General practice

Randomised controlled trial of educational package on management of menorrhagia in primary care: the Anglia menorrhagia education study

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Abstract

Objective To determine whether an educational package could influence the management of menorrhagia, increase the appropriateness of choice of non-hormonal treatment, and reduce referral rates from primary to secondary care.

Design Randomised controlled trial.

Setting General practices in East Anglia.

Subjects 100 practices (348 doctors) in primary care were recruited and randomised to intervention (54) and control (46).

Interventions An educational package based on principles of "academic detailing" with independent academics was given in small practice based interactive groups with a visual presentation, a printed evidence based summary, a graphic management flow chart, and a follow up meeting at 6 months.

Outcome measures All practices recorded consultation details, treatments offered, and outcomes for women with regular heavy menstrual loss (menorrhagia) over 1 year.

Results 1001 consultation data sheets for menorrhagia were returned. There were significantly fewer referrals (20% v 29%; odds ratio 0.64; 95% confidence interval 0.41 to 0.99) and a significantly higher use of tranexamic acid (odds ratio 2.38; 1.61 to 3.49) in the intervention group but no overall difference in norethisterone treatment compared with controls. There were more referrals when tranexamic acid was given with norethisterone than when it was given alone. Those practices reporting fewer than 10 cases showed the highest increase in prescribing of tranexamic acid.

Conclusions The educational package positively influenced referral for menorrhagia and treatment with appropriate non-hormonal drugs.

Introduction

Menorrhagia is an important healthcare problem for women of reproductive age.¹ About 5% of these women attend their general practitioner annually.² A high proportion of all gynaecological referrals are for menstrual problems,³ which results in a high cost to health services. In 1993 about 822 000 prescriptions

for treatment of menorrhagia were written, costing £7m.⁴ The number of operations performed in the United Kingdom rose by 5000 in the 5 years to 1993,⁵ exposing more women to the risks of surgery.⁶⁻⁷

Inappropriate prescribing persists across the medical spectrum.⁸⁻⁹ In one survey only 4.5% of patients received tranexamic acid, the most effective first line treatment for menorrhagia.^{4 10-12} Ineffective treatment will lead to referral and a high chance of surgery, with 60% of referred women undergoing hysterectomy.³ Influencing the knowledge of and therapeutic approach to menorrhagia with an educational package could rationalise prescribing and reduce referral rates from primary to secondary care.

Postgraduate education is an established commitment for general practitioners in the United Kingdom.¹³ There is little evidence that traditional lectures, direct mailings, or guidelines result in a sustained change in physicians' prescribing and referral practice¹⁴ without effective development, implementation, and dissemination strategies.¹⁵⁻¹⁷ Consequently there is a need for methods that facilitate learning and change in prescribing and referral practice.

Educational methods that have a sustained effect on physician behaviour exist.^{18 19} These adapt "social marketing" techniques that are based on the principles of "academic detailing" (see box).²⁰ They involve the use of multifaceted interventions with clear educational and behavioural objectives. By using credible independent academic resources, referenced, authoritative, and unbiased sources of information are presented with concise graphic and written materials. Follow up meetings have been shown to double the effect.^{21 22}

We describe the effect of an educational package on the reported treatment of and referral for menorrhagia in primary care in East Anglia.

Subjects and methods

Education package

We used an intervention in the form of an educational package, incorporating many of the effective features of academic detailing.^{18 19} All general practices in East Anglia were approached and invited to participate. One of the research team visited each practice to meet

Principles of academic detailing

- Conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns
- Focusing programmes on specific categories of physicians as well as on their opinion leaders
- Defining clear educational and behavioural objectives
- Establishing credibility through a respected organisational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues
- Stimulating active physician participation in educational interactions
- Using concise graphic educational materials
- Highlighting and repeating the essential messages
- Providing positive reinforcement of improved practices in follow up visits

partners, as an informal group, for an hour. The educational and behavioural aims and our independent funding were stated at the outset. The educational package consisted of four elements: a visual presentation of evidence taken from the literature,^{4 23} a printed referenced summary, a flow chart for management of menorrhagia, and a follow up visit at 6 months.

We used an interactive style to encourage participation and discussion of points relevant to individual participants. A slide presentation of the aetiology and pathophysiology of menorrhagia was given with a précis of the published randomised controlled trials. Deficiencies in current practice were illustrated and the consequences on management of menorrhagia after referral. We concluded with a summary of the health economics. The main elements of the presentation provided a basis for rational treatment.

