

REDUCING CONSULTATIONS FOR CYSTITIS THROUGH HEALTH EDUCATION

RESEARCH STUDY -- Quantitative with supplementary Questionnaire

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SES/800/042195

ABSTRACT

OBJECTIVE - to evaluate the health education leaflet "Cystitis and what to do about it!" produced by the Health Education Board for Scotland and aimed at reducing recurrence of cystitis.

DESIGN - controlled trial comparing outcomes between patients receiving educational leaflets and controls.

SUBJECTS - 70 women diagnosed with cystitis at general practice consultations at two city practices over 6 weeks.

OUTCOME MEASURES - number of patients with further general practice consultations for cystitis in the 12 weeks following education; patient questionnaires and interviews.

RESULTS - 37% (95% confidence interval (C.I.): 17 to 57%) reduction (from 51% to 14%; $\chi^2 = 10.94$; $p < 0.001$) in number of patients re-consulting in education group compared with controls; good acceptance by patients of leaflet.

CONCLUSION - the use of this leaflet is associated with a statistically significant reduction in the number who re-consult for cystitis. Comments on the design of future studies are incorporated.

INTRODUCTION

Evidence suggests that over 50% of women in the UK suffer from cystitis at some point in their lives, some repeatedly, and that cystitis accounts for just over 1 % of general practice consultations.' The population morbidity and cost to the NHS are therefore appreciable.'

Previous studies have demonstrated the value of health education in affecting disease outcomes and resource utilisation in asthma^{3,4} and Parkinson's disease⁵. A study into the effect of health education to prevent urinary tract infection in spinal cord injury patients⁶ showed some encouraging results.

One study has considered the use of health education aimed at preventing recurrent urinary tract infection. 34 patients were assigned to education or control groups and followed up for three months to find their rates of recurrence for urinary tract infection. The educational intervention consisted of presentations and discussion. A reduction of 0.71 (from 2.18 to 1.47) in the mean number of urinary tract infections per patient at three months between the groups was present although not statistically significant. A statistically significant reduction in the mean number of urinary tract infections per patient was observed within the education group during the three months after education compared with the three months before education (from 2.47 to 1.47). However, a reduction also occurred in the control group although it was smaller (from 2.46 to 2.18) and not reported as significant.

Factors that have been implicated in the development of recurrent cystitis include frequent sexual intercourse, lack of voiding after intercourse, poor feminine hygiene, back to front wiping, low fluid intake, infrequent voiding, intravaginal tampons, chemical agents including deodorants and douches.⁷⁻⁹ A leaflet published by the Health Education Board for Scotland¹⁰ addresses some of these issues, and suggests measures to follow to attempt to prevent cystitis, as well as giving guidelines on what to do if an attack starts. This study considers the use of this leaflet by women who present with symptoms of cystitis to their general practitioners.

METHODS

SUBJECTS

The setting of the study was two city general practices (Practice 1 & Practice 2), consisting of a total of sixteen general practitioners and 23000 patients, many living in socially deprived conditions. Practice 1 was a Primary Care Purchasing Initiative practice; Practice 2 was non-fundholding. 70 non-pregnant women aged 15-80 diagnosed by their general practitioners as having the clinical features of cystitis were entered into two groups. One group was given an education leaflet ° (education group) and a covering letter, and the other group was left alone (control group). Each general practitioner or surgery room was supplied with a yellow and a green form for entering details of ten recruited patients to each of the education and control groups respectively. It was requested that the first ten patients presenting to each general practitioner or surgery room would be recruited to the education group, and then controls for the remainder of the six week recruitment period. This method of randomisation whilst rather simple was chosen over a more complex method (e.g. sealed envelopes) to maximise co-operation of the practices. Priority was placed on recruiting the education group because it was thought that control patients with cystitis could be identified from microbiology laboratory records of urine samples in the event of a shortfall of predicted recruitment. Numbers of patients in each group and a comparison of baseline characteristics are shown in Tables 1 & 2. It can be seen that the ages of the patients in each of the groups are statistically comparable as their confidence intervals overlap. Comparing the proportions of patients who had cystitis in the 12 weeks before recruitment into the study indicates that the education and control groups were similar at baseline ($\chi^2 = 0.00$; $p = 1.00$) and also that the two practices were similar ($\chi^2 = 0.13$; $p = 0.72$).

