OPERATIVE OR CONSERVATIVE TREATMENT FOR TROCHANTERIC FRACTURES OF THE FEMUR

A RANDOMISED EPIDEMIOLOGICAL TRIAL IN ELDERLY PATIENTS

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All elderly patients with extracapsular hip fractures seen in hospitals in Newcastle upon Tyne over a 12-month period were studied and followed up for six months. At one of the hospitals, patients were randomised to treatment by AO dynamic hip-screw or by traction. Complications specific to the two treatments were low, and general complications, six-month mortality and prevalence of pain, leg swelling and unhealed sores, showed no difference between the two modes of treatment.

Operative treatment gave better anatomical results and a shorter hospital stay, but significantly more of the patients treated by traction showed loss of independence six months after injury.

The view has been urged, particularly by Devas (1977), that the treatment of choice for extracapsular fractures of the proximal femur is immediate operative fixation by nail-plate. No randomised trial of operative versus conservative treatment has been published: our recent review of cases treated in Newcastle upon Tyne suggested that conservative treatment might in the longer term produce a lower incidence of painful complications.

Trials of different forms of management of proximal femoral fractures are usually based on cases admitted to particular hospitals. Epidemiological studies in Newcastle (Evans, Prudham and Wandless 1979b; Evans, Wandless and Prudham 1980) demonstrated that different hospitals even in the same city may receive cases that differ in important ways with regard to factors associated with prognosis. If there are interactions between treatment and pre-existing factors in determining the outcome, what is found to be the better treatment at one hospital might have emerged as the worse treatment if the trial had been applied to the patients admitted to another hospital.

Furthermore, our experience suggests that the effective catchment of a particular hospital may vary over time and even with season. The only definitive approach to making the results of controlled trials generalisable is to use an epidemiological base: to collect all the cases occurring in the same population over the same time period as the cases entered into any trial. With this information, the trial results can be extrapolated to the whole population or to the samples that were admitted to other hospitals. Our study aims to test the feasibility of such an epidemiologically-based randomised and controlled trial.

METHODS

For a 12-month period all patients aged 60 years or more with an extracapsular fracture seen at any hospital in Newcastle upon Tyne were interviewed by one of two research workers. The interviewers used a structured questionnaire based on one developed for previous studies in Newcastle (Evans, Prudham and Wandless 1979a) and had been trained in its use. Patients arriving at the Royal Victoria Infirmary (RVI) who were considered fit to undergo operation were invited to enter the study using procedures approved by the district ethical committee. Patients who agreed to enter were stratified according to age (under or over 75), mental test score (under or over 7) (Evans et al 1979a; Ions and Stevens 1987), and the radiographic stability using the classification of Jensen and Michaelsen (1975). Sex was

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0301-620X/89/4138 $2.00
J Bone Joint Surg [Br] 1989;71-B:619-23.

not used as a stratifying variable since a previous study of elderly patients had indicated that this did not affect the outcome of proximal femoral fracture when other variables were taken into account (Evans et al 1979b). Using a system of sealed envelopes, patients within each stratum were randomly allocated for treatment by operation or traction.

Patients allocated to operation had internal fixation with the AO dynamic hip screw (DHS). Operations were performed on routine lists as soon as practicable, under general or spinal anaesthesia with antibiotic prophylaxis, using a C-arm image-intensifier. A standardised routine had been rehearsed for three months before the trial and all but six operations were performed by the same surgeon. The fracture was reduced as accurately as possible and a centrally placed guide wire inserted by air drill. Neck length was measured directly from the guide wire and reaming carried out to 10 mm from subchondral bone. A screw, 20 mm shorter than the total neck length, was inserted to the reamed limit. No additional thread tapping was used in the femoral head. A 4-hole sideplate was attached to the femur; the secondary compression screw was tightened by hand and left in place. Two separate reversible air drills facilitated the surgery and helped to keep the operating time under 30 minutes in most cases.

Patients allocated to conservative treatment were managed on Hamilton Russell traction applied through a heavy threaded pin inserted into the tibia under local anaesthesia. The traction was adjusted to obtain an optimal position and continued until apparent clinical and radiological union.

All patients, whether entered into the trial or not, were followed up and assessed at six months from injury. While they were in hospital, weekly summaries were made of each patient's progress with regards to mobilisation, continence, feeding, use of drugs, and any medical or surgical problems. At six months patients were re-assessed both in an outpatient clinic and by a home visit. For practical reasons these interviews had to be carried out by the observers who knew the treatment group of the patient, so to assess any bias this 'non-blind' assessment might introduce, a subsample of patients were also interviewed by an independent observer who did not know the treatment group. The results showed no evidence of bias; we therefore used the original assessments in our analysis.

