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Original Article

Direct Disclosure of Bone Density Results to Patients: Effect on Knowledge of Osteoporosis Risk and Anxiety Level

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Abstract. If bone mineral density (BMD) screening is to achieve the aim of preventing the complications of osteoporosis, women with low BMD measurements must learn that they are at risk, and women at risk must know about and be willing to adopt and persist with measures that can prevent osteoporosis. In this paper we present the results of a randomized controlled trial designed to examine whether disclosing the results of a BMD scan directly to women, as well as through their general practitioners (GPs), improves their knowledge of their bone density results without adverse psychological sequelae. Direct disclosure resulted in 19% (59% vs 40%; 95% CI for difference in proportions: 9.8% to 27.8%) more women being aware of their BMD status at the spine and 22% (58% vs 36%; 95% CI for difference: 12.2% to 29.8%) at the hip. These differences were observed irrespective of risk status. There was no significant difference in anxiety levels between the randomized groups. We conclude, therefore, that direct disclosure of BMD results to women, as well as to their GPs, leads to increased knowledge of BMD status without increasing anxiety, and that BMD measurement services should consider informing women routinely of their results directly as well as through their GPs.

Keywords: Anxiety; Bone density; Direct disclosure; Knowledge of risk

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Introduction

Osteoporosis is a common condition among elderly women. It is responsible for a high degree of morbidity, mortality and resource use [1]. Management of established osteoporosis is unsatisfactory because most treatment addresses the problem after a major fracture event has occurred. It follows, therefore, that prevention of osteoporosis is desirable. One promising approach is behavior modification based on measurement of bone mineral density (BMD), as BMD has been shown to be predictive of subsequent risk of osteoporotic fracture [2,3].

There are three prerequisites if BMD screening is to prevent the complications of osteoporosis: first, women with low BMD measurements must learn that they are at risk; second, women, particularly those at risk, must know about the measures they can take to prevent osteoporosis; and third, women must be willing to adopt and persist with the preventive measures for a sufficient length of time to reduce their risk of fracture.

Recent research has indicated that women who are aware they have low BMD measurements are more likely to take preventive measures, such as commencing hormone replacement therapy (HRT), taking more exercise and increasing their calcium consumption [4]. However, a 2-year follow-up study of women who were screened in Aberdeen in 1993 indicated that 40% were unaware of their bone density status (unpublished data). At that time, women were only informed of their BMD results through their general practitioner (GP). Furthermore, a satisfaction survey of women attending the screening programme indicated that 91% (unpublished data) of women wanted their scan results sent directly to them as well as to their GP. We therefore believed that

informing women directly of their BMD results would not only increase awareness of BMD status, but would also lead to greater patient satisfaction with the service.

We recognized, however, that a direct disclosure approach could cause anxiety with psychological sequelae. We therefore chose to conduct a randomized controlled trial designed to indicate whether direct disclosure of BMD results to patients leads to increased knowledge of BMD status without disturbance of emotional wellbeing or increased anxiety, and report the results here.

Subjects and Methods

In February 1993, 800 women aged between 45 and 54 years and living within 32 km of Aberdeen in North East Scotland were randomly selected from the Community Health Index (CHI) – a population health register – and invited to attend a BMD screening service at the City Hospital, Aberdeen [5]. Women were further randomly allocated to receive their test results either directly as well as through their GP or just through their GP. Randomization took place before the women were invited for screening.

Women were recruited by means of an initial open letter of invitation followed by a confirmable reminder as previously validated in our study programme [6]. The invitation letter described in lay terms the disease of osteoporosis and, on attendance at screening, women were encouraged to discuss the disease with the radiographer undertaking the scan. Patient information material was also available in the waiting area of the scanning unit. All women were sent an osteoporosis risk factor questionnaire which they were asked to complete before attending for screening. The questionnaire included the Spielberger state-trait anxiety inventory [7] and lifestyle questions such as current activity levels, alcohol consumption, meat consumption and smoking history. Those women who attended screening had a BMD measurement taken using a Norland XR26 densitometer (DXA; Norland, Madison, WI) at the spine (L2–4), femoral neck, Ward's triangle and greater trochanter. The precision of this technique in our hands is 0.9% and 2.8% at the spine and neck of femur respectively [8].

