Informed consent for patients undergoing transsphenoidal excision of pituitary adenoma: Development and evaluation of a procedure-specific online educational resource

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Abstract

Objective: Recent high-profile delict and medical negligence cases now require doctors to take "reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments." To this end, we report the development and evaluation of a procedure-specific online educational resource to support the informed consent process for patients undergoing transsphenoidal excision of pituitary adenoma.

Methods: An interactive educational multimedia website was developed using a combination of text, images, and videos. A telephone questionnaire was devised to evaluate patient understanding that included 15 True/False questions, and administered to separate cohorts of patients on the waiting list for transsphenoidal excision of pituitary adenoma, before and after introduction of the website. Patients were also asked to rate the extent to which they found the website easy to understand and useful on a 10-point Likert scale. Data were compared using the Chi-square and Mann-Whitney U test, with a value of $p<0.05$ considered statistically significant.

Results: In all, ten consecutive patients completed the questionnaire before the introduction of the website, and nine patients afterwards. The median questionnaire scores were significantly greater after the introduction of the website (14 v 12/15; $p=0.002$) and all patients subjectively found the website easy to understand and useful (10/10 in both cases).

Conclusions: An interactive educational multimedia website appears to be a helpful adjunct to the informed consent process for patients undergoing transsphenoidal excision of pituitary adenoma.

Key words: Surgery; Pituitary; Transsphenoidal; Consent

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Introduction

Informed consent is an essential prerequisite to patient autonomy. Recent high-profile delict (breach of duty resulting in harm) and medical negligence cases in the United Kingdom such as Chester v Afshar (2004) and Montgomery v Lanarkshire Health Board (2015) have made it clear that the so-called Bolam test, which asks whether a doctors conduct would be supported by a responsible body of medical opinion, no longer applies to the issue of consent.[1] The law now requires doctors to take "reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments." The Montgomery ruling goes on to explain that "the test of materiality is whether…a reasonable person in the patient's position would be likely to attach significance to the risk…" In simpler terms, "a patient should be told whatever they want to know, not what the doctor thinks they should be told."[2] Practically, this means that appropriate care must be taken to sufficiently explain most or all procedural risks – however small – if there is a possibility of relevance.

Obtaining informed consent in this manner for most surgical and medical procedures can, even at the best of times, be challenging. This is particularly so for procedures that involve the brain and spine. In almost all cases, such procedures carry varying risk of a wide range of complications that can lead to disability or death. Moreover, the procedures themselves are typically complex and can be difficult to convey to patients without a medical background.[3] Unsurprisingly, a recent study found that neurosurgery was the clinical specialty subject to the most medicolegal claims.[4]

We report the development and evaluation of a procedure-specific online educational multimedia resource to support the informed consent process, using transsphenoidal excision of pituitary adenoma as an exemplar.

Materials and Methods

The study was registered as a Service Evaluation study with the University College London Hospitals NHS Foundation Trust Clinical Audit Committee (NHNN2017032).

A prospective before-after cohort study design was adopted. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement was used in the preparation of this section of the manuscript.[5]

Setting and Participants:

The study was conducted at the National Hospital for Neurology and Neurosurgery, which acts as the regional referral centre for pituitary tumours in North London. All cases were discussed in a multi-disciplinary meeting and reviewed by one of two senior neurosurgeons (JG and ND) in their specialist clinics, typically for 30 minutes, where they were counselled about the proposed surgery before being placed on the waiting list for surgery.

Variables and Data sources:

An interactive educational multimedia website (www.myprocedure.net) was developed for patients with pituitary adenoma. The resource was designed to function in a similar fashion to an app ('webapp'), given that over half of all web-browsing activity is now conducted via a mobile device (smartphone or tablet). The text and images on the website were largely based on existing patient leaflets provided by our department. These were supplemented by a series of video animations, which covered the relevant pathophysiology, treatment indications, treatment alternatives, and procedural risks of transsphenoidal surgery (Figure 1 and Video 1). Videos were designed to manage cognitive load, promote patient engagement, and encourage active learning, drawing from the recent educational literature.[6] On-screen text and symbols were used to highlight important information alongside the voiceover. Videos were segmented, with each being approximately two minutes in length. Every effort was made to eliminate extraneous information from the videos, such as music or complex backgrounds. Formative assessment was also used to promote active learning.

