Appendix B.—Length of Stay and Outcome: Elective Surgery

> Of late I have allowed my patients to get up within twenty-four to forty-eight hours and to leave the hospital four to six days after their vaginal celiotomy. I could not fail to notice that these same patients did not present the picture of listlessness and muscular weakness which the same category of patients present after the performance of the same operations by the abdomen with the usual after-treatment (143).

Emil Ries began the movement toward encouraging postoperative patients to walk within the first day or two after surgery with this statement at a meeting of the American Medical Association in 1899. In the same paper, Ries also advocated early postoperative feeding as another means to speed recovery. Although he practiced these principles throughout his career and although this paper received a positive reception, Ries did not influence the majority of surgical practice, which continued to employ long periods of bed rest following surgery.

Although a few other voices were heard in support of "early rising" and even outpatient surgery (131), it was not until the 1930's that this practice was revived in the United States. Leithauser (106) summarized the experience of others, largely European and Russian, and tallied 15,000 reported cases of early postoperative ambulation with only four "fatal emboli. " He showed that the well-documented postoperative decrease in vital capacity (36) improved with early ambulation. He also presented a personal series of 900 patients whom he treated with an average of 1.3 days of bed rest and 4.0 days of total hospital stay. He claimed that his patients did not show a greater than usual incidence of wound dehiscence or infection.

In the 1940's and 1950's, a series of nonrandom controlled studies appeared (18,19,28,59,136,141). Each of them compared a group of surgical patients who had been encouraged to ambulate within a few days of surgery to those who had remained in bed for longer periods of time, frequently over a week. One study (28) analyzed patients from two hospitals, one of which practiced early ambulation. Only patients who had undergone abdominal surgery were examined. The patients at the hospital practicing early ambulation experienced a rate of wound disruption of 0.05 percent while the patients treated more traditionally had a rate of 1.05 percent. The other studies were similar in their use of control populations other than those created by a random allocation procedure. All of the studies found fewer complications in the group that ambulated early, including no increase in recurrences after herniorrhaphy (19).

Even though these studies are subject to the usual criticisms of studies employing nonrandom controls, they were apparently very influential. By the 1950's, early ambulation for surgical patients was a well-established principle of surgical management. Editorial writers (8,23, 103) routinely warned of the dangers of too much bed rest. As they often took pains to point out, however, early ambulation did not mean early discharge (23,103).

As in the myocardial infarction (MI) literature, since the 1950's three different kinds of studies have been performed. The first group comprises data analyses, studies which have examined length of stay (LOS) differences and tried to explain them. Second, there have been a large volume of uncontrolled trials of early ambulation and discharge. And third, a number of randomized clinical trials (RCTs) have been carried out. Each of these groups of studies are reviewed and summarized, with particular attention to RCTs.

Early in the 1960's, many researchers in Great Britain noted that LOS there was much higher than in the United States and Western Europe. Stallworthy (168) criticized a lack of efficiency in British hospitals and called for a decrease in LOS generally accompanied by experiments to document the increased efficiency which he believed would be obtained in the presence of shorter lengths of stay. He wrote (168):

> Any major reform is certain to challenge many traditional concepts and may arouse powerful opposition. Experiments with pilot schemes can be valuable; for once facts prove a contention it is difficult for opposition to survive.

Jones (92) commented that although British LOS had fallen during the 1950's, there was room for further declines. Heasman (75) noted regional differences in British LOS for tonsillectomy (2 to 6 days) and herniorrhaphy (8 to 12 days). She also saw a need for better data on the relationship between LOS and outcome (75):

> Statistically controlled studies are needed to show objectively the effect of different lengths of stay in hospital for uncomplicated cases.

Analyses of LOS differences for surgical patients continued into the **1970's (64,65,119, 157, 178).** These studies continued to show large differences in LOS among surgeons and hospitals, but none of them were successful in building models to explain these variations. One study (119) assessed LOS by surgeon for uncomplicated cholecystectomy at the Marshfield Clinic. This study found that postoperative stay varied among the five surgeons from 5.3 days to 7.3 days.

