ORIGINAL ARTICLE

Role of cognitive function in assessing informed consent for endoscopy

A D Yeoman, M J Dew, L Das, S Rajapaksa

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See end of article for authors' affiliations

Correspondence to:
Dr M J Dew,
Gastroenterology Unit,
Department of Medicine,
Prince Philip Hospital,
Llanelli SA14 8QF, UK;
mike.dew@camarthen.
wales.nhs.uk

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Background: Patient understanding of the consent process is often suboptimal and the reasons for this are poorly understood. In particular the role of cognitive function in assessing the level of understanding of consent has not been evaluated.

Aims: This study aims to assess the level of patient understanding of the informed consent process and the role of cognitive function in those with low levels of understanding.

Methods: The study was prospective, interviewing patients immediately after they had given consent but before undergoing their procedure. Understanding of the reason for the procedure, the risks attendant upon it, details of the procedure itself and post procedure care was scored with the total representing overall level of understanding. A mini mental state examination (MMSE) was then performed with the score recorded.

Results: 100 patients were interviewed. A low level of understanding was shown in 36%. Ninety two patients had a MMSE score greater than 24. All patients with a high level of understanding had MMSE scores greater than 24 compared with 78% of those with a low level of understanding. All patients (n=8) who displayed a MMSE score less than 24 had a low level of understanding. Men displayed poorer levels of understanding than women. A subnormal MMSE only identified 22% of those with low levels of understanding.

Conclusions: Understanding of the consent process is suboptimal. Adequate cognitive function does not predict a high level of understanding of the informed consent process while cognitive impairment precludes it. It is evident, however that factors other than cognitive dysfunction are at play when attempting to explain low levels of understanding.

Informed consent is an ethical concept that has led to a legal requirement and as such represents the cornerstone of good medical practice. Legally and ethically, it is essential that a patient receives sufficient information to make an informed choice, possesses the capacity to make a decision, and voluntarily communicates that decision.¹ When informed consent is being sought it is essential that a patient not only has the capacity to understand but that actual understanding takes place.² All these criteria must be met if a person's consent is to be informed.

However, it has been shown that patients remember only a small proportion of information given to them either in consultations or in the consent process.^{3,4}

The reasons for this are multitude and include age, intellect, effects of medication, health motivation, and cognition.

The role of cognitive function in patient understanding of the informed consent process is poorly understood and has not been subject to study in a clinical setting. It is however recognised that cognitive dysfunction is common among medical inpatients⁵ and in the elderly.⁶ Previous work undertaken in our unit has shown that about one third of outpatients undergoing endoscopy displayed a low level of understanding of the consent they had given just minutes before.^{7,8} Clearly these findings raised doubts as to whether such consent could be deemed informed. Hitherto, the reasons underlying low levels of understanding have not been further explored.

The aim of the study was to record the level of patient understanding of the consent they give for endoscopic procedures and to explore whether impairment of cognitive function is implicated in those showing low levels of understanding.

METHOD

Ethical approval was granted by the Dyfed Powys research ethics committee and 100 consecutive outpatients undergoing endoscopic procedures were interviewed after consent to participate was obtained. All patients undergoing outpatient endoscopy at our unit are sent information leaflets by post before their appointment. This information leaflet is based on British Society of Gastroenterology guidelines.¹⁰ The interview took place immediately after the written consent the patients gave pertinent to their endoscopy but before actually undergoing the procedure. During the interview the patient was asked whether they had received an information leaflet, discussed the procedure with a health care professional, and to recall information relating to four specific aspects of the procedure they had just consented to:

- The reason for the procedure
- The risks of the procedure
- What the procedure entails
- Procedure aftercare

In the absence of standardised criteria for assessment of patients' level of understanding of consent processes we used a system developed for previous studies in our unit that have been published in abstract form.^{7,8} An overall assessment of a person's understanding was made using the scoring system shown in table 1.

The cumulative score represents the patients' overall level of understanding. The maximum score possible was 16 with the minimum being 4 (table 2).

