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Title: Management of hot flushes in UK breast cancer patients: clinician and patient perspectives

Abstract

Introduction: Menopausal problems are among the most prevalent and distressing problems following breast cancer treatment, with 70% women experiencing hot flushes and night sweats (HFNS). A working party was set up to support the development of new research into the management of these problems.

Methods: We conducted surveys to explore the need as perceived by women with breast cancer and establish current UK management practices. A patient survey was conducted through a charity, Breast Cancer Care, and a health professional survey via the UK Breast Intergroup. The HFNS Problem Rating Scale was used, as well as specific questions addressing the aims of the study.

Results: 665 patients responded and 185 health professionals. 28% women had considered stopping adjuvant endocrine treatment because of HFNS, yet 34% had never been asked about HFNS by any health professional. The most commonly offered interventions were SSRIs, such as venlafaxine, yet only 25% patients had been offered these drugs. Cognitive behavioural therapy was rarely suggested (2%) despite good evidence.

Discussion: This study shows a lack of coherence in the management of HFNS in breast cancer survivors, which may lead to reduced adherence to adjuvant therapy. There is an urgent need to develop guidelines to support management of HFNS after breast cancer.

Key words

Menopause, breast cancer, hot flushes, survey, management

Introduction

With improving detection and treatment of breast cancer, nearly 80% of women in the UK survive beyond ten years [1]. This means that there is a large cohort of women living into old age who are left with the long term impact of the disease and its treatment [2]. As well as social and emotional consequences, many women experience a number of symptoms that can impact on their quality of life. While there is an emerging evidence base for the management of these problems, there remains a paucity of good quality research with a clear benefit for women who continue to suffer these problems. Breast cancer clinical trials are monitored and supported in the UK by a national body of clinicians and researchers under the umbrella of the National Cancer Research Institute (NCRI). The NCRI Clinical Studies Group (CSG) for breast cancer has a large portfolio of studies exploring all aspects of treatment for breast cancer, and treating centres throughout the UK contribute to these studies. Patient advocate members of this group identified a gap in the portfolio of studies around the management of symptoms. The most common of these are pain, fatigue, hot flushes, night sweats, cognitive and sexual problems and lymphoedema [3]. A research gap analysis conducted by Breast Cancer Campaign also identified a need for further research in supportive interventions and the translation of findings into practice [3]. In response to these findings a working party was set up by the breast cancer NCRI CSG to stimulate and support the development of new research into the management of these symptoms (Working Group on Symptom Management). It was decided in the first instance to focus on menopausal difficulties of hot flushes and night sweats.

Menopausal problems are among the most prevalent and potentially distressing problems following breast cancer treatment with hot flushes and night sweats (HFNS) being experienced by up to 70% women [4]. HFNS may persist for more than five years once cancer treatment has ended [5]. The result is an adverse effect on all aspects of life, including sleep, social situations, intimacy in relationships and ability to work [6]. HFNS gradually decrease with natural menopause in number and intensity over the post-menopausal years. However, they can be more extreme and persistent with breast cancer due in part to treatments, such as the aromatase inhibitors and tamoxifen, which reduce or interfere with the action of oestrogen in the body [7]. Chemotherapy can induce early menopause; hormone replacement therapy (HRT) is contraindicated and women diagnosed while taking HRT are advised to cease [8]. Those women who experience severe symptoms may consider discontinuing or changing adjuvant endocrine treatments, which are currently recommended to be taken for five to ten years. Recent research shows that less than 50% of women with breast cancer take the full 5 years of anti-oestrogen medication, with a resultant 20% excess in breast cancer mortality [9].

The Working Group on Symptom Management established a multidisciplinary group of expert clinicians and researchers with expertise in the field of HFNS. The group consists of patient advocates, nurses, academic researchers, oncologists, psychologists, statisticians, physiologists, gynaecologists, complementary therapy specialists and representatives from the UK charities Breast Cancer Care, Breast Cancer Campaign and Independent Cancer Patient Voices.

Following recommendations from the Breast Cancer Campaign gap analysis [3] the aims of the group were set to achieve, short, medium and long-term goals. These were: raising awareness; establishing and disseminating current best practice; encouraging development of studies to increase the evidence base and to stimulate new research into the basic science of HFNS to explore mechanisms of flushing in order to develop new drugs and innovations for the management of HFNS. The first piece of work undertaken by the group was to explore the need as perceived by women with breast

cancer and to establish current management practices throughout the UK. This was done by conducting national surveys. This paper reports on the findings of these surveys.

