

type 2 error is, however, 88% with the present data from the two groups. It would require a much larger number of patients taking thrice daily insulin than 15 to show a possible significant difference. The important point is, however, that nocturnal hypoglycaemia is unlikely to be less prevalent with a thrice daily regimen. It remains to be shown whether any conventional regimen can reduce the prevalence of nocturnal biochemical hypoglycaemia and give normal fasting morning blood glucose concentrations at the same time. Continuous subcutaneous insulin infusion offers relatively constant and reproducible insulin profiles,<sup>12</sup> but it has yet to be shown to reduce the prevalence of nocturnal hypoglycaemia.

Whether biochemical asymptomatic hypoglycaemia during the night is harmful cannot currently be answered satisfactorily. The changes seen in neuropsychological performance<sup>13 14</sup> and on electroencephalography<sup>15</sup> when the blood glucose concentration is acutely lowered to hypoglycaemic values seem reversible. Hypoglycaemia does not appear to be harmful provided it is of short duration, although this has never been studied properly. During the night, when alarm symptoms seem to be impaired, the possibility of long and severe hypoglycaemic periods exists. Such periods repeated over years of treatment with insulin could result in morphological and functional changes, primarily in the brain. When aiming for more physiological blood glucose control by means of intensified treatment with insulin it is thus important to evaluate not only the risk of daytime hypoglycaemia but also that of nocturnal hypoglycaemia.

In conclusion, asymptomatic biochemical hypoglycaemia at night is common during twice daily treatment with insulin and

unlikely to be less common with thrice daily insulin regimens. Low values of HbA<sub>1c</sub> might be associated with a higher risk of nocturnal biochemical hypoglycaemia. The bedtime blood glucose concentration seems to be a valuable predictor of nocturnal biochemical hypoglycaemia, and HbA<sub>1c</sub> values might also be helpful in identifying patients at risk.

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# Long term treatment of severe obesity: four year follow up of results of combined behavioural modification programme

H BJÖRVELL, S RÖSSNER

## Abstract

A four year programme of treatment for severe obesity combining standard techniques such as behavioural modification, exercise, nutritional advice, and, in addition, readmission of patients who relapse has been developed. One hundred and seven subjects of both sexes were treated. Thirty nine had their jaws fixed from the start. After four years 104 out of 107 subjects were traced; 33 (31%) had left the programme. The mean loss of weight in the remaining 74 subjects was 11.7 kg (range -20 to 55.5): 14 had lost more than 20 kg, 35 had lost 5-20 kg, 17 had lost 0-5 kg, and eight were above their weight before treatment. The rate of dropping out in this study was lower than that generally reported.

Our data suggest that combined behavioural modification used as a programme for reducing weight may result in a substantial loss of weight for several years even for severely obese subjects.

## Introduction

In the treatment of severe obesity long term follow up is mandatory. Obesity is usually a lifelong condition. Most programmes of treatment, however, last only for weeks or months, and the evaluation of the results rarely lasts for a year or longer.<sup>1-3</sup>

For subjects with incapacitating obesity numerous surgical methods have been developed. Although these have been successful in many cases, they do not cure overweight. Failures, complications, and death may occur even in late stages.<sup>4</sup> Furthermore, they require long term follow up, and normal weight is certainly not effortlessly maintained as was once expected.<sup>5</sup> Even in cases of severe obesity, therefore, non-surgical methods can play an important part provided that these methods initiate a noticeable loss of weight, maintain that loss of weight, identify and prevent relapses, and lead to a high degree of compliance.

The long term effects of various single techniques of reducing weight have generally been poor. Combinations of techniques, however, such as behavioural modification, exercise, and nutritional instruction seem to have more success,<sup>6 7</sup> but long term approaches of this kind are uncommon. One reason for this is that many overweight patients drop out of the programmes. In several studies about 50% of subjects dropped out during the first year of follow up.<sup>8-11</sup>

We report the results of a long term programme that we developed, which combined standard techniques such as behavioural modification, exercise, nutritional advice, fixing the

King Gustav V Research Institute, Karolinska Institute and Department of Internal Medicine, Karolinska Hospital, S-104 01 Stockholm, Sweden

H BJÖRVELL, RN, doctor of medical science  
S RÖSSNER, MD, associate professor

Correspondence to: Dr H Björvell.

jaw, and readmitting all patients who relapsed to the programme. The hypothesis of this study was that such a combined programme would prove better than a programme containing only simple behavioural and dietary instructions.

