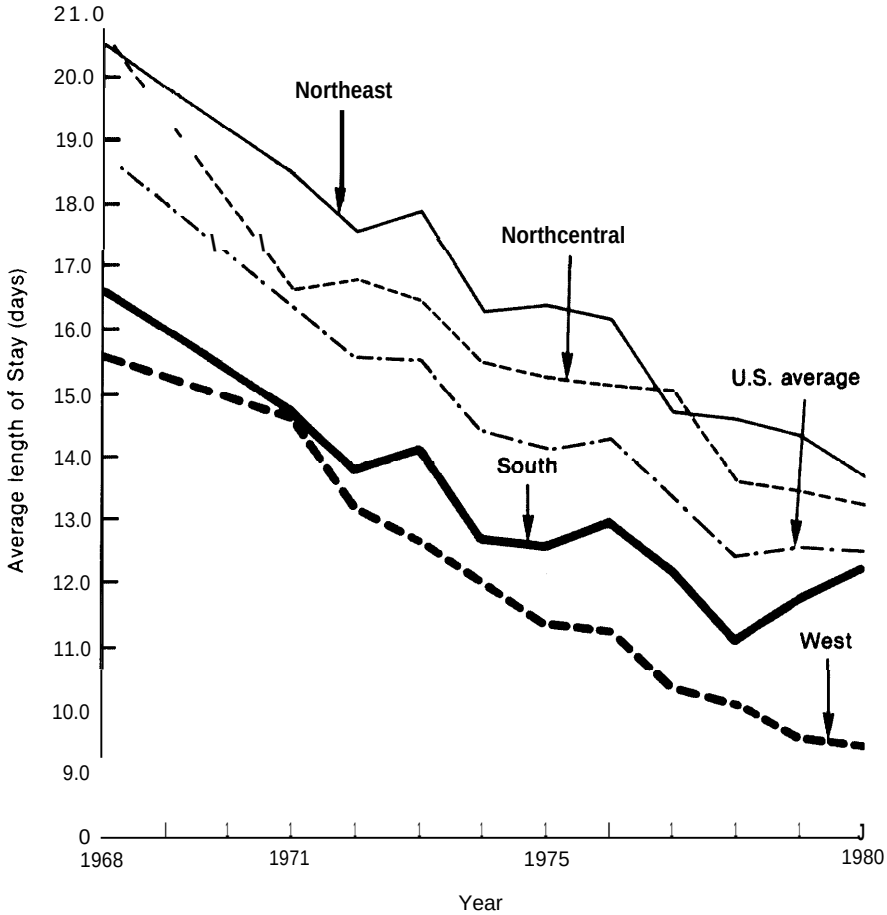
Beginning in the 1960's and accelerating into the 1970's, increasing numbers of research studies of early ambulation for MI patients were published. Associated with the appearance of these studies has been a rapid decrease in the U.S. length of stay (LOS) for MI patients. Figure A-1 describes the extent of this decline by region since 1968. From 1968 to 1980, LOS for MI patients in the United States has declined 33 percent, as opposed to 14 percent for all patients. The decreases for each region have been striking, with the West declining the most **(38** percent), followed by the North-central (35 percent), the Northeast (32 percent), and the South (26 percent).

Three fundamentally different types of studies have been reported in the literature. The first group comprises studies that analyzed clinical data trying to explain variations in treatment practices or to identify characteristics of low-risk MI patients who might be candidates for early discharge. Studies in the second group reported on the effects of early ambulation and discharge programs for MI patients without providing any control data. Studies in the third group also reported on early ambulation and discharge but included control data for comparison, in some instances from randomized clinical trials (RCTs). The studies in each of these groups are reviewed in turn.

Two retrospective studies documented large variations among individual physicians in the care of MI patients. Heasman and Carstairs (76) found that in 1967 among Scottish physicians who each cared for at least 20 MI patients, the average LOS per physician ranged from 10 to 36 days, with physicians at teaching hospitals experiencing a lower median LOS **(20 days)** than physicians at nonteaching hospitals (25 days). No attempt to adjust case mix was made. Duke (46) examined 313 MI patients at a single hospital in Connecticut, all under 65 years of age from 1965 to 1968. He found that physicians differed in how much bed rest they prescribed (the average physician varying from 7 to 15 days), in how long their patients stayed in the hospital (from 21 to 29 days), and in how much bed rest they prescribed as a proportion of the total hospital stay (from 30 to 65 percent). Moreover, there was no relationship between those physicians who prescribed the longest period of bed rest and those who prescribed the longest total hospital stay. Finally, an assessment of the frequency of complications in these physicians' MI patients failed to document significant case mix differences to account for these varying practices.

