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A randomized, controlled comparison of home versus institutional rehabilitation of patients with hip fracture

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Objective: To compare ambulation outcomes between home and institutional rehabilitation of patients with hip fracture.
Design: Randomized controlled clinical equivalence trial.
Setting: The Queen Elizabeth Hospital in Hong Kong.
Subjects: Eighty-one patients with hip fracture.
Intervention: Study group patients (40) were discharged directly home from the acute hospital and visited by a physiotherapist an average of 4.6 times. The control group subjects (41) were discharged to a rehabilitation centre for further treatment lasting on average 36.2 days (SD 14.6) and they received physiotherapy daily.
Main outcome measures: Ambulation ability measured on a categorical scale.
Results: The mean age of the subjects was 75 years (SD 8.3 years). Females comprised 60% of all the subjects and majority were retired or home makers. Both groups of patients improved in their ambulation ability during their rehabilitation period but neither group achieved their pre-ambulatory status by the time of completion of the study. The study group achieved significantly higher ambulation scores ($p < 0.05$) for community and household ambulation compared with the control group by the end of the study, a year after operation.
Conclusion: Five visits by a physiotherapist in the patient's home after discharge from an acute hospital after surgical treatment for hip fracture yielded better results in ambulation ability than one month of conventional institution-based rehabilitation.

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Introduction

The occurrence of hip fracture is devastating to old people because it is often considered as the start of a steady decline and may result in loss of independence, increasing disability and even death. A fractured hip, as a consequence of fall, is one of the major causes of hospitalization in elderly people worldwide. These patients often require an extended programme for their rehabilitation and may therefore stay in hospital longer than would be necessary for their orthopaedic management.[1] Recovery to the previous level of function may be hindered by long-term institutionalization.

Provision of physiotherapy services at home as a follow-up may accelerate discharge from the hospital and at the same time promote rehabilitation to reach the patients' full potential.[2] It has been suggested that almost half of the patients with femoral neck fracture could be discharged directly home after acute care on an orthopaedic ward without jeopardizing their ambulation and functional recovery while others may need long-term rehabilitation in institutional settings.[3]

In Hong Kong, the Working Party on Primary Health Care in 1990, and the Working Party on Rehabilitation Policies and Services in 1992, recommended that community rehabilitation services in Hong Kong should be developed and coordinated. They suggested that an integrated domiciliary rehabilitation team including physiotherapists should become an integral part of primary health care.[4,5]

The provision of physiotherapy services in Hong Kong is traditionally, institution based and domiciliary physiotherapy has only recently started to develop. Two surveys by Kuisma found that 52% of the responding hospitals in 1994 and 90% in 1997 claimed that they offered domiciliary physiotherapy services to their patients. The number of patients visited in their homes by physiotherapists, however, was in most cases less than 20 in the preceding six months.[6]

The objective of this study was to compare the ambulation ability of two groups of patients, domiciliary (i.e. the study group) and conventional institution-based rehabilitation (i.e. the control group). The study hypothesis was that the ambulation ability of the patients in the domiciliary physiotherapy group was not inferior to that of the institution-based physiotherapy group.

Methods

The study design was a randomized controlled equivalence trial in which two groups of patients were compared (Figure 1). The equivalence instead of superiority trial was chosen because it was estimated that the direct cost of domiciliary physiotherapy would be lower than the direct cost of rehabilitation in an institution.[7] The two treatments may be considered equivalent if the confidence interval of the observed differences of the outcomes of the two treatments lies within a clinically acceptable range. If it lies outside, the equivalence cannot be established.[7] A one-sided hypothesis was used because, based on the calculation of known and estimated direct cost of care, it was deduced that the direct costs of domiciliary physiotherapy was considerably less than the direct cost of conventional physiotherapy in an institution. An equivalent outcome of domiciliary physiotherapy, meaning at least as good as and not inferior, would justify implementation of domiciliary physiotherapy for patient groups similar to the study group.

