A clinical trial designed to discover if the primary treatment of varicose veins should be by Fegan's method or by an operation

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SUMMARY

1. *The current practice of operating upon patients with varicose veins as the treatment of choice costs more than £15 millions a year.*

2. *The bulk of this expense is due to the length of time that patients are kept in the ward. If they were treated as outpatients, either by Fegan's method or by operation, the cost would be reduced to one-tenth of what is now spent. Even if the operation were done on a 'short-stay' basis the cost would be reduced to one-third or less.*

3. *Although the long term results of Fegan's method are uncertain there is no doubt that it gives better immediate results than an operation. Moreover, there is no particular type of varicosity or shape of limb which precludes its use.*

FROM 1855 to 1905 varicose veins were treated by sclerosing injections. Ligation at the saphenofemoral junction and stripping dates from 1905. It did not become the standard treatment in this country until about 1950. Now it is the most frequently performed operation in general surgery. Each year in England and Wales 150 000 patients are operated on for varicose veins (Lees, 1969) at a cost of more than £15 millions.

The problem is to decide whether these patients can be treated more cheaply by using Fegan's compression-injection method of sclerotherapy and diverting the money saved to some other surgical task.

If Fegan's method is to become the primary treatment of choice it must be proved that it is as good a treatment as the operation of saphenofemoral ligation and stripping of the long saphenous trunk.

It has been asserted that a patient with varicose veins can be treated by Fegan's method at the cost of £9·77 per head as compared with £44·22 per head if he were operated upon (Piachaud and Weddell, 1972). At its face value this represents an annual saving in England and Wales of over £5 millions.

Under prevailing surgical management it would save nearly three times that amount because the calculation made by Piachaud and Weddell (1972) rested on the fact that the patients who were operated on were sent home in 3·7 days. By contrast, as the authors point out, the latest 'mean national length of stay for varicose vein cases' ranges from 7·5 to 15·7 days, with an average of 11·7 days. This average length of stay in the ward coincides closely with the official figure of 10·5 days (Lees, 1969). At the present time in the Birmingham region 10 days as an inpatient costs £110

(Wall, 1973), and an actuarial analysis by the same regional board found that the average cost per operation was £13·30, inclusive of the pay of the doctors, the nurses, the domestics and 'others', and covering the cost of drugs, dressings and equipment. As a round figure, therefore, the cost of operating on a patient with varicose veins, taking England and Wales as a whole, is about £125.

Piachaud and Weddell (1972) calculated that the cost of the operation alone was £12, which coincides closely with the figure given above of £13·30. This leaves little doubt that the financial disadvantage of the operative method is almost entirely due to the time spent in the ward. The great financial advantage of Fegan's method, which is an outpatient treatment, rests upon this fact.

However, operation can also be performed on outpatients, as has been found both in North America (McPheeters, 1945) and in Britain (Stevens and Dudley, 1961). This practice would virtually abolish the financial disadvantage of treating varicose veins by operating on them.

Before this issue can be decided, properly constructed clinical trials must be carried out or the patients may suffer. Finance must not be the overriding factor. According to Piachaud and Weddell (1972) and to Seddon (1973) the two methods being compared in this trial are of equal merit.

Design of the trial

The present trial was arranged as a random series. Fegan's method was used on all the patients born in a year with an even number, while those born in a year with an odd number were operated upon.

Patients who were operated on were not managed as outpatients because to do so would tend to limit the operation to stripping of one saphenous vein. Clinically, this would have biased the trial in favour of Fegan's method because some patients need more than one long saphenous vein stripped. Therefore the patients were kept in hospital for 2 days because there is no limit to the amount of surgery possible on this basis (Doran et al., 1972).

To avoid confusion the comparison between the two methods was based on whether additional treatment was prescribed at the end of the first year and again at the end of the second year after treatment. Either

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additional treatment was given or it was not. Two years was chosen as the length of the trial. It is well known that with benign conditions of low morbidity it is difficult to maintain an efficient follow-up for longer.

Method of injection-compression
The method used in this trial followed that of Fegan closely, except that ethamolin was used throughout. The quantity injected at each site was 0·5–1 ml. Not more than three or four sites were injected at the same visit into one limb (Fegan, 1964). The 'empty vein' technique recommended by Fegan (1960) was used routinely. There were no overdose effects.

The compression was obtained by bandaging a Sorbo rubber pad over the site of the injection and the application of a full length two-way-stretch elastic stocking over the bandages, held up where needed by a suspender belt, and worn day and night (Fegan, 1965).