The text of the website was analysed using three readability tests by hand: the SMOG Grading, Gunning FOG Index, and Flesch Reading Ease. These tests were selected based on their

suggested use by the U.S. Department of Health and Human Services, and each test uses slightly different criteria to calculate a reading age.[3]

A questionnaire to evaluate patient understanding, comprising 15 True/False questions (Table 1), was devised. These questions were based on a related study, and by an iterative consensus-building approach involving all authors.[7] The questionnaire was then administered by telephone to separate cohorts of patients on the waiting list for transsphenoidal excision of pituitary adenoma, before and after introduction of the website (September 2017 and January 2018 respectively). Patients were also asked to rate the extent to which they found the website easy to understand and useful on a 10-point Likert scale. A final question asked patients to state if they felt more confident in their knowledge and understanding, as a result of the website (Yes/No), followed by an opportunity for open feedback for those who wished to provide it.

Study size and statistical methods:

The sample size was determined on a constraint-based pragmatic approach. We considered a minimum of 6 patients in each group sufficient for meaningful analysis.

Data were analysed using with SPSS v 20.0 (IBM, Illinois, USA). The median and interquartile ranges calculated for non-parametric variables. Data were compared using the Chi-Square test for categorical variables and the Mann-Whitney U test for numerical variables, with a value of $p<0.05$ considered statistically significant.

Results

Participants and Descriptive data:

In all, ten consecutive patients completed the questionnaire before the introduction of the website, and nine patients afterwards. The demographics of these patients are summarised in Table 2. The median age was 43 years (range 21-72 years), male:female ratio was 1:2.2, and the median time on waiting list was 4 weeks (range 1-9 weeks). The cohorts were well matched with no significant difference in age, sex, or time on waiting list ($p>0.05$ in all cases).

Outcome data and Main results:

The SMOG Grading was Grade 9 (reading age 14-15 years), the Gunning FOG Index was Grade 12 (reading age 17-18 years), and the Flesch Reading Ease Text was 60 ("standard difficulty").

Following introduction of the website, all patients, irrespective of age, sex, or time on the waiting list, successfully accessed and completed the learning material. The questionnaire scores before and after the introduction of the website are summarised in Table 3. The median score before was 12/15 (range 9-14/15), and after was 14/15 (range 13-15/15). The median questionnaire scores were significantly greater after the introduction of the website (14 v 12/15; p=0.002).

All patients subjectively found the website easy to understand (median 10/10; range 7-10/10) and useful (median 10/10; range 8-10/10). All patients reported feeling more confident in their knowledge and understanding of the procedure, after having accessed the website and completing the learning material.

Four patients provided open feedback, and all were positive. Patients particularly appreciated the opportunity to go through content in their own time and felt this was a "very helpful and gentle way to learn…" (Participant 4).

Discussion

Principal findings:

We found that an interactive educational multimedia website appears to be a helpful adjunct to the informed consent process for patients undergoing transsphenoidal excision of pituitary adenoma. Reassuringly, all patients were able to access the website following its introduction, irrespective of their age and sex, allaying our concerns that certain patient groups might have difficulty. The calculated reading age was between 14 and 18 years, and subjectively patients found the website very easy to understand, with a median rating of 100% (10/10) on a Likert scale. Moreover, patients using the website performed consistently and significantly better in the

telephone questionnaire, with a median score of 93.3% (14/15), suggesting an improved understanding of transsphenoidal surgery.

Over the last decade there has been an increasing emphasis within most healthcare systems on patient autonomy.[8] Adequate informed consent is rooted in respecting such patient autonomy, and can be said to have been given if a patient has a clear appreciation and understanding of what the proposed treatment involves, including the benefits and risks, whether there are reasonable alternatives, and what will happen if the treatment does not go ahead. Within the United Kingdom, several recent high-profile delict and medical negligence cases have made it abundantly clear that the onus is now on the doctor to ensure that the patient is aware of any and all risks involved in a proposed treatment, and of any reasonable alternative or variant treatments.[1] In practice, securing such consent in patients undergoing complex and high-risk neurosurgical procedures is challenging, and lack of adequate informed consent is said to be a contributor to many medicolegal claims against neurosurgeons.[4] This study focuses on transsphenoidal surgery in particular. However, the principles of implementing electronic multimedia learning, as a vehicle for the improvement of quality of informed consent, can be applied to all medical or surgical disciplines involving procedures. The completed questionnaire also provides robust evidence that an appropriate level of understanding was achieved prior to surgery.