No statistically significant differences were found among surgeons with respect to patient outcome or quality of care, although the surgeon with the longest LOS did have the best outcomes. Seventy-six percent of his patients were asymptomatic and had returned to normal activities, compared with 61 percent of the patients of the surgeon with the shortest postoperative LOS.

The most common type of study in this literature is the uncontrolled trial of early ambulation or early discharge. This usually takes the form of a single surgeon reporting his or his hospital's experience with a particular scheme of this kind of postoperative management. No less than **14** such studies have appeared since Farquharson **(49)** reported the first large series of herniorrhaphies performed on outpatients in **1955.**

Before reviewing the data from these analyses, a discussion of the limits of the present analysis with respect to surgery is appropriate. The logical extension of early discharge for surgical patients is outpatient surgery. This subject will be included in the analysis to follow. However, there are many ways in which to do outpatient surgery. The model that will be discussed here is one in which the only difference in the treatment received by inpatients and outpatients is that the outpatients are discharged without spending a night in the hospital and receive much of their postoperative care on an ambulatory basis after discharge. The same staff and facilities that provide surgical services to inpatients also provide the same services to outpatients. Excluded from this analysis are studies in which both type and place of treatment were varied—e.g., the RCT comparing inpatient surgery and outpatient injection therapy for varicose veins **(34,12).**

This analysis will also not evaluate the establishment of a separate facility designed solely for the provision of outpatient surgery (e. g., a surgicenter). Just as it was beyond the scope of the present analysis to consider the appropriate place of service for provision of services to MI patients (home v. hospital), so is it beyond its scope to consider the most appropriate place of service for surgical patients. This is a very complex question, involving questions of physician training, ancillary staffing levels, nature of anesthesia used, equipment availability, resuscitation capabilities, and other factors. This discussion will be limited to an evaluation of data pertinent to the question of how a hospital can best provide surgical services to its patients.

Equally beyond the scope of the present discussion is the question of the appropriateness of the surgery itself. This is not an analysis of the necessity of surgery as opposed to other treatment modalities. The rest of this chapter will try to answer the following question: Once the decision that a patient should undergo surgery in a hospital has been made, what is the relationship between LOS and health outcome?

Farquharson (49) recalled Ries' work and described a series of 485 patients on whom he had performed inguinal herniorrhaphies under local anesthesia and then discharged. His description of this outpatient surgical procedure merits repeating:

> As a rule the patient is little disturbed by the operation. He climbs down from the operating table, walks out of the theatre, dresses in his lounge suit, and then walks out to the ambulance in which he is taken home. Our aim is to get him back to his own bed while the local anesthetic is still effective.

The usual procedure for inguinal herniorrhaphy patients at that time was 5 to 6 days bed rest (down from 21 days in the early 1940's) and 10 days hospitalization. Farquharson selected patients with home environments conducive to home convalescence, though he gave no objective criteria. He noted a decreasing complication rate, 10 readmission to the hospital for complications in the first 285 patients, but only 1 in the last **200** patients. He reported "some" recurrences without giving actual numbers but asserted that his experience was "at least as good" as that claimed by supporters of more traditional approaches. He also wrote that patients were satisfied with the novel procedure and that one of the most important benefits of the outpatient strategy, aside from monetary saving, was the dramatic reduction in waiting time that was possible. At that time, considerable waiting lists had built up in Great Britain for elective surgical procedures. Sicker patients were admitted to scarce hospital beds ahead of candidates for elective surgery, who were called in for their procedures when inpatient beds and operating time were available. Eliminating the need for a 10-day hospitalization enabled surgeons to operate on more patients during a given time period.

This study establishes the parameters by which all succeeding work may be judged. First, one must recognize that the scope of this study is narrower than those cited previously. Previous studies discussed the early ambulation of essentially all surgical patients. This study and succeeding studies are concerned with even earlier ambulation and discharge of a selected subgroup of elective surgery patients, typically patients with inguinal hernias, varicose veins, and hemorrhoids. Second, outcome measures are difficult to define and measure. Mortality is vanishingly small (122) so other measures must be sought. For hernia patients, the one most clinically important is the recurrence rate. This too is often quite low (under 1 percent) (122). It may also be difficult to compare figures from one study to another. In order to evaluate these figures, it is necessary to know precisely how many patients were fol-

lowed over what time period; one must be able to determine the population at risk for recurrence. Postoperative complications are another possible outcome measure. To be useful, however, careful definitions must be constructed and followed. Patient satisfaction may also serve as an outcome measure, but again careful attention to reliable and valid measurement is important to the production of accurate data. Finally, one may wish to assess the monetary impact of early discharge programs. Since all of the studies that attempt to do this were performed outside the United States, these exercises will have only slight relevance to U. S, health policy. They will serve to illustrate, nevertheless, how, difficult such analyses are to perform.