Those women who were randomly allocated to receive their results directly were sent a letter which stated that they were either in the lowest quarter of BMD at the spine and/or hip, or in the highest three-quarters of BMD for the screened population. This cutoff point for treatment decisions was somewhat arbitrary, but was based on standard clinical practice at the time when the screening programme was commenced in 1991 [5,6,9]. The decision to use this cutoff point predated, by some years, the WHO criteria defining osteoporosis according to BMD [10]. The quartile allocation was based on the results of the first 1000 women screened in the programme.

In addition to the BMD results, all letters contained general osteoporosis preventive advice, such as the importance of smoking cessation, taking exercise and ensuring an adequate intake of dietary calcium. However, for women with BMD in the lowest quarter, the letter advised that they should arrange to visit their GP to discuss the possibility of using HRT when they reached the menopause (see Appendix).

The letter was piloted prior to being used in the trial. The development process was as follows. First, we undertook textual analysis of a draft letter using the Flesch score to assess readability [11]. Second, after we were satisfied with respect to the content of the letter, we gave it to a sample of 20 women of a similar age to the women in the study. These women were given a number of result letters for hypothetical patients; after reading these, the women were questioned to see whether they understood the letters. This process resulted in some minor modifications to the standard result letters.

Those women randomized to receive their results via their GP were simply sent a letter indicating that the results of their scans had been sent to their GP and advising them to contact the practice to discuss them. No lifestyle advice was given in the letter.

Two years after screening, all women were sent a postal questionnaire that assessed anxiety levels, knowledge of BMD risk, current activity levels, alcohol consumption, smoking levels, use of HRT and health status – using the SF-36 [12]. The higher the SF-36 score, the better the health status. As the original Spielberger state-trait anxiety inventory is 40 items long, we used the six-item short form of the state scale in an attempt to maximize the completion rate of the follow-up questionnaire. The six-item form of the inventory has been shown to be reliable (reliability coefficient 0.82) and valid, producing scores similar to those produced by the long form [13]. The higher the score the more anxious is the patient.

Statistical Analysis

This study was designed to detect at least a 10% difference in knowledge of BMD status (from 35% to 45% in the direct disclosure group) or a change of more than a fifth of the standard deviation of anxiety score with 80% power and 5% significance [14,15].

Results for continuous variables are presented as means and standard deviations (SD). Univariate analysis of continuous variables was carried out using Student's *t*-test. Relationships between categorical variables were assessed using the chi-squared statistic with Yates' correction in the 2×2 case. The 95% confidence intervals (CI) are reported where appropriate.

Results

The 799 women (the details for 1 woman were incomplete) randomly selected from the CHI were

Table 1. Baseline characteristics of the direct disclosure and the GP-only disclosure groups

