What factors are associated with a woman's decision to take hormone replacement therapy? Evaluated in the context of a decision aid

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Abstract

Objectives To understand the factors associated with a post-menopausal woman deciding to take hormone replacement therapy (HRT) after reviewing a decision aid (DA) and having a counselling visit with her physician as well as the factors associated with the act of taking HRT 2 months after the counselling interview.

Design A secondary analysis of data collected for a randomized controlled trial evaluating two DAs.

Main outcome results Although 28% of women were uncertain regarding their decision after the counselling interview, only 2.4% of women, at the assessment at 2 months, had not made a decision. The most significant factor associated with the decision to take HRT, after the physician visit, was the physician preference (OR: 62, 95% CI: 13.3, 289.7). Physician preference (OR: 78, 95% CI: 6.2, 975) remained the most significant factor for taking HRT 2 months after the counselling interview followed by low uncertainty about the decision (OR: 0.4, 95% CI: 0.2, 0.7).

Conclusion Physician preference was the factor that was most associated with the woman's decision following counselling and 2 months later. Qualitative evaluation of the interview process involving the patient and physician would determine whether the patient and physician are reaching a shared decision or is the physician preference influencing the patient.

Introduction

The decision by a woman to take hormone replacement therapy (HRT) can be undertaken with considerable uncertainty. Physicians and health-care practitioners remain polarized on who should receive HRT due to the conflicting evidence regarding the benefits and risks of taking HRT.[1,2] Practice guidelines from the American College of Physicians, the Society of Obstetricians and Gynaecologists of Canada, and the Osteoporosis Society of Canada recommend that women should participate in the decision to take HRT and physicians should take into account a women's personal probabilities of outcomes and personal values.[3–5]

O'Connor[6] has developed a Decision Support Framework to guide counselling appropriate for such difficult decisions. The goal of the Decision Support Framework is to enable the patient and the practitioner to make a decision that is informed, consistent with personal values and acted upon. Decision support is provided to address the modifiable determinants of the decision or decision-making process that are suboptimal. For example, patients and practitioners may base their decisions on inadequate knowledge, unrealistic expectations, unclear values, and biased perceptions of others' opinions. Decision support tools provided to patients and practitioners may improve decision-making by providing information about options, outcomes, and probabilities, clarifying the patients' values, providing balanced perceptions of others and structuring the counselling to support shared decision-making.

The framework has been empirically validated by O'Connor *et al.*[6–9] in that decision aids (DA) based on the framework do reduce uncertainty, improve knowledge and expectations, and clarify values. However, these improvements do not always result in changes in decisions, particularly for HRT. It would therefore be illuminating to examine which factors predict choices during and following the process of providing decision support.

This study evaluated the determinants of the decision to take HRT and the decision to follow through with the treatment decision after the counselling interview and 2 months later, respectively.

Methods

Data source

We conducted a secondary analysis of data collected during a randomized controlled trial that evaluated the effectiveness of two decision support interventions (DSI) for the use of HRT. The DSIs were a brief pamphlet of the American College of Physicians describing the options and outcomes in general terms and a detailed decision aid (audio-tape, booklet and worksheet) that included outcome probabilities tailored to clinical risk, values clarification, and guidance in the steps of decision-making. The data collected for the original study was obtained from post-menopausal women recruited from a random sample of practices of community-based family physicians in the Ottawa area. Physicians eligible for recruitment fulfilled the following criteria: they were >5 years since graduation from medical school and <60 years of age. Women eligible for recruitment into the study were 45–69 years of age, post-menopausal for at least 1 year, able to read English, had never used HRT, had no history of osteoporosis-associated fractures, and had no absolute contraindications to HRT.

The family physicians were randomized to one of the DSIs. Therefore, all women recruited by their family physician received the same DSI.

Variables

Data and variables, evaluated as factors influencing the decision to take HRT in the analysis, were guided by the Ottawa Decision Support Framework (see Table 1).[6] Baseline data included the patient and physician demographic and clinical determinants of the decision, as well as the length of the relationship between the physician and the patient, and the patients' preferred role in decision-making. Two quality of life tools were used at baseline: the Short Form 12[10] (SF-12) and the Menopause Quality of Life Scale[11] (MENQoL). Each woman was assessed for her opinion regarding whether or not she would take HRT before the study was started. This variable was not considered as one of the factors for inclusion in the model as the woman's knowledge, values and beliefs were gathered explicitly according to the decision support framework before the interview and would still be operating post-consultation.