RESULTS

A total of 222 patients were identified during the study year. Of these, 88 were admitted to hospitals other than the RVI, and so could not be included in the randomisation: 28 were admitted to the RVI but were not entered into the study. Reasons for exclusion were, about equally, refusal, lack of fitness for operation, and unavailability of informed consent. Therefore 106 patients were

Table I. Details of all patients over 60 with extra capsular fractures of the hip (number and *per cent*)

	Trial patients				Excluded from trial	
	Operation		Traction		RVI	Other hospitals
Total	55	*100*	51	*100*	28	88
Male	10	*18*	17	*33*	9	13
Stable	16	*29*	14	*27*	6	24
Unstable	39	*71*	37	*73*	15	45
Unknown	–	–	–	–	7	19
Mental test score						
0–2	9	*16*	9	*18*	7	27
3–10	19	*35*	15	*29*	12	40
10–13	27	*49*	27	*53*	9	16
Unknown	–	–	–	–	–	5
Other fractures	1	*2*	0	*0*	0	5
Head injury	2	*4*	1	*2*	1	5
Age 60 to 64	3	*6*	5	*10*	0	8
65 to 69	5	*9*	4	*8*	2	3
70 to 74	7	*13*	5	*10*	4	7
75 to 79	9	*16*	16	*31*	8	14
80 to 84	17	*30*	12	*24*	4	24
85 to 89	8	*15*	4	*8*	7	24
over 90	6	*11*	5	*10*	3	8
Living alone	22	*40*	21	*41*	6	28
Residence/ 1	12	*22*	7	*14*	10	30
place 2	32	*58*	32	*63*	16	43
of injury* 3	11	*20*	12	*24*	2	15

* see text for scoring system

Table II. Outcome at six months (number and *per cent*)

	Trial patients				Not entered in trial			
	Operation		Traction		RVI		Other hospitals	
Discharged	36	*65*	30	*59*	16	*57*	45	*51*
Dead	13	*24*	11	*22*	8	*29*	29	*33*
In hospital	6	*11*	10	*20*	4	*14*	14	*16*
Total	55	*100*	51	*100*	28	*100*	88	*100*

Table III. Outcome at six months related to mental test score

	Operation			Traction		
	Mental test score			Mental test score		
	0–2	3–10	11–13	0–2	3–10	11–13
Discharged	4	8	24	2	7	21
Dead	4	6	3	3	4	4
In hospital	1	5	0	4	4	2

Table IV. Outcome at six months related to sex of patient

	Operation		Traction	
	Men	Women	Men	Women
Discharged	7	29	10	20
Dead	3	10	4	7
In hospital	0	6	3	7

Table V. Outcome at six months related to age in years

	Operation		Traction	
	<75	75–	<75	75–
Discharged	12	25	13	18
Dead	3	9	0	10
In hospital	1	5	1	9

Table VI. Hospital stay in days

	Operation		Traction	
Days	Number	Cumulative percentage	Number	Cumulative percentage
1 to 6	11	*20*	13	*25*
7 to 13	1	*22*	0	*25*
14 to 20	8	*36*	0	*25*
21 to 27	5	*45*	1	*27*
28 to 34	3	*51*	0	*27*
35 to 41	4	*58*	1	*29*
42 to 48	4	*65*	1	*31*
49 to 55	1	*67*	1	*33*
56 to 62	2	*71*	3	*39*
63 to 69	2	*75*	3	*45*
70 to 76	2	*78*	4	*53*
77 to 83	1	*80*	4	*61*
over 84	11	*100*	20	*100*
Mean (s.d.)	53.0 (56.5)		79.7 (62.9)	

Table VII. Complications of traction in 51 patients (number and *per cent*)

Pin track infection	8	*16*
Pin loosening	20	*39*
Nerve palsy	0	*0*
Traction sores	5	*10*
Delayed union	2	*4*
Other complications	7	*14*

randomly allocated, 55 to operation and 51 to traction (Table I).

'Residence/place of injury' in Table I is a composite variable which was found to predict survival after proximal femoral fracture (Evans et al 1979b). Patients resident in institutions are placed in category 1, patients in private households who sustained their fracture indoors are in category 2, while patients who suffered their fracture out of doors are in category 3. Rather more men were randomised to traction than to operation, but the two experimental groups were otherwise comparable with no difference in the incidence of head injury or other fractures or the proportion living alone. As expected the RVI patients not entered into the study were older, had lower mental test scores and were more likely to be institutional residents. This also applied to the patients admitted to other hospitals in Newcastle.