Phineas and Lovell (137) reviewed the decreasing LOS for MI patients at the Royal Melbourne Hospital in the early 1960's. Without adjusting for severity of illness, they reported no difference in 3-month mortality among groups of patients with differing lengths of stay.

Figure A-1.—Regional Trends in Length of Stay for Myocardial Infarction



SOURCE *Vital and Health Statistics*, series 13, Nos 2 10 14, 17, 19 23 26, 31 41 46, 55 60 64 (Washington D C National Center for Health Statistics, 1967.82)

Rose (147) reviewed the evidence available in 1972, before any of the RCTs were published, and concluded that a week of bed rest was all that was necessary and that hospital discharge could take place a "few days" after being allowed to walk on the eighth day. Figure A-1 shows that U.S. physicians were a good deal more conservative in their practice; the average LOS in the United States for MI patients was 15.6 days in 1972. Wenger and colleagues (177) surveyed U.S. general practitioners, internists, and cardiologists in 1970 and reported on the treatment pattern that "most physicians" reported. Their treatment of choice was strict bed rest for 3 days, a total intensive care unit stay of 4.5 days, up in a chair by the eighth day, walking by the 12th day and discharged by the 21st day. This report is a good deal more conservative than the actual practice reflected in figure A-1. However, no distribution of physicians is given, so one does not know how much variation in physician reports there was.

The lack of solid data establishing the optimal LOS for MI patients prompted some researchers to analyze clinical data, either retrospectively or prospectively, in an attempt to identify characteristics of a low-risk group that might be able to be discharged earlier than the practice of the time. Wilson and Pantridge (182) evaluated 466 MI patients in Belfast that had survived 3 days hospitalization and found that of those without certain risk factors (shock, serious arrhythmias, and high enzyme levels), lack of persistent ST segment displacement on the electrocardiogram was a good predictor of the absence of late occurring serious ventricular arrhythmias. They suggested that patients in this category, which constituted 26 percent of the total population of MI patients, might be candidates for discharge after only 48 hours, since only a single patient

in that subgroup experienced a late ventricular arrhythmia.

The most often studied criteria for early discharge are those developed by McNeer and his colleagues (11 7) at Duke University. They first observed in 1975 in an analysis of 522 consecutive patients with documented MIs that patients who had suffered a serious complication after the first 4 hospital days also had one during the first 4 days. The complications identified as serious were: death, ventricular fibrillation or tachycardia second or third degree AV block, pulmonary edema, cardiogenic shock, persistent sinus tachycardia or hypotension, atrial flutter or fibrillation, and extension of infarct. They also found that of the patients without complications in the first 4 days, there was no inhospital mortality during an average LOS of 17 days and a 6-month mortality of 8 percent. This compared with an inhospital mortality of 14 percent in the complication group and a cumulative 6-month mortality of 19 percent. In their original series, patients with uncomplicated MIs made up 51 percent of the total MI population.

The Duke criteria have been replicated in three retrospective studies. Worth and colleagues (183) studied 455 definite MIs in four Honolulu community hospitals. They found four patients in whom serious complications first presented themselves between the sixth and eighth days. Three of these patients died in the hospital. All of these patients had been admitted for recurrent MIs. Of the 182 first MIs without complications through day 4, there were no inhospital deaths. Actual LOS at the four hospitals varied in this study from 12 to 18 days for patients with uncomplicated MIs and from 15 to 20 days for those with complicated MIs. Patients with uncomplicated MIs comprised 51 percent of the total population of patients with MIs.

The same criteria were used to evaluate a patient population in a community hospital in North Carolina. Severance and colleagues (158) reported that 81 of 400 MI patients (20 percent) had no serious complications during the first 4 days of hospitalization. Only one of these patients later had a serious complication; this patient survived an extension of his infarct. LOS was 17 days in the uncomplicated group and 18 days for the remainder. There were no deaths in this group during a 1-month followup period. Finally, Skoulas and colleagues (165), applied the McNeer criteria retrospectively to 210 consecutive MI patients in a Kaiser hospital in northern California. Like McNeer, they found that all patients with serious complications had had one during the first 4 days of hospitalization. There were no hospital deaths among the group without complications during the first 4 days and only one death during a 6-month followup period. The 87 patients with uncomplicated MIs comprised 41 percent of the total. They spent the least amount of time in the hospital of any group studied thus far, an average of 7.9 days. The complicated patients stayed only an average of 11.2 days. These patients were treated during 1978-79, and figure A-1 shows that these LOS figures were consistent with the West's average LOS for MI patients of 9.7 days in 1979. Other studies (11 1,163) have attempted to find criteria for early discharge (or safe transfer from intensive care) but none of them has been as successful as the Duke criteria. Other investigators (124,140) have analyzed patients admitted with suspected MIs retrospectively in order to determine criteria for safe early discharge or transfer from intensive care, but these studies have not been replicated, nor their criteria applied prospectively.