The summary and management flow chart acted as aides-mémoire and the focus for critical appraisal at the follow up meeting. The flow chart summarised the evidence based decision pathways for women with regular excessive menstruation. The follow up meeting held 6 months later allowed discussion of specific points and reinforcement of the central message. General practitioners suggested how the flow chart could be modified, thus encouraging "ownership": the ideal way to formulate guidelines.²⁴ Control practices received a monitoring visit at this time.

Randomisation and follow up

Randomisation was at practice level. We identified 306 practices from family health service authority lists. A copy of the contents of the educational package was sent to the regional postgraduate education office for approval for educational allowance (2 hours' disease management). All practices were invited to participate by letter. After 2 weeks a phone call was made to each practice to establish their intention to participate, nominate a link partner, and arrange a meeting. This occurred from October to November 1995. Of the 306 practices, 100 were recruited. Before recruitment all practices were given an identifying number and were randomised to receive the educational package or act as controls by using a computer generated randomisa-

tion table. Randomisation was declared after recruitment. Fifty four practices were randomised to educational intervention. A presentation to the intervention groups of the educational package was given, and the control practices received an introduction to the study. Demographic features of the practices were recorded: fundholding status, training practice status, dispensing status, urban or rural location, list size, branch surgery, and proportion of male partners and partners on the obstetric list.

All practices identified women complaining of menstrual symptoms. Doctors recorded symptoms, therapeutic choices, and referral outcomes on pads of data sheets over 1 year. Completed sheets were returned in stamped addressed envelopes and detailed the name, age, consultation date, and yes-no tick box options describing menstrual heaviness, regularity, frequency, and intermenstrual and postcoital bleeding. Duration of symptoms and return visits were also noted. All consultations were recorded on a separate sheet. Doctors were asked to keep the pad of data sheets in the consulting room to remind themselves to identify and record patients with specific menstrual problems. Doctors in the intervention group were asked to place the flow chart prominently as an aide-mémoire. There were no financial incentives to participate in the study.

Analysis

The effect of intervention was assessed at the level of practices rather than patients, although individual patient data were collected. Analysis was performed on an intention to treat basis by using logistic regression to estimate the effect of intervention on the odds of the main outcome variables. These were the proportions of referrals for each practice and the prescribing of tranexamic acid, non-steroidal anti-inflammatory drugs, and norethisterone, unadjusted and adjusted for the effects of practice attributes. Figure 1 shows a time line of the study structure. Ethical approval was obtained from all eight local research ethics committees.

Fig 1 Recruitment, randomisation, and retention of practices in study over time

Table 1 Treatment and referral outcomes of patients with regular heavy periods. Values are numbers (percentages) of women

Detail	Intervention	Control	χ^2 (P value)	Adjusted odds ratio* (95% CI)
Women referred	76 (20)	54 (29)	5.03 (0.03)	0.64 (0.41 to 0.99)
Women not referred	301 (80)	132 (71)		1
Used tranexamic acid	214 (57)	65 (35)	22.852 (<0.001)	2.38 (1.61 to 3.49)
Not used tranexamic acid	163 (43)	121 (65)		1
Used norethisterone	82 (22)	44 (24)	0.0672 (0.8)	0.69 (0.43 to 1.10)
Not used norethisterone	293 (78)	142 (76)		1
Used mefenamic acid	107 (29)	66 (36)	2.5 (0.1)	0.77 (0.52 to 1.15)
Not used mefenamic acid	268 (72)	120 (65)		1

*Adjusted for fundholding status, training practice status, rural or urban location, list size, branch surgery, proportion of male partners, obstetric list qualification, and for those returning more or fewer than 10 data sheets

Results

Ninety five practices (52 intervention and 43 control) returned at least one data sheet, of which 74 (40 intervention and 34 control) had patients with regular heavy menstruation (menorrhagia). Sixteen of the 100 recruited practices withdrew from data gathering, and five practices failed to return any sheets but still participated in the meetings. The reasons were pressure of work, staff shortage, illness, and break up of partnerships.

In the practices recruited there were 245 male and 103 female partners. The mean list size was 6371 in the intervention group and 5368 in the control group ($P=0.2$). In the intervention group 30% of the partners were women compared with 29% in the control group ($P=0.6$). No significant demographic differences between the two practice groups were observed.

In total 1001 completed data sheets were returned from the 95 practices. Five data sheets did not have a practice identifier code and were eliminated from analysis. The median number of forms returned per practice was seven. There were 607 data sheet returns from the intervention group (mean 12; range 1-36) and 394 returns from the controls (9; 1-24); the difference in the means was not significant. Of the data sheets, 563 were for regular heavy periods (377 intervention and 186 control); any with intermenstrual, postcoital, or irregular heavy bleeding were excluded. There was no significant difference in the proportion of consultations reported between the two groups ($P=0.96$).

