Scientific Research

An Evaluation of FaHRAS Computer Programmes' Utility in Family History Triage of Breast Cancer

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Abstract

Introduction: Rapid and appropriate family risk assessment and triage of patients are essential for patients presenting to a symptomatic breast unit and international criteria for review are well established. Family History Risk Assessment Software (FaHRAS) is a computerized program, involving different modalities of risk assessment, which is available but has not been widely assessed. Aims: This study evaluated the FaHRAS software scoring of family history risk. Its analysis was compared to multi-tool family history risk assessment models in a cohort of 353 patients on a historic family history waiting list. Methods: A recent published pilot study assessed and categorized family history risk in 353 patients on a historic family history waiting list, according to international guidelines including NICE criteria, Gail and IBIS risk estimates. The current study involved a reassessment of all 353 patients using the FaHRAS software program to determine its accuracy and ease of use. Patient demographics and time required to perform the analysis were documented. Results: FaHRAS identified 73 (20.7%) patients had an IBIS family history score of 17% or greater and 89 (25.2%) patients met the NICE guidelines criteria for management beyond primary care. In the previous study, this was 79 (22.4%) and 112 (31.7%) respectively. Using the largest denominator (NICE guidelines), 264/353 (74.8%) patients could be discharged to primary care using FaHRAS. Using this largest denominator, FaHRAS also identified a total of 28 (7.9%) patients requiring referral to tertiary care while the previous study identified 3 (0.8%). Conclusion: This is one of the first studies to validate FaHRAS, which is accurate and easy to use. FaHRAS system can enable clinicians to become more efficient gatekeepers to genetic services.

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1. Introduction

Health care initiatives relating to early detection and management of breast cancer have highlighted awareness of breast cancer as a public health issue [1]. This has resulted in increased referral to symptomatic breast services nationally and internationally [2]. Anxiety and fear relating to inappropriate risk assessment, breast cancer diagnosis and its management can confound a rational approach to its management [3].

One of the main reasons for this increased referral is the fact that an individual's relative(s) may have previously been diagnosed with breast cancer which they perceive to put them at increased risk of the disease. Family history is key to risk classification of breast cancer and indeed a positive family history can significantly influence a woman's risk for breast cancer depending on such issues as number and age of the affected relative(s) [4].

However, risk factors relating to family history are not universally well understood [5]. 20 - 30 percent of women with breast cancer have at least one relative with the disease, but only 5 to 10 percent have a true hereditary predisposition [6]. Triaging patients' appropriate family history risk is important to identify those needing increased surveillance and those who can be maintained in family care [7] [8].

NICE has recently updated its Familial Breast Cancer Guidelines and two of its recommendations are that tools such as family history questionnaires and computer packages exist that can aid accurate collection of family history information and they should be made available. In addition the Guidelines state that when accessible in secondary care, a credible carrier probability calculation method should be used as well as family history to determine who should be offered referral to a specialist genetic clinic [9]. Computerized family history risk assessment programs have been available for some time, but have not been widely assessed in symptomatic breast units [10]. In a previous clinical audit of family history risk assessment, a significant number of inappropriate family history referrals and reviews were occurring [11]. A subsequent study showed that the appropriate referrals had increased from 45% to 78% but there was still room for improvement [12]. This risk assessment was cumbersome and time consuming and newer computer programs have been developed to aid in triage. FaHRAS[®1] is a sophisticated evidence-based software system which enables a user to build and store a family history and to run a variety of analyses against their family history to quantify their risk of developing breast cancer.

This study evaluated FaHRAS software ability to triage family history risk referrals and compare its analysis to that previously undertaken using multi-tool family history risk assessment models.

2. Methods

An ethically approved study was undertaken at Letterkenny Hospitals' Breast Unit as a two stage evaluation of family history risk assessment. Letterkenny Hospital Breast Unit, established in 1998 as a satellite to its parent centre 250 km away in Galway University Hospital, is a designated breast cancer service under the National Cancer Control Programme in Ireland [13]. The Breast Unit treats almost 80 new cancer patients per annum, in addition 1800 new patients and 1500 review patients currently attend the Breast Unit. The Unit had a historical family history recall review waiting list of 353 patients. This had built up over a period of 8 years serviced by three different locum breast surgeons.

The first stage of this study reviewed the medical charts of 353 patients on a family history recall list. Risk stratification was objectively assessed using the NICE guidelines, Gail model and modified Tyrer-Cuzick (IBIS) risk assessment tools [9] [14] [15]. The 353 patients were then triaged into GP review or breast clinic review [11].

The second stage of the study, reported in this paper, re-evaluated the data on these 353 patients utilizing the FaHRAS software program. The software was donated from the University of Nottingham spinout company FaHRAS, where it has been developed. The FaHRAS software had been beta tested in two specialist familial breast cancer units before being released. Risk assessment models used included the NICE Guidelines as used by the NHS, IBIS (Tyrer-Cuzick) and BOADICEA Model Risk Assessments [16]. Patient history, including a family history evaluation, was entered into the FaHRAS programme. Their lifetime risk and ten-year risk for the development of breast cancer was documented and the risk of gene defect BCRA 1 and 2 were calculated using the FaHRAS programme. **Table 1** outlines the criteria for referral to primary, secondary and tertiary care utilizing existing best practice guidelines [9]. The accuracy of the software's risk assessment was evaluated by completing a risk assessment on the 353 patients and making a comparison with the risk assessment already com-

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Table 1. Criteria for risk stratification into primary, secondary and tertiary care.