Farquharson (49) discussed all of these issues but provided data on only one, complications requiring admission to hospital. Without having a control group with which to make comparisons, these results cannot be judged good or bad. Stephens and Dudley (169) reported data similar to the previous study in 1961. Of 212 patients on their waiting list for hernia or varicose vein surgery, they selected 164 (77 percent) as candidates for outpatient surgery, excluding those over age 70, with complicating medical problems, or with homes too distant or incompatible with immediate postoperative convalescence. No specific criteria were given regarding the medical exclusions or what constituted an unsuitable home environment. These patients were operated under general anesthesia and discharged 5 to 8 hours later. The initial recovery from anesthesia took place in a general ward bed. These authors reported no serious postoperative complications, though there was a high incidence (27 percent) of nausea and vomiting until the premeditation schedule was altered (171). Recurrence data were not reported. Patients reported a high degree of satisfaction (96 percent) with outpatient treatment. No financial data were presented, but a significant impact was claimed in reducing the size of the waiting list.

Williams (180) described similar results with a small series of patients and raised an additional issue. He noted that the general practitioners in Great Britain were being asked to increase their workload as a result of outpatient surgery programs. Dean and Wilkinson (41) confirmed Williams' opinion that most general practitioners were in favor of selective outpatient surgery despite the increased visits required by it, chiefly because of its salutary effect on elective surgery waiting lists. Ruckley reported two series of patients, primarily those with hernias and varicose veins, who had outpatient surgery (152, 153). Both groups of patients experienced a complication rate of 10 percent in the postoperative period, and 6 percent of the second group of patients could not be discharged as planned because of complications. An additional 2 percent of patients had to be readmitted after discharge because of complications. There were no fatalities, and the complications were not considered serious enough to entertain thoughts of discontinuing the program. No data on patient selection were given except that no patients over 68 years were included. The remaining uncontrolled study (11) of outpatient surgery added no new data.

The principal conclusion that may be drawn from this body of data on ambulatory surgery is that these authors have succeeded in identifying a subgroup of patients with inguinal hernias and varicose veins in Great Britain who can have surgery performed on an ambulatory basis with a very low rate of serious complications and an even lower mortality rate. However, in the absence of adequate control data, one cannot be sure that this same subgroup would not have done even better as inpatients.

The group of studies on early discharge for elective surgery follows a pattern quite similar to the group just reviewed on ambulatory surgery. Aldridge (6) reported a l-percent complication rate with a discharge program at 48 hours postoperatively for herniorrhaphy patients. No selection or recurrence data are given, and high rates of satisfaction among patients, staff, and general practitioners were claimed. Hockey (84) reported the results of a program in which a nurse provided home followup care in order to permit early discharge for patients undergoing herniorrhaphy, appendectomy, and other surgical procedures. The author estimated, using usual LOS figures for her patient population, that 4.7 days per patient were saved as a result of the program. No complications could be identified that could clearly be related to the early discharge program, though 6 of 126 patients were readmitted in the postoperative period for unrelated problems. Again, high rates of satisfaction were claimed. No selection criteria were given.

One of Ruckley's reports (153) on outpatient surgery also contained a series of patients discharged early. He estimated a saving of 3 to 6 days per patient depending on the procedure using the same method as Hockey, No other data were given. Doran (45) reported on 705 patients discharged within 48 hours following herniorrhaphy and varicose vein surgery. These patients represented 77 percent of all patients evaluated, again with no criteria for acceptance specified beforehand. Only 5.4 percent could not be sent home earl y because of immediate postoperative complications, and an additional 9 percent developed late postoperative complications at home. None of these proved serious but 0.9 percent did require readmission.