Table 1: Sources of patients

| Group | Practice 1 | Practice 2 |
|-------------------|------------|------------|
| Education | | |
| <i>Recruited</i> | 14 | 21 |
| Control | | |
| <i>Recruited</i> | 1 | 16 |
| <i>Laboratory</i> | 13 | 5 |
| <i>Total</i> | 14 | 21 |
| Total | 28 | 42 |

Table 2: Baseline characteristics

| Group | Mean age \pm 95% C.I. | Number with cystitis in last 12 weeks (%) |
|-------------------|-------------------------|---|
| <i>Education</i> | 37.5 \pm 5.5 | 7 (20%) |
| <i>Control</i> | 45.5 \pm 6.2 | 7 (20%) |
| <i>Practice 1</i> | 40.7 \pm 6.5 | 5 (18%) |
| <i>Practice 2</i> | 42.0 \pm 5.6 | 9 (21%) |
| <i>All</i> | 41.5 \pm 4.2 | 14 (20%) |

SAMPLING

A sample size of just over 120 patients was calculated as necessary to give 70% power at 5% significance level. This was assuming re-consultation rates at 12 weeks of 40% (control group) and 20% (education group), a halving of re-consultation rate being the effect defined as clinically useful. The control group re-consultation rate was estimated on the basis of data in the Appendix. Out of a patient group of 23000, about 70 would be expected to consult for cystitis during the six week recruitment period available (incidence at general practitioner consultations is 268 per 10000 female person years in the 16-74 age group"). 52 patients were in fact recruited during the six weeks (Table 1). These patients were unequally distributed between the education and control groups with 14 recruited to the education group and only one to the control group in Practice 1, and 21 recruited to the education group and 16 to the control group in Practice 2. Practice 1 was still collecting the education group by the end of the recruitment period, with the one control patient being someone whom a doctor had recruited, but had accidentally forgotten to also give the patient a leaflet. In Practice 2, it transpires that some of the doctors were aiming to recruit to the education group first, but others in the same practice were alternating recruitment to the education and control groups. The possible effects of this unequal randomisation will be considered later. Further patients were identified by reference to the microbiology laboratory records of urine samples sent from the practices over a similar time period as patient recruitment occurred. 18 patients were recruited as controls in this fashion to even out the sizes of education and control groups to increase statistical efficiency, bringing the total number of patients in the study to 70, split equally between education and control groups.

RECORD SURVEY

The two groups were followed up for 12 weeks from their presenting consultation by reference to their notes to find the number of further consultations for cystitis. Consultations within a week of the original or those that appeared to be persistence of the original infection were not included. Consultations were recorded by week after the initial consultation.

QUESTIONNAIRES & INTERVIEWS

Information was also sought from all 35 in the education group by postal questionnaires. Interviews were requested and carried out with the two who were willing. Interview questions were open-ended, focusing on patient views about the leaflet and its perceived benefits. Seven patients replied to the first questionnaire and three to a second mailing which omitted the question about willingness to be interviewed.

RESULTS

RECORDSURVEY

In the 12 weeks following intervention, the two practices remained similar in their proportions of re-consulting patients ($\chi^2 = 0.02$; $p = 0.89$). However, when the education and control groups are compared it can be seen from Tables 3 & 4 that there were large, statistically significant reductions in the proportion of patients re-consulting. There is still a significant result taking either practice alone and comparing the education and control groups, or using control groups that were either recruited by doctors or found from microbiology laboratory reports. When the control group was split into recruited and laboratory derived patients within the practices, the subgroups became too small to analyse usefully.