Patients over 50 years old who were admitted with a fractured proximal femur to an acute general hospital, the Queen Elizabeth Hospital (QEH), were the study population. Patients with concomitant serious conditions and those who were living alone or spent more than 4 hours alone during the day were excluded for safety reasons. The ethics committee of the Queen Elizabeth Hospital approved the study and all subjects signed a written consent to participate in the study. Altogether 81 subjects were recruited and they were allocated randomly into the study group (40 subjects) and the control group (41 subjects). The sample size was calculated based on an equivalence trial and a one-sided hypothesis. The following formula was used to calculate the sample size.[7]

$$n = 2\, s^2/\blacktriangle^2\, [z(1-\alpha) + z(1-\beta)]^2$$

where n it the required sample size for each group, s is the standard deviation of the ambulation ability score of similar patient group in 1995

at the discharge from QEH, ▲ is the clinically acceptable difference between the expected outcomes of the two groups and $z(1-\alpha) = 1.64$, $z(1-\beta) = 0.52$ as derived from the tables of standard normal distribution for one-sided hypothesis, for $\alpha = 0.05$ and $\beta = 0.3$, representing a statistical power of 70%.

It was decided that if the 95% confidence interval of the true differences of the outcomes between the two groups was in the range ± 0.5, the differences would not be clinically important and the outcomes could be considered as equivalent. The value 0.5 was half of one score in the scale of 0–4 used in the outcome measure of this study. It was reasoned that half a score difference in the patient's performance would not be clinically important for the individual patients or the group of patients. For example, it could be pos-

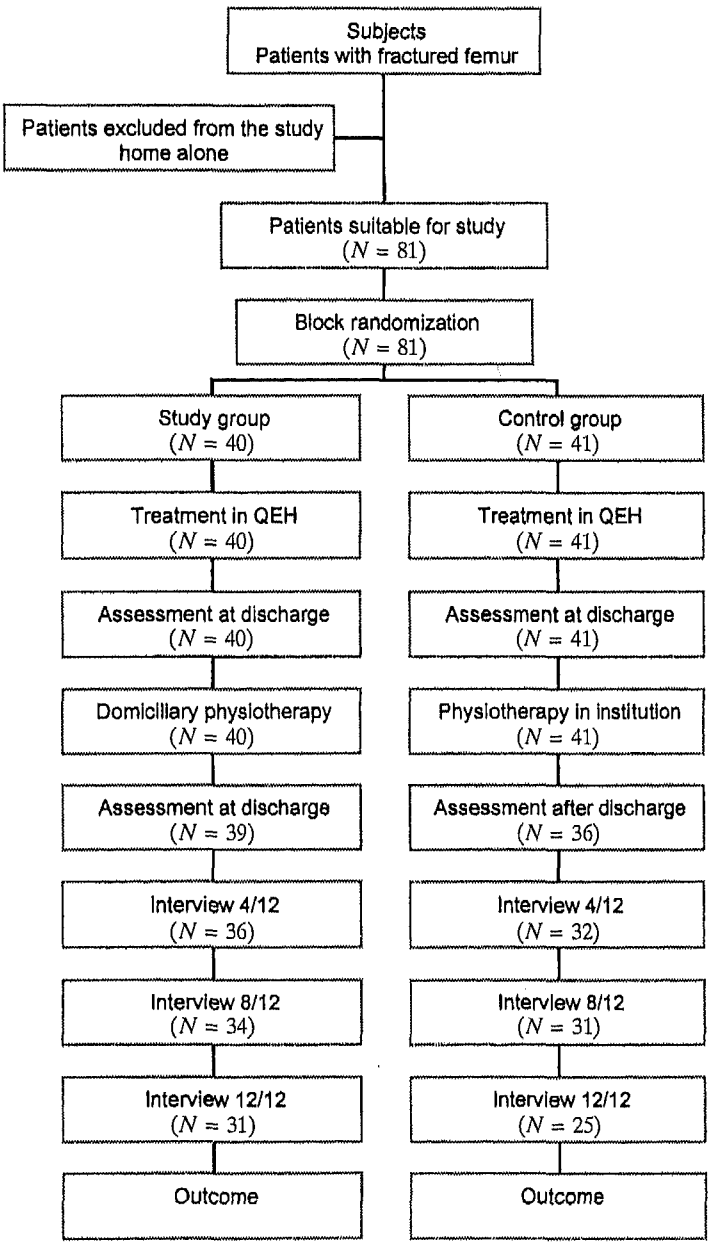

Figure 1 Study protocol.

