The Journal of Laryngology & Otology (2014), ***128***, *249–254*.

doi:10.1017/S0022215114000449

MAIN ARTICLE

Prospective, randomised, controlled trial comparing delivery of patient information for functional endoscopic sinus surgery via website versus printed leaflet

S HENNEY[1], R IRVING[2]

[1]*Department of Otorhinolaryngology, South Warwickshire NHS Foundation Trust, Warwick Hospital, and*
[2]*Department of Otorhinolaryngology, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital, UK*

Abstract

Objective: To compare the efficacy of two modes of delivery of information for patients undergoing functional endoscopic sinus surgery: website and printed leaflet.

Methods: A two-centre, prospective, single-blinded, randomised, controlled trial was conducted, comparing mode of information delivery. Adult patients were randomly allocated to receive pre-operative information regarding functional endoscopic sinus surgery, either via a website or a printed leaflet. Primary outcomes, measured by questionnaire, were: readability, usability and recall of complications.

Results: Fifty-eight patients were recruited. Fifty met the inclusion criteria, of which 40 were analysed in the study (20 patients per group), meeting the power criteria set. There were 18 male and 22 female patients, ranging in age from 21 to 76 years (mean, 47 years). Patients found both the printed leaflet and the website readable, and were satisfied with the usability of both modes. There were similar rates for recall of complications in both study arms.

Conclusion: Patient information on functional endoscopic sinus surgery can be provided either as a printed leaflet or a website, with similar rates for usability, readability and recall of complications. These findings could help tailor the provision of pre-operative information for patients undergoing functional endoscopic sinus surgery, based on patient preference.

Key words: Endoscopy; Informatics; Otorhinolaryngologic Surgical Procedures; Paranasal Sinuses; Disease; Complications; Patient Satisfaction; Questionnaires

Introduction

It is important that patients understand the indications for any planned surgery, as well as the potential benefits and risks. It is obligatory for a patient to be well informed before they provide consent. The General Medical Council document entitled 'Consent: patients and doctors making decisions together' (2008)[1] states that clinicians have a legal and moral obligation to disclose specific information. This includes the nature and purpose of treatment, its benefits and potential risks, the consequences of not receiving it, and any alternative therapies available.

Studies have shown that many patients have insufficient knowledge of the surgery they are about to undergo, and often, alarmingly, little understanding of potential complications.[2,3] Standardised, well-written patient information leaflets are available at most ENT departments and are produced by ENT UK. This information is widely distributed at the consultation stage. It is unclear if this printed information is the most effective way of helping to inform patients prior to surgery. This study therefore set out to compare modes of pre-operative patient information provision.

In a survey of 300 British adults by Coulter and Ellins,[4] 80 per cent of people said they were likely to seek out health information from sources other than their healthcare provider. Sources of information, in order of decreasing frequency, were: doctor, internet and/or websites, followed by leaflets and/or books.

There are a number of features that make a website an attractive medium of information delivery, such as instant and continuous availability, options for interactivity, and the potential to provide immediate feedback.[5] Another possible advantage is that larger numbers of people can

Accepted for publication 24 June 2013

be reached at a lower cost, as compared with printed information.[6] However, here may be disadvantages to providing patient information via a website; for instance, it may be more difficult to read or process information from a computer screen.[7]

Unfortunately, a significant proportion of patients do not understand and may forget much of the pre-operative information given to them. This study endeavoured to investigate whether a newer mode of communication, a website designed to provide patient information, would be of benefit to patients undergoing surgery.

Recalling the risks of surgery is one technique for gauging how much of the information provided has been processed and remembered. Several studies in the head and neck surgical literature have reported poor patient recall of pre-operative information.[2,3] Overall, the patient recall rate of potential surgical complications was 39–48 per cent.