Table 3: Re-consultations for cystitis over 12 weeks

| Group | No consultations | Consultations |
|-------------------------------|------------------|---------------|
| <i>Practice 1</i> | 17 | 11 |
| <i>Practice 2</i> | 20 | 12 |
| Education | | |
| <i>Practice 1</i> | 12 | 2 |
| <i>Practice 2</i> | 18 | 3 |
| Total | 30 | 5 |
| Control | | |
| <i>Recruited^a</i> | 8 | 9 |
| <i>Laboratory^b</i> | 9 | 9 |
| <i>Practice 1</i> | | |
| Recruited ^a | 0 | 1 |
| Laboratory ^b | 5 | 8 |
| Total | 5 | 9 |
| <i>Practice 2</i> | | |
| Recruited ^a | 8 | 8 |
| Laboratory ^b | 4 | 1 |
| Total | 12 | 9 |
| Total | 17 | 18 |

^athe part of the control group who were recruited at consultations; ^bthe part of the control group who were identified from laboratory reports.

Table 4: Significance testing

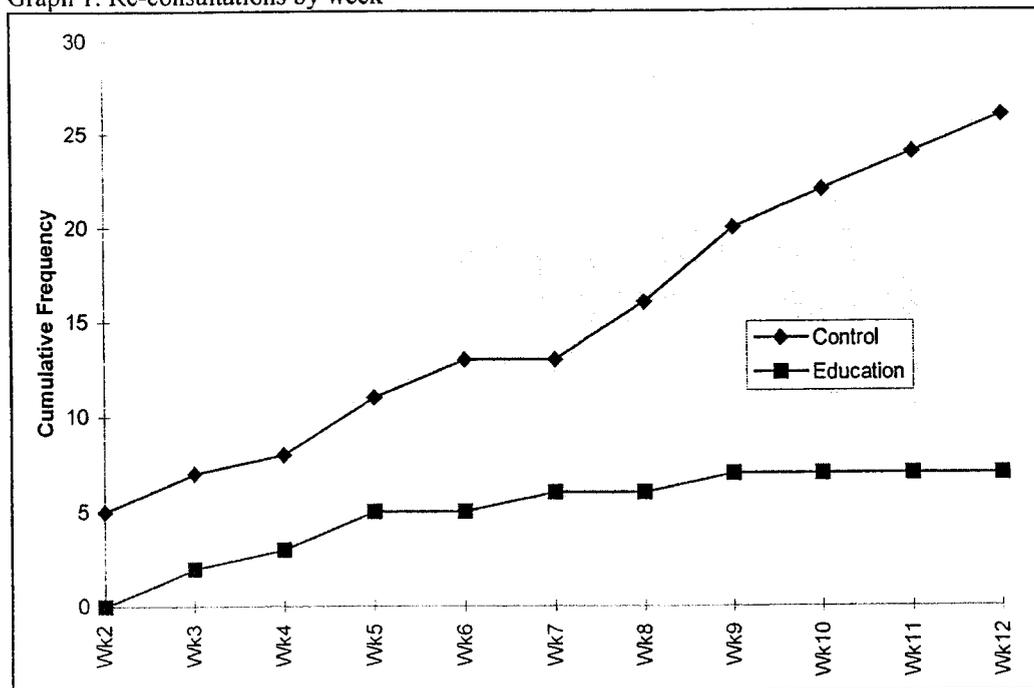
| Education vs Control | % reduction \pm 95% C.I. | χ^2 | p |
|-------------------------------|----------------------------|----------|----------|
| <i>Recruited^a</i> | 39 \pm 26% | 8.69 | 0.0032 |
| <i>Laboratory^b</i> | 36 \pm 26% | 7.80 | 0.0053 |
| <i>Practice 1^c</i> | | | |
| Recruited | 86 \pm 12% | 4.29 | 0.039 |
| Laboratory | 47 \pm 29% | 6.45 | 0.011 |
| Total | 50 \pm 28% | 7.34 | 0.0067 |
| <i>Practice 2^d</i> | | | |
| Recruited | 36 \pm 27% | 5.54 | 0.019 |
| Laboratory | 6 \pm 37% | 0.10 | 0.75(NS) |
| Total | 29 \pm 24% | 4.20 | 0.040 |
| <i>Total^e</i> | 37 \pm 20% | 10.94 | <0.001 |

^awhole of education group compared only with the part of the control group who were recruited at consultations; ^bwhole of education group compared only with the part of the control group who were identified from laboratory reports; ^ceducation group in Practice 1 compared with control group in Practice 1; ^das c but Practice 2; ^ewhole of education group compared with all controls together.