Doran also reported high rates of satisfaction among patients and referring general practitioners, in large part due to reductions in waiting time for surgery. Chant and colleagues (33) reported a similar study of 105 herniorrhaphy patients with a complication rate of 10 percent. Cannon and colleagues (30) reported an early discharge study in unselected hernia patients and found that they were able to plan early discharge for 54 of 104 patients (52 percent) but only able to discharge 24 within that targeted period.

Finally, two reports from the Shouldice Clinic in Toronto (87,55) suggest that attainable rates of mortality and recurrence for elective herniorrhaphy are small indeed. The first report from 1965 (87) documented an operative mortality rate of **0.05** percent among 30,946 patients between 1945 and 1960. This Clinic treats only hernia patients and reported a recurrence rate of 0.6 percent. Although precise data on years of followup were not provided, many patients were followed for 10 years or more. The Clinic uses local anesthesia on adults and ambulates patients on the day of surgery with discharge 72 hours following the operation. In the first series, a wound infection rate of 1.8 percent was reported, but no complication data except that for recurrence were reported in the second.

The most serious deficiency of this group of uncontrolled studies on outpatient surgery and early discharge is the lack of an appropriate comparison group. The implications of this failing have already been discussed. In addition, without a strictly defined set of selection criteria, it is difficult to know precisely to which kinds of patients the results might apply. Similarly, without preset, uniform criteria for what constitutes complications, it is difficult to compare one series to another or even patients within a single series if more than one physician determines the presence or absence of complications. In this group of studies, complication rates ranged from O to 10 percent. How much of this variation is attributable to differences in implicit criteria among individual physicians? Finally, none of these studies reported hernia recurrence rates precisely in terms of person-years of followup.

Before discussing the true RCTs, two studies should be mentioned. Palumbo and Sharpe (135) describe a trial of early ambulation of herniorrhaphy patients in which patients were ambulated at different times postoperatively: at O to 1 days, 3 to 10 days, or after 10 days postoperatively. The study found lower rates of complications and recurrences in the earliest ambulated group. Unfortunately, this study is described briefly as part of a larger review and its methods are so inadequately delineated that it is impossible to ascertain the kind of research design that was employed. The word "randomized" is used in the abbreviated description of the study, but the sample sizes are so unequal that one wonders if random allocation could really have been used. It is also not clear in which of the three groups (if any) the patients who were ambulated on the second postoperative day belong. Finally, no LOS figures are given to allow one to determine whether this was an early discharge program as well.

Similar problems are present in the study reported by Kornhall and Olsson (101). They apparently compared a series of 54 patients operated on for hernia repair as outpatients with a matched sample of 54 patients randomly selected from among those who received their repairs as inpatients, with a mean hospital stay of 3.4 days, though the report's description of the study design is vague. This is thus a comparison of outpatient surgery with early discharge following inpatient surgery, a most interesting research question. Unfortunately, the small sample size and the lack of a truly random allocation procedure makes the result of no difference in complications difficult to interpret.

The true RCTs are summarized in table B-1. Patients in the first study (121) cited in the table were randomly allocated from a list of patients awaiting hernia repair after their general practitioners approved. The study group was discharged after 1 night in the hospital while the long-stay group was kept 5 to **6 days. No actual** LOS figures are given, but it is reported that 10 of the 11 short-stay patients with complications prior to discharge were kept past the first postoperative day. There were no statistically significant differences in complications or recurrence rate (assessed at 1 year in three-fourths of the patients in both groups). The recurrence rate was 3 percent in the early group, 6 percent in the late. The study did document a significantly increased use of general practitioners and nurses postoperatively by the short-stay group (2.4 visits per person v. 0.6).