Furthermore, the patients were instructed to walk 3 miles a day and to avoid standing (Fegan, 1965). The bandaging was examined at the hospital each week. At these visits the previous injection sites were examined and any additional injections required were given.

Table I: RESULTS AT THE END OF THE FIRST YEAR

Treatment	Total limbs	No. lost	Limbs examined No.	Limbs examined %	Additional treatment No.	Additional treatment %
Fegan	280	49	231	82·5	56	24·2
Operation	222	26	196	88·3	88	44·8

Compression over the injection sites was maintained for 6 weeks at least after the last injection.

Before taking the final decision that the treatment was complete the patients were told to remove the stockings and bandages 2 days before they were due to be seen and to take a bath, replacing the stockings only. In this way the skin, corrugated by the bandages, has time to become smooth, which makes the final assessment much easier. If no additional injections were needed the elastic stockings alone were reapplied for a further 6 weeks, when the stockings were discarded and the patient followed up at increasing intervals up to 2 years from the start of the treatment.

Patients
Because the division and ligation of the incompetent perforating veins in the leg which cause ulceration are so uniformly successful in healing the ulcer it was considered unjustifiable to include such cases in the trial. Therefore, all patients presenting with an open varicose ulcer were excluded. This series numbers 331 patients with varicose veins uncomplicated by ulceration. Of this total, 182 patients were treated primarily by Fegan's method and 149 were operated upon. In the Fegan group 98 patients had bilateral varicose veins and in 84 the varicosities were confined to one leg. In the group who underwent operation 73 had bilateral varicose veins and in 76 they were unilateral. Presented as individual limbs, the Fegan group contains 280, and the operative group 222, making a total of 502 limbs for the whole series.

Table II: EFFECT OF FOLLOW-UP LOSSES ON RESULTS: χ^2 TEST

Result	Observed no. of failures, maximum possible Fegan	Observed no. of failures, maximum possible Operation	Observed no. of failures, minimum possible Fegan	Observed no. of failures, minimum possible Operation
Observed successes	224	134	175	108
Expected successes	199·68	158·32	157·85	125·15
Observed − expected	+24·32	−24·32	+17·15	−17·15
(Difference)² ÷ expected	2·9670	3·7428	1·8633	2·3501
Observed failures	56	88	105	114
Expected failures	80·32	63·88	122·15	96·85
Observed − expected	−24·32	+24·32	−17·15	+17·15
(Difference)² ÷ expected	7·7376	9·3037	2·4070	3·0367
χ^2	23·7511		9·6571	
P	0·01		0·01	

Table III: EFFECT OF FOLLOW-UP LOSSES ON RESULTS: χ^2 TEST

Result	Observed no. of failures, maximum for Fegan, minimum for operation Fegan	Observed no. of failures, maximum for Fegan, minimum for operation Operation	Observed no. of failures, minimum for Fegan, maximum for operation Fegan	Observed no. of failures, minimum for Fegan, maximum for operation Operation
Observed successes	224	108	175	134
Expected successes	185·18	146·82	172·35	136·65
Observed − expected	+38·82	−38·82	+ 2·65	−2·65
(Difference)² ÷ expected	8·1379	10·2642	0·0410	0·0517
Observed failures	56	114	105	88
Expected failures	94·82	75·18	107·65	85·35
Observed − expected	−38·82	+38·82	−2·65	+2·65
(Difference)² ÷ expected	15·8932	20·0451	0·0652	0·0823
χ^2	54·3404		0·2402	
P	0·01		0·10	

Results

As far as possible the observations made in this trial will be reported as the number of limbs treated. In patients with bilateral varicose veins the severity and the site of the varicosities in the two limbs seldom match. Furthermore, after a patient with bilateral varicosities has been treated one limb may be a success and the other a failure.

The results at the end of the first year are set out in *Table I*. The interpretation of this table is made difficult by the 75 limbs which, for a variety of reasons, were 'lost'. There are four possibilities:

1. All the 75 limbs which were 'lost' could have been successes.

2. All the 75 limbs which were 'lost' could have been failures.

3. The 49 limbs in the Fegan group which were 'lost' could have been successes but the 26 limbs in the operative group might have been failures.

4. The 26 limbs in the operative group which were 'lost' could have been successes and the 49 limbs in the Fegan group which were 'lost' could have been failures. *Tables II* and *III* show the calculation of χ^2 for each of these four possibilities.

