ORIGINAL ARTICLE

Comparative study on the evaluation of patient's satisfaction on esophagogastroduodenoscopy and colonoscopy between a pre-filled and standard hand-written consent form in Hospital Kuala Lipis

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ABSTRACT

Introduction: Informed consent is the patient's self-determination authorization of a choice made by themself before any intervention is performed by the health care provider. It should be a structured process that includes the disclosure of relevant procedural information, benefit, risk, and other treatment option.

Materials and Methods: An open-label static group comparison experimental design was conducted in a single-centred study starting from April 2021 until January 2022 among patients who were going for OGDS and Colonoscopy at Hospital Kuala Lipis. The patients were stratified by 2-by-2 randomization to either the standard hand-written pre-filled consent forms. The satisfaction was assessed using Gastrointestinal Endoscopy Satisfaction Questionnaire version 2. The difference in the satisfaction was analyzed using multifactorial ANOVA.

Results: The percentage score of satisfaction on the endoscopic procedure using pre-filled was significantly higher than standard form consents (mean difference: 18.36 (95%CI: 14.15, 22.58)) and the effect size was large (partial ή = 0.399). The difference in percentage score of satisfaction was associated with gender (p = 0.003) and medical officers' years of working experience (p < 0.001).

Conclusion: The pre-filled consent form fulfils the ethical and legal aspects of the informed consent process and should be used in endoscopic and other invasive procedures in Malaysia. It is suggested that a formal training, exposure to course in communication skills, breaking bad news on patient consent among junior doctors need to be taken to improve patients' satisfaction of the endoscopic procedure to make them more satisfied.

KEYWORDS:
Patient's satisfaction, esophagogastroduodenoscopy, colonoscopy, pre-filled consent form, standard hand-written consent form

INTRODUCTION

Informed consent has evolved over the past decades from an ethical concept to a legal principle. It is constructed on the ethical principles of respecting patients' autonomy and self-determination to empower them in making their own decisions. Taking consent for any procedure is not just about taking signature from patients on the consent form, but it is a decision-making process involving a competent person who fully understands the procedure and the possible complication that may occur and makes a decision without coercion.[1] It also has a mutual connection and trusts in-between clinician and patient with patient's autonomy being the main concern. Furthermore, it is a legal duty of healthcare professionals to obtain valid consent from patients as required by the Malaysian Medical Council.[2] Material risks relevant to the patient should be informed for the patient to make an informed decision. The more risk of the procedure, the more disclosure of information must be done.[3] A valid and complete consent form must include the detail of the process of the procedure, associated risks, how the procedure will be performed, post-procedure management, and other alternative options. The information must also include any benefit, risk, and procedure limitation, any tissue sampling, image recording, and presence of a supervisor for the trainee to perform any invasive procedure.[4]

The consent form was introduced back in 1900 by Major Walter Reed for his clinical trial to search for the cause of yellow fever infection.[5] It was then legally decided in the courts in the case of *Mohr v Williams* [1905] 104 N.W. 12, *Pratt v Davis* [1906] 79 N.E. 562, *Rolater v Strain* [1913] 137P. 96 and *Schloendorff v Society of New York Hospital* [1914] 105 N.E. 92.[6] The principles of the judgement were for respecting patients' autonomy in making decisions. It also emphasizes the duty of healthcare professionals to give complete information regarding the procedure, which covers both the ethical and legal duties.[7] The consent documentation consists of two parts: the consent form and the patient information sheet. The content of these documents must be in layman terms

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without any medical jargon. It also must be complete, simple, and easy to understand.[1]