Those with an overall assessment of understanding score of 8 or less were deemed to have a low level of understanding insufficient to render their consent truly informed while

Table 1 Assessment of understanding

	Score
No understanding:	
Unable to offer any reason for having the procedure	1
Unaware of any risk the procedure carries	1
Does not know what the procedure entails	1
Unaware of what will happen after the procedure	1
Poor understanding:	
Relates to symptoms and needs a test to evaluate	2
Has an idea that risk is involved but cannot name one	2
Knows a brief outline of procedure	2
Knows there is a recovery time before home	2
Fair understanding:	
Aware of abnormality being looked for but unsure if management will change as a result	3
Name some but not all risks	3
Describe some aspects of the procedure	3
Understand that sedatives mean they cannot drive/drink alcohol	3
Good understanding:	
Knows exactly why a procedure is performed and the probable benefits	4
List all the risks consented for	4
Describes in detail what will happen during the procedure	4
Describe in detail the post-procedure assessment and probable after effects	4
Total score	/16

those with a score 9 or above were deemed to have a high level of understanding and therefore having given informed consent. Differences between age groups and sex were analysed using the above nomenclature for clarity of data interpretation.

After assessment of understanding the patient underwent the mini mental state examination (MMSE) to screen for cognitive dysfunction with the score being recorded. The MMSE is the most validated assessment of cognitive function⁹ and was chosen for the study because of this and its ease of implementation (see fig 1).

When using the MMSE a score of less than 24 is considered a marker for cognitive impairment and so for the purposes of this study a score greater than 24 was considered "normal".

Eighty four per cent underwent upper gastrointestinal endoscopy with 16% undergoing lower gastrointestinal endoscopy (colonoscopy or flexible sigmoidoscopy).

Statistical analysis of the data was performed using ordinal logistic regression with the data modelling low understanding and the outcomes represented as odds ratios.

RESULTS

There were 36 men and 64 women in the study population. The age range was 19–82 with a mean of 56 years and a median of 52 years (table 3).

Ninety two per cent of patients reported receiving written information providing details of the procedure and 98% of patients reported speaking to a health care professional about the procedure at some point before giving consent (figs 2 to 6).

Fifty three per cent of procedures were day case procedures having previously been seen by a consultant and 47% were open access procedures referred directly for endoscopy by their general practitioner.

Ninety two per cent of patients had a normal MMSE score with 8% having a score of less than 24. None of the patients interviewed had a history of any dementing illness recorded at the time of their endoscopy.

Ordinal logistic regression was used to analyse the relation between low level of understanding and sex, a one point fall in the MMSE score and age (table 4).

DISCUSSION

These results raise doubts as to the validity of the consent given in over one third of patients undergoing endoscopic procedures and questions how "informed" their consent actually is.

Such low levels of understanding occurred against a backdrop of high levels of information dissemination via leaflets and prior discussion with health care professionals as recommended by professional bodies (GMC, BSG).^{10 11}

Can deficiencies in cognitive function explain these findings?

We have shown that increased understanding is reflected in a progressive, incremental rise in the mean MMSE score. All patients with a high level of understanding had a MMSE score greater than 24.

This does not predict however that a normal MMSE score will lead to sufficient understanding as 50% of patients rated as having no understanding and 83% of those with poor understanding had MMSE scores >24.

Eight patients in total had a subnormal MMSE score, all of which displayed low levels of understanding that could render their consent uninformed.

Ordinal logistic regression analysis shows that for every fall in one point in the MMSE score a person will be 0.5 times as likely to be down a level of understanding or, put another way, a one point increase in the MMSE score leads to a person being twice as likely to have a higher level of understanding.

Sex had no impact on mean MMSE scores but logistic regression analysis shows that men are about 3.5 times more likely to be down a level of understanding than women.

The mean MMSE, as expected, fell with increasing age as did level of understanding, yet once we controlled for low MMSE score and male sex there was no relation between age and level of understanding.