tulated that, if a patient had a score 3.5 instead of 4 (independent without walking aids) or 3 (independent with walking aids) in ambulation, she or he would be able to walk independently half of the time with a walking aid and the other half of the time without it. This would not make a marked difference to independence in ambulation because the patient would still be independent in the task all the time. For the whole group of patients, this could mean that half were able to walk independently without a walking aid and the other half with a walking aid. Clinically this would not be an important difference because elderly people often use walking aids. The same would apply at the other levels of the scale. Therefore the difference of no clinical importance was set at 0.5.

The instrument to evaluate the subjects' ability to walk was the ambulation ability score incorporated in the 'patients admission and assessment form' (PAAF), which was designed for this study.

Ambulation ability was divided into five categories: (a) Community ambulatory, (b) Household ambulatory, (c) Walking on flat surface, (d) Transfer from bed to chair, (e) Bed/chair bound. Subjects were assessed in each category and given a score based on their level of independence, namely: 4 = independent without aids, 3 = independent with aids, 2 = able to walk with minimum assistance/supervision, 1 = able to walk with maximum assistance, 0 = unable to walk.

At the time of the first meeting, when demographic data and the data on the subjects' ambulatory status were collected using the 'patient admission and assessment form', the physiotherapist screened the patients for inclusion in the study. The patients who were included in the study were allocated to the study or control group using blind block randomization. The block randomization was performed by the researcher before the trial started. A letter indicating the group was placed in a sealed envelope and the envelopes were kept in the randomized order in the office of a senior therapist who was not involved in the study. At the first meeting when the patients were allocated to the two groups, the physiotherapist opened the sealed envelopes.

At discharge, the patients in the control group were admitted to the rehabilitation hospital for further treatment as residents in the centre and the patients in the study group discharged from the QEH to their homes to continue post-operative rehabilitation. Masking of the treatment could not be done, because the personnel had to know in good time where the patient was to be discharged for planning purposes.

An independent person not involved in the treatment of these patients at any time, conducted telephone interviews at four, eight and twelve months after surgery. The interview included the same ambulation outcome measures as the PAAF.

The demographic data on a nominal or ordinal scale in the assessment form, e.g. yes/no, normal/moderate/severe, were analysed and presented as numbers and percentages. Chi-squared test was used to test the statistically significant difference between the two groups.[8]

The demographic data expressed as interval and ratio scales and the ambulation scores in the categorical scale were presented as means (M), standard deviations (SD), modes and medians as appropriate. An unrelated Student's t-test was used to test for statistically significant differences.[7]

The data for the main outcome, i.e. ambulation ability, which was measured in ordered categorical scales, were tested for equivalence. The statistical significance was tested using a 95% confidence interval to check whether the scores were within the range of the clinically acceptable equivalence. One-way ANOVA was used to test for statistically significant differences between the two groups in the repeated measures of ambulation. The ambulation ability score in each category was set as dependent variable and the group, study group or control group, was set as the factor. The SPSS 10.0 for Windows computer package was used in the statistical analysis.

Results

Eighty-one subjects were recruited and randomly allocated into the study group (40) and control group (41). The characteristics of the two groups of subjects were very similar with regard to age, gender, social background, living situation, pre-

injury health status, type and side of fracture, surgical intervention and recovery from the incident. Ambulation ability before the injury was also very similar between the two groups and none of the characteristics were statistically different. The mean age of the subjects was 75 years (SD 8.3) with the youngest 54 and oldest 91 years. Females (49) comprised 60% of all the subjects and the majority were retired or home makers. The average length of stay in the operating hospital was 11.9 days (SD 2.9) for the study group and 10 days (SD 2.8) for the control group. The study group received physiotherapy during 4.6 home visits (SD 2.2) and were also visited by a community nurse 1.5 (SD 0.6) times on average, totalling 6 (SD 2.4) visits. The control group stayed in the rehabilitation hospital on average 36.2 days (SD 14.6) and were seen by physiotherapist daily.