One cannot conclude from these studies that patients without complications in the first 4 hospital days following a MI can safely be discharged after that time. None of these studies was a prospective trial of early discharge. In three of the four, LOS for the uncomplicated MIs was 2 weeks or longer, and no attempt had been made actively to discharge these patients earlier than their physicians thought appropriate. It is thus not at all clear that earlier ambulation in preparation for earlier discharge would not have proved disadvantageous. The fact that all of these studies used almost identical criteria and found similar results lends added weight to the potential reliability and validity of these criteria as predictors of good prognosis and, therefore, of candidates for early discharge. Better data are needed, however, in order to establish this proposition conclusively.

Eight studies (2,22,26,27,35,53,173,174) report the results of early ambulation and discharge programs without providing control data. Table A-1 summarizes the most important findings from these studies. It is very difficult to draw any definitive conclusions from these studies. First of all, none of them was performed in the United States. Second, the study populations varied considerably. Four included only men, and two excluded the elderly. Third, the protocols used by the individual studies also varied. Even if attention is confined to those studies published in the 1970's, the period of bed rest varied from 1 to 3 days. Ambulation began on day 4 to 6, and discharge was planned from day 7 to 14. Fourth, results are reported inconsistently.

Some studies report results for high- and low-risk groups, usually those patients able to be discharged according to the protocol are separated from those with complications to whom the protocol for early discharge could not be applied. Other studies report results for the entire MI patient population. Some

Table A-1.—Uncontrolled Studies of Early Mobilization and Discharge for MI Patients

Study[a]	Patient population	Deaths before ambulation (%)	Protocol	Results (% of those ambulated) In hospital: Death (%)	In hospital: Nonfatal reinfarct (%)	Followup: Time	(cumulative): Death (%)	(cumulative): Nonfatal reinfarct (%)
1 Brummer, 1956	332 consecutive MIs	22	Bed rest 2 wks (mean . 16 days) Walk day 15 Discharge day 21 (mean . 23 days)	1	04	6 mo	8	9
2 Brummer, 1966 . . .	775 consecutive MIs	28	Bed rest 10 days (mean) Discharge day 19 (mean)	2	1	1 mo.	3	4
3 Adgey, 1969	102 consecutive MIs, under 70, survived admission, discharged 18 days	—	Discharged 18 days	—	—	2 wks.	o	0
4 Royston, 1972,	200 consecutive males with MI	11	Bed rest 3 days (60$%<5 days) Walk day 4 Discharge 11-14 days (97% < 14 days)	A	?	6 mo.	11	?
5. Tucker, 1973	342 consecutive males with MI	15[b]	Bed rest 24 hr. Walk day 6 Discharge 7-10 days (mean = 8 days)	?	2	6 wks.	22	4
6. Chaturvedi, 1974	275 consecutive MIs surviving 6 days in hospital	—	Low risk (680/0 discharged by day 7)	7	?	3 mo. 1 yr.	0 2	? ?
			High risk (64°/0 discharged by day 11)	7	?	3 mo. 1 yr.	6 11	? ?
7. Gelson, 1976 ..,	405 consecutive males with MIs	15[c]	Bed rest 24 hr. Walk day 6	?	7	6 wks.[d]	7	3
			Discharge 7-8 days (76% by day 8)			6 wks.[e]	8	16
8. Thornley, 1977	142 consecutive males under 65 with MIs	11	Bed rest 2 days (mean . 5 days) Walk day 4 Discharge 10-14 days (mean . 15 days)	2	?	24 wks	6	10

[a] See Reference list for complete citations of studies in table
[b] No data on deaths before ambulation Figure given is all inhospital deaths Followup data are given as percent of total patient population
[c] No data on deaths before ambulation Figure given is all inhospital deaths
[d] Of 27 I patients discharged by day 8
[e] Of 87 patients discharged after day 8

report results in terms of only those patients that could be ambulated, others for the entire group. All of these difficulties combined make it extremely difficult to interpret the data provided by these studies. For example, all of the studies that report death during inpatient ambulation found that some patients died during this process (1 to 4 percent). Would these patients have benefited from a longer period of bed rest? Or would more have died as the result of complications of bed rest? Without control groups carefully selected so as to be comparable to the study groups, these questions cannot be answered. Similar questions can be raised concerning the data reported on outpatient mortality, which ranged from a low of zero in 2 weeks, to a high of 7 percent in 6 weeks. Why did the 7 percent result occur in studies which employed only 24 hours of bed rest when another study with 10 days bed rest found a 1 percent outpatient mortality? Again, answers to these questions cannot be derived in the absence of control populations.