Methods

Aim

The aim of the study was to investigate the perceptions amongst patients and health care professionals of the level of unmet need relating to HFNS in women with breast cancer, and current management practices.

Objectives

The study objectives were to:

- I. Explore the perceptions and level of need relating to HFNS
- 2. Explore prescribing patterns in the UK to manage HFNS
- 3. Explore use of alternative and complementary methods for managing HFNS
- 4. Explore patients' experience of interactions between patients and health care professionals (HPs)

Design

Two separate on line surveys, one for patients and one for health professionals, were set up and managed independently in order to target the appropriate groups. This study was subject to approval by the host organisation's [10], Research Committee and in accordance with their Code of Good Research Practice, which conforms to the provisions of the Declaration of Helsinki.

Study setting and participants

Patient survey

The patient survey was hosted by Breast Cancer Care, the only specialist breast cancer support charity working throughout the UK. This charity has a very active website with around 2 million unique website visitors and 700,000 unique online forum visitors each year, and more than 120,000 Twitter followers. A link to the survey was posted onto the online discussion forums on the Breast Cancer Care website and via the charity's Twitter account. The survey link remained live for two weeks and reminders were posted twice within this time on both Twitter and the online discussion forums. There were no inclusion/exclusion criteria.

Health professional survey

The health professional survey was aimed at those health professionals working specifically in the field of breast oncology. In order to target this specific audience the UK Breast Intergroup database was identified which holds records of 800 multidisciplinary oncology health professionals, including surgeons, medical and clinical oncologists, research and breast care nurses. This database was chosen as the aim was to explore practice in the UK and it is the most comprehensive multidisciplinary database of health professionals working in breast cancer in the UK. An email was sent to all those on the database with a link to the on line survey. The instrument used was Survey Monkey.

Outcome measures

For the patient survey the HFNS problem rating scale was used [11]. This gives a hot flush problem rating calculated as the mean of three items each measured on a 10 point scale (low to high), e.g. "To what extent do you regard your flushes/sweats as a problem?" (I = not at all a problem, I0 = very much a problem). Women are also asked to given a retrospective estimation of the number of HFNS experienced in the past week [11]. Problem rating is associated with help-seeking and quality of life and has been recommended as an important patient reported outcome measure in trials of HFNS treatments [12-13].

Other questions were developed specifically to address the aims of the study and included both closed multiple choice questions and open questions using free text boxes. Age at diagnosis, current age, past and current treatments were also recorded. The open question responses are reported elsewhere.

Women were asked if they had ever been asked about HFNS by any health professional and what treatments had been offered. We asked what they had tried, including complementary therapies, what helped and what they had had to pay for. We also asked if women were having HFNS while on endocrine therapy, were they bad enough to make them want to stop taking it. Finally we asked a question about the delivery of interventions: 'Some treatments/ interventions for hot flushes can be delivered in different ways. If you could choose, which would you prefer?'

For the health professional survey questions were developed to address the aims of the study and basic demographics, such as age, gender and discipline were included. Other questions related to how much the professional regarded hot flushes to be a problem and what treatments they used, including hormonal and non-hormonal drugs, complementary therapies and services. We also asked whether these services, including menopause clinics and psychological services, were available locally and whether they were free.

Analysis

Descriptive statistics are given. For the HFNS problem rating scale each of the items are reported separately and an overall average of the three items given. Hot flushes and night sweats are reported separately. Results from the two surveys are presented separately.

Results

I. Patient survey

665 women completed the patient survey and over 500 responses were received in the first 48 hours of the survey being live.

Almost half of the women in the sample (48.6%, n = 323) were between 45 – 54 years of age at the time of diagnosis. Current age ranged from 25-69 (median 50). There was a wide range of treatments that respondents had received or were currently receiving. I 10 (16.5%) patients had been treated with chemotherapy only, I 56 (23.5%) patients had been treated with endocrine therapy only. Eighteen (2.7%) patients had chemotherapy and trastuzumab treatment, 264 (39.7%) patients had chemotherapy and endocrine therapy, 2 (0.3%) patients had trastuzumab treatment and endocrine therapy and 84 (12.6%) patients had all three treatments (table 1).