It will be seen that except for the last contingency where all the 26 limbs in the operative group which were 'lost' are successes, and all the 49 limbs in the Fegan group which were 'lost' are failures, the Fegan method is superior to the operative method with values for P of less than 0·01. In the fourth permutation the two methods are equal in value. It is likely, therefore, that the initial response of varicose veins to compression-sclerotherapy is better than that to operation.

Table IV sets out the results at the end of the second year. They are of interest but of little value. They are of interest because they suggest that performing an operation before administering a course of sclerotherapy does not improve the results of sclerotherapy on its own. However, they are of little value because the efficiency of the follow-up during the second year fell from 85·1 to 66·9 per cent, the number of limbs 'lost' increasing from 75 to 166.

Table V shows an attempt to discover if pati'two whose varicose veins were mainly due to incompetents at the sephenofemoral junction, judged by the ence tourniquet' and calf exercise tests, ought to be treated primarily by operation. This is not the case; 49·6 per cent of the limbs on which a long saphenous stripping was done required Fegan injections at the end of the first year, compared with 23·7 per cent of those who received sclerotherapy as their primary treatment.
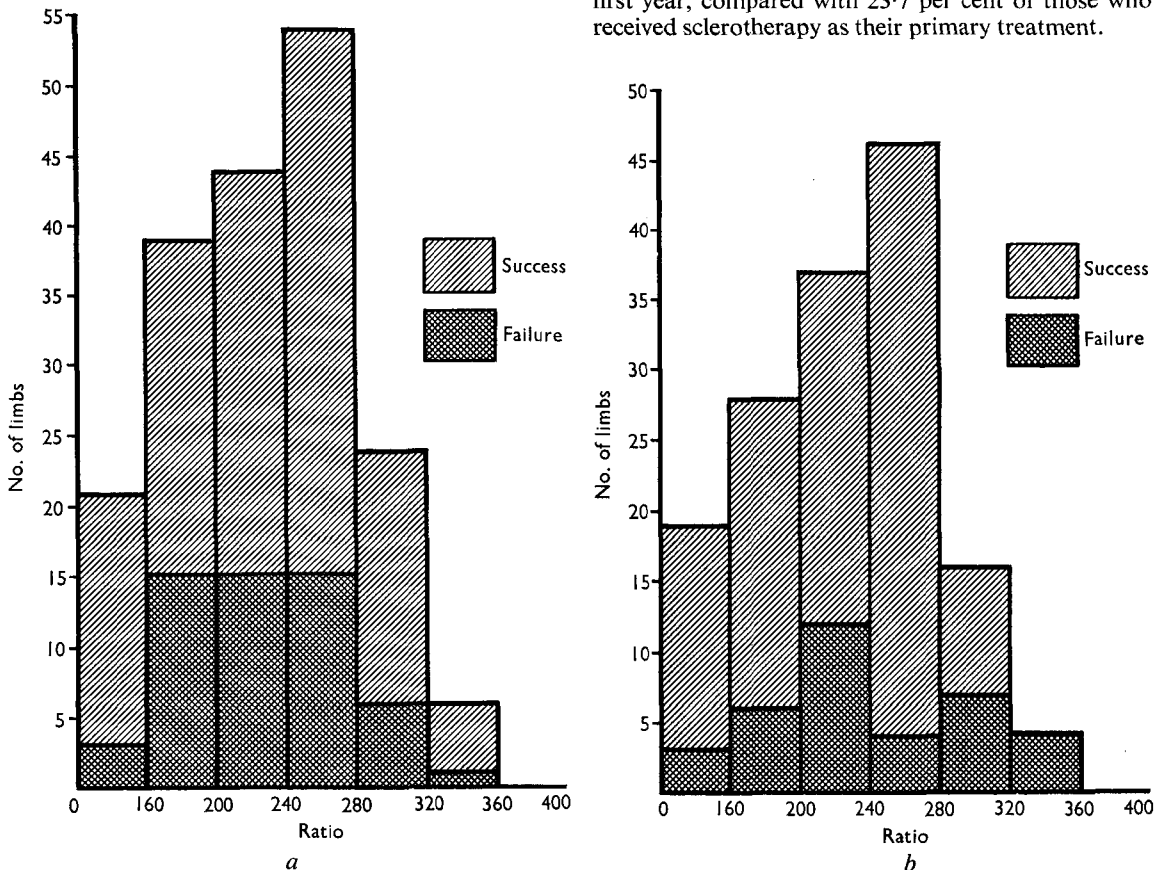

Fig. 1. Results of sclerotherapy in relation to the configuration of the limbs. The limbs with the most slender thighs are represented by the column on the far left: those with the most bulky thighs by the column on the far right. *a*, At the end of the first year the failures were not concentrated amongst those with fat thighs and short legs. *b*, Results at the end of the second year supports the view that good results can be obtained on fat short legs if enough care is taken with the technique.