Functional endoscopic sinus surgery (FESS) is a commonly performed procedure; it has a number of associated risks, some of which are potentially serious.[8] The occurrence of complications resulting from FESS remains one of the greatest sources of litigation facing otorhinolaryngologists today.[9]

The present study aimed to investigate whether, in addition to standard oral pre-operative information provision, a website-based mode of information delivery was more effective than printed patient information leaflets. The findings may help in providing appropriate information in the mode most suitable for individual patients undergoing FESS.

Materials and methods

Trial design

This study was a two-centre, prospective, single-blinded randomised, controlled trial (RCT) (Figure 1).

Participants

The study comprised adult patients (aged 16 years or over) scheduled to undergo FESS or endoscopic nasal polypectomy. Those patients without access to the internet were excluded.

A pilot study was conducted, in which satisfaction with patient information was assessed. The pilot study was designed to gather information prior to the RCT, to inform a sample size calculation. It was calculated that 38 patients would be required (19 in each (website or printed leaflet) arm) to detect a significant reduction in satisfaction (a 1-point reduction on a 5-point scale) between groups with 80 per cent power and 95 per cent confidence. In order to recruit the required number of patients in the time frame available, two busy units formed this two-centre trial.

Study settings

The settings were the ENT departments at the University Hospital Birmingham and the University Hospital North Staffordshire, UK.

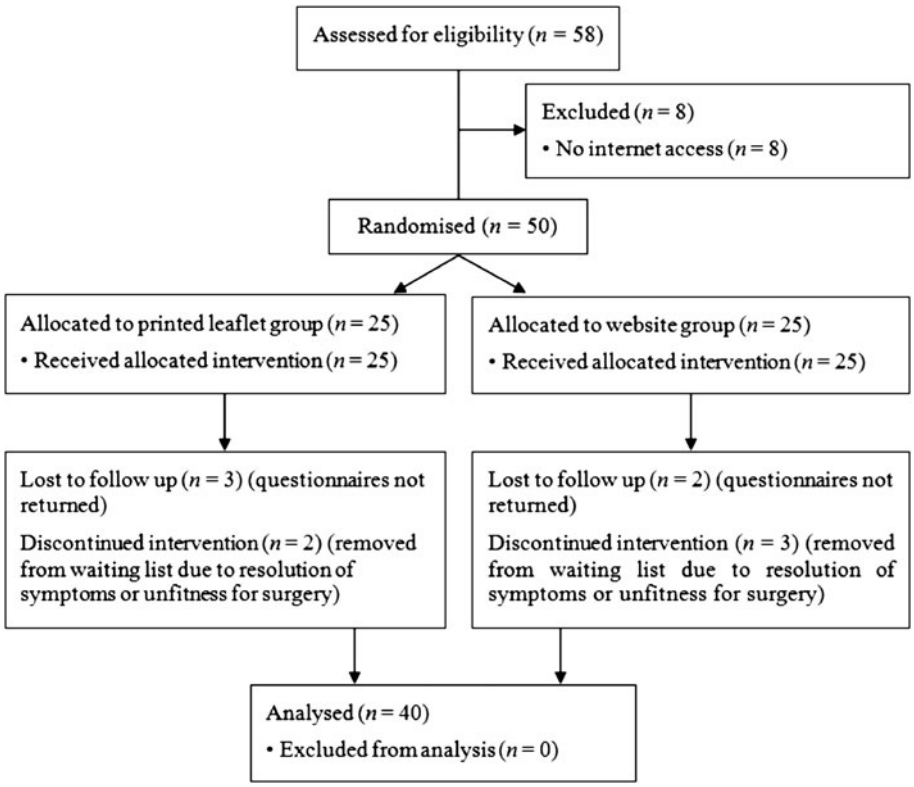

FIG. 1
Study protocol flow diagram.

https://doi.org/10.1017/S0022215114000449 Published online by Cambridge University Press

Randomisation

In order to balance group sizes in this relatively small RCT, a form of restricted randomisation was used. Randomisation was carried out using a random permuted block system.