Variable	Direct disclosure (max. *n* = 292)	GP-only disclosure (max. *n* = 284)	Significance of difference between groups
Categorical variables	*No. (%)*	*No. (%)*	*p* value
Alcohol consumer	208 (74.6)	209 (77.1)	0.55
Current smoker	65 (22.8)	61 (21.9)	0.88
Current user of HRT	55 (22.9)	56 (23.0)	0.99
Activity compared with others in same age group:			
More active	44 (15.5)	34 (12.2)	
Average	167 (59.0)	164 (59.0)	
Less active	72 (25.4)	80 (28.8)	0.43
Educational level (highest):			
No qualifications	79 (32.0)	74 (30.0)	
'O' levels	66 (26.7)	62 (25.1)	
'A' levels	19 (7.7)	25 (10.1)	
Degree/professional qualification	47 (19.0)	55 (22.3)	
Postgraduate qualification	16 (6.5)	15 (6.1)	
Other	20 (8.1)	16 (6.5)	0.82
Continuous variables	*Mean (SD)*	*Mean (SD)*	*p* value
Age (years)	49.2 (2.8)	49.3 (2.9)	0.84
BMD, hip (g/cm^2)	0.87 (0.13)	0.86 (0.12)	0.32
BMD, spine (g/cm^2)	1.05 (0.17)	1.04 (0.17)	0.25
Height (m)	1.61 (0.07)	1.61 (0.06)	0.91
Weight (kg)[a]	64.7 (1.19)	64.9 (1.17)	0.84
Spielberger six-item state score	37.9 (13.0)	37.4 (13.0)	0.68

[a]Geometric mean.

Table 2. Characteristics at follow-up of all screened women

Variable	Direct disclosure (max. *n* = 258)	GP-only disclosure (max. *n* = 257)	Significance of difference between groups
Categorical variables	*No. (%)*	*No. (%)*	*p* value
Knowledge of BMD status, hip:			
Correct	134 (57.5)	85 (36.3)	
Incorrect	14 (6.0)	14 (6.0)	
Did not know	85 (36.5)	135 (57.7)	<0.001[a]
Knowledge of BMD status, spine:			
Correct	130 (58.6)	93 (39.7)	
Incorrect	7 (3.2)	9 (3.8)	
Did not know	85 (38.3)	132 (56.4)	<0.001[a]
Current smoker	57 (22.3)	52 (20.3)	0.60
Continuous variables	*Mean (SD)*	*Mean (SD)*	*p* value
Exercise levels:			
(1 = never, up to 5=more than 2 h per week)	3.3 (1.4)	3.4 (1.4)	0.70
Anxiety levels:			
Spielberger six item score	38.0 (13.1)	36.1 (12.6)	0.12
Change in Spielberger score from baseline	0.31 (12.59)	–1.11 (13.09)	0.24
SF-36 dimensions:			
Physical functioning	81.9 (22.1)	81.3 (22.4)	0.77
Social functioning	84.2 (22.7)	87.2 (22.4)	0.12
Role physical	74.9 (37.6)	77.0 (36.0)	0.51
Role emotional	77.2 (36.5)	83.1 (32.8)	0.06
Mental health	70.5 (17.8)	73.6 (17.8)	0.05
Energy and fatigue	59.2 (20.1)	59.4 (20.8)	0.92
Pain	73.7 (26.4)	74.9 (24.5)	0.61
General health perception	69.5 (21.9)	70.7 (20.4)	0.52

[a] *p* values for the distribution of responses across the three categories.

Table 3. Characteristics at follow-up of 'at-risk' women

Variable	Direct disclosure (max. n = 80)	GP-only disclosure (max. n = 100)	Significance of difference between groups
Categorical variables	*No. (%)*	*No. (%)*	p value
Knowledge of BMD status, hip:			
Correct	30 (42.9)	16 (18.2)	
Incorrect	6 (8.6)	12 (13.6)	
Did not know	34 (48.6)	60 (68.2)	0.003[a]
Knowledge of BMD status, spine:			
Correct	28 (44.4)	25 (26.9)	
Incorrect	3 (4.8)	7 (7.5)	
Did not know	32 (50.8)	61 (65.6)	0.07[a]
Current smoker	18 (22.5)	26 (26.0)	0.77
Current use of HRT	37 (46.3)	41 (41.0)	0.58
Use HRT for low bone density/to prevent osteoporosis (% of those who use HRT)	29 (78.4)	28 (68.3)	0.46
Continuous variables	*Mean (SD)*	*Mean (SD)*	p value
Exercise levels (1 = never, to 5 = more than 2 h per week)	3.1 (1.4)	3.0 (1.5)	0.92
Anxiety levels:			
Spielberger six item scale	38.2 (12.6)	36.3 (12.9)	0.35
Change in Spielberger score from baseline	–0.44 (13.15)	–0.63 (14.52)	0.93
SF-36 dimensions:			
Physical functioning	78.7 (24.7)	80.4 (23.9)	0.65
Social functioning	80.6 (25.1)	86.6 (23.8)	0.10
Role physical	70.2 (41.3)	77.8 (35.1)	0.20
Role emotional	74.7 (37.9)	82.5 (32.7)	0.16
Mental health	68.7 (18.1)	72.0 (18.0)	0.22
Energy and fatigue	57.5 (19.5)	58.4 (21.3)	0.78
Pain	72.9 (25.4)	74.1 (24.6)	0.75
General health perception	65.8 (23.1)	69.4 (22.1)	0.30