94% of respondents (627/665) reported currently experiencing hot flushes. Of these, 38% (207/534) reported having 6 - 10 hot flushes a day. The mean hot flush problem rating score was 6.2 and the mean night sweats problem rating score was 7.2 (see table 2). 82% of respondents (546/665)

reported experiencing night sweats. 83% of respondents (514/621) had not experienced hot flushes prior to breast cancer diagnosis. In total 643 (97% of 665) reported either hot flushes or night sweats. 73 women (11%) had been taking hormone replacement therapy when they were diagnosed with breast cancer. Not all participants answered all questions. All data is reported where given.

28% (142/506) of women said they had considered stopping taking endocrine therapy because of their HFNS. There were no differences in age group or different treatment (i.e. tamoxifen or aromatase inhibitors) between those who had considered stopping and those who had not.

Oncologists were the most likely health professional to ask women about HFNS (259/665), with around one third (201/665) being asked by their breast care nurses. Surgeons were the least likely to ask (95/665) and 34% (223/665) of women were not being asked by anyone.

Women were most likely to have been offered SSRIs (selective serotonin reuptake inhibitors) or SNRIs (selective noradrenaline reuptake inhibitors) for management of HFNS and, of these, the most common were venlafaxine and citalopram. However, only 25% women had been offered SSRIs and many reported that they had not found them helpful – See table 3. Furthermore, of those who had been prescribed pharmacological interventions large numbers reported side effects (see table 3). The most frequent complementary therapies women reported that their health professionals had suggested were acupuncture (18%) and evening primrose oil (16%) (Table 4). Cognitive behavioural therapy was rarely suggested (2%) and only 1.5% had been offered referral to a menopause clinic. Frequently these treatment options had to be paid for. A number of the interventions were reported as being useful, with exercise, reflexology and cognitive behavioural therapy being most likely to be useful, and black cohosh and evening primrose oil the least likely to be helpful (Table 4).

The most popular form of intervention delivery amongst these women was face to face alone with a health care professional (n=350), followed by on line information (n=234), followed by written information (n=187), with groups (n=148) and over the telephone (n=64) being less popular.

2. Health professional survey

There were 185 health professional respondents, including 23 (12%) surgeons, 70 (38%) oncologists and 80 (43%) nurses. 74% of respondents were women and 26% were men. Overall, 97% of the sample had direct clinical contact with patients. When asked about hot flushes, 94% of respondents agreed or strongly agreed that the management of hot flushes is an unmet need, but reported that only 10 –30% of their patients have severe hot flushes.

Non-hormonal treatments were the most likely to be offered as an intervention for HFNS, particularly selective serotonin (and norepinephrine) reuptake inhibitors. Venlafaxine was the most frequently prescribed, being offered by 76.9% of respondents. Clonidine was also prescribed fairly frequently (by 36.9% respondents). However, a small number of respondents were also prepared to prescribe hormone replacement therapy (12.5%) or progesterone (8%) (Table 3).

Non pharmacologic therapies were offered by health professionals, with some preferring to offer self-management or complementary therapies before offering any medication. 51% suggested exercise, 46% relaxation and 56% suggested psychological services, although only 20% specified cognitive behavioural therapy. The complementary therapy most frequently recommended by health professionals was acupuncture (50%), followed by evening primrose oil (43%). Black cohosh and vitamin E were recommended by 12% respondents. The least likely service to be offered was a

dedicated cancer menopause clinic, presumably because this was not available. Even general menopause clinics were rarely offered and infrequently available (Table 4).

Discussion

Although the sample of health professionals surveyed in this study recognised that HFNS are an unmet need, a sizable proportion (34%) of the group of patients reported that they had never been asked about HFNS. This is of particular concern as 28% women experiencing HFNS also reported that they had considered stopping taking their endocrine therapy because of these symptoms. It is of note that surgeons rarely ask about HFNS, although this could reflect the fact that it is oncologists who are prescribing and monitoring the use of endocrine therapies. It is disappointing that only one third of women had been asked about HFNS by breast care nurses as they could be in a position to support these women. While disappointing, this may reflect current models of care offered by many breast care nurses. Nurse initiated meetings are common around the time of diagnosis and surgery, while ongoing follow up is often left to the patient to initiate. Our findings may reflect limited contact with breast care nurses at a time when people are ending primary treatment for breast cancer and the consequences of treatment are becoming a concern for cancer survivors.