Interventions

In addition to the provision of verbal information, which outlined the management options along with the associated benefits and risks, all patients received pre-operative information that was either website-based or presented in the form of printed leaflets.

The content of information provided was identical. The website address (for the website-based information)[10] was printed on a sheet of A4 paper in a sealed envelope for the website group. Those in the printed leaflet group received the same information, printed as a leaflet, again enclosed in a sealed envelope. A standard method of ensuring allocation concealment was used, namely, sequentially numbered, opaque, sealed envelopes, held in the out-patient departments.

Blinding

Demographic data including age and gender were collected once consent to participate had been obtained. All further data were collected with the use of questionnaires. Two questionnaires were posted to patients, 7 days following surgery, with a pre-paid return addressed envelope. Questionnaires were scored by a researcher who was blinded to the intervention patients received.

Outcome measures

Three primary outcome measures were used to compare the two modes of information provision, namely the recall of complications, and the patients' impressions of readability and usability. In the first questionnaire (Appendix 1), patients were asked to recall as many of the complications associated with their surgery as possible, with a potential maximum of three (i.e. bleeding, eye problems and spinal fluid leak). The other outcome measures, readability and usability of information mode, were assessed in the second questionnaire (Appendix 2). Responses to statements referring to the readability and usability of information mode were made on five-point Likert-type scales. Patients specified their level of agreement or disagreement on symmetrical agree–disagree scales. Thus, the scales (ranging from 1 = strongly disagree to 5 = strongly agree) captured the intensity of patients' feelings.

Statistical methods

Non-parametric tests were used throughout the analysis as the data were ordinal in nature. The Mann–Whitney U test was used to examine differences between the two information mode groups (printed leaflet *vs* website) for each of the outcome measures (readability, usability and recall of complications).

Results were deemed statistically significant if $p < 0.05$. All statistical analyses were conducted using the Statistical Package for the Social Sciences software, version 17.0 (SPSS; IBM, Armonk, New York, USA).

Ethical considerations

Full applications for approval to conduct the research were submitted (using the Integrated Research Application System) to the National Research and Ethics Service and local research ethics committee, and applications for research governance approval were submitted to the National Health Service research and development office committees. The committees approved the ethics of the research.

Results

A total of 58 patients were recruited; 8 patients were excluded from the study because they did not have internet access. Five participants were lost to follow up, and 5 were removed from the waiting list because of resolution of symptoms or medical ill health, leaving 40 patients. There were 18 males and 22 females, ranging in age from 21 to 76 years (mean, 47 years). Twenty patients received website-based information only and 20 received printed information leaflets only. Sixteen patients were recruited from the University Hospital Birmingham and 24 from the University Hospital North Staffordshire.

Data summary

Data on patients' impressions of readability and usability for the two delivery modes, and on patients' recall of complications, are shown in Table I and in Figures 2–4.

The median readability score was 4 for both groups; the interquartile range was also identical (4–5). Both the printed leaflet group and the website group had a

TABLE I
READABILITY, USABILITY AND RECALL DATA

Parameter	Readability*		Usability*		Complication recall†	
	Leaflet	Website	Leaflet	Website	Leaflet	Website
Median	4	4	4	4	2	2
Interquartile range	4–5	4–5	4–5	3.75–5	1–3	1–2.75
Range	3–5	3–5	3–5	3–5	0–3	0–3

*Scale of 1 to 5; †scale of 0 to 3.

https://doi.org/10.1017/S0022215114000449 Published online by Cambridge University Press