**Subjects and methods**

The 107 subjects were referred to or had written to the obesity unit at this hospital because of severe overweight. Two programmes were available: the "Medicine 5" programme and the jaw fixation programme. The subjects admitted had to be severely overweight (body

mass index >29 for women and >30 for men; body mass index = weight (kg)/height (m)<sup>2</sup>.<sup>12</sup> They had made several serious attempts to reduce weight previously and had somatic or psychological complications, or both. They also needed living conditions that allowed regular check ups to record weight and have group sessions. These facilities were evaluated during repeated interviews. For patients who chose jaw fixation as the first treatment an acceptable dental state to enable fixation was a prerequisite.<sup>13</sup> Of the patients screened for these alternative programmes, about 10% did not qualify for either of them. All subjects were screened by one of us (SR).

The combined behavioural treatment programme was called the Medicine 5 programme after the ward where the treatment was given. Sixty eight subjects (53 women) entered this programme, and 39 (28 women) entered the jaw fixation programme. In addition, 16 obese subjects (13 women) who received only brief instructions on reducing weight were selected as a control group. All patients filled out a questionnaire concerning the history of their weight. Weight was measured in indoor clothes and without shoes.

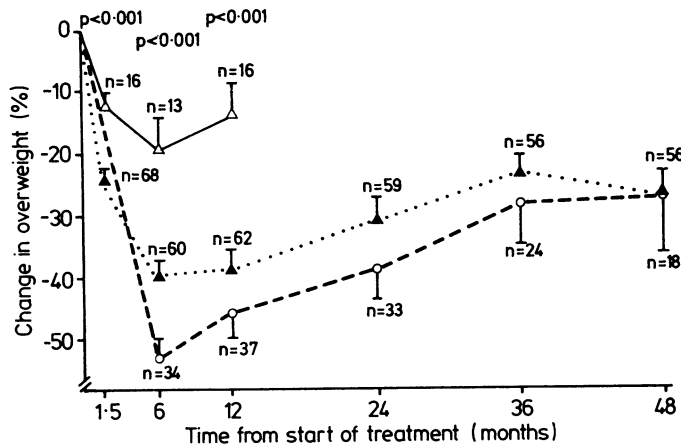


FIG 1—Percentage of change in overweight in subjects after treatment for losing weight. Control group (△—△); Medicine 5 group (▲...▲); and jaw fixation group (○—○).

**THE MEDICINE 5 PROGRAMME**

This programme was conducted in small groups, mostly of five subjects, at a ward for day care. Each patient was treated for six weeks. Three main points were focused on during the treatment.

Firstly, lessons on behavioural modification close to standard techniques described elsewhere,<sup>14-17</sup> including strategies to prevent relapse,<sup>18</sup> were supervised by one of us (HB) twice a week over six weeks. The behavioural treatment was combined with training in low energy cooking conducted by a dietitian. The daily intake of energy during the stay in hospital was about 2.4 MJ (600 kcal), containing about 60 g protein, 16 g fat, and 54 g carbohydrate; vitamins and minerals were substituted. Furthermore, a programme of exercise adapted for these obese subjects was conducted in groups or individually by a physiotherapist three times a week. The patients also had a weekly programme for other activities such as swimming, walking, and "shopping exercises."

TABLE I—Details of obese subjects before treatment. (Values are means (SEM) (and ranges))

	Medicine 5 group		Jaw fixation group		Control group	
	Women	Men	Women	Men	Women	Men
No of cases	53	15	28	11	13	3
Mean (SEM) age (years)	46 (2)	41 (4)	36 (2)	38 (3)	47 (3)	41 (7)
Mean (SEM) weight (kg)	111.4 (2.5)	137.9 (5)	110.8 (2.5)	154.2 (6.1)	121.1 (3.1)	137.7 (3.5)
Mean (SEM) height (cm)	166 (1)	179 (2)	168 (1)	184 (2)	171 (1)	183 (4)
Mean (SEM) body mass index*	40.5 (0.9)	42.9 (1.3)	39.3 (0.8)	45.3 (1.4)	41.6 (1.3)	41.4 (2.2)
Mean (SEM) percentage overweight†	69 (4)	71 (5)	64 (3)	81 (6)	74 (5)	66 (9)

\*Body mass index is weight (kg)/height (m)<sup>2</sup>.