Table IV: RESULTS AT THE END OF THE SECOND YEAR

Treatment	Total limbs	No. lost	Limbs examined		Additional treatment	
			No.	%	No.	%
Fegan	280	102	178	63·6	39	21·3
Operation	222	64	158	71·2	26	16·4

There is no statistical difference between the two methods. Nearly half of the patients in the operation group had received a course of injections at the end of the first year.

Table V: SITES OF MAIN VALVULAR INCOMPETENCE

Vessels needing treatment	Fegan	Operation
Long saphenous vein alone	184 (23·7%)	149 (49·6%)
Long and short saphenous veins	20 (45·0%)	12 (33·3%)
Long saphenous and leg perforating veins	9 (11·1%)	25 (28·0%)
Long and short saphenous veins with leg perforating veins	None	9 (33·3%)
Short saphenous vein alone	10 (30·0%)	None
Leg perforating veins alone	1 (0·0%)	1 (0·0%)
Hunter's canal perforating vein alone	7 (14·3%)	None

Percentages in parentheses are the proportion in each group needing additional treatment at the end of the first year.

Table VI: EFFECT OF SITE OF THE VARICOSITIES

Site of varicosities	Fegan	Operation
Both thigh and leg	121 (30·6%)	122 (51·6%)
Knee and leg	107 (20·5%)	71 (40·8%)
Thigh only	3	3

Percentages in parentheses are the proportion in each group needing additional treatment at the end of the first year.

Table VII: EFFECT OF PRELIMINARY OPERATION ON NUMBER OF INJECTIONS NEEDED

No. of injection visits	Primary Fegan injections, clinical trial limbs (%)	Postoperative Fegan injections	
		Clinical trial limbs (%)	141 'Extra' limbs (%)
1– 5	64·6	82·4	77·7
6–10	23·8	14·0	19·0
11+	11·6	3·6	3·3

Table VI records the results of operation and Fegan's method in relation to the site of the varicosities. Fewer limbs treated primarily by sclerotherapy required additional treatment at the end of the first year than those operated upon, irrespective of site.

Fig. 1 analyses Fegan's (1963) opinion that obesity makes it hard to get a good result with sclerotherapy because maintaining the required compression is extremely difficult. This problem was tested by subtracting the circumference of the calf from that of the thigh and dividing the difference by the length of the limb. This measures the configuration of the limb. The figures show that although technically difficult, good results can be obtained on short limbs with very fat thighs.

Finally, the possibility that fewer injections would be needed per limb if a preliminary operation had been

carried out was examined. This was suggested more than 20 years ago (McElwee and Maisel, 1947), but Fegan (1963) denies it.

In 1968 Reid and Rothnie reported from Reading a series of 974 patients (1358 limbs) treated by sclerotherapy with encouraging results. Now, for about 10 per cent, where the whole limb is involved from the groin to the ankle at a high pressure, limited surgery is carried out on a 'short-stay' basis prior to sclerotherapy (Rothnie, 1973).

Table VII details the number of visits for injections paid by the patients who were treated primarily by Fegan's method and by those who, having been operated upon, needed injections for residual or recurrent varicosities. The results support the opinion that a preliminary operation reduces the number of injections required subsequently. The results in a further 141 limbs, which were all operated on before the start of this trial and all needing Fegan injections for residual and recurrent varicosities, also support this view.

Conclusions

1. The initial response of varicose veins is better if Fegan's method is used than if they are operated upon.

2. Fegan's method is not contra-indicated by primary saphenofemoral incompetence or by fat thighs provided that, in the latter case, great care is taken with the technique.

3. Which method is better in the long run may never be known owing to the great difficulty of maintaining the efficiency of the follow-up for more than a short time.

4. It is likely that preliminary operation reduces the number of injections required subsequently.

5. The policy of treating varicose veins initially by Fegan's method will probably save money, beds and theatre time, without any detriment to the patient.

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