Hormone replacement therapy acceptability to Nottingham post-menopausal women with a risk factor for osteoporosis

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Summary

In Nottingham we have assessed the acceptability of oral hormone replacement therapy (HRT) for an at-risk group of post-menopausal women for osteoporosis. One hundred post-menopausal women between the ages of 50 and 70 years who had sustained a distal radial fracture were offered oral HRT. There was a 36% overall uptake of HRT with 9% of patients unable to take HRT because they had medical contraindications. The uptake in the 50-55 year age group was 54%. We conclude that in prospective studies of HRT for osteoporosis up to 50% of patients may not wish to take HRT and therefore study design should allow for this level of uptake.

Introduction

Hormone replacement therapy (HRT) is being prescribed increasingly both for the treatment of unpleasant menopausal symptoms and for the prevention of osteoporosis. Previous studies have shown the beneficial effects of HRT upon osteoporotic bone[1-5], and Christiansen in Denmark has demonstrated an actual increase in bone mass in women during opposed oestrogen therapy[6].

In Nottingham we have studied the acceptability of HRT from a post-menopausal woman's point of view when offered it for the benefit of her bones rather than for menopausal symptoms.

Methods

Patients who have sustained a fracture of the distal radius are considered to have a risk factor for osteoporosis. We selected every post-menopausal woman between the ages of 50 and 70 years who presented at Nottingham University Hospital with a distal radial fracture between December 1988 and March 1989. We estimated that by 50 years of age most women would have ceased regular monthly bleeding, and HRT may be of little value over the age of 70 as oestrogen intolerance is believed to increase with age.

The Nottingham post-menopausal fracture and re-fracture study undertaken in 1987/88 showed distal radial fractures to be the most commonly occurring fracture in this age group, and the majority are believed to be in part related to osteoporosis (Scott BW *et al.*, in preparation). The same study showed there to be a 15.5% risk of sustaining a fracture of another bone over a 6-year period following a distal radial fracture compared with a normal risk of 5%. This study also identified an 11% risk of fracturing a hip during the 7 years following the wrist fracture. These facts were carefully explained by two women trained in counselling to women who had sustained a distal radial fracture, as well as pointing out the other benefits and effects of HRT. Obvious disadvantages of the treatment were also explained - the inconvenience of the daily pill taking and the common monthly bleed resulting for those women with an intact uterus.

Women interested in taking HRT were questioned on their past medical history for contraindications which included any of the following:

breast or endometrial carcinoma
myocardial infarction
thromboembolic disease
cerebrovascular accident
active liver disease
hypertension (uncontrolled)

Patients were also advised of possible side effects such as mild initial nausea, breast tenderness or slight fluid retention but that it was likely that these symptoms would soon settle. Regarding long-term risks they were informed that opposed therapy had removed the risk of endometrial carcinoma but that research work had indicated there might be an effect on breast carcinoma - either a small lowered risk or a very slightly increased risk of breast cancer[7-9].

Height and weight were recorded and blood pressure taken. If the diastolic reading was over 100 the patient was referred to the GP with a letter explaining the fact and HRT was withheld in the first instance. A patient subsequently successfully treated could in future be considered for HRT. None of the patients screened had a raised systolic reading independent of a raised diastolic reading. A blood sample was taken for a baseline follicle stimulating hormone (FSH) assay, so that future FSH levels could be monitored and used as a test of compliance. An appointment was made for each entrant into the study who was interested in HRT to have a full gynaecological check up. This examination included an abdominal examination to exclude any masses, and a vaginal examination. At the vaginal examination the size, shape and position of the uterus, if present, were noted and the adnexa were felt to exclude any tumours. A cervical smear was performed if there had not been one done in the last 3 years. An ultrasound of the pelvis was then performed to confirm the size of the uterus and the absence of any ovarian pathology. The breasts were carefully examined; one woman was found to have a mass in her right breast which required surgical intervention. Only then did the patient receive her 3 months supply of pills.

There are many combined oestrogen regimens now commercially available with various routes of administration. Prempak C, an oral preparation,

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was used for our women with an intact uterus (natural oestrogen 0.625 mg daily continuous plus norgestrel 0.15 mg days 17-28) and Premarin (unopposed conjugated oestrogen 0.625 mg) was used for those who had undergone a hysterectomy in the past.