Referral rates from reported consultations for menorrhagia are shown in table 1. The education

package had a significant effect with referral rates 31% (9/29) lower in the intervention group, adjusted for demographic attributes in the practices. Patients in the intervention group had an increase in odds of receiving tranexamic acid of 2.4, an unadjusted increase of over 63% (56.8/34.9) compared with controls (table 1). Treatment with norethisterone did not differ significantly between the two groups, with 22-24% of all patients receiving it (table 1). Treatment with mefenamic acid was monitored specifically as it is commonly prescribed for menorrhagia or dysmenorrhoea, unlike other non-steroidal drugs. Intervention practices used mefenamic acid less commonly than controls but this was not significant (table 1). Both groups prescribed other non-steroidal anti-inflammatory drugs at the same rate.

Consultations with either no treatment prescribed or after one or more treatments could result in referral. Table 2 shows the proportion of patients treated with tranexamic acid, mefenamic acid, and norethisterone or combinations of treatments who were referred to hospital during the period of the study, for intervention and control groups separately.

A logistic model of the effect of practice attributes on the likelihood of treatment with differing therapies independent of randomisation showed that fundholding or branch surgery status had no significant association with treatment or referral. There was, however, a significant positive association between training practices and prescription of norethisterone (odds ratio 1.71; 95% confidence interval 1.15 to 2.55), also noted with list sizes greater than 5000 patients (1.74; 1.13 to 2.68) and when the proportion of male partners in practices exceeded 75% (1.51; 1.02 to 2.25). Significant associations were also noted between dispensing practices and prescription of mefenamic acid (1.77; 1.23 to 2.54) and urban practice location with prescription of tranexamic acid and mefenamic acid (1.81; 1.3 to 2.53 and 0.57; 0.4 to 0.82, respectively).

There were equal numbers of consultations in practices returning 10 or more data sheets and in those returning fewer than 10 (figure 2). There was a substantially greater effect of intervention on both referral and treatment in those practices returning fewer than 10 data sheets.

Discussion

There is clear evidence that changes in practice were effected. We have shown a lower referral rate and a proportionately higher level of appropriate prescribing with the use of this educational approach. The implications for patients, general practitioners, and the

Table 2 Proportion of patients referred with respect to treatment received and intervention status of the practice. Denominator varies according to number of cases prescribed that particular treatment—for example, in intervention group of 163 women with menorrhagia who were not prescribed tranexamic acid, 26 were referred. For each treatment number of referrals with respect to intervention or control grouping is constant. Values are proportions (percentages) of women

Treatments	Intervention	Control
No tranexamic acid	26/163 (16)	32/121 (26)
Tranexamic acid only	23/132 (17)	13/42 (31)
Tranexamic acid plus other treatments	27/82 (33)	9/23 (39)
Total referrals/total cases	76/377 (20)	54/186 (29)
No mefenamic acid	52/270 (19)	34/120 (28)
Mefenamic acid only	4/42 (10)	8/44 (18)
Mefenamic acid plus other treatments	20/65 (31)	12/22 (55)
Total referrals/total cases	76/377 (20)	54/186 (29)
No norethisterone	49/293 (17)	36/142 (25)
Norethisterone only	9/30 (30)	9/24 (37)
Norethisterone plus other treatments	18/54 (33)	9/20 (45)
Total referrals/total cases	76/377 (20)	54/186 (29)

Fig 2 Cases of menorrhagia reported against proportion referred to hospital from each practice. Equal numbers of cases were reported from practices returning more or fewer than 10 data sheets, thus allowing balanced comparison of reporting behaviour in terms of number of data sheets received and referral and treatment behaviour

health service in terms of cost and outcome are considerable.

Changes in referral

A 31% lower referral rate could result in fewer therapeutic surgical procedures as 60% of women referred with menstrual disorders will have a hysterectomy.³ We have shown a short term outcome that should be monitored in follow up studies.

Participation in a research project and having a special interest in menorrhagia within a practice may constitute an unavoidable bias. There were no restraints placed on communication between practices, but we believe this would be minimised by geographical factors in a predominantly rural area. This pragmatic study set out to change practice in a realistic context and we accept the potential influence of contemporary publications such as *Effective Health Care and Drug and Therapeutics Bulletin*.^{4 25} One of these was released just as the study started and was mentioned by several of the participants at meetings.⁴ Despite all of these factors we still effected a change in practice.