Most surgeons receive minimal training on informed consent, and tend to underestimate how much patients want to know.[9] Similarly, most patients are not healthcare literate, and may struggle to fully understand proposed treatments if medical terms are used.[3] The use of adjuncts, such as the educational website reported here, may therefore help overcome these communication barriers between surgeons and patients.[10]

Comparison with other studies:

We found that all patients were able to access the website following its introduction, albeit in a relatively small cohort. Data on use of the Internet amongst different demographic groups is mixed. Within the United Kingdom, approximately 90% of adults regularly access the Internet.[11] Adults aged 75 years and over have consistently been the lowest users of the Internet, but this

has doubled from 20% in 2011 when surveys began, to 41% in 2017. The proportion of women who access the Internet in this age group is also lower, with 35% of women aged 75 years or over using the Internet regularly compared to 47% of men, but this gap is similarly rapidly closing; the largest increase in the number of recent internet users was in women aged 75 years and over, which trebled from 0.3 million in 2011 to just over 1 million in 2017. Overall, our study findings are reassuring, and national data suggests access to the Internet is likely to further increase. Additionally, whilst all our patients successfully accessed the website in their own time, and using their own internet-enabled devices, there is scope for healthcare-providing entities to facilitate access to electronic learning resources. For example, scheduled sessions utilising local library computing resources.

The calculated reading age of the website was between 14 and 18 years using the SMOG grading and Gunning Fox Index, and "standard difficulty" using the Flesch Reading Ease Score, which compares favourably to other online materials. Fahey *et al* assessed the reading age of existing websites for patients undergoing transsphenoidal surgery, and found that most materials were written for a grade level of 14 (reading age of 20-21), and were "difficult".[3] However, the website does still fall short of the recommended reading age for Grade 6 (reading age 11-12 years). We speculate that the fact all patients subjectively reported the website was easy to understand reflects the use of educational resources such as videos alongside the text.

Videos are an increasingly popular educational tool. In a recent narrative review, Cynthia Brame summarised the literature on the use of videos in education, including how to manage cognitive load, promote engagement, and encourage active learning.[6] Consideration of these elements converged on a few recommendations that we followed when developing videos for the website: Videos were kept brief, approximately two minutes in length; audio and visual elements were used in a complementary manner to convey and explain concepts; signalling was used to highlight key concepts; a conversational, enthusiastic style was used to enhance engagement; and guiding questions were used to promote active learning.

We found that patient understanding of transsphenoidal surgery consistently and significantly improved following introduction of the website, and this is in keeping with related studies. In the largest of these, Park *et al* introduced an intense educational and interactive informed consent

process for patients with unruptured intracranial aneurysms that included patient education using information booklets, a cartoon book, a video, an initial physician-patient interview, answering a questionnaire, a second physician-patient interview based on the questionnaire results, and finally consent.[7] Overall, patient understanding improved significantly compared to patients that underwent a standard consent process in other neurosurgical centres (11.9/13 v 10.2/13; $p<0.001$).

Patient confidence in their knowledge is an important factor in the establishment of informed consent. We found that all patients felt confident in their knowledge of their procedure after accessing the website, and it is hoped this increased their satisfaction with the overall consent process, though this was not separately assessed. Bowers *et al* used multimedia presentations to successfully improve understanding in patients undergoing minimally invasive vascular procedures, and found that satisfaction also improved as a result.[12] Hallock *et al* found a similar relationship between patient understanding and satisfaction in an observational study of adult women seeking surgical treatment for pelvic floor disorders.[13]

Limitations:

The present study has several limitations. The single centre before/after cohort study design was based on a constraint-based pragmatic approach and, while sufficient for meaningful analysis, is liable to bias from confounding factors. The single procedure chosen as an exemplar for this study – transsphenoidal surgery – may also be particularly well suited to this sort of standardised approach as the operation and associated risks are relatively consistent. The extent to which procedure-specific educational resources are therefore generalisable is unclear, though we are cautiously optimistic that custom solutions can be designed in most cases.

Conclusions

An interactive educational multimedia website appears to be a helpful adjunct to the informed consent process for patients undergoing transsphenoidal excision of pituitary adenoma. It is hoped that greater patient understanding will result in improved patient satisfaction, and that in the near future similar electronic learning resources can be developed for other procedures.

These resources are intended only to be an adjunct to the wider informed consent and decision-making processes. It is possible to create resources that are successful in educating patients and explaining the standardised aspects of a certain procedure, such as ours. However, personalised discussion and decision-making is still well within the realm of the physical doctor-patient encounter. We feel that establishing a balance between standardised learning resources and individual doctor-patient discussion is key in the pursuit of fully informed, professionally and legally valid, consent.

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Tables

Figures

Figure 1. Screenshot of video illustrating the location of the pituitary gland

11 ## Videos

12 Video 1. Introductory outlining the location and function of the pituitary gland

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