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A Study of the Compliance with Guidelines on Consent for Endoscopic Procedures: Matters are much more Complex

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Abstract

Background: Consent is an agreement between the patient and the doctor to undergo a diagnostic test or treatment. Endoscopy is a recognised test for diagnosis and treatment for many diseases of digestive tract. New guidelines have been published by the British Society of Gastroenterology regarding consent in endoscopy.

Aims and objectives: This study aims to measure the compliance with guidelines on endoscopy as a diagnostic and therapeutic test.

Methods: All patients who had Gastroscopy, Flexible Sigmoidoscopy or Colonoscopy in two consecutive weeks during March 2016 at a district general hospital in United Kingdom were identified through patient records. Time gap between receiving information and signing the consent for the procedure was determined.

Results: Total of 231 cases were studied. Distribution of cases was Gastroscopy 103, Flexible Sigmoidoscopy 24 and Colonoscopy 104 cases. Taking all the procedures together, our study showed that all patients were given at least 24 hours to make an informed decision regarding the procedure and sign the consent.

Conclusion: New guidelines incorporate some new requirements for consent in endoscopy. Further studies should evaluate these in future.

Keywords: Consent; Endoscopy; Gastroscopy; Flexible sigmoidoscopy; Colonoscopy; Compliance; Guidelines

Introduction

Autonomy is a fundamental right of all human beings. Every individual can choose for himself or herself what happens to the body, and indeed if anything at all. Medical profession respects this autonomy by offering consultations, investigations and treatment only with an informed consent. If consent is not obtained, then it breaches the basic human right of the patient. British Society of Gastroenterologist states "Treatment without informed valid consent will usually imply that autonomy has been somehow overridden and will thus constitute a breach of article 2, 3 or 8 of the Human Rights Act (1998)"

Consent is an agreement between the patient and the doctor to consult, investigate and treat. However the patient must clearly understand the risks, benefits, alternatives, nature of intervention and the reasons for all. Whereas the consent can be implied and not directly implicit or in words, for example by nodding head etc.like any other procedure, endoscopy requires informed consent which should have been signed without any pressure or coercion and having had a reasonable time to think except in emergency circumstances when only little time may be available.

British Society of Gastroenterologists has published new guidelines on consent in endoscopy [1]. It particularly emphasizes on having written consent from the patient. It also asks for clear documentation that risks and benefits have been explained.

This study aims to look at the compliance with consent procedure for Diagnostic and Therapeutic Endoscopy procedures. This directly reflects quality in endoscopy which is a medical diagnostic and therapeutic test.

Methods

All patients who had OGD, Flexible Sigmoidoscopy or Colonoscopy in two consecutive weeks during March 2016 at a district general hospital in the United Kingdom were identified through patient records. Time gap between receiving information and signing the consent for the procedure was determined by going through the notes, electronically or manually. The process involved determining the date of first consideration for the procedure, then the date of giving first written information about the procedure to the patient including the consent form. Then the date of the procedure was noted and checked if consent was signed in the procedure room or outside and whether the consent was checked prior to the procedure. These aspects would indicate level of compliance with the consent guidelines.

Results

Total of 231 cases were studied. Distribution of cases was Gastroscopy 103, Flexible Sigmoidoscopy 24 and Colonoscopy 104 cases. Taking all the procedures together, our study showed that all patients were given at least 24 hours to make an informed decision

regarding the procedure and sign the consent. 10 patients each were given 6, 8 or 14 days for it and maximum of 13 cases were given 9 days. (Table 1 and Figure 1)

Number of Days	All procedures
1	3
2	5
3	1
4	3
5	4
6	10
7	4
8	10
9	13
10	4
11	8
12	7
13	9
14	10
Total	91
>14	140
Grand Total	231

Table 1: Lists days given for all procedures.

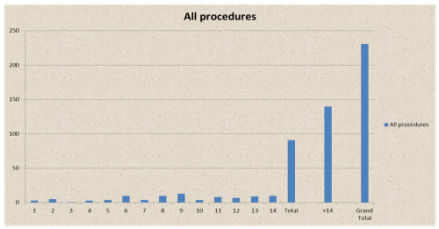

Figure 1: Diagrammatic representation for all procedures.

The data was further analysed to see if consent procedure varied according to the procedure undertaken. 58 patients for colonoscopy, 65 patients for gastroscopy and 17 patients for flexible sigmoidoscopy were given at least 14 days to make an informed decision and sign the consent.

Table 2 below lists days given against the number of patients for individual procedures. Figures 2, 3 and 4 respectively give the diagrammatic presentation of the same for colonoscopy, gastroscopy and flexible-sigmoidoscopy procedures.