[a] p values for the distribution of responses across the three categories.

invited by post to attend for screening. Eighteen letters were returned by the post office and 74% (576/781) of women attended for screening and had a BMD measurement. This included 292 (75%) of the direct disclosure group and 284 (73%) of the GP-only disclosure group. There was no difference in the age of women who attended for screening compared with those who did not attend (mean (SD) age was 49 (2.8) years and 49 (2.9) years respectively, p = 0.30). The 576 women who attended for screening constitute the study population reported here, as results disclosure is only relevant if a woman has attended for screening.

There were no differences between the two randomized groups at time of screening in terms of age, BMD measurements at hip or spine, self-reported body weight, height, educational level, anxiety levels, HRT use or lifestyle factors such as alcohol consumption and smoking status (Table 1).

The 576 women invited for screening were to be sent a follow-up questionnaire 2 years after screening. The questionnaire was, however, sent out to only 572 women as 4 had a life-threatening illness (e.g. breast cancer) at the time of screening. Nineteen of these were returned by the post office and a further 2 women had either died or had developed a life-threatening disease. A final response rate of 93% (515/551) was achieved for the 2-year follow-up questionnaire. The results are examined initially for all women studied (Table 2), and then for those women whose BMD was in the lowest quartile and deemed to be at risk of future osteoporosis (Table 3).

Table 2 shows the characteristics of the two randomized groups at follow-up. There was a marked difference in the proportions of women who correctly reported their BMD status between the disclosure groups. Direct disclosure resulted in a 19 percentage point difference (59% vs 40%; 95% CI for difference in proportions: 9.8% to 27.8%) in women being aware of their BMD status at the spine and a 22 percentage point difference (58% vs 36%; 95% CI for difference in proportions: 12.2% to 29.8%) at the hip.

There was no difference in women's reported exercise levels at follow-up nor in current smoking status between the randomized groups.

There was no significant difference between the groups at follow-up in terms of final anxiety level. Changes in anxiety scores since screening were calculated, with a positive change indicating an overall increase in anxiety level. Although the direct disclosure group indicated a marginal increase in mean anxiety level and the GP-only group indicated a marginal mean decrease this difference was not statistically significant. The relevant dimensions of the SF-36 health status

questionnaire that measure emotional wellbeing are the role emotional dimension and the mental health dimension. Although not statistically significant, there was a tendency for role emotional and mental health scores to be slightly higher in the GP-only group, indicating a potentially better mental health state than those in the direct disclosure group.

The results at follow-up for 'at-risk' women, defined as those with either a spine or hip BMD in the lowest quartile, are summarized in Table 3. As before, direct disclosure resulted in a 25 percentage point difference (43% vs 18%; 95% CI for difference in proportions: 10.6% to 38.8%) in women being aware of the BMD status at the hip and a 17 percentage point difference (44% vs 27%; 95% CI for difference in proportions: 2.3% to 32.8%) at the spine.