Patients' ambulation ability was evaluated before admission, at discharge from the hospital, at discharge from treatment and three times after completion of the physiotherapy. The equivalence of the outcomes and the *p*-values of one-way ANOVA test were calculated. The study group had equivalent and even better scores in all the ambulation categories in all the measurement situations. Table 1 shows the mean (*M*), standard deviation (SD), number of subjects at each measurement time (*N*), 95% confidence

Table 1 Ambulation scores

Variable	*M* (SD)		*n*		95% CI NDPT M–DPT M		EQUI	*p*-value
	Control group	Study group	Control group	Study group	Low	High		
Pre-injury								
Community ambulation	3.78 (0.52)	3.85 (0.36)	41	40	−0.23	0.10	E	0.36
Flat surface ambulation	3.90 (0.30)	3.90 (0.30)	41	40	−0.11	0.11	E	0.77
Discharge QEH								
Flat surface ambulation	1.93 (0.52)	2.55 (0.55)	41	40	−0.82	−0.43	E*	0.00**
Discharge PT								
Community ambulation	2.06 (1.32)	2.97 (0.55)	32	37	−1.30	−0.52	E*	0.00**
Flat surface ambulation	3.31 (0.47)	3.51 (0.56)	36	39	−0.40	−0.01	E*	0.04*
1st interview 4/12								
Community ambulation	2.83 (0.91)	3.29 (0.57)	30	35	−0.76	−0.15	E*	0.02*
Flat surface ambulation	3.50 (0.62)	3.75 (0.44)	32	36	−0.46	−0.04	E*	0.06
2nd interview 8/12								
Community ambulation	2.76 (1.06)	3.39 (0.56)	29	33	−0.98	−0.29	E*	0.00*
Flat surface ambulation	3.61 (0.72)	3.79 (0.41)	31	34	−0.42	0.05	E	0.21
3rd interview 2/12								
Community ambulation	3.28 (0.76)	3.50 (0.51)	25	32	−0.50	0.05	E	0.01*
Flat surface ambulation	3.79 (0.45)	3.88 (0.34)	25	32	−0.26	0.09	E	0.12

M, Mean; SD, standard deviation; *N*, number of subjects; 95% CI NDPT M–DPT M, 95% confidence interval of the differences of the means; EQUI, equivalence; *p*, probability value of the one-way ANOVA test.
*Statistical significance at the *p* level 0.05.
**Statistical significance at the *p* level 0.01.

interval (95% CI), E, indicating that equivalence was established and *p*-value when comparing the community ambulation scores of the two groups of subjects at different times.

Only the two categories of ambulation scores, i.e. in the community, which was the highest measured level of ambulation in most times, and walking on a flat surface, which was the highest measured level at the time of discharge from the acute hospital, will be discussed here.

The ambulation ability between the study group and the control group was not statistically significantly different in the two categories (p = 0.36 and 0.77) before the incident, although the scores for the study group were slightly higher in the community ambulation category.

When the patients were discharged from the operating hospital, either to home (study group) or to the rehabilitation hospital (control group), it was neither possible nor appropriate to assess whether the patients were able to walk in the community. Therefore the ability to walk on a flat surface was the most appropriate measure at this stage. The flat surface ambulation score at this time was higher in the study group (N = 40, M 2.6, SD 0.6) than in the control group (N = 41, M 2.0, SD 0.5). This was a statistically significant difference when tested by one-way ANOVA test ($p < 0.0005$) even though the mean difference was only about half a score (0.6).

At the completion of the rehabilitation, differences still existed between the two groups. The study group were one score higher (N = 39, M 3, SD 0.6) in the community ambulation category than the control group, (N = 36, M 2, SD 1.3) and this was a statistically significant difference (p = 0.001). The mean scores in walking on level ground were 3.5 (study group), and 3.3 (control group). At discharge from physiotherapy all the patients were able to walk on level ground independently with or without walking aids, but the difference between the two groups in this category was also statistically significant (p = 0.04).

The ambulation status after completing the physiotherapy was evaluated through telephone interviews four, eight and twelve months after the surgery, and the same scale was used in the assessment as in the previous times. Most of the patients scored 3 or 4 in all categories in all interviews. The study group maintained significantly better scores in the community ambulation throughout the study. The scores in the flat surface ambulation were not significantly different between the groups after discharge from physiotherapy.