Five studies **(21, 66, 69, 102, 116)** reported the results of early discharge programs for MI patients and also reported results for control groups that were selected in a nonrandom manner. In the first such trial, Groden **(66)** reported on **105** men with MIs. Patients were allocated to the early or late discharge groups based on which of two consultants cared for them. Early discharge consisted of bed rest for 2 weeks, mobilization on day 15 and discharge on day 22. Late discharge consisted of bed rest for 3 weeks, mobilization on day 25, and discharge on day 36. Survival data were presented only for the period of hospitalization: 18 percent of the early discharge and 22 percent of the late discharge group died prior to discharge. Clearly,

these two groups may have differed in more ways than the treatment they received. Selection of a control group from among patients of a different physician than that of the study group is a less than adequate research design. Moreover, the lack of provision of outpatient mortality data is another serious defect.

Harpur and colleagues (69) reported a study in which patients admitted to one hospital were mobilized after 7 days of bed rest and discharged on day 15 and those admitted to a second hospital were mobilized after 3 weeks of bed rest and discharged on day **28.** The two hospitals received admissions on alternate weekdays and weekends. In addition, the hospitals changed roles in the study at 4-month intervals for a 2-year period in order to ensure that both early and late discharge programs were carried out by both institutions. This study found that mortality at 8 months was 5 percent in the early group and 8 percent in the late group. Nonfatal complications were equally distributed. The two groups returned to work at about the same rates (about 75 percent of those eligible), but the early group returned about 2 weeks sooner than the late group.

Boyle and colleague (21) reported on a group of Ml patients who were discharged from their hospital within 10 days. They compared the experience of this group with that of patients remaining in the hospital more than 10 days. They found that after adjusting for severity of illness, there was no difference in 3-month mortality for the intermediate severity group for those patients discharged in less than 10 days compared with those who stayed longer than 10 days. They also found nonsignificant differences for the other severity groups and concluded that their program was not harmful.

Some of the problems associated with choosing a control group in a nonrandom fashion have already been discussed. In the Boyle study a new problem arises. The data presented are quite consistent with the hypothesis that early discharge is harmful. The argument is as follows: One would expect that of a total population of MI patients those who would be discharged early would be the ones with less severe infarcts. Thus, one would expect those discharged early to experience a lower mortality rate than those more complicated patients who were unable to be discharged early. Therefore, a study that found, as this one did, that its early discharge patients had the same mortality experience as their late discharges might be appropriately subject to the criticism that its early discharge program had in fact been harmful to those low-risk patients who participated in it. The only way to produce data not subject to arguments of this kind is by the employment of a random allocation strategy of study and control subjects.

Lamers and associates (102) described a unique study in 1973. They tested the difference between mobilizing MI patients on the 10th hospital day as opposed to the 20th day, while holding total LOS constant at 30 days. This study is included in the present discussion, because its report does not explicitly state that subjects were randomly assigned. They may have been, but no statement to this effect appears in the published report. In this study, patients were evaluated for possible inclusion on the ninth hospital day. This procedure eliminated 119 of the 555 patients admitted with definite MIs who had died before day 9. An additional 148 were eliminated because of the presence of complications, and 86 were eliminated because of "statistical problems. " Thus, 202 patients (36 percent) were assigned to early and late mobilization groups.

The study protocol involved a graded schedule of mobilization beginning with dangling the legs over the side of the bed, then sitting in a chair, and finally beginning to walk only 4 days into the schedule. Thus, the early group was not actually ambulatory until day 14, the late group not until day 24. Compared with the programs summarized in table A-1, this is a very conservative early mobilization scheme. There were no inhospital deaths in either study or control groups. At an average followup period of 18 months, the early mobilization group had experienced a mortality rate of 17 percent, while 15 percent of the late group had died. The question that this study tried to test is an interesting one: What is the effect of early ambulation on MI patients, independent of total hospital LOS?