The second study was performed in Cali, Colombia (48). Its criteria for inclusion were very strict, resulting in the elimination of **82** percent of patients before random assignment. It appears from the report that the study design was needlessly complex. It required that patients who passed the inclusion criteria be matched on a large set of clinical and sociodemographic variables. Then, one member of each pair created by the matching was randomly assigned either to outpatient surgery or to regular inpatient postoperative care. Some of the eligible population was excluded, because no matched pair could be found. This helped to reduce drastically the fraction of patients available for study and rendered the results questionable since so many patients were eliminated prior to random assignment. Two other deficiencies compound this problem, First, patients were eliminated from study if there was an

Table B-1 .—Randomized Clinical Trials in Outpatient and Short-Stay Elective Surgery

Study[a]	Study populations	Percent Included	Protocols and (sample sizes) Early (E)	Late (L)	Complications (J~O) E	L
1 Morris, 1968	., Men, 21 -65; hernia: no chronic disease, good home, referral	7	Discharge 1 day post-op (92)	Discharge 5-6 days post-op (93)	27	19
2 Echeverri, 1972	1-59; hernia, varicose veins: no chronic disease; good home, no post-op complications	18	Discharge 3-5 hrs. post-op (44)	Regular Inpatient (44)	5	7
3. Gerson, 1976	No chronic disease; good home, multiple diagnoses	7	Discharge early to home care (399)	Regular LOS (184)	—	—
4 Russell, 1977	18-70; hernia; hemorrhoids, no chronic disease, good home	60	Discharge 5-6 hr. post-op (55)	Discharge 5-6 days post-op (56)	45	30
5 Simpson, 1977	Cholecystectomy; vagotomy; no chronic disease, simple surgery, good home	59	Discharge by criteria (53) (LOS = 7.6 days)	Discharge planned at 10 days postop (47) (LOS = 9.7 days)	23	26
6 Adler, 1978	18-64; hernia; varicose veins; no chronic disease, good home	?	Discharge 2 days postop (117)	Discharge 6-7 days postop (107)	13	5
7 Ruckley, 1978	., Over 60 only if fit, hernia, varicose veins, no chronic disease; good home	74	Discharge 4-6 hr postop (117)	Discharge at 2 days postop from ward from conv[b] (122)	home (121)	ward conv[b] 36 24 39

[a] See Reference list for complete citations of studies in table
[b] Convalescent hospital

intraoperative or immediate postoperative complication or if a blood transfusion was used. Thus, it is not known how many patients for whom outpatient surgery might be planned would be unable to be discharged immediately because of complications. Second, 13 of the 44 pairs were eliminated after surgery due to errors in selection and matching. Thus, data on convalescence are given for only 31 pairs. Complication data, however, are given for all 44 pairs. It is not clear why the methodological problems were sufficient to eliminate 13 pairs from one analysis but not the other. These methodological problems and the setting of this study —i.e., a socioeconomic environment so different from that of the United States—make its results of slight relevance to the present analysis.

The study reported by Gerson and Berry (54) has few design flaws but several important analytical ones. In this study, patients were randomly assigned to a study group that was eligible to receive home care following discharge if the attending physician so desired and to a control group that was treated by the usual hospital postoperative stay. The authors included a large number of surgical and a few medical conditions. These illnesses were selected after a preliminary study indicated that the selected conditions presented the best opportunity for the substitution of home care for inpatient care. The study excluded patients with multiple diagnoses or complications that might extend LOS and patients whose homes did not meet certain safety standards. Eligible patients were randomly assigned to study and control groups at a 2:1 ratio. The researchers either selected candidates poorly or did not have the enthusiastic cooperation of attending physicians, because only 176 of 399 home care candidates were actually referred to the home care program and, presumably, discharged early. The remainder stayed in the hospital for a usual postoperative or convalescent course.

Unfortunately, no LOS data are provided for the study and control groups. Data are provided only for those study patients who were discharged to home care and for all the remaining patients (study patients remaining in the hospital without home care referral and control patients). One cannot determine whether the program succeeded in reducing overall LOS for all the study patients without LOS data on the entire study group. This study apparently squandered the ability of random allocation to create comparable patient groups by failing to analyze the correct data.

Instead, the authors proceeded to analyze five surgical conditions for which the subgroup of study patients had shorter LOS than the remaining combined group. They found no differences in rates of return to work among the study patients who received home care, the study patients who did not receive home care, and the control patients. They also found somewhat better functioning at home in the study patients receiving home care and concluded that this might be a beneficial result of the program. This is a mistaken conclusion. While one might conclude that another study should be done the candidates for which would be drawn from among only those subgroups who actually experienced shorter lengths of stay in conjunction with the home care program, the study provides no information to suggest that the home care program was successful. It did not demonstrate that the home care program reduced overall LOS for eligible patients. From an analytic point of view, it is fallacious only to eval-

uate those subgroups of an experimental population which seemed to have derived a benefit from the experiment without also considering those apparently suffering a negative result. The authors appear to have done just that, It may well be that home care after hospital discharge can produce benefits as a treatment in and of itself. This study fails, however, in the effort to document that it can substitute for inpatient convalescent care.

