Screening, supplements and the use of hormonal replacement therapy in postmenopausal women in a family medicine department prior to the publication of the Woman's Health Initiative report

Russel Kirkby, MD, MBChB, MPrax Med, MFGP; Abdulaziz Al Saif, MD, CCFP, ABFM, DPHC

Background: Many guidelines and recommendations exist on the management of the menopause. Because it is not certain what women do or what management they receive in practice, we studied what was prescribed for postmenopausal women and what screening they had undergone.

Patients and Methods: A retrospective chart review was conducted on all postmenopausal women between the ages of 56-59 years who had no absolute contraindications to taking hormonal replacement therapy (HRT) and were frequent enough attendees at the family health clinic to ensure that postmenopausal issues had been addressed and screening and follow up performed. The women were patients of the family medicine department at a tertiary care hospital in Saudi Arabia.

Results: Sixty-one percent had taken HRT at some time after the menopause, including 42% of Saudis and 87% of non-Saudis. Forty-six percent of all women were taking HRT at the time of the study, including 30% of Saudis and 70% of non-Saudis. Fifty-one percent of all women were taking calcium supplements, 49% were taking vitamin D supplementation, and 63% had undergone a bone mineral density evaluation. There were notable differences in percentages between Saudis and non-Saudis. Sixteen percent of all women had never had a mammogram, including 26% of Saudis and only 3% of non-Saudis.

Conclusion. Many postmenopausal women with access to medical care were not screened nor were they taking supplements in accordance with published guidelines. There was a discrepancy in the management of Saudi and non-Saudi women that could be explained partially by the high percentage of medical professionals among non-Saudi women who are more likely to actively seek medical attention. Our study showed a large proportion of women on HRT, the standard of care before the publication of the Women's Health Initiative study.

Key words: Postmenopausal women, hormone replacement therapy, calcium supplementation, vitamin D supplementation, bone mineral density, mammography.

uidelines and recommendations for the management of the menopause range from doing nothing, "as it is a normal phenomenon" to aggressive screening and hormonal and other replacement therapy. For example, the search term menopause, used on the web site for the National Guideline Clearinghouse,1 results in 40 guidelines for perusal. Mammography yields 25 and osteoporosis yields 68. Many countries develop their own guidelines and different specialties do likewise. There are often differences and variations in the guidelines produced by academies, colleges, gynecologists, endocrinologists, radiologists and generalists. The use of hormones is also a problematical area and is even more so with the release of the findings of the Women's Health Initiative (WHI).² The WHI investigators recommended that all women currently on hormone replacement therapy (HRT), especially those From the *Dept of Family Medicine, King Faisal Specialist Hospital & Research Centre Riyadh Saudi Arabia.

Correspondence to: Russel Kirkby, MD, MBChB, MPrax Med, MFGP Department of Family Medicine, MBC 62 King Faisal Specialist Hospital & Research Center P.O.Box 3354, Riyadh 11211 Saudi Arabia Email:kirkby@kfshrc.edu.sa

Ann Saudi Med 24(3):175-178

who are taking the combined HRT, must be re-counseled to weigh risks and benefits of HRT on an individual basis.

With this plethora of guidelines and recommendations, what actually happens in the practical situation? What are women taking and how are they managed? As we were not sure of what actually occurs in our own clinic, we decided to study this issue by means of chart review.

Patients and Methods

We reviewed the charts of postmenopausal women who regularly attended our clinic before April of 2000. The Department of Family Medicine at the King Faisal Specialist Hospital and Research Centre in Riyadh, Saudi Arabia, caters to the primary medical care of employees and eligible dependents of employees of the hospital. We have approximately 18 000 registered patients. They are seen on an appointment system and can choose which