When the patients were contacted for the last time, after a year from the operation (study group 32 subjects, control group 25 subjects), the average ambulation ability of all the respondents was above 3. This showed that all of them were independent with or without walking aids in all the ambulation situations but neither group had reached their pre-injury status.

Figures 2 and 3 show the mean scores in community ambulation and walking on a flat surface of the two groups throughout the study. The trend of improvement after discharge from QEH is steeper in the control group than in the study group in both graphs but the control group did not reach the level of the study group. The ambulation ability in the community was not tested at discharge from QEH and therefore is not shown in the graph.

Discussion

The results of this study showed that the ambulation ability in the domiciliary physiotherapy group was at least as good as in the conventional institution-based physiotherapy group and this finding supported the study hypothesis. The domiciliary group received only five sessions of physiotherapy after discharge from the acute ward, while the control group stayed in rehabilitation over a month receiving physiotherapy daily. Ceder *et al.*[9] suggested that rehabilitation of elderly patients with hip fracture in institutions may render them passive, while rehabilitation at home in the familiar environment can promote independence and increase self-confidence, which in turn may lead to better functional status. This conclusion is supported by the findings of the current study.

The contribution of the longer stay in the operating hospital to the better ambulation ability in the domiciliary group is difficult to determine. The patients in the domiciliary group could not be discharged home until they were able to walk with minimum supervision. The fact that all the

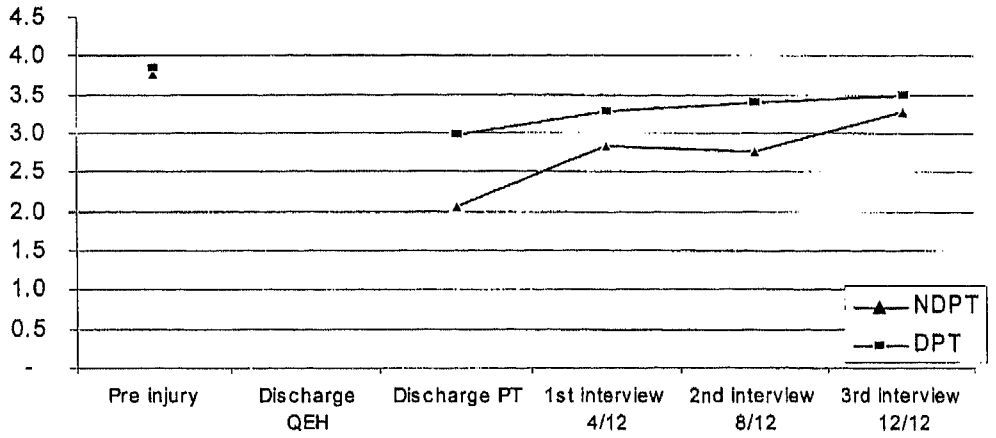

Figure 2 Mean community ambulation scores during the study. NDPT, control group; DPT study group. 'Preinjury' indicates ambulation score before the incident; 'Discharge QEH', indicates ambulation score at discharge from the operating hospital; 'Discharge PT' indicates ambulation score at discharge from physiotherapy; '1st interview 4/12' indicates ambulation score at the first telephone interview 4 months after operation; '2nd interview 8/12' indicates ambulation score at the second telephone interview 8 months after operation; '3rd interview 12/12' indicates ambulation score at the third telephone interview 12 months after operation.