All women were given literature on HRT and osteoporosis provided by the National Osteoporosis Society and those who were undecided after the first approach were seen again when they next attended the Fracture Clinic. Those who rejected were asked to study the literature and to reconsider. Their reasons for rejection were carefully noted.

Results

One hundred women were counselled between December 1988 and the end of March 1989. Approximately 30% of the women counselled had heard of HRT through the media (television or the popular press) or a friend and 50% knew something about osteoporosis. The uptake of HRT in the group who had heard of it was not significantly different from the uptake of the group who had not. Of the 100 women counselled 66 expressed an initial interest in HRT. Four of these women were already taking HRT through their own GPs for post-menopausal symptoms, and following counselling continued to do so. After further consideration only 32 of the remaining 62 women decided in favour of the therapy when subsequently interviewed in Fracture Clinic.

On examination nine of these women were found to have contraindications. Six had unacceptably high blood pressure; one was diagnosed as having a breast carcinoma following referral to our gynaecologist as mentioned previously and the remaining two had past histories of uterine carcinoma and deep vein thrombosis respectively. Thus an overall uptake figure of 36% for HRT was achieved.

Reasons for rejecting HRT were varied and are shown in Table 1. A number of women would not be specific - they were vague or generally opposed to the treatment for a variety of reasons.

Two women counselled showed an obvious lack of understanding - one was also a poorly controlled epileptic and we felt it was inappropriate to include them in the trial. One woman, having expressed a desire for HRT, was subsequently dissuaded in the Fracture Clinic by a previously counselled patient who was strongly opposed to HRT. Interestingly, this latter patient was the only one in the study who was positively against HRT because she was convinced it had caused a large intestinal cancer she had suffered 8 years previously.

The uptake success by age group is shown in Table 2.

Table 1. Reasons for rejection by patients (HRT offered to 100 patients)

Past medical history	5
Return of periods	9
Aversion to gynaecological examination	2
Tablet taking	10
Limited understanding	2
Dissuaded by other patient	1
Non intervention	3
Non specific	23
Total	55

Table 2. Uptake of HRT related to age group

Age group (years)	*Total No of women*	*No of women accepting HRT*	*% age uptake*
50-55	24	13	54
56-60	29	12	41
61-65	28	8	29
66-70	19	3	16

Table 2 demonstrates the greater willingness of the younger women to take HRT and it is this age group of course who are likely to derive the greatest benefit from the treatment.

After one year we recalled the 23 women we had started on HRT and wrote to the four already taking it via their own GP but who had agreed to take it long term as prophylaxis for osteoporosis. Five women had stopped the therapy including one of the four taking it via her GP. Two women had gained what they felt to be an unacceptable amount of weight but could not say whether this was due to increased appetite. Two women had suffered unacceptably heavy periods which had not moderated with time and one woman taking HRT via her GP had developed a fear of breast cancer which had been caused by recent press and television coverage of HRT.

Most of the remaining 22 women taking HRT were positive regarding the therapy. Nine women were enthusiastic and said they felt so much better they wished they had taken HRT years ago, (four of these women were aged between 50 and 60 and five were between 60 and 70 years old). Periods were lighter or the same in all but one woman who reported heavier bleeding than prior to the menopause. This woman was also experiencing premenstrual tension. Five women reported a slight weight gain but this had stabilized in all but one woman who confessed to a large increase in appetite since starting HRT. Nine women experienced breast tenderness when they first began therapy but this had become less troublesome with time. Four of the younger women (50-60 age group) reported mildly painful periods and five complained of slight premenstrual tension. Nine women also complained of a mild 'bloated' feeling prior to their monthly bleed but in most cases this was improving with time. Four women suffered a slight increase in frequency of micturition. Ten women reported an improvement in the condition of their hair, eight an improvement in their skin and nine an improvement in their nails. Seven women felt they had increased powers of concentration and 12 women found they had much more energy since taking HRT. Six women, all aged between 50 and 60, had noticed an increase in their sexual responsiveness.

Discussion

We felt the overall uptake of HRT to be low with the most important disadvantages to the patient highlighted as daily pill taking and monthly bleeding. However this low acceptability is important in the context of further trials and studies on the use of HRT in the treatment and prophylaxis of post-menopausal osteoporosis, and should be taken into account when designing prospective studies in the future. In this study the HRT was offered free of charge. Normally a prescription for HRT - of the opposed type - incurs

a *double* prescription charge in the UK for women under 60 and if this had been instituted the number of women in that age group entering the study might have been even lower.

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