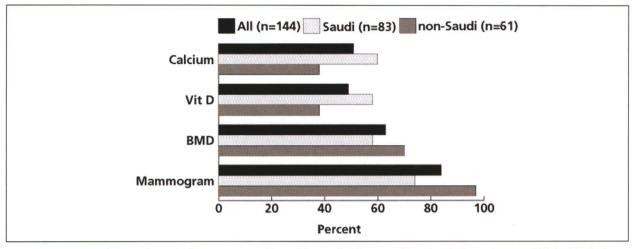


Figure 1. At the time of the study, 51% of women were taking calcium and 49% were taking vitamin D supplements, 63% had had a bone mineral density measurement, and 84% had had a mammogram performed.

practitioner they prefer. Otherwise they are assigned to a practitioner on a "first available" basis. As part of a quality improvement project in our department, we reviewed our management of postmenopausal women in the department during 2002. The 15 clinicians who took part in the study included 13 family physicians, 1 nurse practitioner and 1 gynaecologist. The group included practitioners who had trained in Saudi Arabia, Sudan, Ireland, Canada, the United States, Britain, Syria, and South Africa.

The survey was conducted between April and December of 2002. Each practitioner reviewed between 12 to 15 charts each and filled in a standardised answer sheet. Incomplete answer sheets were returned to reviewers for completion. The authors checked discrepancies or inconsistencies by reviewing the answer sheet and the clinical record of the patient.

Eligible women had to be postmenopausal and between the ages of 55 to 60 years. The recorded ages were those entered in the admission database. Many patients know their Hijerian birth date but not the Gregorian birth date. The Gregorian year of birth was recorded on the patient's chart and this was taken as the year of birth. Exclusion criteria were a first visit after 1 April 2000, an inactive chart (ineligible for care or who had left the service), contraindication to HRT (prior thrombosis or venous embolism, active liver disease, undiagnosed vaginal bleeding, known or suspected estrogen-dependent cancer of the breast or endometrium), or infrequent attendance (no visit to the clinic for more than a year in the 3 years prior to the start date of the study). These criteria were intended to ensure that an adequate time had been spent in the clinic to evaluate issues of menopause and address the need for HRT.

Results

Of 205 charts, 144 (70.2%) women were eligible for

the study and 61 (29.8%) were excluded; the reasons for exclusion were infrequent attendance (86% of excluded charts), an HRT contraindication (11%), and menstruation (3%). Fifty-eight percent of the eligible women were Saudi, 68% were dependents and 32% were employees at King Faisal Specialist Hospital. Women ranged in age from 56 to 59 years.

Thirty-nine percent had never used hormones after menopause. Among Saudis, 42% had used hormones, while 87% of non-Saudis had used hormones. Forty-six percent of all women were currently using hormones and 15% had discontinued hormones because of side effects (25%, n=5), a patient decision to discontinue (25%, n=5), breast cancer (5%, n=1), or a breast lump (5%, n=1). Eight (40%) were unclear why HRT was discontinued. Those using hormones were taking them appropriately. Of those taking hormones, 31.1% had had a hysterectomy and were taking estrogen alone. Women with a uterus were taking estrogen and progesterone—8.2% as a cyclical regimen and 60.7% as a continuous daily regimen.

At the time of the study, 51% of women were taking calcium and 49% were taking vitamin D supplements, 63% had had a bone mineral density measurement, and 84% had had a mammogram performed (Figure 1). There were notable differences between Saudis and non-Saudis in these percentages. Twenty-six percent of Saudi women had never had a mammogram compared with only 3% of non-Saudi women. Twenty-four percent of all women had had a mammogram in the last year and 55% had had a mammogram in the last two years, including 52% of Saudis and 73% of non-Saudis.

Discussion

The mix of the eligible patients very closely reflected the mix of the total patient population at King Faisal Specialist Hospital in nationality (Saudi or Non-Saudi), age, and employee or dependent status. Thus, we believe our survey accurately reflects the care of all women in this age range. There is no reason to believe that we would treat any other postmenopausal women differently. The survey data accurately reflects the care experienced by patients attending different doctors in what is effectively a multi-partner practice with patients not assigned to any particular health care provider.