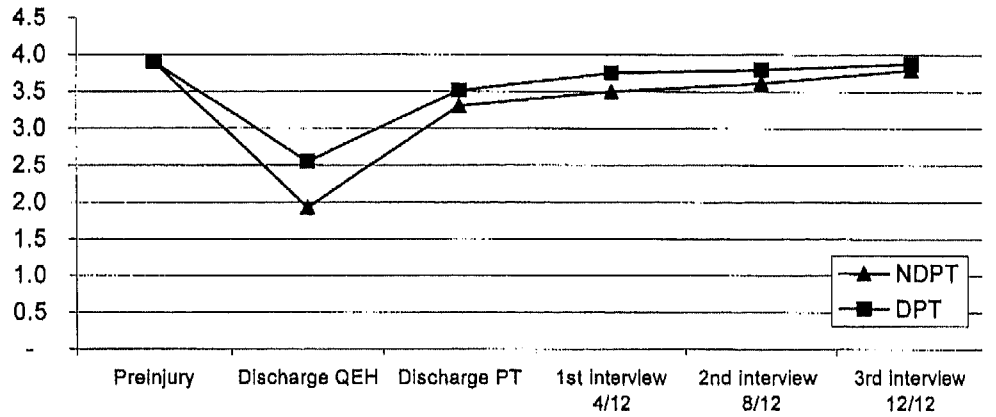

Figure 3 Mean ambulation scores on flat surface during the study. For key see Figure 2.

subjects started walking on average on the third or fourth day after operation, the control group patients 0.3 days earlier than the study group, may indicate that there were no differences in the progression between the groups while staying in QEH. The move from the acute care to the rehabilitation hospital may have initially interrupted the rehabilitation process at a critical point and therefore delayed the progression of the control group. This may imply that early transfer of patients from acute hospital may in fact delay patients' recovery. To evaluate the effect of the two extra days in the operating hospital on the progression of rehabilitation, the outcomes should be measured in both groups at the same time after the operation.

The ambulation ability of the domiciliary group remained better than that of the control group and all the patients in the domiciliary group were able to walk independently in all circumstances at the completion of the study. This indicates that on average five visits by a domiciliary physiotherapist is sufficient to improve the ambulation ability of these patients to the opti-

Clinical messages

- In elderly people who have suffered a hip fracture, direct discharge home with domiciliary physiotherapy is as effective as 36 days of inpatient rehabilitation.
- The domiciliary group needed two extra days in the acute hospital and five sessions of home-based therapy.

mum level, which the month-long rehabilitation in the institution was not able to match. The potential of saving in the cost of rehabilitation by discharging suitable patients directly home with the support of few sessions of domiciliary physiotherapy is significant.

In randomized controlled trials the intervention as well as the randomization should be masked. Even though the treatment in the acute hospital was the same, in principle, the team members treating the intervention group knew that the patients would be discharged directly home and therefore they may have adjusted their treatment practices in order to facilitate the discharge. This could not be helped in the current study because the discharge had to be planned early enough to prepare the patients and their families, and to arrange for transport and medication so that the patient was ready to go home. If the subjects had been randomized to the study and control group later, for example around the fifth day after operation and all of them prepared for discharge home, the treatment bias may have been avoided. This practice may, however, be seen as unethical from the control group patients' and their families' point of view, who may have made plans for going home and then had to postpone them. Randomized controlled trials in a real clinical practice cannot follow strictly the same rules as randomized controlled trials in a laboratory environment and the interpretation of the results must also take into account these practical limitations.

Equivalence trials are not commonly used in assessing outcomes of rehabilitation. No previous studies were found on which to base the clinically acceptable limits for the equivalence. The clinically acceptable limits were set based on professional judgement. A further inquiry among the concerned parties would give a better starting point, when deciding on a clinically acceptable range for the equivalence of outcomes.

Conclusion

The equivalence in the ambulation outcomes was established, meaning that patients receiving physiotherapy at home achieved at least as good results as the patients staying in a rehabilitation centre. The study hypothesis is therefore accepted. In fact the study group did better and the results were statistically significant.

The results of this study show that domiciliary physiotherapy for patients with hip fracture is an effective alternative to the institutional care. The patient group has to be carefully selected though. Living alone or not having adequate support at home may exclude patients from home rehabilitation unless alternative community care is available. Resources from the extended rehabilitation services in institutions should be redirected to strengthen the physiotherapy services in the acute care setting. Domiciliary physiotherapy services together with home support should be developed to suitable groups of patients. Future research should be conducted to determine what would be the ideal length of stay in the acute hospital, which patient groups would benefit most from domiciliary physiotherapy and how the physiotherapy services should be financed and organized. An accurate and comprehensive cost analysis should also be conducted in order to implement the most cost-effective health care services.

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