Analysis also revealed the highest reduction in the 15-29 age group in numbers of patients re-consulting (49% reduction; $\chi^2 = 5.30$; $p = 0.021$). Smaller, less significant reductions were seen in older age groups.

Graph 1 shows the natural history of the control group over the 12 week follow up as the cumulative frequency of return visits, and the modified history of the education group who had fewer re-consultations at all points.

Graph 1: Re-consultations by week



QUESTIONNAIRES

Table 5 shows the results of the postal questionnaires. The response rate was disappointing even with a second mailing. Patients were asked whether they had read the leaflet, whether it had been useful, whether they had learnt anything, whether they had followed any of the guidelines on preventing further attacks, and whether they would recommend the leaflet to a friend with a similar problem. The majority of the patients who responded had read the leaflet and found it very or quite useful, with 8 out of 10 learning and recommending, and 6 out of 10 following guidelines.

INTERVIEWS

The two patients that were interviewed were very positive about the leaflet. One said, "I didn't know much about it [cystitis] before... but reading it [the leaflet] just seemed to open it up to me." She told how she was a diabetic and used to get cystitis "all the time", but has had no problems since receiving the leaflet, and found the leaflet "really useful". The other patient told how she had changed her nylon underwear for cotton and how she thought this had helped. Both of the patients who were interviewed had answered in the most positive sense to nearly or all the items on the returned questionnaires.

Table 5: Questionnaire results

| Group | 1st mailing | 2nd mailing | Total |
|-------------------|-------------|-------------|-------|
| Responders | 7 (of 35) | 3 (of 28) | 10 |
| Read? | | | |
| Yes | 7 | 2 | 9 |
| No | 0 | 0 | 0 |
| Partly | 0 | 1 | 1 |
| Useful? | | | |
| Very | 3 | 1 | 4 |
| Quite | 4 | 1 | 5 |
| Useless | 0 | 1 | 1 |
| Learning? | | | |
| Yes | 6 | 2 | 8 |
| No | 1 | 1 | 2 |
| Follow? | | | |
| Yes | 5 | 1 | 6 |
| No | 2 | 2 | 4 |
| Recommend? | | | |
| Definitely | 6 | 2 | 8 |
| Maybe | 1 | 1 | 2 |
| No | 0 | 0 | 0 |

DISCUSSION

STATISTICAL POWER

Two factors increased the statistical power of the study over that expected. Firstly, the control group re-consultation rate was higher than expected at 51%. Secondly, the education group re-consultation rate was 17% which is a reduction to a third of that of the controls. These factors give the study nearly 90% power at 5% significance level.

RECRUITMENT & RANDOMISATION

Randomisation was one of major methodological problems of this study. As was seen in the methods, different doctors randomised their patients differently. It may be that at the simplest level they just gave out leaflets as they felt appropriate in a random but not randomised fashion. However, it would seem clear that despite poor randomisation techniques, there was no obvious selection bias as the education and control groups were similar in age and in their histories of cystitis in the 12 weeks before the start of the study. It is also evident that the different methods of randomisation in the two practices did not really matter as both had similar results and the practices as a whole (taking the education and control groups together) were also similar in their cystitis histories both in the 12 weeks before and after recruitment into the study. The method of recruiting extra controls can be seen not to have been a confounding factor as exclusion from analysis does not alter the significance of the result.

THE INTERVENTION

It is possible that differences in reading ability between patients could be a confounding factor. Compliance with instructions in the leaflet is unknown. The only hint of compliance is the self-reported questionnaire items regarding whether the leaflet was read, and whether anything was learned and followed. Self-reported behaviours may not be accurate, and also since such a small proportion of questionnaires were returned, it is very possible that the selection returned were not representative of the whole group. The three responders to the second mailing were less positive about the leaflet.