Until recently, observational studies suggested that HRT, besides other benefits, reduced the risk for cardiovascular disease3-5 and osteoporotic fractures.^{6,7} The recommendations for cardiovascular disease have now changed following additional trials, which have indicated that HRT is harmful rather than beneficial in cardiovascular disease.^{2,8-12}This study was started before the recent data was published, and recommendations were still based on data from the observational findings. Forty-six percent of our patients were taking hormones at the time of the study, and 61% had taken hormones at some time after their menopause. Addressing the results of the latest findings with this number of patients has obvious logistical implications in re-evaluating therapy and allaying fears and anxieties.

The data on calcium and vitamin D from various studies are confusing and contradictory. There is evidence that calcium alone is beneficial in reducing the rate of loss of total body bone mineral density, ^{13,14} yet Hosking et al produced evidence that increased calcium intake did not prevent early postmenopausal bone loss.¹⁵ In a study of identical twins Hunter et al conducted a randomized co-twin, placebocontrolled, double-blind trial over 2 years to measure the effect of vitamin D3 supplementation on bone density and bone metabolism in young postmenopausal women.¹⁶ They concluded that "vitamin D supplementation, on its own, cannot be recommended routinely as an osteoporosis prevention for healthy postmenopausal women with normal vitamin D levels under the age of 70 years." In a metaanalysis of vitamin D treatment in preventing osteoporosis in postmenopausal women, the authors concluded that Vitamin D decreases vertebral fractures and may decrease nonvertebral fractures.¹⁷ In a Cochrane review, Gillespie summed up the dilemma by concluding that uncertainty remains about the efficacy of regimens that include vitamin D or its analogues in fracture prevention.¹⁸

In a study of combined calcium and vitamin D supplementation, Baeksgaard et al showed a positive effect on bone mineral density even in a group of women of early postmenopausal age, with a fairly good initial calcium and vitamin D status.¹⁹ Yet Cooper et al concluded that in younger postmenopausal women (age, 56 years), whose average baseline serum 25-hydroxyvitamin D concentration was well within the normal range, the addition of 10 000 U vitamin D twice weekly to calcium supplementation of 10000

mg per day did not confer benefits on BMD beyond those achieved with calcium supplementation alone.²⁰ The Saudi population has a lower bone mineral density than their agematched western counterparts and there is a high prevalence of low serum vitamin D.^{21,22,23}

The consensus opinion of The North American Menopause Society is that at least 1200 mg per day of calcium is required for most women; levels greater than 2500 mg per day are not helpful. A daily intake of 400-600 IU of vitamin D is recommended, either through sun exposure or through dietary intake or as a supplement. ²⁴ The National Osteoporosis Foundation advises all patients to obtain an adequate intake of dietary calcium (at least 1200 mg per day, including supplements if necessary) and vitamin D (400-800 IU per day for individuals at risk of deficiency). ²⁵ Fiftyone percent of all patients in our survey were taking calcium supplements, including 58% of Saudi patients and 38% of non-Saudi patients. Forty-nine percent of all patients were taking vitamin D supplementation, including 58% of Saudi patients and 38% of the non-Saudi patients.

Although not all experts agree, The North American Menopause Society recommends that bone mineral density be measured in all women with bone loss and in those who are at least 65 years of age, regardless of additional risk factors. Testing is also indicated for all postmenopausal women younger than age 65 with one or more of the following risk factors for fracture: a nonvertebral fracture after menopause, low body weight (<127 lbs, or 57.7 kg), or a first-degree relative who has experienced a hip or vertebral fracture.²⁶ The U.S. Preventive Services Task Force makes no recommendation for or against routine osteoporosis screening in postmenopausal women who are younger than 60 years or in women aged 60 to 64 years who are not at increased risk for osteoporotic fractures.²⁷ The National Osteoporosis Foundation recommends BMD testing for postmenopausal women under age 65 who have one or more additional risk factors for osteoporosis (besides menopause).²⁸ Despite these recommendations and the age range of our patients, only 63% had undergone a bone mineral density evaluation, including 70% of non-Saudis and 58% of Saudis.