Endoscopy (esophagogastroduodenoscopy (OGDS) and colonoscopy) is a procedure in which the gastro-intestinal tract (GIT) is viewed through a lighted, flexible tube with a camera at the end (endoscope). The upper endoscopy is an inspection of the upper part of the GIT (from esophagus to small intestines) that can be viewed by a thin flexible tube inserted through mouth. Whereas the colonoscopy is an inspection of the entire large bowel (from the distal rectum to the cecum) that can be viewed by a flexible tube inserted through the rectum. OGDS and colonoscopy are the two endoscopic procedures that contain a pre-filled consent form, which is routinely being used in Ministry of Health (MOH) hospital. The standard form of consent, which is the older version of the informed consent form requires the doctor to concurrently explain and write all the detailed information before the patient signs it. There are possibilities that the information may be inadequately explained as the doctor may be rushing to complete all the procedures while filling up the consent form. The information might also be missed and below the professional standard. Besides, the information retention might also be affected by the person taking the consent itself.[8]

The information contained in the pre-filled consent form was created and validated by a group of experts in endoscopic procedures in the General Surgery fraternity, which included all the information necessary for these two procedures. There are a few reasons to support the use of a pre-filled consent form. Examples include the lack of experience and knowledge, especially in junior doctors taking consent, time constraints in government hospitals, missing important information, and lack of awareness on the importance of documentation in the consent form. These factors depict that a pre-filled consent form is better to gain patients' understanding and satisfaction.[9] Importantly, using a standard blank form consent form with the potential of lack of disclosure and information in the consent may lead to patients' misunderstanding and confusion regarding the procedure.[10] Inadequate information may also lead to patients' dissatisfaction if the outcome is not as expected.[3]

Medical negligence is a major challenge in several countries, including Malaysia.[11] It has been a significant concern in recent years, as the number of claims has risen in Malaysia. Issues with informed consent may have contributed to the rise in medical negligence cases in the country and worldwide.[12] Disclosure of information is a core component of informed consent[13] and should include material risks, other alternative options, and legal requirements of adequate information given to patients.[14] The major concern with information disclosure is that patients do not receive adequate information as they are supposed to.[15] These can lead to patients' poor understanding and knowledge regarding the procedure. More importantly, this may lead to medical litigations due to a lack of information during the informed consent process. The pre-filled consent form appears to fulfil the inadequacy of the standard consent form.

By using a pre-filled consent form, it will standardize the information given and minimize information retention.[8] It will also assist the doctor to disclose the information according to the professional standard as there is a significant variation of disclosure between junior and senior doctors.[9] This variation of disclosure was based on the person's experience and knowledge.[16] Therefore, this pre-filled consent will reduce the variability and insufficient information experienced in the standard hand-written form concerning legal disputes for poor documentation.

There is also a gap between the standard consent form and pre-filled consent in terms of the patient's satisfaction. Certain factors are associated with the satisfaction of both these pre-filled and standard hand-written consent forms, such as lack of experience and knowledge especially among junior doctors on taking consent, time constraints (especially in government hospitals), missing to include important information, and lack of awareness regarding the significance of documentation in the consent form. These factors indicate that a pre-filled consent form will improve the patient's understanding and satisfaction. The lack of disclosure and information in the consent may lead to patient misunderstanding and confusion regarding the procedure. Inadequate information may also lead to patient dissatisfaction if the outcome deviates from the original plan. Hence, this pre-filled consent form will improve patients' understanding and satisfaction with the informed consent process and the procedure. Therefore, this study was conducted to evaluate patients' satisfaction with the pre-filled consent form and standard hand-written consent form on the endoscopic procedure of OGDS and colonoscopy.

MATERIALS AND METHODS

An open-label static group comparison experimental design was conducted in a single-centred study starting from April 2021 until January 2022. The study population involved patients who were going for OGDS and colonoscopy at Hospital Kuala Lipis from November 2021 until January 2022. Screening of the patients was performed in an outpatient general surgical clinic. The eligible patients were identified and briefed about the research purpose and objectives. The patients were recruited only by the principal investigator to reduce the inter-reliability issue. The patients' information sheet containing brief information about the study and the procedure was given to the patients. Informed consent was obtained from the patients before starting the data collection. There was no blinding in this study.

Sampling Method

Simple random selection (SRS) was used to enroll patients from Hospital Kuala Lipis, who were scheduled for OGDS and colonoscopy. The patient was consented and met the eligibility criteria. The research continued the recruitment until the required sample size was attained.