The study reported by Russell and colleagues (154) is a trial of outpatient surgery and usual inpatient care for nonelderly patients with hernias and hemorrhoids. The requirements for absence of chronic illness and for adequate home support for early discharge that are typically present in these studies were also present here. Nine patients were eliminated after random allocation because of medical problems identified by family physicians (2) or inadequate home environments determined at preoperative interviews (7). Thirteen additional patients were eliminated from study because their surgery did not take place for a variety of reasons. Therefore, only 60 percent of the originally screened group entered the trial. The authors comment that although strict definitions of complications were not employed, researchers were encouraged to report all complications, "however slight ." Due to small sample sizes the large difference in complication rate noted in table B-1 is not statistically significant at the 5-percent level ($p > 0.1$). The authors comment that the high rate of complications in the short-stay patients was the result of a large difference in the hemorrhoid patients, an occurrence they attributed to the postoperative use of a particular kind of dilator. They reported anecdotally a decrease in complications after use of this dilator was discontinued following the conclusion of the study. The study did document a significant difference in the number of visits made by patients to their general practitioners or district nurses. The short-stay patients made an average of eight visits per person during an unspecified period of followup while the long-stay patients made an average of four.

The study reported by Simpson and colleagues (161) was a well-designed and well-executed RCT. They studied the difference between employing a rigid notion of when postoperative discharge could occur (10 days) and the use of criteria to determine fitness for discharge. Ten days was chosen as the fixed day of discharge because it represented the modal discharge day for uncomplicated patients receiving the two operations studied here: cholecystectomy and vagotomy. The criteria included items describing healthy wound appearance, adequate feeding, and freedom from complications. The study demonstrated a significant reduction in average LOS for the criteria-based discharge group (7.6 v. 9.7 days) and a complication rate that was no different. This study thus documented that flexible, clinically based criteria for discharge can result in shorter lengths of stay for cholecystectomy and vagotomy patients when compared to a plan of discharge fixed at the mode.

The sixth study summarized in table B-1 (3,4) is a trial of short-stay versus more traditional stay, a design similar to the first RCT. This study excluded the elderly and accepted referrals from general practitioners if they considered their patients with hernia or varicose veins to be medical and social candidates for early discharge. Patients were randomly assigned to discharge at either 2 days or 1 week postoperatively, although no actual LOS figures are given. The difference in complication rate, which is almost entirely due to a large difference in complication rate for the varicose vein patients (O v. 13 percent), is of borderline statistical significance ($p < 0.1$). All of the complications were felt to be of minor clinical significance, none apparently requiring readmission to hospital. This study also is the only one that measured hernia recurrences in terms of person-years at risk. The rates were an identical 0.02 per person-year at risk for the study and control groups assessed with an average followup of 2.3 years per patient.

This study also measured cost more carefully than any other. Although its direct relevance to U.S. policy is slight since it was carried out in Great Britain, the general findings are instructive. The authors found a definite saving in hospital costs. These savings were all but offset, however, by an increased cost in the study group due to longer time off from work and to increased costs to patients and families in the short-stay group. The net social saving was, therefore, slight. The difference in time from surgery to return to work was accounted for entirely by the difference observed in the male patients: 34.5 days for the long-stay group v. 38.2 days for the short-stay group. This difference is not statistically significant but turned out to be economically significant in the savings calculations. Patient satisfaction showed no differences between the two groups, but the families of the short-stay patients were significantly less pleased about the policy of early discharge than the families of the long-stay patients were about their relatives' stays. General practitioners approved the policy, despite the increase in their workload. Finally, this study is notable for having published a report that deals solely with questions of methodology and the technical difficulty of performing such a study (4).