Similar responses were given by patients and health professionals about management of HFNS by both pharmacologic and non-pharmacologic interventions, which suggests that this is a fairly accurate picture of the current prescribing patterns in the UK currently. The majority of health professionals were prescribing SSRIs, but only 25% women in this survey had been offered these and few had found them helpful. Furthermore, most of the women who had tried these medications reported that they came with side effects. Paroxetine and fluoxetine appear to reduce the effectiveness of tamoxifen and so should be avoided in these cases [14]. Although gabapentin and megestrol acetate were generally well tolerated, these were less likely to be prescribed. There is a concern about the safety of progesterones for the treatment of HFNS after breast cancer, as progestogens given as part of hormone replacement therapy increases the risk of developing breast cancer [15]. However, this may not translate into promoting metastatic spread in those already diagnosed with breast cancer and, indeed, new data suggests tumour suppression [16]. The use of gabapentin has declined since the introduction of SSRIs for hot flushes, but there is evidence to show that it may be as effective as venlafaxine [17] and our results indicate lower side effects.

The wide range of treatments that our respondents were receiving suggests that HFNS are not just a problem for those people receiving endocrine therapy, but includes those who had chemotherapy alone.

Health professionals frequently recommended complementary therapies for which there is no evidence, such as evening primrose oil, and some therapies that might be contraindicated, such as black cohosh. There is one small trial on evening primrose oil, which showed it to be ineffective [18]. It is not clear whether black cohosh has oestrogenic effects and liver toxicity has been reported [19]. Health professionals did recommend acupuncture, for which there is some evidence [20] and for some people this is freely available, although not for all. Cognitive behavioural therapy was rarely offered, although there is good evidence that this is helpful for this group of women [21-22] and our patient respondents found it helpful. These findings are supported by a large study of over 10,000 postmenopausal women's use of complementary and non-medical treatments for menopausal symptoms [23]. The study concluded that although more women use over-the-counter medicines, behavioural/lifestyle approaches seem to provide better relief of HFNS. This also fits with our finding that women reported benefit from therapies such as CBT, exercise, reflexology, relaxation and

vitamin E. There is conflicting data on the benefits of exercise and reflexology [24-25]. One study showed a benefit with vitamin E although this was clinically small [26] and there is evidence for the use of relaxation [27]. Due to conflicting data there is a need for further research into therapies such as exercise, reflexology and acupuncture. Given the persistence of recommendation of evening primrose oil and the very limited evidence regarding its benefit there may also be a need for further research in this area. Current NICE guidelines in consultation [28] suggest that women should be referred to specialist menopause clinics; however, this was rarely reported as being offered, nor were they available. There was clear discrepancy around the UK in terms of what was being recommended, what was available and what patients had to pay for.

Limitations

The two surveys were similar but not identical which meant that some direct comparisons could not be made. The patient survey was self-selecting, so is likely to have included women at different stages of cancer as well as those with metastatic disease. It is also likely that the women who elected to answer the survey were those who were troubled by HFNS so that the survey will be biased towards those with problematic HFNS and possibly those who found current management solutions to be ineffective. Our sample may be younger than the norm with most of them being diagnosed between 45 and 54. This is lower than the peak age for diagnosis of breast cancer in the UK population, which is between 65 and 69⁽²⁹⁾. It is likely that those women who were younger at diagnosis will have had a different treatment profile and may have been more likely to experience troubling HFNS.

The health professional survey was targeted at those working in the field of breast oncology, with nearly a quarter responding to the survey. These are likely to be those most concerned about this issue and most aware of the need and potential solutions. People who know little about the subject may be less likely to respond to a survey of this kind.

Conclusion

It is of concern that considerable numbers of women had thought about stopping adherence to adjuvant endocrine therapy to prevent breast cancer recurrence as a result of their HFNS, yet many were still not being asked by any health professional about this issue. There is a need to evaluate current pathways of care to ensure that they are meeting patient need. For example, the establishment of end of treatment clinics may elicit troublesome symptoms. However, even when this problem is being assessed there is clear inequity of access to services and interventions and women are paying for interventions that have been recommended, despite a lack of evidence of effectiveness. At present, clinicians are making individual decisions based on personal experience and availability of local services. The lack of agreed guidelines for managing hot flushes after breast cancer may limit both the access and availability of appropriate interventions.

As a working group, it is evident that there is a need to continue to support an agenda for research into understanding the physiology of flushing and to develop and test new interventions, as well as to drive the implementation of effective interventions, and the development of agreed guidelines for the management of hot flushes and night sweats in the context of breast cancer.