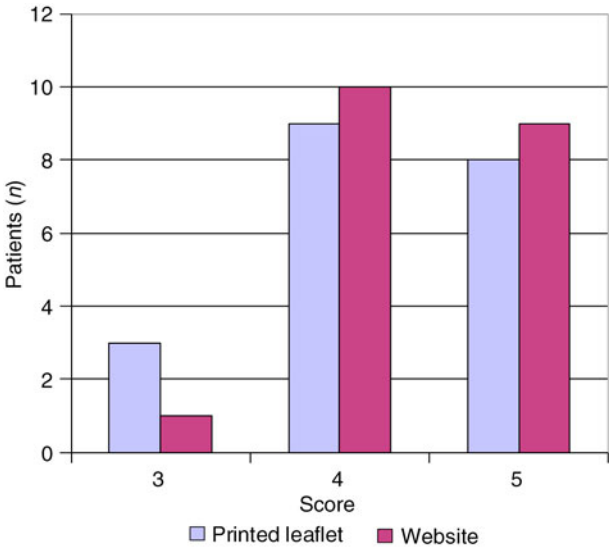

FIG. 2
Readability scores for printed leaflet versus website.

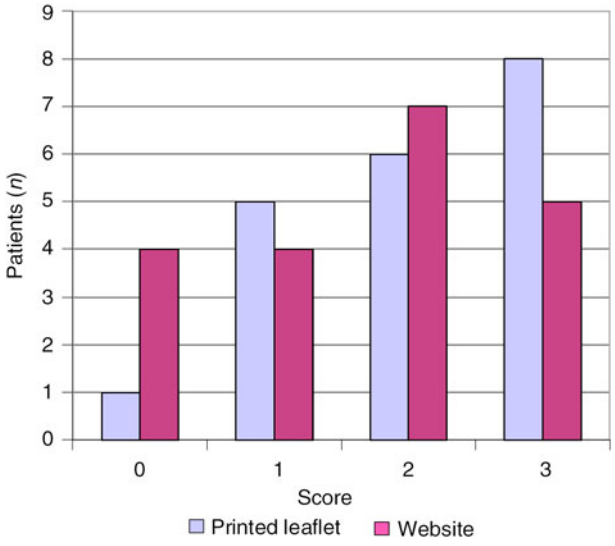

FIG. 4
Recall scores for printed leaflet versus website.

median usability score of 4; the interquartile range was greater for the website group. In contrast, the interquartile range for the recall of complications was smaller in the website group than in the printed leaflet group, but the median number of items recalled was identical at two items for both groups.

The frequencies of favourable readability scores were similar for both the printed leaflet group and the website group. The frequency of the highest score was marginally higher for the website group. The Mann–Whitney U (two-tailed) test for patient perception of readability revealed no statistically significant difference between the printed leaflet group and the website group ($p = 0.616$).

The frequencies of favourable usability scores were similar for both the printed leaflet group and the website group. The frequency of the highest score was marginally higher for the printed leaflet group. The Mann–Whitney U (two-tailed) test for patient perception of usability revealed no statistically significant difference between the printed leaflet group and the website group ($p = 0.260$).

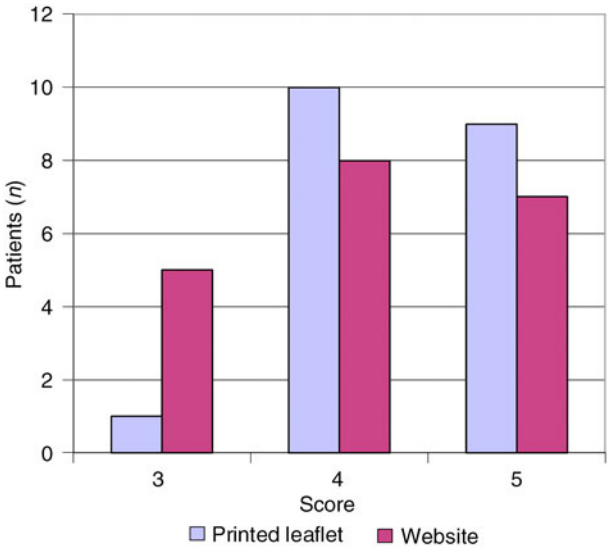

FIG. 3
Usability scores for printed leaflet versus website.