Unfortunately, several study design and reporting flaws make the results of the Lamers study difficult to interpret, even leaving aside the question of whether or not the subjects were randomly assigned. First, the study did not really test "early" ambulation as that term has now come to be understood. The previously described programs aimed for ambulation between days 4 to 6. Thus, the stud, was testing treatments that, even in the late 1960's, were not considered by most U.S. physicians to be innovative. Second, the study failed to report its followup data in adequate form. Life table analysis must be used if participants have not all been followed for the same time period. The reported data do not allow one to determine how many person-years of risk were contributed by each group. Thus, the outcome data are somewhat difficult to interpret.

Finally in this group of nonrandomly controlled studies, McNeer and his colleagues (116) have described an early discharge program in which they applied their own criteria in a prospective fashion. Of 158 consecutive MI patients, 67 had none of the complications previously described by the fifth hospital day. All 67 of these patients (42 percent of all patients

with MIs) were candidates for early discharge according to the criteria, but only 33 were actually discharged at 1 week. In 33 of the remaining 34 cases, the reason for the lack of an early discharge was either a home too distant for the followup nurse visits planned by the study or a home environment not conducive to MI convalescence. The patients who were discharged at 1 week were visited by a specially trained nurse practitioner equipped with a transmitter for cardiac rhythm monitoring every other day for the first week and every third day for the second week following discharge. The study reported no deaths in either subgroup of the 67 patients with uncomplicated MIs either at 3 weeks or at 6 months of followup. There were five nonfatal complications at 6 months in the early group and nine in the late group.

This study and its accompanying editorial generated some lively correspondence. The editorial commenting on the study (149) concluded that: "It is now clear that certain patients designated as 'low risk' can be discharged from the hospital at the end of one week." The correspondence that followed (125) both criticized and praised the study's design and findings. There is first of all the issue of the selection of the control group. Once again the lack of a random assignment subjects the study to several lines of criticism, each concluding that the study and control groups might have differed in ways other than their LOS. Even though the groups appeared well-matched when the usual demographic and clinical variables were assessed, the late subgroup did experience more late nonfatal complications (26 v. 15 percent). This could indicate that they were somewhat sicker than the early group at the outset, or that their less optimal home environment predisposed them to poorer outcomes, or that their longer hospital stay somehow made their outcome somewhat worse. There is no way to answer these questions in the absence of a random assignment design.

A much more serious question is raised by the small sample sizes in the early and late groups in this study. In part, the question is what can be concluded by a demonstration of no statistical difference between two experimental groups or, more precisely, by a failure to reject the null hypothesis. In this study, for example, if it is assumed that the zero percent mortality rate at 6 months in the late discharge group is correct, then if the true 6-month mortality rate in the early group is in fact 5 percent, this study stood a 63-percent chance of being unable to recognize it at the 5-percent significance level. The "power" of the study in this circumstance was, therefore, only 0.37. * If the true mortality rates were 1 percent in the late group and 6 percent in the early group, the power of this study to reject the null hypothesis of no difference between the two rates would be only 0.30. The small sample size also prevented the difference in the rate of nonfatal complications noted above from attaining statistical significance at the 5-percent level. The problem of small sample sizes will be discussed later in greater depth.

These technical issues aside, the fact remains that neither the early nor the late subgroup experienced any deaths at 6 months of followup. This fact certainly means that McNeer and his colleagues have been successful in identifying a low-risk subgroup of patients who came for care to the Duke Coronary Care Unit. It is also true that this study produced the lowest mortality rate reported for any study reviewed in this analysis. No other group has reported a 6-month mortality rate for its low-risk MI patients that is this low. This observation raises the question of whether the Duke population of MI patients is somehow different from others or whether their combination of treatments is somehow peculiarly successful. Unfortunately, these questions cannot be resolved until further prospective studies, hopefully RCTs, have been done.

The last group of studies to be reviewed includes 5 RCTs that have evaluated early discharge for MI patients. Their results are summarized in table A-2. The first (86) and most well known, was conducted in Boston and randomly assigned patients with uncomplicated MIs to 2- and 3-week LOS subgroups. The early discharge group was ambulated on day 12, the late group on day 17. It is noteworthy that only 17 percent of MI patients who survived to the day of assessment for participation in the study (day 5) were selected for randomization. Of those survivors rejected, 90 percent were excluded due to complications of infarction, due to a MI within 6 months of the current admission, or due to other medical illnesses. The early and late groups were fairly well matched, except that significantly more of the late patients had experienced previous angina than the early patients (23 v. 7 percent) ($p < 0.05$, chi square). Postrandomization complications prolonged the hospital courses of seven early patients and three late patients, but actual LOS figures were not reported for the two groups. There were no inpatient deaths. None of the outcome differences listed in table A-2 was statistically significant at the 5-percent level using the chi-square test.

