Women's decisions about hormone replacement therapy after education and bone densitometry

Evidence

Études

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Abstract

Background: The decisions that postmenopausal women make about whether to start hormone replacement therapy may depend on the potential risks and benefits of such therapy as well as their risk for osteoporosis-related fractures. This study examined the decisions made by women at risk for osteoporosis-related fractures who were educated about hormone replacement therapy and who were given information about their bone mineral density.

Methods: The study employed a prospective cohort design. Thirty-seven postmenopausal women with risk factors for osteoporosis-related fractures were recruited from an orthopedic clinic at a teaching hospital in Hamilton, Ont. The women were given an education kit (consisting of an audio tape and a workbook) to clarify the benefits and risks of hormone replacement therapy. Two to 4 weeks later, densitometry of the hip and the lumbar spine was performed. A summary of the risks, the densitometry findings and decisions about hormone replacement therapy were given to the women's family physicians for follow-up. Outcome measures included decisions about hormone replacement therapy, as well as use of such therapy and other medications at 12 months.

Results: After the education component alone, 10 (27%) of the women requested hormone replacement therapy. After densitometry testing, 4 more requested hormone replacement therapy (for a total of 14 women [38%]). At 12 months, 2 (5%) of the women had been lost to follow-up. Of the remaining 35, 6 (17%) were receiving hormone replacement therapy, 7 (20%) were using bisphosphonates, and 24 (68%) were taking calcium supplements.

Interpretation: These preliminary findings suggest that the combination of education about hormone therapy and feedback about bone density is associated with an increase in the use of hormone replacement therapy and other preventive medications by women at risk for osteoporosis-related fractures. However, the observed increase was small and so the clinical significance must be confirmed and clarified.

Résumé

Contexte : Les décisions que les femmes ménopausées prennent au sujet de l'hormonothérapie de remplacement peuvent dépendre des risques et des avantages éventuels d'une telle thérapie, ainsi que de leur risque d'être victimes de fractures liées à l'ostéoporose. Dans le cadre de cette étude, on a examiné les décisions prises par des femmes à risque de fractures liées à l'ostéoporose qui ont reçu de l'information au sujet de l'hormonothérapie de remplacement et de leur densité minérale osseuse.

Méthodes : L'étude était une étude de cohorte prospective. On a recruté 37 femmes ménopausées présentant des facteurs de risque de fractures liées à l'ostéoporose dans une clinique d'orthopédie d'un hôpital d'enseignement de Hamilton (Ont.). Les femmes ont reçu une trousse d'information (constituée d'une bande audio et d'un cahier de travail) qui a clarifié les avantages et les risques de l'hor-

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monothérapie de remplacement. De deux à quatre semaines plus tard, on a procédé à une densitométrie de la hanche et de la colonne lombaire. Un résumé des risques, les résultats de la densitométrie et les décisions relatives à l'hormonothérapie de remplacement ont été communiqués aux médecins de famille des femmes en cause pour suivi. Les mesures de résultats ont inclus les décisions prises au sujet de l'hormonothérapie de remplacement, ainsi que l'utilisation de la thérapie en question et d'autres médicaments à 12 mois.

Résultats : Après le volet éducation seulement, 10 (27 %) des femmes ont demandé une hormonothérapie de remplacement. Après une densitométrie, quatre autres ont demandé une hormonothérapie de remplacement (ce qui a porté le total à 14 femmes [38 %]). À 12 mois, deux femmes (5 %) ont été perdues au suivi. Des 35 autres femmes, 6 (17 %) suivaient une hormonothérapie de remplacement, 7 (20 %) prenaient des bisphosphonates et 24 (68 %) prenaient des suppléments de calcium.

Interprétation : Ces résultats préliminaires indiquent qu'on établit un lien entre l'éducation sur l'hormonothérapie et la rétroaction sur la densité osseuse, d'une part, et l'augmentation de l'hormonothérapie et d'autres médicaments préventifs chez les femmes exposées aux fractures liées à l'ostéoporose, de l'autre. L'augmentation observée a toutefois été plutôt limitée et c'est pourquoi il faut confirmer et clarifier la signification clinique.