Number of Days	Colonoscopy	Gastroscopy	Flexible sig
1	2	1	0
2	3	1	1
3	1	0	0
4	1	2	0
5	1	3	1
6	6	4	1
7	1	2	0
8	6	4	1
9	8	4	0
10	3	1	2
11	1	5	0
12	3	4	0
13	5	3	0
14	5	4	1
Total	46	38	7
>14	58	65	17
Grand Total	104	103	24

Table 2: Lists days given against the number of patients for individual procedures.

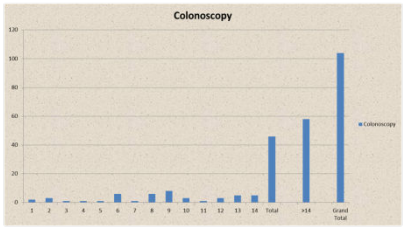

Figure 2: Diagrammatic representation for Colonoscopy .

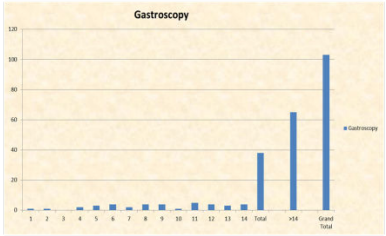

Figure 3: Diagrammatic representation for Gastroscopy procedure.

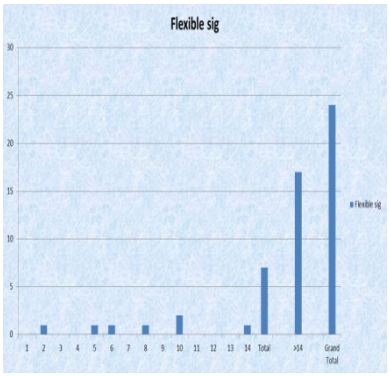

Figure 4: Diagrammatic representation for Flexible-Sigmoidoscopy procedure.

All patients had their consent checked pre-procedure by a trained nurse or the doctor and all consents were signed before entering the operating theatre.

Conclusions

This study has provided a good snapshot of the level of compliance with guidelines to take consent for diagnostic and therapeutic endoscopic procedures including colonoscopy, gastroscopy and flexible sigmoidoscopy but excluding cystoscopy and bronchoscopy. Our data has shown a good compliance with guidelines for consent in all of the above procedures. This study is however representative of one district hospital in the United Kingdom and cannot be representative of the situation in some of the other hospitals. There is therefore a need to conduct further such studies in other hospitals either singularly or as a part of a multi-centre study.

Two weeks make a reasonable period to see the trend because the selection of the time period was at random, and without any notice to endoscopy department, so can be taken to have excluded any bias from pre-notice. Furthermore, 231 cases captured within this time is a good number to analyse.

The study did not include those patients who refused to have the procedure done. New guidelines require clear documentation about such situations and that all risks of not having the procedure should have been discussed. Moreover, documentation is to be done as to why the patient did not want the procedure and what was done to address those concerns. Further studies should incorporate this into analysis data. It is now mandatory to have documentation on records of staff training in Consent process and also the record of improved versions of written consent forms over time. More studies are needed to look at compliance with these new outcome measures and identifying how easy or difficult it would be to implement them.

In 2008 the General Medical Council (GMC) published guidelines on consent titled "patients and doctors making decisions together" [2]. It is worth noting that patient is mentioned first in this title and before the doctor. Although this GMC guideline is not specific for endoscopic procedures, but underlying principles are the same. This document brought the concept of patient partnership into consent. It also gave guidance regarding situations when patient lacks capacity to make an informed decision. This document provided detailed breakdown of the process including; how to share information, discuss complications, determine scope of decisions, how to express and document consent. The new guidelines are specific to endoscopy and go much beyond the remit of GMC guidelines and look at endoscopy service as a whole. Further advice can be sought from Mental capacity Act 2005 [3], Adults with Incapacity (Scotland) Act 2000 [4] and from work by Hughes on ethical issues in dementia patients [5] and Mental capacity Act code of Practice 2007 [6] for taking consent when patients lack capacity to make an informed decision. Previous guidelines on consent were given by the government [7]. The previous more specific BSG guidelines on consent for endoscopy were discussed in detail by Elizabeth Smee incorporating tissue storage issues as well [8] and good guidance was provided by Shepard et al through the BSG document in 2008. [9]. The new BSG guidelines recommend having a clear scope of consent prior to procedure and warn against exceeding beyond the limit of the consent achieved, unless during the procedure, failure to intervene would cause immediate harm [10]. Furthermore, the new guidelines discuss consent issues like; emergency endoscopy, withdrawal of consent during the procedure, video and photo recording and level of seniority of the endoscopist etc. It would be useful to measure the impact of these new guidelines on improving the quality of endoscopy in future.

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