CLINICAL USEFULNESS

In practice, this leaflet would be used at the discretion of the practitioner with patients who were felt to have cystitis. Cystourethritis, cystitis and urinary tract infection are terms which are used somewhat interchangeably, incorporating irritative lower urinary tract symptoms, asymptomatic bacteriuria, significant bacteriuria and the urethral syndrome.' As the interpretation of the term "cystitis" will vary between practitioners, the term was left undefined to more accurately reflect the potential use of the leaflet.

As well as aiming to prevent recurrent cystitis by modification of behaviour, the intervention leaflet has a section on what to do when an attack starts; a 3 hour plan of self-treatment is presented which may in part be responsible for the lower rate of re-consultation amongst the education group. This reduced resource utilisation is obviously beneficial in an economic sense, as well as empowering the patient to manage their own illness where appropriate. Guidelines in the leaflet encourage the patient to consult their doctor if they are pregnant, if they have haematuria or if the attack lasts for longer than a day or two.

CONTAMINATION OF GROUPS IN PRACTICE STUDIES

In any community based study there is a real possibility of contamination between the groups: individuals who have received the leaflet may have had contact with or even lent the leaflet to some of the control group. It is also possible that the results of this study may not be generalisable due to the possible additive effect of the letter given out with the leaflet. A similar effect could also occur due to the fact that 24 out of the 35 follow up questionnaires were sent out before the end of the 12 week follow up period, the assumption being that receiving a questionnaire may itself be a further intervention. However, even for the last recruited patient, their questionnaire was received after at least seven weeks' follow up. Analysis on seven weeks' follow up for all patients showed a 17% reduction in numbers re-consulting between education and control groups (from 31% to 14%; $X_z = 2.92$; $p = 0.087$). Whilst not statistically significant, the result was strong considering the short follow up interval. It would therefore seem unlikely that the questionnaire significantly affected the results. Both interviews occurred after the end of the 12 week follow up period.

COST

The only cost in this study of the education programme was the supply of the leaflets, which is minimal. For the 35 patients in the education group, only 7 further consultations occurred in the 12 weeks following intervention compared with 26 in the control group. This represents an opportunity cost saving equivalent to 19 consultations, which assuming a consultation time of 7.2 minutes per patient³ totals 137 minutes. If these results are generalisable, the use of this leaflet would seem a cost-effective means of preventing further consultations for cystitis.

FURTHER WORK

The principal problem with this study was randomisation, the limits of time resulting in selection of simple methods. Greater resources would provide the opportunity to remove uncertain selection biases and incorporate variables such as educational achievement, ethnicity, consulting background and symptom complexes present in the initial episode which have been shown to be predictors of recurrence⁴. Such studies would be useful in establishing further the benefits of this leaflet.

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APPENDIX

CONTROL GROUP RE-CONSULTATION RATE

In one study,[§] 18% of women with a urinary tract infection had a further infection in the three months following the initial episode. Both the initial infections and the recurrences were culture confirmed rather than based on clinical features as in this study. Another study[¶] found a mean of 2.18 (standard deviation = 1.13) recurrences of urinary tract infection per patient in a three month period. Assuming a normal distribution, then it can be estimated that about five out of six of these women experienced at least one recurrence (since one standard deviation below the mean is just over one recurrence per person and one tail of a normal distribution that starts at one standard deviation from the mean represents about one out of six of the distribution). However, the patients in this series were in an out-patient setting. National morbidity statistics^{||} showed an average (in the 16-74 age group) of 244 individuals presenting to their general practitioner with cystitis per 10000 person years, but 326 consultations. This implies that up to one third re-consulted at some time within the next year. Further data gleaned from examination of microbiology laboratory records showed that between a third and a half of individuals submitting a urine sample had another one sent in the three months following. All the above data provide a guide as to the possible re-consultation rate in 12 weeks, which was predicted for this study as 40%.

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