Hormone replacement therapy reduces the risk of osteoporotic fractures associated with the decline in estrogen levels after menopause, but the side effects and a potential increase in the risk of breast cancer must be considered in the decision to begin such therapy.[1] Given the predictive validity of bone mineral density for fractures,[2–4] densitometry may help women decide whether to begin hormone replacement therapy. It appears that the proportion of women with low bone mineral density who use hormone replacement therapy is greater than the proportion of those with normal density who do so,[5] which suggests that densitometry results influence the therapeutic decision. More recently, decision aids[6,7] have been developed to help women weigh a range of benefits and risks associated with hormone replacement therapy. These aids take into account differences in risk for osteoporosis, cardiovascular disease and breast cancer and allow women to assign their own values to those risks.

These developments prompted the questions that guided this preliminary study: How does educating women affect their decisions about starting and continuing hormone replacement therapy? Does education lead to other preventive behaviours? How much of the variability in decision-making is accounted for by bone mineral density alone?

Methods

Subjects

Postmenopausal women (in whom menses had been absent for 12 months or more) were recruited from consecutive patients referred to an orthopedic clinic at a teaching hospital in Hamilton, Ont., between November 1996 and April 1997. Approximately 95% of the women attending this clinic are referred by their family physicians and 5% by specialists. An orthopedic clinic was chosen for this study because fractures occurring after menopause are associated with an increased risk of osteoporosis,[4] so we expected to be able to recruit sufficient numbers of women with normal and with low bone mineral density.

The Canadian Osteoporosis Society clinical practice guidelines[8] include as risks for osteoporosis ovariectomy before age 45 years, a family history of osteoporosis, corticosteroid use for more than 3 months and having been postmenopausal for 5 or more years. Other risk factors for osteoporotic fractures include body weight lower than at age 25,[9] standing or walking for 4 hours or less per day,[9] daily calcium intake of 288 mg or less,[10] daily caffeine intake of more than 2 cups of coffee (for this risk factor, 1 cup of tea or cola was considered equivalent to 0.5 cup of coffee)[9] and smoking.[11]

The inclusion criteria for our study were occurrence of any postmenopausal fracture, one or more of the risk factors for osteoporotic fractures suggested in the Canadian Osteoporosis Society clinical practice guidelines,[8] or 4 or more of the risk factors for osteoporotic fractures identified by prospective studies.[9–11] Exclusion criteria were undiagnosed abnormal genital bleeding, history of thrombophlebitis or thromboembolic disorders, acute liver disease, pregnancy and history of breast or uterine cancer.

Design and protocol

The study employed a prospective cohort design. The

women were approached by a research nurse at the clinic who screened them for eligibility. The women were informed that their participation did not depend on their taking hormones. Those who gave informed consent to participate attended a group session (each involving 2 or 3 patients) 2 to 4 weeks later. During this session an assistant handed out education kits outlining the benefits and risks of hormone replacement therapy and administered a knowledge test. Individual appointments for bone densitometry were scheduled within 2 to 3 weeks of the group session. Each women was asked to bring a completed work sheet entitled "My own benefits and risks" to the appointment.

The education kit, developed at the University of Ottawa,[6] consisted of an audio tape and an illustrated workbook. The kit outlined the scientific evidence supporting long-term hormone replacement therapy; this information was based largely on the results of a meta-analysis by Grady and colleagues,[1] which have been incorporated into the US guidelines for counselling women about hormone replacement therapy.[12] The kit described the nature and consequences of osteoporosis, cardiovascular diseases and cancer of the uterus and breast; the effect of hormone replacement therapy on the risk of each disease and on menopausal symptoms; the methods of administration of the therapy; the side effects; and alternative methods of preventing osteoporosis, such as calcium supplementation and lifestyle changes.

The women were asked, immediately before the bone densitometry, to select 1 of the following 3 statements to indicate their preferences regarding hormone replacement therapy: "I would start estrogen replacement therapy regardless of my bone density findings;" "I would decline estrogen replacement therapy regardless of my bone density findings;" "I would start estrogen replacement therapy only if my bone density were low."