Following review of the DSI (either the decision aid or pamphlet) and within 24 h of a counselling interview with their physician their 'perception of the decision' was measured. Based on the Decision Support Framework[6] knowledge of HRT, expectations of benefits and risks and whether they were realistic, uncertainty

Table 1 Independent variables

Time frame	Patient variables	Patient–physician variables	Physician variables
Baseline	Age, employed, education, hysterectomy, smoker, years to last menstrual period, medical history assessing risk for coronary heart disease, osteoporosis, and breast cancer, quality of life scales i.e. MENQoL and SF-12	Length of relationship, patient's desired role in decision-making	Age, gender, CCFP certification, year of graduation from medical school after 1978, satisfaction with autonomy in practice, usual prescribing pattern of HRT
After counselling interview	Uncertainty, knowledge, realistic expectations, values	Decision satisfaction, patient's actual role in decision-making	Physician preference for HRT
Composite baseline / post-counselling variable		Achievement of desired role in decision-making	

measured using the decision conflict scale[12] and personal values regarding the benefits and risks of HRT were assessed. The decision satisfaction inventory[13] was used to measure satisfaction with the decision and the decision-making process. The patients' actual role in the decision-making process was assessed and a composite variable 'achieved role' was constructed based on a match between the patients' desired and actual role in decision-making. Afterwards, the preference of the physician was assessed by asking 'if the decision to start HRT for this patient was up to them alone would they prefer the patient to start HRT?' The preference of the physician was included for consideration in the model as we wanted to capture all the variables that were operating pre-consultation and the impact of the decision aid and the counselling interview on the effect of the decision of the woman to take HRT. The DA serves as a tool for the interview and the patient thinking on whether or not to take HRT.

Analysis

Data from the first 126 patients and their associated physicians were used to develop two statistical models predicting the decision immediately after the counselling interview and whether the woman was taking HRT 2 months after the counselling interview. The decisions were classified as 'yes' or 'no', and any woman who was uncertain was excluded at the time point where the model was developed was from that particular model.

The statistical analysis was performed using SAS© (Ver. 7; SAS Institute, Inc., Cary, NC, USA). Univariate analysis was performed using the student's *t*-test for continuous variables and chi-square (χ^2) for categorical variables. Generalized estimating equations (GEE) were used in the univariate analysis to adjust for physician, as the physician was the unit of randomization.[14–16] Any variables achieving a significance of $P < 0.10$, adjusted or unadjusted for the physician, were considered for inclusion in the model. The physician was accounted for in the multivariate model development stage using GEE with a forward stepwise method for addition and removal of variables with a significance level of 0.05 using a hierarchical model building approach.[17]

The intervention was a design variable and therefore it was included in all multivariate models. Possible colinearity was identified based on clinical experience and the variable added first was retained in the model. First-order interactions were assessed for variables where clinical experience suggested a possible interaction. First-order interactions between the DSI and each variable included in the models were also assessed.[18]

The variables were reviewed for contribution to the predictive ability of each model using the Hosmer and Lemeshow goodness-of-fit statistic (HL).[19] Models were tested for overfitting using the generally accepted rule that there must be at least 10 outcome events for each covariate and the heuristic shrinkage estimator of van Houwelingen and le Cessie (a shrinkage coefficient <0.85 suggests overfitting).[17] The reproducibility of the final model was evaluated with the next 46 patients enrolled in the study using the HL test to assess the goodness-of-fit of the model.

Results

One hundred and twenty-six patients and 31 physicians were used to develop the statistical models. Sixteen physicians and their 74 patients were randomized to the decision aid group and 15 physicians and their 52 patients were randomized to the pamphlet group.

Table 2 summarizes the variables measured in the current study. The 126 women in the development model had an average age of 55.6 years, were well educated, and employed outside the home. There were slightly fewer female than male physicians and the Canadian College of Family Physicians (CCFP) certified the majority of the physicians.

The descriptive statistics for the women analysed in the validation set are also presented in Table 2.

The variables that were significantly related to the decision to take HRT in the univariate analysis are presented in Table 3. For the decision after the counselling interview a number of variables became significant when an adjustment was made for the physician (Table 2): whether or not the physician held CCFP certification, and if the length of the patient–physician relationship was >5 years. These variables were variables that were measured at the physician level.