	Primary Care	Secondary Care	Tertiary Care
Lifetime risk of breast cancer	<17%	≥17% - <30%	≥30%
Risk of a BRCA1or BRCA2 mutation	-	-	>20%

pleted on the same 353 patients by clinicians during the above mentioned clinical audit. Further evaluation involved assessing whether the management recommendations of FaHRAS for primary and secondary care would correlate with the triage recommendations which were manually assessed in the clinical audit. The length of time taken to input the data, plot the family tree and to complete the three risk assessments was recorded for the 353 patients.

3. Results

A total of 353 patients' family history and risk factors were assessed using the FaHRAS programme. Mean age of patients assessed was 49.1 ± 11.5 years (range 21 - 76). The distribution of patients reaching the criteria for family history triage review in the first and second stage of this study is shown in **Table 2**.

Using FaHRAS, 73 (20.7%) patients had an IBIS score of 17% or greater. In the first stage 79 (22.4%) reached this threshold value in the audit conducted. Review of the 6 discordant cases identified incorrect data entry relating to age, menopausal status and family history.

In addition 89 (25.2%) patients met the NICE guidelines criteria for management beyond primary care compared with 112 (31.7%) patients meeting the NICE guidelines for referral during the initial clinical audit. **Table 3** demonstrates how FaHRAS changed the triage code from clinical assessment alone, reducing the number referred to secondary care from 109 to 61. It did increase the number referred to tertiary care.

Using BOADICEA risk assessment, 2 (0.25%) patients reached the criteria as high risk for a BRCA1 or BRCA2 mutation and referral to tertiary care was recommended.

The mean length of time taken to complete the risk assessment was 3.9 ± 0.6 minutes, with a range of 3-6 minutes. With increasing experience of using the FaHRAS system, the length of time needed to input the data decreased. The mean length of time taken to input data for the first 100 patients was 4.7 ± 0.5 minutes. In comparison, the mean length of time taken to input data for the final 100 patients was 3.1 ± 0.2 minutes.

4. Discussion

FaHRAS provided an acceptable and reliable means for assessing patients' risk of breast cancer. The study suggested that, using the largest denominator (NICE guidelines) slightly less patients needed review beyond primary care however 7.1% more needed review in tertiary care than the initial reported audit recommended. The differences in triage recommendations highlight the difficulties that can arise in risk stratification of patient with a family history.

There are several reasons why FaHRAS risk assessment using IBIS could be more efficient than the modified Tyrer-Cuzick internet based risk assessment tool which was used in the previous audit. The FaHRAS enables the user to input with systematic thoroughness. The FAHRAS software programme enabled users to obtain a three generation or greater family history of not just breast cancer but many types of cancer and allows updates of family history. The Tyrer-Cuzick risk assessment tool allows users to obtain a three generation family history pedigree which can lead to an underestimated cancer risk as it only allows for a family history of breast cancer to be taken into account [17].

The FaHRAS programme was significantly better at interpreting the NICE criteria for referral to specialist genetic services than the clinician based assessment performed during the audit. It highlights what has been shown in previous studies that computer programmes for interpreting family history of breast and ovarian cancer can produce more appropriate management decisions in comparison to other methods [18]. This study shows that computer based software such as FaHRAS can provide accurate risk assessment and could enable clinicians to be more effective gatekeepers to genetic services [17]. Even following regional education programs initiated in our area referral systems without routine computer aided systems will result in 22% inappropriate referrals [12].

Table 2. Risk stratification of patients based on each risk assessment tool.

	Clinical Audit n = 353			FaHRAS n = 353		
	Primary Care	Secondary Care	Tertiary Care	Primary Care	Secondary Care	Tertiary Care
IBIS	274	79	0	280	71	2
Gail	296	57	0	-	-	-
NICE	241	109	3	264	61	28
BOADICEA	-	-	-	351	0	2

Table 3. Summary of NICE Recommendations in the previous audit and using the FaHRAS programme.

NICE Recommendation	Clinician n = 353	FaHRAS n = 353
Refer to Primary Care	241	264
Manage in Secondary Care	109	61
Offer referral to specialist genetics surveillance	3	28

Although the BOADIECA risk assessment tool was not used in the previous audit, the FaHRAS programme enabled the probability of detecting a BRCA1 or BRCA2 mutations [16]. Previous studies using the BOADIECA model have shown that BOADIECA in comparison to other models can accurately predict the overall number of mutation detected [19]. Two women in this study were classed as "high risk" for a BRCA mutation using the BOADIECA risk assessment. The identification of women who are high risk for a BRCA 1 or BRCA 2 mutation is important as genetic testing can be targeted towards individual patients who are more likely to test positive [20].

The mean length of time taken to input the data into the FaHRAS system does require time which would result in longer consultation times. The mean time to complete a risk assessment was 3.9 minutes over the whole study. This ranged from a mean time of 4.7 minutes for the first hundred patients to 3.1 minutes for the final 100 patients. The FaHRAS programme compares favorably to other computer based programmes which can take up to 15 minutes to input all the relevant data [17]. If computer based programs are used it enables pedigrees to be generated and for family history information to be stored. FaHRAS is therefore ideal in a well resourced breast system and could be completed by trained breast nurses.

This study shows the important role that computer based programmes such as FaHRAS could have in the assessment of patients with a family history of breast cancer. The FaHRAS system could enable clinicians to become more efficient gatekeepers to genetic services and reassure clinicians in their classification of women as low risk who can be managed in primary care. It has facilitated a major restructuring of the manner we undertake our risk assessment, triage and referral process. FaHRAS helped identify that 264/353 (74.8%) at our clinic could have been cared for in primary care. However further development of the FaHRAS could be undertaken to reduce the time required to complete for each patient and have linkages with hospital based computer systems and those in primary care.

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