The last study in this group (151) is a unique trial of outpatient surgery and short-stay surgery for hernias and varicose veins. The study assessed three different modes of postoperative care: home, inpatient surgical ward, and convalescent hospital. Patients were

randomly assigned to immediate home discharge (4 to 6 hours postoperatively), to 48 hours in hospital, or to 48 hours in a convalescent hospital. Also unique in this study is the fact that neither surgeons nor anesthetists were aware of which patients were assigned to which groups. The study had the usual exclusion criteria, not specified in detail prior to the study.

Significant differences were observed in complication rates, with the hospital ward patients experiencing the lowest rate of complications. The difference among groups in total complication rate is significant at the 5-percent level (chi-square 7.2, d.f. 2). Over half of the complications were accounted for by delayed wound healing. Only three patients assigned to the convalescent hospital and two home care patients required postoperative hospital stays because of operative or anesthetic problems; all were discharged 1 day postoperatively. Only three patients required readmission to the hospital during the followup period; all three had been in the hospital group. As in the previous studies in this group, the complications were regarded by the authors as "medically trivial, " and the large majority were managed on an outpatient basis. Patient satisfaction was high, though precise data were not reported. Again, patients receiving outpatient surgery required more attention from local physicians and nurses than did patients kept in hospital.

Four of these seven studies tested outpatient short-stay surgery in various combinations and in a methodologically sound manner (3,121,151,154). The results are remarkably consistent. In each case, a substantial number of patients were identified who could undergo outpatient or short-stay surgery for their hernias, varicose veins, or hemorrhoids without serious complications. In each case, the long-stay group had fewer complications, but these were judged minor in all studies. The results of these RCTs and the other studies reviewed here have undoubtedly played a major role in the dramatic fall in LOS that has occurred in the United States for hernia patients since 1968. Figure B-1 depicts the decrease by region. The U.S. average LOS has declined by 35 percent, that of the Northeast by 46 percent, the Northcentral by 28 percent, the South by 21 percent, and the West by 42 percent. These data suggest that an increasing number of U.S. surgeons, particularly in the West, are discharging more of their inguinal hernia patients at an earlier postoperative date. Many of these patients were probably discharged on the second postoperative day, the most common target for the early discharge programs reviewed here. Are they right? Should discharge on the second day after inguinal herniorraphy be the rule instead of the exception?

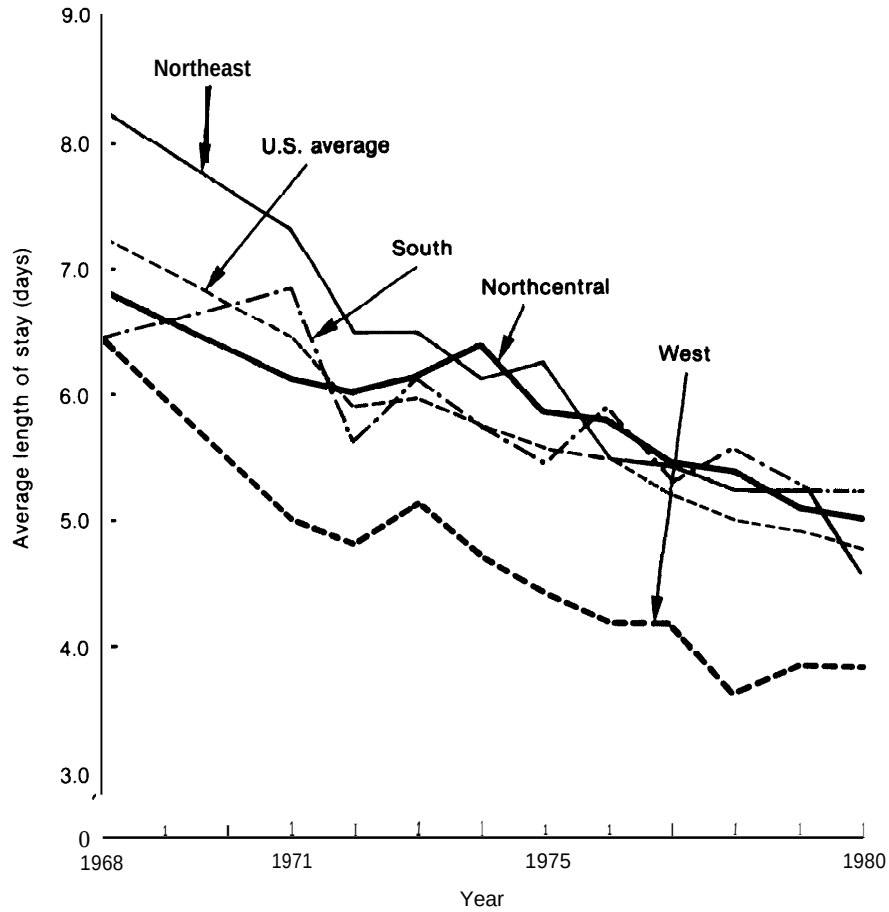
At this point, the issue of statistical power once again arises. Using herniorrhaphy as a model, it is clear that the two most important outcome measures from a clinical standpoint are operative mortality and recurrence rate. Operative mortality was reported in two studies reviewed here (87,135). It was the same in both of these large series: 0.05 percent. In order for a study to have even a 50-percent chance of distinguishing a doubling of this operative mortality, one would have to randomly assign over 16,000 patients each to study and control groups. It is thus highly unlikely that we will ever have comparative data on operative mortality from RCTs such as those reviewed here on which to base decisions concerning appropriate postoperative management. A sample size of 2,000 would be required before one would expect even one operative death. Clearly, studies with sample sizes of 90 to 120 cannot observe anything useful regarding surgical mortality in elective herniorrhaphy.