The average operation time was 28 minutes (range 15 to 90 minutes) and the average time in traction was 51 days with a maximum of 150 days.

Outcome. Table II summarises the overall outcome at six months. There are no great differences between the operative and traction groups except that 10 traction patients were still in hospital compared with six of the operated group. Of patients admitted to the RVI 24% had died compared with 33% of the patients admitted to other hospitals. This is to be expected from the difference in the three risk factors noted above (Evans et al 1979b).

Table III shows the outcome at six months according to mental test score (MTS). As expected there is a definite association between low MTS and poor outcome, but there is no evidence of any difference between the two treatment groups. Comparing 'poor' outcome (dead or still in hospital at six months) with 'good' outcome (discharged alive before six months) a low MTS was significantly associated with outcome at $p=0.008$ for operation and $p=0.0006$ for traction (Fisher's test). Table IV shows that sex is not related to outcome in either treatment group. Table V shows outcome by age group; there is a suggestion of a possible interaction with treatment. In the operated group there was no association between the age and outcome ($p=0.33$ by Fisher's test) but there was in the traction group ($p=0.003$). However, in the high age group treatment was not significantly related to outcome ($p=0.13$). The residence/place of injury score was related to overall outcome in that 13% (3/23) of patients who suffered their fracture out of doors had a 'poor' outcome compared with 42% (35/83) of the other two groups, but there was no difference between the treatment groups.

Length of stay. Table VI sets out the length of hospital stay for each of the two treatment groups. The difference in mean length of stay is nearly 27 days; this is an underestimate since more patients in the traction group than in the operation group were still in hospital at the end of the six-month follow-up. Using the Kolmogorov-Smirnov two-sample test (Siegel 1956) the difference in hospital stay was significant ($p<0.01$).

Complications. No patient in the *operated group* needed re-operation or secondary traction. Migration of the capital screw occurred in three patients and two shaft screws backed out several turns in one patient. One patient had radiographic non-union at follow-up. There were no wound infections and no cases of separation or fracture of the implant or penetration of the screw into the hip.

Twenty patients (39%) in the *traction group* (Table VII) showed loosening of the pin and eight (16%) had

minor infection of the pin track. Five patients (10%) developed skin sores from the traction apparatus but no patient had symptoms or signs of nerve compression. Two patients had radiographic non-union at follow-up.

Complications general to both groups are given in Table VIII. Despite the longer mean length of stay of traction patients there are no significant differences in the rates of these complications.

Findings at six months

Anatomical results. Radiographs at six months from injury showed anatomical neck–shaft angles in 31 (89%) of the 35 operated patients seen and 20 (51%) of the 39 reviewed patients allocated to traction ($p<0.001$). Three operated patients had varus deformity of over 20° compared with 19 of the traction patients ($p<0.001$). Only one patient (from the operation group) had a valgus deformity of over 20°. Rotational misalignment was recognised in 24 (67%) of 36 reviewed patients in the operation group and in 13 (36%) of the 36 patients reviewed in the traction group ($p<0.05$). Fixed flexion deformity was recorded in nine (26%) of the operation group and 14 (36%) of the traction group ($p>0.05$). Twenty-six (70%) of the 37 patients reviewed after operation had no shortening of the affected leg compared with 17 (44%) of the 39 treated by traction ($p<0.05$). Seven (19%) of 37 operated patients and 21 (54%) of patients in the traction group had leg shortening greater than 1 cm ($p<0.01$). Overall, therefore, the operated group showed a better average result in anatomical terms.

There was evidence that fractures classified as unstable gave the worst anatomical results after traction. Within the stable group, only one of 10 patients treated by operation showed a leg length difference greater than 1 cm compared with 4 of 9 patients after traction ($p=0.098$ by Fisher's test). In the unstable fractures, leg length differences greater than 1 cm occurred in 6 of 24 in the operation group and 18 of 27 in the traction group ($p=0.003$). Hip flexion deformity among the unstable fractures was also more common in the traction group (13/27) than in the operated group (5/23) ($p=0.049$), but there was no difference among the stable fractures (4/11 operated group and 1/9 traction group, $p=0.2$). In stable fractures 3 of 11 in the operated and 5 of 9 in the traction group showed misalignment ($p=0.205$). In the unstable fractures the corresponding figures were 8 of 24 in the operated and 17 of 26 in the traction group ($p=0.023$).