Declaration of Interest statement

None of the co-authors have any conflicts of interest to declare

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 Accessed 12th June 2017

Tables

Table 1: Adjuvant treatments taken by patients

Adjuvant treatment	Number of patients (%)
No treatment	31 (4.7)
Chemotherapy only	110 (16.5)
Trastuzumab only	0
Endocrine therapy only	156 (23.5)
Chemotherapy & Trastuzumab	18 (2.7)
Chemotherapy & Endocrine therapy	264 (39.7)
Trastuzumab & Endocrine therapy	2 (0.3)
All 3	84 (12.6)
Total	665

Table 2: Hot flush/Night sweat scores

	Hot flushes		Night sw	
	n	Mean (SD)	n	Me
Hot flush daily frequency	534	3.0 (1.2)		
Problem	632	6.5 (2.5)	570	7.
Distress	628	6.3 (2.7)	567	6.
Interfere with daily routine	626	5.8 (2.8)	565	7.
Overall HFNS Score	624	6.2 (2.6)	563	7.

Table 3: Drug treatments offered – patient and health professional perspectives

	Detient neverestive (n-CCT)			
	Patient perspective (n=665)			
Drug treatment	Frequency suggested by HP (%)	Side effects*	Helped*	
SSRIs				
Paroxetine (Seroxat)	5 (0.8)	1	1	
Venlafaxine (Effexor)	61 (9.2)	33	29	
Desvenlafaxine	0	0	2	
Fluoxetine (Prozac)	28 (4.2)	10	8	
Sertraline (Lustral)	14 (2.1)	9	9	
Citalopram (Cipramil)	54 (8.1)	22	29	
Escitalopram (Cipralex)	1 (0.2)	4	0	
Gabapentin (Neurontin)	29 (4.4)	11	16	
Stellate ganglion block	0	0	0	
Hormone replacement therapy (HRT)	18 (2.7)	12	21	
Megestrol acetate (Megace)	13 (2)	5	8	
Clonidine (Catapres/Dixarit)	61 (9.2)	25	35	

^{*} Those reporting side effects or whether drugs helped were not necessarily those who reported that HPs suggested

¹¹ women reported currently having neither hot flushes nor night sweats. All have been left in the analysis as it cannot them in the past.

Table 4. Complementary therapies offered to patients – patient and health professional perspectives

Thorany	Pa	Hea		
Therapy	Suggested by HP (%)	Helped (%) ¹	Have to pay (%) ¹	Suggested to patie
Acupuncture	120 (18)	61 (50.8)	43 (36)	92 (50)
Homeopathy	39 (5.9)	20 (51.3)	31 (80)	36 (19)
Relaxation class	62 (9.3)	35 (56.5)	34 (55)	86 (46)
Exercise class	59 (8.9)	48 (81.4)	53 (90)	95 (51)
Reflexology	44 (6.6)	34 (77.3)	26 (59)	64 (35)
Cognitive Behaviour Therapy	12 (1.8)	9 (75.0)	10 (83)	37 (20)
Vitamin E	27 (4.1)	16 (59.3)	29 (100)	23 (12)
Black Cohosh	22 (3.3)	4 (18.2)	17 (77)	23 (12)
Red clover	15 (2.3)	8 (53.3)	17 (100)	-
Evening primrose oil	107 (16.1)	49 (45.8)	96 (90)	80 (43)
Menopause clinic	10 (1.5)	6 (60)	4 (40)	46 (25)
Psychological services	-	-	-	104 (56)
Dedicated cancer menopause clinic	-	-	-	18 (10)
Reiki	-	-	-	32 (17)
Nothing	151 (22.7)	n/a	n/a	-

Notes:

¹ Calculated as a % of those who were recommended the intervention. All other % are given as a proportion of the to

Current knowledge on the subject

- Many women with breast cancer suffer hot flushes and night sweats (HFNS)
- Adjuvant endocrine therapies may contribute to HFNS
- Hormonal interventions are not recommended for HFNS in women who have had breast cancer
- There is a lack of clarity regarding management of HFNS after breast cancer

What this study adds

- 28% women with breast cancer experiencing HFNS consider stopping adherence to adjuvant endocrine therapy because of HFNS
- 34% women never asked by health professionals about HFNS
- Patients and clinicians alike recognise that HFNS are an unmet need
- Health professionals frequently recommend complementary therapies for which there is no evidence or which may be contraindicated
- Despite proven effectiveness cognitive behavioural therapy is rarely offered
- There is inequity of access to services and interventions for HFNS
- There is a need for agreed national guidelines for how to manage HFNS in the context of breast cancer.