Patients were asked to recall as many complications as possible. There were three complications stated in the information provided, hence the recall scores ranged from 0 to 3. The results were similar for both groups, with a tendency towards a better recall rate in the printed leaflet group. The Mann–Whitney U (two-tailed) test for recall of complications revealed no statistically significant difference between the printed leaflet group and the website group ($p = 0.256$).

Discussion

Principal findings

The results of this study indicate no significant differences in the patients' perceptions of readability and usability of a printed patient information leaflet versus website-delivered patient information. Furthermore, there was no statistically significant difference between groups in the number of complications recalled.

Comparison with prior work

This study is unique in evaluating the readability, usability and complication recall rate of identical patient information delivered via a printed leaflet or via a website.

The finding that the website-delivered patient information was as effective as that delivered via a printed leaflet is in line with expectations and findings from previous studies.[11] However, information provided through print media may be more easily available, accessible and easier to read.[7] Having to use a computer and navigate a website may have been a barrier

https://doi.org/10.1017/S0022215114000449 Published online by Cambridge University Press

for some in terms of the time, effort or planning required to gather the relevant information. In addition, a lack of motivation or skills required to use internet-based media may negatively impact on patients' perception of readability and usability.

The findings of this study add to the evidence regarding the use of interactive and print-delivered interventions with identical content, and provide important new insights regarding patients' perceptions of the readability of the information and the usability of the mode of delivery. Findings from this and previous studies suggest that web-based information may be as successful as printed leaflets in informing patients pre-operatively; however, there are patients who find this mode less acceptable. Efforts are needed to increase the readability and usability of the current ENT UK website, patient information leaflet. About Functional Endoscopic Sinus Surgery; this may lead to improved recall of surgical complications. For certain patients groups with a preference for web-based information, websites can be at least as useful as a printed leaflet.

Limitations

This was a two-centre, prospective, single-blinded, randomised controlled trial designed to compare standard practice with a different mode of information delivery. A number of patients did not have English as their first language; therefore, the pre-operative information delivered may not have been as helpful as anticipated. Hence, it may be useful to produce the patient information leaflet and website in several different languages, especially in areas with a large diversity of ethnic groups.

In the current study, only those with access to the internet were included; this reduced the generalisability of the study. A study of comparative mode of delivery effectiveness rather than efficacy would use 'intention to treat' analysis. In using this method, even non-computer users could be randomised to the website group; their inability to access the information would better reflect a real-world situation. Such a study would require greater numbers to produce meaningful results.

The current study compared identical patient information delivered either via a website or via a printed leaflet. The use of the website to provide a 'pdf' or Word document is not interactive and may therefore limit the advantages of using website-based information.

Questionnaires completed on the day of surgery may have generated more accurate data, particularly for recall of complications. In the current study, patients completed the questionnaires post-operatively, which may have enabled additional reading. The research ethics committee suggested that this method would be less stressful for patients.

Future research

Patient information has to be standardised and reviewed to ensure that it is comprehended by the targeted population. A qualitative study capturing patients' preferences and attitudes towards pre-operative information provided via both printed leaflets and websites would be illuminating.

The current study could be expanded to assess website-based information versus printed information leaflets in other settings, for example in otological surgery.

- **In this study, 58 patients received information on endoscopic sinus surgery via a website or a printed leaflet**
- **There were no significant differences between groups in recall of complications or perceptions of usability and readability**
- **Patient information may be provided by printed leaflet or website according to patient preference**

With a larger study, it would be interesting to assess the educational achievement and reading age of the patients, to ensure groups were similar at baseline. The use of a population of similar-aged patients would have excluded a potentially confounding factor, as age may affect the ability to recall.[12] A larger trial would also lend itself to intention to treat analysis.

Following the provision of high quality information tailored to individual patients, future studies may like to research the effect of a decision aid on decision making for a range of ENT conditions.