Randomization

A stratified 2 by 2 block randomization was applied in this study. First, it was stratified into the method of endoscopy (OGDS and colonoscopy). Then 2 by 2 block randomization was applied to obtain an equal number of patients in each

group (group A: pre-filled and group B: standard hand-written (standard) consent forms).

Intervention
There were two consent forms used in this study:

1) *Standard Handwritten Consent Form*
   This consent form was used officially by the Ministry of Health, Malaysia. It has two pages. The first page was about the details of the patient's name, address, procedure and signature of the patient's or next of kin, healthcare provider, witness, and translator if needed. Meanwhile, the second page is about the procedure information. This page was intentionally left bank, requiring the healthcare provider to fill up this page before or while explaining to the patient. The patient or the next of kin was then required to sign both pages of the consent form.

2) *Pre-Filled Consent Form*
   This form was the same as the standard handwritten form with additional procedure names and detailed information, specific for a particular procedure. The healthcare provider must provide a detailed explanation before the patient or next of kin signs it.

The main framework of the standard handwritten and pre-filled consent form is the same as in a standard MOH consent form but both of these forms have a few differences. The main difference in the pre-filled consent form is that the information for the specific procedure has been written in the form compared to the standard handwritten form which is empty. The other difference is that the standard consent form can be used in all procedures; however, the pre-filled consent form has specific information based on the procedure. For example, the pre-filled consent form for endoscopy can be used only for endoscopy procedures, not for another type of invasive procedure.

Assessment
The outcome of this study was the patient's satisfaction score on the endoscopic procedure of the consent form. The score has been assessed using the Gastrointestinal Endoscopy Satisfaction Questionnaire (GESQ) version 2.17. It was developed by Hutchings, Cheung[17] with high internal consistency. It consists of 21 items with four domains, which are skills and hospital (seven items; Cronbach's $\alpha = 0.83$), pain and discomfort during and after endoscopy (four items; Cronbach's $\alpha = 0.84$), information before endoscopy (five items; Cronbach's $\alpha = 0.80$), and information after endoscopy (five items; Cronbach's $\alpha = 0.76$). Item 15 has a dichotomous option (yes and no), items 3, 13, and 14 are presented using 3-point Likert scales, whereas the remaining items have 5-point Likert scales. Eight items (items 1 to 8) were used to assess the patient's satisfaction. All items were assessed before the patients were discharged from the hospital in both groups. All the items were summed up and divided by the number of valid responses. The score was then transformed to the range 0–100 using the formula: ([score-lowest possible/score range] × 100).

For this analysis, the lower score depicts lower satisfaction. Notably, the score was calculated if the patient responded to at least 50% of the questions. If patients had completed fewer than 50% of the questions, it is considered missing. The approval to utilize the questionnaire, "Gastrointestinal Endoscopy Satisfaction Questionnaire" (GESQ), was obtained from the original author, Professor Hayley Hutchings on 5th May 2021 via official email: h.a.hutchings@swansea.ac.uk

Method of Data Collection
A face-to-face interview was employed for the assessment using GESQ. Five medical officers in General Surgery Department in Hospital Kuala Lipis were selected to collect the data. Their working experience ranged from 1 to 5 years, familiar enough with the procedure of endoscopy, assisted and performed many endoscopies guided by the specialist. A briefing on how to conduct the assessment has been done to reduce the inter-rater reliability among the interviewer.

Duration of Participation
The respondent was only approached once for this study, and the questionnaire took between 15 and 30 minutes to be completed.

Statistical Analysis
The collected data were initially entered into the Microsoft Excel (2019) spreadsheet and transferred to the Statistical Package for Social Sciences, version 24 for analysis. The descriptive statistics were presented using mean and standard deviation for normally distributed numerical data while either median and interquartile range were presented for non-normal distributed numerical data. Categorical data were presented in the form of absolute number and their corresponding percentages. The score of the satisfaction for the pre-filled and standard hand-written consent forms was presented using mean and standard deviation.