The final models developed for the two decisions regarding the use of HRT are outlined in Table 4. After the counselling interview, the relative odds of taking HRT for a woman with physician preference was 62 (95% CI: 13.3, 290) than without physician preference. For each unit increase in the physical subscale of the MENQoL (more physical symptoms), the odds increased by a factor of 2.3 (95% CI: 1.3, 4.0) that patients would take HRT. For each unit increase in the vasomotor subscale of the MENQoL (more vasomotor symptoms), the odds increased by a factor of 1.4 (95% CI: 1.1, 1.7) that patients would take HRT.

These data were validated using the data set of 55 patients, nine patients were excluded as the data was missing for physician preference leaving 46 patients. Of these 46 patients, eight were uncertain, 15 decided to take HRT after the counselling interview and 23 did not. The HL was 8.40 ($P = 0.20$) indicating that this model was a good fit.

The relative odds of HRT 2 months after the counselling interview for women with physician preference was 78.0 (95% CI: 6.2, 975) than without physician preference. For each one unit increase in the uncertainty subscale of the decision conflict scale (measured on a scale of 5), a woman was less likely to take HRT with an odds ratio of 0.4 (95% CI: 0.2, 0.7). The odds of taking HRT were increased by a factor of 4.0 (95% CI: 1.4, 11.8) if the woman had a positive family history of heart disease. For each unit increase in the psychological subscale of the MENQoL (more physical symptoms), the odds increased by a factor of 2.0 (95% CI: 1.4, 3.0). The data were validated using the data set of 46 patients. After excluding five unsure women, 41 remained, of which 14 were taking HRT 2 months after the counselling interview. The HL was 12.452 ($P = 0.13$) indicating that this model was a good fit.

Discussion

This is the first study undertaken to identify the factors associated with the decision to take HRT in the context of the Decision Support Framework. The Decision Support Framework is a construct that is useful in clinical situations with value-laden decisions. Identification of the preference of the physician as a strong factor associated with the decision to take HRT is an important finding. Physician preference was

Table 2 Descriptive statistics for the variables assessed for the development and validation sets

Variable category	Variable name	Development set ($n = 126$)	Validation set ($n = 46$)
Design	Randomized to DA	74 (58.7%)	17 (37.0%)
Baseline opinion	'I would consider taking HRT.'	16 (12.7%)	4 (8.7%)
Baseline patient characteristics	Employed outside home	72 (57.1%)	37 (80.4%)
	At least some post-secondary education	86 (68.3%)	34 (73.9%)
	Current smoker	14 (11.1%)	2 (4.3%)
	Hysterectomy	35 (27.8%)	5 (10.9%)
	Coronary heart disease	6 (4.8%)	0.0 (0.0%)
	Hypertension	31 (24.6%)	5 (10.9%)
	Diabetes	5 (4.0%)	4 (8.7%)
	High cholesterol	32 (25.4%)	7 (15.2%)
	Fibroids	23 (18.3%)	6 (13.0%)
	Low bone density	22 (17.5%)	5 (10.9%)
	Family history of heart disease	41 (32.5%)	8 (17.4%)
	Family history of breast cancer	20 (15.9%)	4 (8.7%)
	Mean (SD), age (years)	55.6 (6.3)	54.0 (4.2)
	Median (IQR) L MP (years)	7.6 (2.2–13.6)	4.5 (2.0–9.2)
	MENQoL Vasomotor subscale[a] [Mean (SD)]	2.8 (1.9)	3.2 (1.8)
	MENQoL Psychosocial subscale [Mean (SD)]	3.0 (1.6)	3.4 (1.8)
	MENQoL Physical subscale [Mean (SD)]	3.3 (1.3)	3.4 (1.4)
	MENQoL Sexual subscale [Mean (SD)]	2.5 (1.9)	2.8 (2.0)
	SF 12 Physical subscale[b] [Mean (SD)]	26.3 (5.8)	26.1 (5.8)
	SF 12 Mental subscale [Mean (SD)]	51.9 (7.0)	52.7 (6.4)
Baseline physician characteristics	Satisfaction with autonomy	100 (79.4%)	40 (87.0%)
	Year of graduation after 1978	64 (50.8%)	27 (58.7%)
	No. patients/week >120	51 (40.5%)	16 (34.7%)
	Female gender	59 (46.8%)	24 (52.2%)
	Canadian College of Family Physicians	90 (71.4%)	26 (56.5%)
After visit patient characteristics	Knowledge[c] [Mean (SD)]	76.7 (17.5)	79.1 (17.3)
	Realistic expectations [Mean (SD)]	32.2 (22.5)	30.5 (21.7)
	Value of heart disease[d] [Mean (SD)]	7.5 (2.8)	7.1 (2.6)
	Value of osteoporosis [Mean (SD)]	7.1 (2.9)	7.4 (2.6)
	Value of side-effects [Mean (SD)]	7.9 (2.4)	8.0 (2.1)
	Value of breast cancer [Mean (SD)]	8.2 (2.5)	8.3 (2.2)
	Decision Conflict Scale[e] [Mean (SD)]	2.1 (0.6)	2.5 (0.5)
	DCS Uncertainty subscale [Mean (SD)]	2.6 (1.0)	3.1 (1.0)
	DCS Knowledge subscale [Mean (SD)]	1.9 (0.6)	2.2 (0.6)
	DCS Supported subscale [Mean (SD)]	2.0 (0.6)	2.4 (0.5)
	DCS Values subscale [Mean (SD)]	2.0 (0.6)	2.3 (0.6)
	DCS Satisfaction subscale [Mean (SD)]	2.0 (0.7)	2.5 (0.6)
Patient–physician characteristics	Relationship >5 years	68 (54.0%)	28 (65.1%)
	Patient achieved decision role	67 (53.2%)	20 (46.5%)
	Satisfaction with decision[f] [Mean (SD)]	11.3 (2.0)	11.2 (1.6)
	Satisfaction with process[f] [Mean (SD)]	46.8 (7.5)	45.9 (7.2)
After visit physician characteristic	Physician preference for HRT	65 (51.6%)	25 (54.3%)