Seventy-eight (43%) of the at-risk women were currently using HRT 2 years after screening (46% and 41% in the direct disclosure group and the GP-only group respectively) compared with 77 (24%) of women not deemed to be at risk (21% in the direct disclosure group and 28% in the GP-only disclosure group). Of those at-risk women who were using HRT, 78% of those in the direct disclosure group reported that they were using HRT for low bone density or for the prevention of osteoporosis compared with 68% in the GP-only group (95% CI for difference in proportions: –9.4% to 29.6%).

There was no evidence of a difference in anxiety between the direct disclosure group and the GP-only group for the at-risk women; neither was there any evidence of differences in the mental health or role emotional scores.

At-risk women were defined as those with either a spine or hip measurement in the lowest quartile. Looking at those women for whom both measurements were in the lowest quartile, however, direct disclosure resulted in 35% (52% vs 17%; 95% CI for difference in proportions, 12.1% to 58.3%) more women being aware of the BMD status at the hip and 33% (52% versus 19%, 95% CI for difference in proportions: 8.1% to 57.5%) at the spine.

Discussion

If bone mineral measurement is to achieve the aim of preventing the complications of osteoporosis, women with low BMD first need to learn that they are at risk. Looking at our study control group, who received information through the current standard practice of disclosure via the GP, only a third of women overall correctly identified their BMD risk status 2 years after screening, and only about a fifth of those women deemed to be at risk of osteoporosis were aware of their risk status. Our study has shown that direct disclosure of BMD results to the woman as well as through her GP resulted in around a 20–30% absolute increase in the proportion of women who correctly identified their BMD. It is interesting to note, however, that in our study a smaller proportion of the high-risk women correctly identified their BMD status compared with low-risk women. This difference can be primarily attributed to those women who were at risk at only one site; where either the hip measurement or the spine measurement fell within the lowest quartile but not both. When we examine those at risk at both sites, similar levels of awareness are noted in the direct disclosure group. Whilst it is possible that a small proportion of the women allocated to the direct disclosure group were able to find the original letter sent 2 years earlier informing them of the results of their scan, we believe that this is unlikely to have happened in more than a small number of individuals and, in any case, would not invalidate the conclusion that direct disclosure results in increased knowledge of osteoporosis risk.

The principal concern about direct disclosure of BMD results is increased anxiety levels. Our study has shown, however, that there was no clear evidence of increased anxiety levels in the direct disclosure group compared with the GP-only disclosure group. The relevant dimensions of the SF-36 health status questionnaire that measure emotional wellbeing were also examined. Although not statistically significant, there was a tendency for those in the GP-only group to display slightly better role emotional and mental health scores. This was not, however, borne out in those women for whom results disclosure should have the most impact, that is those women deemed to be at risk of osteoporosis. Although we identified the role emotional dimension of the SF-36 as a relevant dimension *a priori*, over half the women in the sample achieved maximum scores. The three questions in the SF-36 relating to the role emotional dimension examine issues such as accomplishing less than one might like and cutting down the amount of time spent on work or other activities. Because our population of women is made up of generally healthy individuals, it is not surprising that such high overall scores were achieved. It should also be noted that all women screened in this program were relatively young and the risk of fracture, even among those with low BMD, will be low within the next 5–10 years. As the screened population ages, however, our study cannot exclude the possibility that women who have received their results directly might become significantly more anxious as their risk of fracture increases.

To avoid osteoporosis, it is not, however, sufficient for a woman to know that she is at risk. She must then be willing to adopt and persist with measures that have been shown to reduce the risk of developing the disease. Increased exercise levels have been shown to be preventive of osteoporosis [16]. Our study suggests, however, that there was no difference in the exercise levels recorded by at-risk women in the direct disclosure group compared with the GP-only group. This compares with the findings of Rubins and Cummings [4], who found that women who are aware they have low BMD are more likely to take preventive measures.