The second reported trial (118) was carried out in Scotland and excluded patients over 70 years of age and patients with complications as assessed on the seventh hospital day. A far greater proportion of patients was included in this study (69 percent) than in the previous one (17 percent). This study also differed

* All power calculations performed here are done using the binomial approximation for proportions, a method which overestimates power slightly for very small proportions

Table A-2.—Randomized Clinical Trials of Early Discharge for MI Patients

Study[a]	Exclusions	Percent survivors included	Protocols (sample sizes) Early (E)	Late (L)	Followup period	Outcomes (%) Mortality E	L			Return to work E	L
1. utter, 1977 . .	Complicated MIs assessed on day 5	17	Walk day 12 Discharge day 14 (69)	Walk day 17 Discharge day (69)	mo.	4	7	26	22	58	49
2. lasgow, 1973	Over 70 years complicated MIs assessed on day 7	69	Walk day 7 Discharge day 21 (269)	Walk day 21 Discharge day (269)	12 mo.	11	15	10	o	—	1
3. Hayes, 1974	Complicated MIs assessed on day 3	71	Walk day 4 Discharge day 9 (107)	Walk day 9 Discharge day 16 (82)	6 wks.	7	7	6	5	2	2
4. Bloch, 1974	Over 70 years complicated MIs assessed on day 3	80	Walk day 8 Discharge day 21 LOS = 21 days (77)	Walk day 22 Discharge day 28 LOS = 33 days (77)	11 mo.	6	10	12	14	—	—
5. Ahlmark, 1979	Over 70 years complicated MIs assessed on day 4	75	Walk day 6 Discharge day 8 (128)	Walk day 12 Discharge day 15 (124)	3 mo.[b]	5	2	9	12	35	23

[a]See Reference list for complete citations of studies in table.
[b]All outcome percentages for this study are based on the number of patients in each group who did not suffer inpatient complications that prevented them from being ambulated or discharged on the target dates (early group = 106 patients; late group = 100 patients) (see text).

from the previous one in that those patients randomly assigned to the early discharge group were permitted to walk at an earlier time (day 7 v. day 12) but were kept in the hospital for a longer total time (21 v. 14 days). Those allocated to the late group were both ambulated later and discharged later than their counterparts in the previous study. Once again the two groups were well matched with one slight exception—the early group contained slightly more males than the late group **(83 v. 74** percent; chi square, $p < 0.05$). As with the previous study, however, actual LOS figures were not reported. Unlike the previous study, however, this study showed significant inhospital mortality, 5 percent in the early group and 4 percent in the late group. The remainder of the cumulative l-year mortality displayed in table A-2 occurred after discharge. None of the differences in outcomes was statistically significant at the 5-percent level.

Hayes and colleagues (71) reported a study from England that assessed MI patients on the third hospital day and excluded 29 percent of those patients surviving to be assessed as too ill to participate in the trial. In this study, patients were randomly allocated to early and late mobilization groups but were then sent to different hospital wards, based on a monthly schedule. Each hospital ward alternated on a monthly basis treating first early, then late patients, or vice versa. This design feature was employed in order to avoid having both early and late discharge patients on the same ward at the same time, apparently in order to avoid nursing confusion. Unfortunately, this scheme broke down during the trial when some wards became too full to accept patients. As a result, some patients were unable to go to the ward to which they had been randomly assigned. More unfortunately, when this occurred, the patients were sent to the ward with the most empty beds. Since this ward was most often a ward practicing early discharge, more patients were allocated to the early discharge group than to the late discharge group (107 v. 82). It is thus clear that the random assignment procedure in this study was seriously flawed. The early mobilization and discharge group in this study was treated with the earliest ambulation of any study in this group (day 4). The late group was treated with the earliest ambulation of any late study group (day 9). The two groups were fairly well matched on the following variables: age, sex, duration of pain, average blood pressure, site of infarct, and average enzyme levels. The 6-week mortality rate given in table A-2 conceals the fact that in this study all of the mortality in the late group occurred during the hospital stay, while four of the seven deaths in the early group occurred prior to discharge. There were no statistically significant differences between the two groups in the overall outcome measures.

The fourth RCT was performed in Switzerland and reported by Bloch and colleagues (17). Patients with documented MIs were assessed on the third hospital day and those with uncomplicated MIs who were also under age 70 were randomly assigned to early and late mobilization groups. Only 20 percent were excluded, the lowest figure of all the RCTs. The protocols for treatment in this study were very comparable to those used in the Glasgow study, with ambulation on day **8** and 22 for the early and late groups respectively and discharge on day 21 and **28.** The actual lengths of stay for the early and late groups were 21 and 33 days. Again the groups were well matched. There was significant inpatient mortality in this study, with the rates being 5 percent and 6 percent in the early and late groups respectively. As with prior studies, no statistically significant differences were observed in the outcome variables listed in table A-2.