†Percentage overweight =  $\frac{W - NW}{NW} \times 100$  where W is weight (kg) and NW is weight corresponding to body mass index, which is 24 for women and 25 for men using subject's actual height.

TABLE II—Details of subjects after six weeks of treatment and up to four year follow up. (Values are means (SEM) (and ranges))

	Medicine 5 group		Jaw fixation group		Control group
	Women	Men	Women	Men	
Mean (SEM) change in weight					
After six weeks	-10.0 (0.4)	-12.2 (1.0)			-5.4 (0.9)
After one year	-15.0 (1.5)	-30.9 (4.8)	-21.5 (4.8)	-23.7 (7.0)	-6.8 (2.5)
After two years	-12.3 (1.7)	-24.9 (7.5)	-16.2 (2.1)	-26.4 (8.5)	-6.8 (2.5)
After three years	-10.5 (1.6)	-17.1 (8.6)	-10.5 (2.9)	-17.5 (7.6)	-6.8 (2.5)
After four years	-11.5 (1.8)	-18.4 (9.3)	-9.4 (3.3)	-5.1 (8.6)	-6.8 (2.5)

TABLE III—Distribution of loss of weight at four year follow up in Medicine 5 and jaw fixation groups

Amount of weight lost (kg)	20	15	10	5	0	5	10	15	20	25	30	35	40	45	50	55	60
No of patients:	2	1	3	2	17	13	14	8	5	2	0	2	0	1	3	1	

Secondly, after this programme a follow up of four years was planned as a maintenance support. During this period all patients had the opportunity of taking part in one out of two weekly booster sessions and weigh ins free of charge at the hospital. These sessions were conducted by one of us (HB). At one of the weekly meetings a dietitian was available for advice on preparing food. All patients who did not show up for booster sessions as scheduled were repeatedly contacted by telephone or letters, or both.

Thirdly, to avoid a relapse shorter periods (two weeks) of "rehearsals" at the ward were offered when necessary. Sixty seven subjects rehearsed at least once. One subject rehearsed six times. Clinical data for all but two patients on the Medicine 5 programme were available at the four year follow up.

#### THE JAW FIXATION PROGRAMME

This programme is described in detail elsewhere.<sup>13</sup> The time of fixing was not predetermined. The jaw was generally unfixed when the rate of losing weight levelled off. After unfixing the jaw subjects were treated for two weeks with the Medicine 5 programme and the same follow up as for the patients in the Medicine 5 group. Of the 33 subjects followed up for at least two years, 24 were followed up for three years and 18 for four years.

At the four year follow up data on patients who had dropped out of the two programmes were obtained by letters or telephone calls to the subjects concerned or their relatives.

#### THE CONTROL PROGRAMME

To evaluate whether a simple intervention would have effects similar to those of the comprehensive Medicine 5 programme, 16 consecutive subjects (13 women) were selected (by SR) from among patients who were eligible when screened for the Medicine 5 programme. They had two interviews of 45 minutes and received a written programme on reducing weight containing the principles of the Medicine 5 programme. They were then given the opportunity to monitor their weight elsewhere and were invited to participate in an ordinary programme at the obesity unit after one year.

#### STATISTICS AND CALCULATIONS

Statistical tests were performed according to standard methods.<sup>14</sup> Thus the differences between sexes with regard to change in weight during the six weeks of treatment and four years of follow up in the Medicine 5 group were tested by repeated one way analyses of variance as occurred between the Medicine 5 and jaw fixation groups. One way analyses of variance were used to test differences in loss of weight between the three groups, and Scheffé's test was used for further analysis of these differences. Furthermore, the relation between change in weight and other characteristics of the subjects was expressed in Pearson's product moment correlation coefficient or Kendall's rank correlation coefficient.

The percentage overweight was calculated as  $\frac{W - NW}{NW} \times 100$  (W is weight before treatment (kg) and NW is weight corresponding to body mass index, which is 24 for women and 25 for men). These values for body mass index have been suggested as the upper boundary for desirable weight.<sup>12</sup> The change in percentage of overweight before treatment and the change in weight in kilograms are given.

The research protocol was approved by the ethical committee of this hospital.