Dual energy x-ray absorptiometry was performed at the hip and lumbar spine (between the second and fourth lumbar vertebrae).[8] All measurements were obtained at one hospital location using a single machine. Two to 4 weeks after the densitometry, the women were contacted by the clinic nurse and informed of their risk category. Women were considered to have normal bone density if the measured values for the hip and spine were not lower than 0.99 standard deviation (SD) below the mean for young adults (i.e., peak bone density). Women whose bone mineral density was 1 or more SD below peak at either site were considered to have low bone mineral density; their risk was classified as moderate (1 to 1.99 SD below the peak), high (2 to 2.99 SD below the peak) or very high (3 SD or more below the peak). After they had been given the densitometry results, the women were asked again whether they would consider hormone replacement therapy. Those wishing more time to make a choice were contacted 2 weeks later.

When they agreed to participate in the study, the women were advised that there would be a repeat knowledge test after the densitometry; it was hoped that this would encourage home study. The repeat knowledge tests were held within 2 weeks of densitometry. Thirty-four of the 37 women attended.

The patients' family physicians were given a computer print-out of the densitometry results in absolute terms and in relation to peak bone density levels. Density levels between 1 and 2.5 SD below peak bone density were reported as indicating osteopenia, and osteoporosis was reported for density levels lower than 2.5 SD below peak. Although the family physicians did not receive a copy of the education kit, they were informed that their patients had been given the kits and that its contents could be reviewed with the women.

A telephone questionnaire was administered 12 months after the densitometry to determine whether the women were receiving hormones or using other therapies.

Data analysis

Nonparametric statistics suitable for small samples and nominal scaling were used. Fisher's exact test was performed when comparing 2 independent samples of women.[13] The McNemar statistic was calculated for comparisons made within the same group of women.[13]

Results

Thirty-seven of the 49 women approached for the study met the inclusion criteria and provided consent and baseline data. The demographic characteristics of the participants and their main risks for osteoporosis are shown in Table 1. The mean age was 58.5 (SD 10.3) years. Twenty-five (68%) of the women were attending the orthopedic clinic for fractures, 6 (16%) for surgical follow-up, and 6 (16%) for physical complaints, including 3 with back pain. Eleven (30%) of the patients had fractures of the wrist, which is characteristic of osteoporosis. None were being followed for vertebral or hip fractures, which are also characteristic of osteoporosis.

The 12 women who did not meet the study criteria were similar in terms of age (mean 61.2 [SD 11.2] years) and risk factors. Eight (67%) of these women had fractures, 1 (8%) had a family history of osteoporosis, 1 (8%) had been postmenopausal for more than 5 years, and 1 (8%) had 4 of the risk factors identified by prospective studies.[9–11]

In the survey conducted immediately before the bone densitometry, 10 (27%) of the 37 women reported that

they would take hormones regardless of the densitometry results (Table 2), 12 (32%) said they would not take hormones, and 11 (30%) indicated that their decision would be conditional on the results of densitometry. Four (11%) were undecided. After densitometry, 4 more women decided to request hormone replacement therapy (for a total of 14 women [38%]).

A comparison of the subgroups with normal and low bone mineral density indicated that the proportion with normal density who wished to start hormone replacement therapy (6 of 16 [38%]) and the proportion with low density (1 SD or more below peak) who wished to do so (8 of 21 [38%]) were virtually identical.

Two (5%) of the 37 women were not available at 12-month follow-up. At that time, we learned that 2 (6%) of the remaining 35 women had started and then stopped hormone replacement therapy within 1 month. Six (17%) of the women were receiving hormone replacement therapy; compared with the baseline rate, when none of the women were receiving therapy, this was a significant change (McNemar test, $p = 0.031$). Seven (20%) of the women had started taking bisphosphonates, which was also a significant increase over baseline ($p = 0.016$).