For more than two decades expert groups have uniformly agreed that screening mammography reduces mortality from breast cancer among women in their 50's and 60's, even though there has been disagreement about other age groups.²⁸ Gotzsche and Olsen strongly challenged these beliefs in 2000 and 2001 by questioning the validity of the data and stating that only trials of satisfactory quality showed no benefit in mammographic screening.^{29,30} Once or twice annual mammography is recommended by twelve different North American groups quoted in a clinical practice article in the April 24, 2003 issue of the New England Journal of Medicine.³¹ Our study shows that 16% of our patients had never had a mammogram, including 26% of Saudi patients,

while only 3% of the non-Saudi patients had never had a mammogram. Fifty-five percent of all patients had had a mammogram within the last two years; the figures for Saudis were 42% and non-Saudi patients were 73%.

The medical management of the menopause as regards mammographic and bone mineral density screening, hormonal replacement therapy, calcium and vitamin D supplementation remains a problematical and controversial area with many varied and often-contradictory recommendations. This descriptive study reveals interesting data as to what postmenopausal women in our clinic took and what screening was performed on them at the time of the study. Many postmenopausal women with access to good medical care are not screened nor are they taking supplements in accordance with published guidelines. In all aspects there was a noticeable difference in the screening and taking of hormones and supplements by Saudi and non-Saudi patients. This discrepancy might be explained partially by the high percentage of medical professionals among non-Saudi women in our practice population, who are more likely to actively seek medical attention.

Acknowledgements

We thank Dr. A. Al Nasser, Chairman of the department, for permission to conduct the study; Our colleagues who performed the chart review and Reema Al-Oumi for the data collection.

References

1. US Agency for Healthcare research and Quality. National Guideline Clearinghouse. http: //www.guideline.gov. (accessed 4 May 2003).

2. Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. JAMA. 2002;288:321-333.

3. Barrett-Connor E, Grady D. Hormone replacement therapy, heart disease, and other considerations. Annu Rev Public Health. 1998;19:55-72.

4. Grady D, Rubin S, Petitti D, Fox CS, Black D, Ettingher B, et al. Hormone therapy to prevent disease and prolong life in postmenopausal women. Ann Intern Med. 1992;117:1016-1037.

 Stampfer M, Colditz G. Estrogen replacement therapy and coronary heart disease: a quantitative assessment of the epidemiologic evidence. Prep Med. 1991;20:47-63.

Wells G, Tugwell P, Shea B, Guyatt G, Peterson J, Zytaruk N, et al. Meta-analyses of therapies for postmenopausal women vs. Meta-analysis of the efficacy of hormone replacement therapy in treating and preventing osteoporosis in postmenopausal women. Endocr Rev. 2002;23(4):529-539.

 Villareal D, Binder E, Williams D, Schechtman K, Yarasheski K, Kohrt W. Bone mineral density response to estrogen replacement in frail elderly women: a randomized controlled trial. JAMA. 2001;286: 815-820.

 Hulley S, Grady D, Bush T, Furberg C, Herrington D, Riggs B, et al. Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women. Heart and Estrogen/progestin Replacement Study (HERS) Research Group. JAMA. 1998;280:605-613.

 Grady D, Herrington D, Bitmer V, Blumenthal R, Davidson M, Hlatky M, et al. Cardiovascular disease outcomes during 6.8 years of hormone therapy (HERS II). JAMA. 2002;288(1):49-57.

 Viscoli C, Brass L, Keruan W, Sarrel P, Suissa S, Horowitz R. A clinical trial of estrogen-replacement therapy after ischemic stroke. N Engl J Med. 2001; 345:1243-1249. 11. Simon J, Hsia J, Cauley JA, Richards C, Harris F, Fong J, et al. Post-menopausal hormone therapy and risk of stroke: the Heart and Estrogen/ progestin Replacement Study (HERS). Circulation. 2001;103:638-642.

 Clarke SC, Kelleher J, Lloyd Jones H, Slack M, Scholfiel PM. A study of hormone replacement therapy in postmenopausal women with ischaemic heart disease: the Papworth HRT atherosclerosis study. BJOG. 2002;109:1056-1062.