The story is similar, but not quite as hopeless, with respect to recurrence rate. Assuming a 2-percent recurrence rate (greater than that achieved by the Shouldice Clinic, but equal to that seen in one of the RCTs (54)) a study with a sample size of 120 would have only a 23-percent chance of rejecting the null hypothesis of no difference if the true recurrence rate in a study population of short-stay patients was 4 percent. If the sample sizes were increased to about 400 in each group, the power would increase to 0.5, or to 0.7 if the sample sizes were about 700. Such a study would be difficult and expensive to carry out, but is feasible.

The real issue here is whether such studies are worthwhile or whether we are willing to take the risk that operative mortality and recurrence rates may be somewhat higher in early discharge or outpatient surgery programs in order to reap their monetary benefits. What are these benefits? The studies reviewed here that did attempt to measure the benefits associated with these programs concluded that a small net benefit is present. It is difficult to assess how these studies might have been different in this regard had they been performed in the United States. Higher hospital costs might have increased the value of the net benefit, but higher wages might decrease it, given slightly longer convalescent times for short-stay patients.

Posing the question of whether the benefits are worth the costs raises difficult issues of how to trade off monetary savings for quality of medical care. In this instance, it certainly seems from the RCTs just reviewed that one trades a somewhat higher rate of minor complications for the monetary savings. And based on the statistical discussion just concluded, one may also be trading an unknown increase in the small

Figure B-I.— Regional Trends in Length of Stay for Patients With Inguinal Hernia



SOURCE *Vital and Health Statistics*, series 13, Nos 2, 10, 14, 17, 19, 2326, 31, 41, 46, 55, 60, 64 (Washington, D C National Center for Health Statistics, 1967-82)

but real risk of operative mortality or recurrence. Is the increased minor complication rate an acceptable side effect of these programs? Precisely what kinds of complications do these studies label as minor? The list is long. Morris (121) described chest and wound infections, hematomas of the wound, scrotum, and spermatic cord, unexplained fever, and thrombophlebitis. Ruckley (151) observed, in addition, a 23-percent rate of delayed wound healing in the outpatient surgery group as opposed to 14 percent in the hospitalized group. This usually consisted of a serous discharge from the wound. It is not clear from any of the reports how long these complications persisted or how much disability they caused. Presumably, all were short-lived. At best they seem minor annoyances, at worst potentially serious and debilitating illnesses.

How does one measure the cost of an additional 8 to 15 percent incidence of complications of this kind? Even were such a measure available, one would not have a reliable figure for gross savings calculated from a study performed in the United States. Does this lack of data and the possibility of increased operative mortality or recurrence in programs of early discharge or outpatient surgery justify further large and expensive RCTs? The studies reviewed here cannot provide answers to these questions but have provided the data necessary to formulate them.