At follow-up, the percentage of women with low bone mineral density who were receiving hormone replacement therapy was not significantly different from the percentage with normal bone mineral density who were receiving such therapy (4 of 19 [21%] v. 2 of 16 [12%], $p = 0.68$), although this result may be due to low study power. Similarly, bone mineral density was not predictive of calcium use ($p = 0.72$). However, a significantly greater percentage of women with low bone mineral density were taking bisphosphonates compared with those with normal density (7 of 19 [37%] v. 0 of 16 [0%], $p = 0.009$).

Table 1: Characteristics of 37 women participating in a study of factors affecting decisions about hormone replacement therapy (HRT)

Characteristic	No. (and %) of women
Reason for orthopedic assessment	
Fracture	25 (68)
Surgical follow-up	6 (16)
Physical complaint	6 (16)
Risk factor for osteoporotic fractures	
Postmenopausal fracture	25 (68)
Ovariectomy	2 (5)
Family history of osteoporosis	1 (3)
Corticosteroid use for > 3 mo	2 (5)
Postmenopausal for ≥ 5 yr	4 (11)
4 or more other risk factors for osteoporotic fracture*	3 (8)
Education	
High school or less	25 (68)
More than high school	12 (32)
English as a first language	28 (76)
HRT previously started and stopped	3 (8)

*Other risk factors for osteoporotic fracture[9–11] include weight loss with age, reduced activity levels, low calcium intake, high caffeine intake and smoking.

Interpretation

After education and densitometry, 38% of the women in our study expressed a desire to begin hormone replacement therapy. Only 6 of the 35 women available at follow-up were receiving such therapy, although 13 were using either hormone replacement therapy or bisphosphonate and 24 were taking calcium, noteworthy results from a disease prevention perspective.

These findings suggest that education was associated with the decision to start hormone replacement therapy even when bone mineral density was normal. However, this effect was lost when actual therapy was evaluated at follow-up. At follow-up, 11 (58%) of the 19 women with low bone mineral density were taking either hormones or bisphosphonates, but only 2 (12%) of the 16 with normal bone mineral density were taking one of these types of medication.

The low rate of hormone replacement therapy may be accounted for by the availability of bisphosphonates, which were not discussed in the education kit. This alter-

Table 2: Therapy decisions made by study participants at time of densitometry and type of therapy at 12-month follow-up

Bone mineral density	Decision point; no. (and %) requesting HRT			Type of therapy at 12-month follow-up; no. (and %) of women*				
	n	After education	After BMD test	*n*	HRT	Bisphosphonates	Calcium	None
Normal BMD	16	5 (31)	6 (38)	16	2 (12)	0	10 (62)	6 (38)
Low BMD	21	5 (24)	8 (38)	19	4 (21)	7 (37)	14 (74)	4 (21)
1–1.99 SD below normal	9	2 (22)	3 (33)	7	1 (14)	1 (14)	5 (71)	2 (28)
2 SD or more below normal	12	3 (25)	5 (42)	12	3 (25)	6 (50)	9 (75)	2 (17)
All participants	37	10 (27)	14 (38)	35	6 (17)	7 (20)	24 (68)	10 (28)

Note: BMD = bone mineral density, SD = standard deviation.
*Two of the participants (both with bone mineral density between 1 and 1.99 SD below normal) were not available for follow-up.

native may not have been a factor in the women's initial indication of preferences about hormone replacement therapy; however, information about bisphosphonates provided later by family physicians, specialists or other sources (e.g., educational materials, media and personal contacts) may have led some women to re-evaluate their decision about hormone replacement therapy.

It is also possible that not involving family physicians in the education sessions may have led women to decide against hormone replacement therapy for reasons other than the availability of alternative therapies. A physician education manual has since been added to the education kit,[6] which may affect future findings.

The women's decisions may also have been a function of the risk factors that this population had for cancer and heart disease. For example, women with a personal history of cancer were excluded from the study, although those with a family history of this disease were not.

Finally, the decision not to take hormone replacement therapy is valid if it is informed and reflects a woman's values. Consequently, measures of knowledge or ease of decision-making[14] could be meaningful.

In summary, future research should include control groups, larger samples, different risk groups, a range of outcome measures and more involvement of family physicians.

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