Function. At six months from injury the ranges of hip movements were measured. Differences between the groups reflected the rotation and adduction deformities which, as noted above, were more prevalent in the patients managed by traction.

At the time of injury, 33 patients having operation and 33 having traction had been living alone or with a spouse. Of the operated group, 24 were alive and discharged from hospital after six months and three had moved into residential care. Of the traction group, 20 were alive and had left hospital at six months, four had moved into residential care and two had been discharged to live with children. Thus, including those still in hospital, nine (16%) of the operation group had lost independence compared with 16 (31%) of the traction group ($p<0.05$).

Table VIII. Complications during hospital stay (number and *per cent*)

	Operation		Traction	
Urinary incontinence	34	*62*	27	*53*
Faecal incontinence	25	*45*	22	*43*
Mental confusion	20	*36*	19	*37*
Tranquillisers prescribed	11	*20*	13	*25*
Heel sore – blistering only	6	*11*	8	*16*
full thickness	2	*4*	1	*2*
Sacral sore – blistering only	8	*15*	4	*8*
full thickness	2	*4*	1	*2*
Deep venous thrombosis – probable	1	*2*	0	*0*
possible	1	*2*	0	*0*
Pulmonary embolism – probable	1	*2*	2	*4*
possible	2	*4*	3	*6*

Table IX. Residual problems at six months follow-up

		Operation n=41*	Traction n=40
Pain	None	22	16
	Occasional	7	14
	Daily	12	10
	Mild	11	10
	Moderate/severe	8	14
Leg swelling	Present	5	9
	Absent	36	31
Unhealed sore	Present	5	5
	Absent	36	35

* one patient lost to follow-up

Table IX lists the other problems at six months and shows that half or more of survivors in both groups suffered some pain and a smaller proportion had a swollen leg or an unhealed pressure sore. There were no significant differences between the two treatment groups.

We defined a number of subgroups of patients, but were unable to identify any in which patients treated by traction did better than those who underwent operation.

DISCUSSION

The routine use of operative treatment for trochanteric fractures was temporarily abandoned at the RVI after an unpublished, prospective trial of McLaughlin osteosynthesis compared with skeletal traction, showed that the use of a fixed-length nail-plate did not reduce the fatality or complication rates. Accelerated discharge from hospital which operation may allow was observed only in the minority who had stable fractures. The remainder suffered an unacceptably high incidence of local complications directly related to the operation. Skeletal traction

gave similar functional results and avoided these technical problems; it was chosen as a safe reference standard against which alternative methods of treatment could be evaluated.

A central finding of the present randomised trial is that the AO dynamic hip screw provides a safe operative method of internal fixation for trochanteric fractures, with a low risk of serious technical complications when used in the manner described. General complication rates in patients operated on and those treated by traction were essentially similar, perhaps contrary to expectation.

However, nearly all the operations were carried out by the same surgeon, according to a strict protocol, and with an average operating time of 28 minutes. Complication rates might be expected to be higher if the technique was followed less precisely, particularly with reference to the exact placement of the screw in the femoral head. Prolonged operation times bring their own complications in the form of pressure sores initiated on the operating table.

In terms of fatality, and the prevalence of pain, leg swelling and unhealed sores at six months we found no difference between the two treatments. Operation gave a better anatomical result and the hospital stay was longer for patients treated by traction, with a difference in mean stay of 27 days, and more patients still being in hospital at six months. The cost of this increased stay is offset to some extent by the marginal costs of operative treatment, but account should be taken of the opportunity costs of unoccupied houses and the travel costs of hospital visiting, as well as the effect on the patient of a prolonged hospital stay in enforced dependence and limited mobility.

The overall six-month fatality of 23% compares favourably with other published series (Jensen 1981), but it must be emphasised that meaningful rates can only be computed if all cases in a defined population are included in the calculations. Our study has shown the importance of establishing the epidemiological base of a controlled trial: it was clear that the patients not included in the study were significantly different in important ways from those entered.

If the results had differed between any significant subgroups, the conclusions would have had to be extrapolated to the wider population of potential patients. In fact, we did not identify any subgroup for which traction was preferable to operation, but our study has shown the feasibility of such epidemiologically-based trials. Two problems that have arisen and will require further trials are the high prevalence of pain and the management of those patients for whom operation does not appear to be a practical option.

This study was supported by a grant from the Newcastle District Research Committee.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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