According to prior estimates the 1001 consultation forms returned were 60% less than that expected, an observation made in other studies.² This raises the question of whether our reported referral and prescription rates are representative. That intervention had a definite effect in those practices reporting 10 or fewer consultations suggests that if the true effect of intervention differs from that observed here then it is actually larger. This will be investigated in further work. Reporting more or fewer than 10 data sheets is possibly a reflection of forgetfulness to record data, as found in other studies.²

Decision making

The referral process is complex. The patient is influenced by many factors: severity of symptoms,

other problems, relatives' and their own preconceptions and attitudes. Influences on the doctor include training, attitudes, interviewing techniques, and confidence in managing the particular symptom pattern.²⁵ Within a group of doctors with differing educational needs a reluctance to change treatments may occur for economic reasons, lack of interest, or doubts about the relevance of the advice.²⁶ A "research-practice gap" is suggested by Dowie to explain this difference between perception of information and its value to practitioners.²⁷ Educators must bridge this gap as research findings are often reflected belatedly or not at all in the prescribing behaviour of physicians.^{9 28 29} The challenge faced by our study group was to deal with all these points.

Changes in treatment

Despite published randomised controlled trials, tranexamic acid has remained a little used drug.¹⁰ Our educational package emphasised the low risk of antifibrinolytic drugs and encouraged their use as the rational first line treatment. Consequently an increase of 63% in the prescription of tranexamic acid was observed in the intervention group and, when the drug was given as a single agent, 45% (17 v 31) fewer referrals were made. The education package seemed to give participants the confidence to use tranexamic acid, which may be due to "demystification" of the drug, observed benefits, and patient feedback.

More appropriate prescribing at the primary care stage should lead to fewer referrals to hospital. Referral rates stratified by prescribed treatment are set out in table 2. Our intervention seems to be associated with a lower rate of referral. Higher rates of referral were observed in association with the less effective norethisterone as single agent treatment compared with other single treatments. Combinations of treatments were invariably associated with higher rates as they presumably reflect failed first line treatment or cases less amenable to any given treatment. There was, however, a reluctance to give up an "old favourite," suggesting that education failed to convince participants of the established negative aspects of norethisterone.^{11 30-32}

Of the practices' demographic features that influenced treatment, urban location seemed to favour tranexamic acid, and this significant change in prescribing practice may reflect a greater susceptibility to educational themes. A high proportion of male partners, larger list size, and being a training practice, however, were associated with higher prescribing of norethisterone. There may be less awareness among male partners, perhaps in larger practices, of the disadvantages of norethisterone. It is surprising that training practices should prescribe the relatively ineffective norethisterone more often. This suggests that maintaining knowledge in this topic is a particular issue for trainers.

Study design

The prevalence of objectively measured menorrhagia is half that expressed by patients subjectively.³³ The use of the subjective complaint of "regular heavy loss that is a problem for the patient" allowed general practitioners to record and manage consultations that pragmatically reflect the real clinical problem as objective

Key messages

- Menorrhagia (regular excessive menstruation) affects many women and treatment is a considerable use of resources
- Appropriate non-hormonal treatments are not always offered before referral, which often results in therapeutic surgery
- An educational package with independent academics in small informal groups presenting visual, graphic, and written material can positively influence doctors' behaviour
- Increasing appropriate non-hormonal treatments for menorrhagia results in fewer referrals

measurements of menstrual loss are not routinely available.

This study used techniques that significantly influence behaviour^{19 22 34} and is a model for future postgraduate education strategies. Further research into methods of sustaining change in practice is needed.

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Competing interests: None declared.

Contributors: GRKF was involved in study design, implementation of the educational package, study management, data collation, analysis, and paper preparation and approval. AP was involved in conception, study design, funding, implementation of the educational package, analysis, and paper preparation and approval. TG was involved in the implementation of the educational package, study management, data collation and analysis, and paper preparation and approval. RMN was involved in data collation, analysis, and paper preparation and approval. SWD was involved in conception, study design and funding, and paper preparation and approval. NED was involved in conception, study design and funding, and paper preparation and approval. SKS was involved in conception, study design and funding, and paper preparation and approval. GRKF and AP are the guarantors.

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Endpiece

For a fee

Who in the rainbow can draw the line where the violet tint ends and the orange tint begins? Distinctly we see the difference of the color, but where exactly does the first one visibly enter into the other? So with sanity and insanity. In pronounced cases there is no question about them. But in some cases, in various degrees supposedly less pronounced, to draw the line of demarcation few will undertake, though for a fee some professional experts will.

Billy Budd, Herman Melville,
Dale Books, 1978

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