#### Results

Table I shows the age, weight, height, body mass index, and percentage of overweight of the subjects before treatment. The subjects in the jaw fixation group were slightly younger than those in the other groups. The average values for body mass index were similar in all groups.

#### CHANGES IN WEIGHT

Table II shows the change in weight and figure 1 shows the change in percentage of overweight before treatment. The women in the Medicine 5 group lost most weight (mean (SEM) 16.7 (1.1) kg (range

4-46)) six months after entering the programme; the men lost most weight after one year (mean 30.9 (4.8) kg (9.3-59.5)). Changes in weight were not significantly different between the sexes during the six weeks of treatment. Neither the change in weight nor the change in percentage of overweight before treatment differed significantly between the sexes during the four year follow up. The mean loss of weight of 12.6 kg at the four year follow up for women and men together was highly significant ( $p < 0.001$ ).

Those who had their jaws fixed did so for a median of five months (range 0.5-16.5 months) for women and six months (1-19) for men. The mean loss of weight during this period was 21.1 (1.6) kg (range 5.8-43) for the women and 29.1 (5.6) kg (range 2.5-63) for the men. The mean loss of weight was 8.7 kg ( $p < 0.01$ ) at the four year follow up for women and men together. The differences in weight between women and men during the four year follow up were not statistically calculated as only three men were followed up for four years.

There was a positive correlation between how long the jaws were fixed and weight before treatment ( $r = 0.38$ ,  $p < 0.05$ ) but no significant correlation between how long the jaws were fixed and change in weight at the four year follow up.

After one year the mean loss of weight was 6.8 kg ( $p < 0.05$ ) in the control group. The subjects in this group lost most weight after six months (mean 9.2 (2.4) kg (range -1.8 to 22.4)). The loss of weight after one year was significantly lower in the control group compared with the Medicine 5 (18.1 kg) and jaw fixation groups (20.0 kg) ( $F(2, 112) = 7.61$ ,  $p < 0.001$ ). There was no significant difference between the Medicine 5 and jaw fixation groups with regard to change in weight during the four year follow up (fig 1).

For all subjects followed up at four years ( $n = 74$ ) the mean loss of weight was 11.7 kg (-20.0 to 55.5), or 27% of the overweight before treatment. Fourteen subjects lost more than 20 kg, 35 lost 5-20 kg, 17 lost 0-5 kg, and eight were above their weight before treatment when evaluated at the four year follow up (table III).

In the Medicine 5 group there was a significant positive correlation between the change in weight at four year follow up and the number of booster sessions during each year of the follow up: first year  $r = 0.33$ ,  $p < 0.01$ ; second year  $r = 0.30$ ,  $p < 0.05$ ; third year  $r = 0.28$ ,  $p < 0.05$ ; and fourth year  $r = 0.44$ ,  $p < 0.001$ . No such correlation was found in the jaw fixation group. Questions concerning family history of overweight, marital state, smoking, and use of alcohol did not help explain differences in the loss of weight after four years.

#### ATTRITION ANALYSES

After four years a total of 21% of those who entered the treatment programmes had dropped out, including 12 subjects in the Medicine 5 group. (No one dropped out during the first six weeks of treatment.) Five of these subjects did not show up after that period, one man died during the second year and one during the fourth year, and five subjects dropped out during the second and third years.

Ten subjects in the jaw fixation group dropped out: two during each of the first, second, and fourth years and four during the third year. Three men could not be traced. Table IV shows the moment of and reasons for dropping out and available data on changes in weight in the attrition group. Figure 2 summarises the entire study and its results.

#### Discussion

The combined behavioural treatment approach to obesity in this study shows that loss of weight begun with intensive treatment can continue even in severely obese subjects provided they are carefully monitored. This suggests that combined behavioural treatment with intense follow up, including booster sessions, may be effective even after the first period of treatment. This agrees with what Perri *et al* found in their evaluation of different programmes for treating obesity.<sup>20</sup> The only group that maintained its loss of weight for one year after treatment was the one that received behavioural treatment, training to prevent relapse, and contact after treatment. Craddock<sup>21</sup> and Binnie<sup>22</sup> concluded that active support and encouragement might have a considerable long term effect on reducing weight. Ashby and Wilson, however, were not able to show that booster sessions help maintain loss of weight.<sup>23</sup> Our results show that the rate of dropping out can be kept low if intensive encouragement is available for a long time.