Table 2 Score of level of understanding

Overall level of understanding	Cumulative score
No understanding	4
Poor understanding	5–8
Fair understanding	9–12
Good understanding	>12

The mini mental state examination

Orientation
 Year, month, day, date, season _____/5
 Country, county, town, hospital, ward (clinic) _____/5

Registration
 Examiner names three objects (for example, apple, pen, and table)
 Patient asked to repeat objects, one point for each. _____/3

Attention
 Subtract 7 from 100 then repeat from result, stop after five subtractions. (Answers: 93, 86, 79, 72, 65)
 Alternatively if patient errs on subtraction get them to spell world backwards: D L R O W
 Score best performance on either task. _____/5

Recall
 Ask for the names of the objects learned earlier. _____/3

Language
 Name a pencil and a watch. _____/2
 Repeat: 'No ifs, and or buts.' _____/1
 Give a three stage command. Score one for each stage (for example, 'Take this piece of paper in your right hand, fold it in half and place it on the table.' _____/3
 Ask patient to read and obey a written command on a piece of paper stating: 'Close your eyes.' _____/1
 Ask patient to write a sentence. Score correct if it has a subject and a verb. _____/1

Copying
 Ask patient to copy intersecting pentagons.
 Score as correct if they overlap and each has five sides. _____/1

Total score: _____/30

Figure 1 The mini mental state examination.

Overall, 36% of patients had low levels of understanding yet only 8% had subnormal MMSE score so it is evident that there are other factors at play when attempting to explain why levels of understanding are low.

Men showed lower levels of understanding of the consent process—the reasons for which reasons are unclear. In some it may reflect a lack of interest in the consent process for procedures they may see as “routine” or reflect blind faith in the profession “I’ll leave it to you doctor”.

Figure 2 Patients' overall understanding of procedure.

How then do we improve the informed consent process?

To achieve this goal it is clear that we need to ensure that patients actually understand the appropriate amount of information they are given. The best way of achieving this is difficult to ascertain. The MMSE is a well validated screening tool and this study confirms its usefulness in identifying a proportion of patients that will not understand. However, to introduce routine MMSE before any consent process would be extremely time consuming, rendering the whole process impracticable especially for high volume procedures such as endoscopy. In addition a subnormal

Figure 3 Relation of mean MMSE to overall understanding.

Table 3 Patients by age and MMSE

	Age group							
	<20	21-30	31-40	41-50	51-60	61-70	71-80	80+
Number of patients1 (n = 100)	6	9	19	22	22	19	2	
Number MMSE<24 (n = 8)	0	0	1	1	2	1	2	1

Table 4 Predicting low understanding

Variable	Odds ratio	95% Confidence limits	p Value
Male	3.467	1.406 to 8.547	0.0069
MMSE score	0.471	0.345 to 0.643	<0.0001
Age	0.989	0.961 to 1.019	0.4759

Figure 4 Mean MMSE by age. **Figure 5** Level of understanding by age. **Figure 6** Level of understanding by sex.

MMSE score identified only 8 of 36 patients (22%) with low levels of understanding and so most patients would not be identified by this means.

How we detect true levels of understanding in this large patient group remains unresolved but there is evidence that the use of different information formats such as simple texts and video presentations may increase understanding.^{12 13}

Further study is required to confirm these findings. If certain groups such as men consistently demonstrate low levels of understanding then it may be possible to target such groups in terms of providing greater levels of discussion and the use of other forms of information dissemination in conjunction with a brief method of assessment of understanding.

CONCLUSIONS

The informed consent process is a complex one and this study confirms that actual understanding of consent, even in the presence of widespread information dissemination and prior discussion between patients and doctors, is difficult to achieve. While this study confirms that the MMSE is a useful screening tool for detecting cognitive dysfunction (which is strongly associated with low levels of understanding), identification of cognitive dysfunction accounts for only a fifth of those patients with low levels of understanding.

As a result the optimum method of establishing those with low levels of understanding has yet to be determined and it is evident that cognitive dysfunction plays only a part in this.

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Authors' affiliations

A D Yeoman, M J Dew, I Das, S Rajapaksa, Gastroenterology Unit, Department of Medicine, Prince Philip Hospital, Llanelli, Wales

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