The fifth RCT is from Sweden, reported by Ahlmark and colleagues (s), They assessed patients on the fourth hospital day and excluded those over age 70 and those with complicated MIs. They randomly assigned 75 percent of the patients surviving to day 4 to early and late discharge groups. The essentials of the protocol are given in table A-2 and are similar to those of Hayes. Unfortunately, the researchers in this study compromised the random assignment process in a serious way. They excluded from the study all patients who had complications during hospitalization that precluded the possibility of discharging them at the appropriate time, day 8 or day 15. It is reported that 24 patients in the late group and 21 patients in the early group were so excluded. Even worse, followup data are not provided for these patients, making it impossible for the reader to add them back into the analysis retrospectively. The number of inhospital deaths is not reported for this group of excluded patients, although it is reported that one patient in the early group died in bed 4 days after admission while undergoing the early phases of the early mobilization protocol. This is the reason that the outcome measures reported for this study in table A-2 are given in terms of percent of patients discharged, instead of patients randomly allocated as is the case with the other studies. As with the other studies, no significant differences in the outcome measures were noted.

Before analyzing these studies further, a word is necessary about two other RCTs that compared home and hospital care for a selected sample of MIs initially determined to be uncomplicated **(82,113).** These studies have not been included in the present analysis

for two reasons. First, they are not directly concerned with the issue of hospital LOS and health outcome. The question of the most appropriate institutional setting in which to care for particular kinds of patients is a question separate from the one presently under consideration. Secondly, both these studies were done in England. The present social and medical-legal pressures that exist in the United States make it practically impossible either to perform such a study in this country or to care for any significant number of MI patients at home. Thus, this medical option is not viable in the United States at the present time.

From both clinical and health policy perspectives, the most important question that these RCTs can answer is: Does early discharge carry with it a negative health impact? A well-designed and well-executed RCT should be able, within certain limits, to provide the answer to this question. It is evident from the previous description that the third and fifth studies in table A-2 had their random assignment procedures sufficiently compromised that they cannot be considered true RCTs. They will be discussed later. The remaining three studies all showed similar results. The early discharge group fared slightly better than the late group in each of the three studies with respect to mortality (17, 86, 118) The studies also have in common the fact that none of the differences was statistically significant. There are also important differences among the studies. Two of the three excluded elderly patients, and one included only 17 percent of those patients who were evaluated for possible participation. Each of the studies assessed their patients for possible inclusion on different days, and each used somewhat different exclusion criteria and mobilization protocols.

What, then, can be concluded regarding the health impact of early mobilization and discharge for MI patients? After sifting through all of the studies that have been reported and narrowing the field down to these remaining three RCTs, the most rigorously designed and executed of all the studies that have been done, what conclusions can be drawn? The most important conclusion that can safely be drawn is that early mobilization and discharge, when applied under the terms stated in these studies, clearly does not pose a major health hazard to patients with uncomplicated MIs, as defined in these studies.

The issue of statistical power must still be discussed. Even the study with the smallest sample size (i. e., the first study in table A-2 with samples of 69 in each group) has an excellent chance of finding a large difference in mortality between the early and late groups. For example, assuming the control or late group had the same mortality as it actually had (7 percent), if the study or early group had a true mortality rate of 30 percent, the study design actually employed would have had only a 3-percent chance of making a Type II error at the 5-percent level of significance and falsely accepting the null hypothesis of no difference. The power of the design under these circumstances would be 0.97. However, the smaller the difference that is of interest, the greater the chance of making a Type II error. For example, most physicians would certainly agree that if the true mortality rate for uncomplicated MI patients discharged early were 10 percentage points greater than for those discharged late, none should be discharged early, This same study, again assuming a 7-percent mortality rate for the late group, has a power of only 0.57 if the true mortality rate of the early group is 17 percent. Thus, one could expect to make a Type II error barely less than half the time in trying to observe a difference in mortality rates of this magnitude with this study design.

Table A-3 displays some similar power calculations for the three true RCTs just identified. It is clear that while all of these study designs are sufficiently robust to detect large differences, none is especially powerful in trying to detect a difference of 5 percent. From a clinical perspective, it is certainly prudent to perform an experiment with small sample sizes first to rule out the possibility of a large negative effect before proceeding to a large trial to evaluate the possibility of much smaller negative or positive effects. However, such an initial experiment may not provide sufficient evidence by itself to justify adoption of the experimental treatment.