 Reid IR, Ames RW, Evans MC, Gamble GD, Sharpe SJ. Long-term effects of calcium supplementation on bone loss and fractures in postmenopausal women: a randomized controlled trial. Am J Med. 1995; 98(4): 331-335.

14. Aloia JF, Vaswani A, Yeh JK, Ross PL, Flaster Dilmanian FA. Calcium supplementation Ε, with and without hormone replacement postmenopausal therapy to prevent bone Ann Med. 1994:120(2):97-103. loss. Intern 15. Hosking DJ, Ross PD, Thompson DE, Wasnich RD, McClung M, Bjarnason NH, Ravn P, Cizza G, Daley M, Yates AJ. Evidence that increased calcium intake does not prevent early postmenopausal bone loss. Clin Ther. 1998;20(5):933-944.

16. Hunter D, Major P, Arden N, Swaminathan R, Andrew T, MacGregor AJ, Keen R, Snieder H, Spector TD. A randomized controlled trial of vitamin D supplementation on preventing postmenopausal bone loss and modifying bone metabolism using identical twin pairs. J Bone Miner Res. 2000;15(11):2276-2283. 17. Papadimitropoulos E, Wells G, Shea B, Gillespie W, Weaver B, Zytaruk N, Cranney A, Adachi J, Tugwell P, Josse R, Greenwood C, Guyatt G. Osteoporosis Methodology Group and The Osteoporosis Research Advisory Group. Meta-analyses of therapies for postmenopausal osteoporosis. VIII: Meta-analysis of the efficacy of vitamin D treatment in preventing osteoporosis in postmenopausal women. Endocr Rev. 2002;23(4):560-569. 18. Gillespie WJ, Avenell A, Henry DA, O'Connell DL, Robertson J. Vitamin D and vitamin D analogues for preventing fractures associated with involutional and post-menopausal osteoporosis (Cochrane Review). In: The Cochrane Library. Issue 2. Oxford: Update Software;2003.

19. Baeksgaard L, Andersen KP, Hyldstrup L. Calcium and vitamin D supplementation increases spinal BMD in healthy, postmenopausal women. **Osteoporos Int.** 1998;8(3):255-260.

20. Cooper L, Clifton-Bligh PB, Nery ML, Figtree G, Twigg S, Hibbert E, Robinson BG. Vitamin D supplementation and bone mineral density in early postmenopausal women. Am J Clin Nutr. 2003;77(5): 1324-1329.

21. El-Desouki M. Bone mineral density of the spine and femur in the normal Saudi population. Saudi Med J. 1995;16:30-35.

22. Sadat-Ali M, Al Habdanl, Marwan S. Bone mineral density measurement of distal radius in Saudi Arabian females. Ann Saudi Med. 1996;16:414-416.

23. Sedrani SH,et al. Sunlight and vitamin D status in normal Saudi subjects. Am J Clin Nutr. 1983;38: 129-132.

24. The North American Menopause Society. The role of calcium in peri- and postmenopausal women: consensus opinion of the North American Menopause Society. **Menopause.** 2001;8(2):84-95.

 National Osteoporosis Foundation. Physician's guide to prevention and treatment of osteoporosis. Belle Mead (NJ): Excerpta Medica, Inc.; 1999:28. 26. Management of postmenopausal osteoporosis: position statement of the North American Menopause Society. Menopause. 2002;9(2):84-101.

27. U.S. Preventive Services Task Force. Screening for osteoporosis in postmenopausal women: recommendations and rationale. Ann Intern Med. 2002;137(6):526-528.

28. Preventive Services Task Force. Screening for breast cancer: recommendations and rationale. Ann Intern Med. 2002;137:344-346.

29. Gotzsche PC, Olsen O. Is screening for breast cancer with mammography justifiable? Lancet. 2000;355:129-134.

30. Olsen O, Gotzsche PC. Cochrane review on screening for breast cancer with mammography. Lancet. 2001;358:1340-1342.

31. Fletcher SW, Elmore JG. Mammographic Screening for Breast Cancer. N Engl J Med. 2003;348:1672-1680.