DA-decision aid, SD-standard deviation, IQR-interquartile range, LMP-last menstrual period.

[a] Menopause Quality of Life Scale (MENQoL) range (0 symptoms least bothersome to 6 most bothersome).

[b] Short Form (SF) 12 Physical and Mental scales are scored using a norm-based method to have a mean of 50 and a SD of 10 in the general U.S. population with a higher number worse.

[c] Knowledge and Realistic Expectations are scored out of 100.

[d] Value Scale (range 0–10) higher number more valued.

[e] Decision Conflict Scale (DCS) (range 1–5) higher number more decisional conflict.

[f] Satisfaction with decision (range 0–15), satisfaction with process (range 0–50) higher number more satisfied.

Table 3 Characteristics associated with the decision to take hormone replacement therapy (HRT). Analysis Results for decision measured immediately and 2 months after the counselling visit (significant variables only)

	Post-visit HRT use		Post-visit (2 months) HRT use	
Variable name	Yes (34)	No (57)·	Yes (29)·	No (94)
I would consider HRT (not in model)	14 (41.2%)	0 (0.0%)	12 (41.3%)	3 (3.2%)
Baseline patient characteristics				
Hysterectomy	16 (47.1%)	11 (19.3%)	15 (51.7%)	19 (20.2%)
Fibroids	10 (29.4%)	8 (14.0%)	–	
FHx of heart disease	15 (44.1%)	14 (24.6%)	17 (58.6%)	24 (25.5%)
FHx of breast cancer	2 (5.9%)	16 (28.1%)	1 (3.4%)	19 (20.2%)
Age (years) [mean (SD)]	53.7 (5.2)	56.4 (6.1)*	52.9 (4.5)	56.4 (6.4)
MENQoL Vasomotor subscale [Mean (SD)]	3.6 (2.2)	2.6 (1.7)	3.5 (2.3)	2.6 (1.7)
MENQoL Psychosocial subscale [Mean (SD)]	3.7 (1.4)	2.8 (1.5)	4.0 (1.4)	2.7 (1.5)
MENQoL Physical subscale [Mean (SD)]	3.8 (1.1)	3.0 (1.2)	4.0 (1.2)	3.1 (1.3)
MENQoL Sexual subscale [Mean (SD)]	3.0 (2.1)	2.2 (1.7)	3.4 (2.3)	2.2 (1.7)
SF 12 Physical subscale [Mean (SD)]	28.7 (5.2)	24.6 (5.4)	28.7 (5.6)	25.6 (5.7)
Baseline physician characteristics				
Female gender	11 (32.4%)	29 (50.9%)**	10 (35.0%)	46 (49.4%)**
CCFP	24 (70.6%)	42 (73.7%)**	–	
After visit patient characteristics				
Value of heart disease [Mean (SD)]	8.9 (2.0)	6.6 (3.2)*	9.0 (2.2)	7.2 (3.0)
Value of osteoporosis [Mean (SD)]	7.6 (2.7)	6.5 (2.9)	–	
Value of side-effects [Mean (SD)]	–		6.9 (3.0)	8.0 (2.5)**
Value of breast cancer [Mean (SD)]	7.4 (3.0)	8.9 (1.9)	7.0 (3.0)	8.6 (2.2)
DCS Uncertainty subscale [Mean (SD)]	–		2.3 (0.8)	2.6 (1.0)**
DCS Values subscale [Mean (SD)]	–		1.9 (0.5)	2.1 (0.6)
DCS Satisfaction subscale [Mean (SD)]	1.8 (0.5)	1.8 (0.6)**	1.8 (0.5)	2.1 (0.7)
Patient–physician characteristics				
Relationship >5 years	18 (52.9%)	32 (56.4%)**	–	
Physician preference for HRT	30 (88.2%)	15 (26.3%)	27 (93.1%)	36 (38.7%)
Satisfaction with decision [Mean (SD)]	11.3 (2.2)	12.3 (1.6)	–	
Satisfaction with process [Mean (SD)]	45.2 (8.2)	48.7 (7.2)	–	