Conclusion

The present study indicated that information on FESS can be provided to patients either as a printed leaflet or via a website, with similar scores for recall of complications and perceptions of usability and readability. There were no significant differences between modes of information delivery; therefore, patient preference could be taken into account when selecting a delivery mode in order to optimise information provision. Future large trials would benefit from an intention to treat analysis for pre-operative information provision. Printed leaflets and website-based information can support patients undergoing FESS.

Acknowledgements

We gratefully acknowledge all the patients who participated in this research. We also thank all the ENT departmental staff at the University Hospital Birmingham and University Hospital of North Staffordshire for making this study possible.

References

1 General Medical Council. Consent: patients and doctors making decisions together (2008). In: http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp [21 April 2012]

https://doi.org/10.1017/S0022215114000449 Published online by Cambridge University Press

2 Chan Y, Irish J, Wood S, Rotstein L, Brown H, Gullane P *et al*. Patient education and informed consent in head and neck surgery. *Arch Otolaryngol Head Neck Surg* 2002;**128**: 1269–74
3 Hekkenberg RJ, Irish JC, Rotstein LE, Brown DH, Gullane PJ. Informed consent in head and neck surgery: how much do patients actually remember? *J Otolaryngol* 1997;**26**:155–9
4 Coulter A, Ellins J. Effectiveness of strategies for informing, educating, and involving patients. *BMJ* 2007;**335**:24–7
5 Griffiths F, Lindenmeyer A, Powell J, Lowe P, Thorogood M. Why are health care interventions delivered over the internet? A systematic review of the published literature. *J Med Internet Res* 2006;**8**:e10
6 Oenema A, Brug J, Lechner L. Web-based tailored nutrition education: results of a randomized controlled trial. *Health Educ Res* 2001;**16**:647–60
7 Murphy JM, Long JF, Holleran TA, Esterly E. Persuasion online or on paper: a new take on an old issue. *Learn Instr* 2003;**13**: 511–32
8 Khalil HS, Nunez DA. Functional endoscopic sinus surgery for chronic rhinosinusitis. *Cochrane Database Syst Rev* 2006; (3):CD004458
9 Bolger W, Kennedy D. Complications of surgery of the paranasal sinuses. In: Eisele D, ed. *Complications in Head and Neck Surgery*. St Louis: Mosby Yearbook, 1993;458–70
10 About functional endoscopic sinus surgery (FESS). In: https://entuk.org/docs/patient_info_leaflets/09007_fess [14 February 2014]
11 Marshall AL, Leslie ER, Bauman AE, Marcus BH, Owen N. Print versus website physical activity programs: a randomized trial. *Am J Prev Med* 2003;**25**:88–94
12 Pothier DD. Many patients may not understand consent forms. *BMJ* 2005;**330**:1151

Appendix 1. Questionnaire 1: recall of complications

Patient identification number:

How many risks associated with your surgery can you remember? Please list them.

Appendix 2. Questionnaire 2: patient information, readability and usability

Patient information number:

Please answer each question below

1 Which group or groups describes you best?

☐ Internet access at home: ☐ Broadband ☐ Dial-up
☐ Internet access at work
☐ Internet access at home and work
☐ Internet used previously for health-related search

2 The information was clear and understandable:

☐ Strongly agree
☐ Agree
☐ Neither agree nor disagree
☐ Disagree
☐ Strongly disagree

3 The website/leaflet was easy to use:

☐ Strongly agree
☐ Agree
☐ Neither agree nor disagree
☐ Disagree
☐ Strongly disagree

Address for correspondence:
Mr S Henney,
Warwick Hospital,
Lakin Road,
Warwick CV34 5BW, UK

E-mail: scott.henney@doctors.org.uk

Mr S Henney takes responsibility for the integrity of the content of the paper
Competing interests: None declared

https://doi.org/10.1017/S0022215114000449 Published online by Cambridge University Press