Commencing HRT has also been shown to prevent the development of osteoporosis. The administration of HRT to asymptomatic women has, however, been the subject

of considerable debate [16]. In our study, 23% of all women were using HRT prior to screening (20% of at-risk women). Two years after screening, 43% of the at-risk women were using HRT. A previous study of HRT uptake after population screening estimated the use of HRT in postmenopausal women (including women who had had a hysterectomy) prior to the screening program at 26%, with post-screening HRT use at 49% (95% CI: 41% to 57%) [17]. Our estimate of 43% lies within the confidence interval of the previous study, which looked only at postmenopausal women. This current study will include some at-risk women who are still premenopausal and who may go on to receive HRT. Thus our estimate of increased HRT uptake of 23% (43% –20%) in at-risk women almost certainly underestimates the effect of screening on HRT use amongst postmenopausal women. Although there was no significant difference in HRT use in the at-risk group sent their results directly compared with the women receiving their results via their GP (46% as compared with 41%), it is interesting to note that of those who were using HRT in each group, a greater proportion of those in the direct disclosure group gave low bone density or prevention of osteoporosis as the reason for HRT use. We must, however, interpret this result with caution, because of the small numbers involved and because this particular study was not set up to measure differences in HRT uptake directly but was rather powered to examine improved knowledge of BMD status. A larger study, currently under way in our center, aims to address the issue of HRT and the true benefits, if any, of direct disclosure on the uptake of HRT. Others have indicated that knowledge of BMD does increase uptake of HRT although the method of disclosure of results was not discussed [4,18]. This larger study is powered to detect a 15% difference in HRT use between the two groups of women; however, the current study would only have the power to detect a 25% difference in uptake between the two groups.

Whilst BMD measurements may encourage greater uptake of HRT among women with low BMD the converse may also be true. Women with high or normal BMD and who do not require HRT for the alleviation of menopausal symptoms, and are possibly at low risk of cardiovascular disease, may feel able to discontinue using HRT. Indeed given recent evidence that women with high BMD are at increased risk of breast cancer, then such women may be justified in ceasing their use of HRT [19]. For women with intermediate BMD values, however, there may be utility in considering follow-up BMD or assessment of bone loss rates by bone metabolism markers so that those with the highest rates of loss can also be advised to consider HRT.

The clinical implications of our study are that bone density measurement services should consider informing women of their measurement results directly, as well as through their GP, as this leads to greater awareness of bone density status on behalf of the patient with no detrimental effect on the patient's mental wellbeing. The study indicates the need for GPs to be aware that results of screening tests may frequently not be made available to patients, highlighting the requirement for them to consider a mechanism whereby such results can best be conveyed to the patient. Only a larger study, such as the one currently under way in our center, will be able to assess whether this method of disclosure also increases uptake of HRT.

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Appendix. Patient letter

Dear

I am writing to tell you of your bone scan results.

Your back and hip bone are *below* average (in the lowest 25%) in thickness and density. I wish to reassure you that you do NOT have osteoporosis (brittle bones), but these results mean if your bones get any thinner then you may be at risk of osteoporosis in later life.

So your family doctor and I would wish to stop your bones getting any thinner.

The main reason why your bones can get thinner is the menopause (change of life). When women have their menopause their bodies stop producing a hormone and this causes bones to get thinner. To stop your bones getting thin your family doctor can give you HORMONE REPLACEMENT THERAPY to replace your natural hormones which you lose when you have your menopause.

Not all women can take, or want to take, HORMONE REPLACEMENT THERAPY. If you can't take hormone replacement therapy your doctor can tell you about other things you can do to help you keep your bones strong.

For example, stopping smoking and taking more exercise will help your bones.

I just want to remind you that you do not have osteoporosis but you do have bones which are below average thickness. So to stop you getting osteoporosis I advise you to visit your General Practitioner (family doctor) for advice on hormone replacement. I enclose an information sheet about osteoporosis and I have sent a copy of your results to your doctor.

Yours sincerely

Dr David M. Reid
Consultant Rheumatologist

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