Legend: Same as Table 2.
* $P < 0.1$ only for analysis unadjusted for correlation.
** $P < 0.1$ only for analysis adjusted for correlation.

assessed after the patient had reviewed a DA and the patient and physician had a counselling interview. The physician was asked if the decision to take HRT was up to them alone would they recommend HRT for a particular patient or not.

Several hypotheses may account for why physician preference was so influential. First, the physician may be confirming the patient's preference for HRT. Indeed, many of the women who started the visit with a baseline opinion that they would consider HRT ended up in favour of HRT. Secondly, the physician and the women may be reaching a decision together in a shared decision-making process. Lastly, the physician may be dominating the decision-making process and pushing the women towards the choice of HRT, although the physician's usual prescribing pattern of HRT was not significantly associated with the decision to take HRT.

Our study is the first study to explore the patient–physician relationship and the decision-making process between the women and her physician for the decision to take HRT and demonstrate the complexities of the interaction between the patient and the physician. Previous work has shown that the advice of the physician is an important factor in identifying women who are or were taking HRT or would consider taking HRT.[20–24] Our study is the first to assess

Table 4 Models for decisions of hormone replacement therapy

	Post-visit OR (95%) CI	Post-visit (2 months) OR (95%) CI
Variables		
Intervention	0.3 (0.1, 1.0)	0.6 (0.1, 2.3)
Physician preference	62.0 (13.3, 290)	78.0 (6.2, 975)
MENQoL Physical subscale	2.3 (1.3, 4.0)	
MENQoL Vasomotor subscale	1.4 (1.1, 1.7)	
MENQoL Psychological subscale		2.0 (1.4, 3.0)
DCS Uncertainty subscale		0.4 (0.2, 0.7)
FHx of heart disease		4.0 (1.4, 11.8)
Model Statistics		
Hosmer and Lemeshow	8.04 ($P = 0.43$)	6.53 ($P = 0.59$)
Shrinkage	0.88	0.86
External validation	12.04 ($P = 0.15$)	12.45 ($P = 0.13$)

OR = odds ratio.
CI = confidence interval.

the influence of the physician prospectively and at the time when the actual decision is being made.

Future studies should explore the patient–physician relationship to understand better the amount of negotiation and patient-centred discussion, and its effect on the decision.

Women who were taking HRT 2 months after the counselling interview had less uncertainty in their choice, i.e. they had a lower decisional conflict on the uncertainty subscale of the decision conflict scale than those who did not choose HRT. This factor did not contribute to the model for the decision to take HRT immediately after the counselling interview. Immediately after the counselling interview, 35 women were excluded from model development, as they had not made a decision to take HRT. Two months after the counselling interview all but three women had made a decision. Therefore, the higher uncertainty in the group that declined HRT use 2 months after the interview could be a default decision. The decision conflict scale and the uncertainty subscale could be evaluated in future studies to examine if further information, counselling, or more support is required for these women in the decision-making process. We need to better understand how the physician can aid in the decision-making process for women who are still uncertain in their decision after the physician visit.

These results may not be generalizable for a number of reasons. The models developed were exploratory or hypothetical in nature due to the small sample size. Our patient population was predominantly of Caucasian race, married, and well educated.

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