The subjects in the jaw fixation group lost more weight than

those in the Medicine 5 group, although there was no significant difference between the groups. They also regained more weight during follow up. Possibly these subjects did not adhere to behavioural modification treatment after the jaw fixation programme. Alternatively, two weeks at the start of the behavioural treatment programme were not long enough for this group to adopt new habits.

Heavier subjects had their jaws fixed for longer than those who were less obese, but still the duration of the fixation did not correlate significantly with the final loss of weight. The heaviest subjects may have kept their jaws fixed even when the rate of losing weight had levelled off, hoping for further loss of weight

We conclude that a combined behavioural programme of reducing weight with long term follow up may result in sustained loss of weight in several severely obese subjects. These principles of treatment have recently been adopted in the primary health care system of the county of Stockholm. As the programme comprises a combination of common techniques we believe that it could be repeated to advantage in other obesity units.

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TABLE IV—Attrition analysis of 22 patients who left programme

Case No and sex	Programme	Time of adherence to programme (months)	Reason for attrition	Weight after four years compared with weight before treatment (kg)
1 F	Medicine 5	1.5	Lack of interest in dieting	7 ↑
2 F	Medicine 5	1.5		16 ↑
3 F	Medicine 5	24		7 ↑
4 M	Medicine 5	1.5	Dissatisfaction with programme	?
5 M	Medicine 5	1.5		52 ↓ (after shift to surgery)
6 M	Jaw fixation	12		?
7 M	Jaw fixation	24		3 ↑
8 M	Medicine 5	1.5	Alcoholism	?
9 M	Medicine 5	12		66 ↓
10 M	Jaw fixation	2	Jaw fixation too big a handicap	28 ↓ (after three years)
11 F	Jaw fixation	24	Pregnancy	3 ↓
12 F	Jaw fixation	27		6 ↓ (after three years)
13 M	Jaw fixation	24	Inability to understand programme	11 ↑
14 M	Medicine 5	12	Death	22 ↓ (after one year)
15 M	Medicine 5	36		3 ↓ (after three years)
16 F	Jaw fixation	8	Shift to surgery	38 ↓ (after three years)
17 M	Jaw fixation	12		Dead after surgery
18 F	Jaw fixation	36		Waiting for surgery
19 F	Jaw fixation	36		20 ↓
20 F	Medicine 5	28	Shift to jaw fixation	4 ↑
21 F	Medicine 5	28		12 ↓
22 F	Medicine 5	29		15 ↓

or fearing a relapse, or both. The optimal duration for jaw fixation is still not determined.

As far as we know no long term results of jaw fixation are available for comparison. Short term results have varied. Garrow reported on two patients with fixed jaws who lost more than 40 kg in five months.<sup>24</sup> Rodgers found that all his patients lost weight, and 10 out of 17 patients lost a mean of 25.3 kg over six months.<sup>25</sup> In another study 11 out of 14 women with fixed jaws who lost 6.8 kg had regained some weight within six months.<sup>26</sup> These results should be compared with the mean loss of weight of 26 kg at the end of six months and 8.7 kg at the end of four years achieved in our study.

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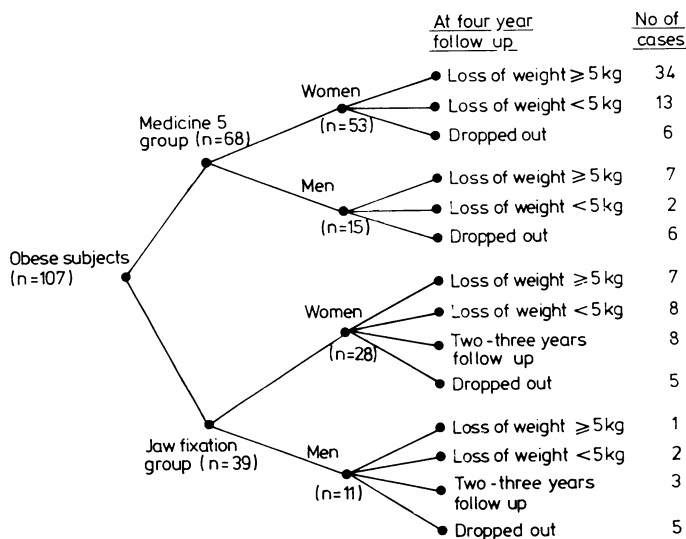


FIG 2—Summary of study and its results.

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