Another way to analyze the data is to take a closer look at the actual study results instead of hypothesizing about possible results. For example, one can construct 95-percent confidence intervals for the difference between the mortality rates in the early and late groups in each of these RCTs. In doing this, one finds that the data in the first study are compatible with differences ranging from 11 percent in favor of the early

Table A-3.—Power of Randomized Clinical Trials on Early Discharge for MI Patients

Study[a]	Statistical power under three alternative hypotheses		
	5 %[b]	10 %[c]	20 %[d]
1. Hutter, 1977	0.26	0.57	0.94
2. Glasgow, 1973 ... , ...	0,45	0.90	0,9999
3. Bloch, 1974	0.25	0.53	0.94

[a] See Reference list for complete citations of studies in table
[b] Chance of appropriately rejecting the null hypothesis of no difference at the 5-percent significance level if the true mortality rate for the early group was 5 percentage points greater than the actual rate experienced by the late group
[c] Chance of appropriately rejecting the null hypothesis of no difference at the 5-percent significance level if the true mortality rate for the early group was 10 percentage points greater than the actual rate experienced by the late group
[d] Chance of appropriately rejecting the null hypothesis of no difference at the 5-percent significance level If the true mortality rate for the early group was 20 percentage points greater than the actual rate experienced by the late group

group to 5 percent in favor of the late group. The second study varies from 9 percent in favor of the early group to 2 percent in favor of the late group. And the third study varies from 13 percent in favor of the early group to 5 percent in favor of the late group.

The best data available to answer the question of the effect of early discharge on the health status of uncomplicated MI patients suggests that it is most unlikely that a large negative health impact will ensue. The data do not, however, exclude a small negative impact, on the order of a mortality rate at 6 months to 1 year that is 5 percentage points greater in the early than in the late group. Many clinicians would undoubtedly feel that this is a clinically significant risk. The data are also consistent with the possibility that early discharge is associated with a modest (about 10 percent) decrease in mortality. A much larger study than any of these RCTs would have to be designed in order to settle the issue definitively. One additional point should be raised in the context of the Medicare program. Since two of the three RCTs excluded patients over age 70, as did a number of the other less sophisticated studies, one must admit that there is a special dearth of data from which to draw any informed conclusions with respect to the elderly and early MI discharge.

Is there any additional information to be gleaned by adding the data from the studies previously reviewed? While accepting the fact that they are less rigorous than the RCTs, one can look generally at the results obtained by the five nonrandom controlled studies and the two flawed RCTs (5, 21, 66, 69, 71, 102, 116), Across all of these studies the mortality rate for the early group varied from O to 18 percent and that for the late group from O to 22 percent, with a followup period that varied from O to 18 months. In two of the studies (5,102), the early group experienced a greater mortality at followup than the late group; in three (21, 71, 116), the mortality rates were equal; and in the remaining two **(66,69),** the late group experienced a greater mortality rate than the early group. This group of studies appears to come down squarely on the middle of the fence between early and late discharge.

Going back to the studies summarized in table A-1 is equally fruitless. One can conclude that some of these research groups do indeed appear to have identified groups of MI patients at low-risk for early discharge, with mortality rates comparable to those seen in the RCTs. But these data shed no further light on the question of whether these low-risk patients would have done even better with longer periods of bed rest and hospitalization. In addition, as in the RCTs many of the earlier studies excluded the elderly, and some excluded females. These studies do not therefore help to bridge the information gap for these population subgroups.

One final comment is in order. It has been concluded from this review that the best data on early discharge for uncomplicated MI patients demonstrate that 3 weeks hospitalization is not a lot worse than 4 weeks (17,118). There is also some evidence, albeit somewhat less sturdy, that 2 weeks is not a lot worse than 3 weeks (86). Figure A-1 demonstrates, however, that the U.S. average LOS for all MI patients was down to 12.6 days in 1980 and down to a mere 9.6 days in the West. Unless there are massive problems with diagnosis coding, the LOS for patients with uncomplicated MIs must be even briefer. U.S. physicians may have adopted an early discharge policy for MI patients that is more aggressive than a conservative assessment of the available data would justify. Does this imply that medical practice today is reaching the opposite extreme to that of medical practice 40 years **ago?** Can a series of editorials be expected soon decrying the abuse of early ambulation and discharge for MI patients? Additional research is required before an optimal LOS for MI patients can be defined.