The comparison of the respondents' percentage satisfaction scores for the pre-filled and standard consent forms based on socio-demographic characteristics was analyzed using one-way ANOVA. The satisfaction score on the endoscopic procedure for the pre-filled and standard hand-written consent forms was compared using multifactorial analysis of covariance (MF-ANOVA) to adjust for other variables of interest such as type of procedure, patients' age, gender, race, education, occupation and experience of doctor taking the patient's consent.

Approval of The Study
This study was approved by the Medical Research & Ethics Committee, Ministry of Health Malaysia on 13 September 2021 (NMRR-21-1622-61046) and the Universiti Teknologi MARA Research Ethics Committee (REC/12/2021 MR/926).

RESULTS

A total of 156 patients were invited to this study. However, only 130 patients were involved in this study. Four patients declined to participate, whereas 22 had already had endoscopic procedures. The overall response rate was 85.5%. The characteristics of the patients who received the standard and pre-filled consent forms are shown in Table I.

Table I: The characteristics of the patients who received the Standard and Pre-filled consent forms

Variable	Consent Form		Total, N = 130, n (%)	*p* value[a]
	Prefilled, N = 65, n (%)	Standard, N = 65, n (%)		
Gender:				
Male	34 (52.3)	35 (53.9)	69 (53.1)	0.860
Female	31 (47.7)	30 (46.2)	62 (46.9)	
Race:				
Malay	29 (44.6)	28 (43.1)	57 (43.8)	0.971
Chinese	24 (36.9)	23 (35.4)	47 (36.2)	
Indian	9 (13.8)	11 (16.9)	20 (15.4)	
Orang Asli and others	3 (4.6)	3 (4.6)	6 (4.6)	
Age:				
Less than 40	15 (23.1)	13 (20.0)	28 (21.5)	0.303
40–59	35 (53.8)	29 (44.6)	64 (49.2)	
60 and above	15 (23.1)	23 (35.4)	38 (29.2)	
Educational level:				
Primary	10 (15.4)	9 (13.8)	19 (14.6)	0.086
Secondary	43 (66.2)	52 (80.0)	95 (73.1)	
Tertiary	12 (18.5)	4 (6.2)	16 (12.3)	
Occupation:				
Professional	10 (15.4)	4 (6.2)	14 (10.8)	0.176
Non-professional	23 (35.4)	26 (40.0)	49 (37.7)	
Not working	5 (7.7)	3 (4.6)	8 (6.2)	
Housewife	27 (41.5)	29 (44.6)	56 (43.1)	
Pensioner	0 (0.0)	3 (4.6)	3 (2.3)	
Procedure:				
OGDS	33 (50.8)	32 (49.2)	65 (50.0)	0.861
Colonoscopy	32 (49.2)	33 (50.8)	65 (50.0)	
Doctor's experience who assesses the patients				
Less than 1 year	14 (21.5)	17 (26.2)	31 (23.8)	0.136
1–2 years	15 (23.1)	18 (27.7)	33 (25.4)	
2–3 years	10 (15.4)	16 (24.6)	26 (20.0)	
More than 3 years	26 (40.0)	14 (21.5)	40 (30.8)	

[a]Variables with a $p < 0.05$ are considered significant. Statistical test: Chi-square test.

The majority of the respondents were male (53.1%), Malay (43.8%), aged between 40 and 59 years old (49.2%), having secondary educational qualification (73.1%), housewives (43.1%), and medical officers with working experience of 3 years and above (30.8%). An equal number and proportion of respondents were subjected to the OGDS and colonoscopy procedures. Among those who received the pre-filled consent form, most of them were males (52.3%), Malay (44.6%), aged between 40 and 59 years old (53.8%), having secondary education (40.0%), housewives (41.5%), having OGDS procedure (50.8%) and medical officers with working experience of 3 years and above (30.8%). Meanwhile, for those who received the standard consent form, the majority of them were males (53.9%), Malays (43.1%), aged between 40 and 59 years old (44.6%), having secondary education (80.0%), housewives (44.6%%), subjected to colonoscopy procedure (50.8%), and medical officers with 1–2 years working experience (27.7%). Comparisons between the socio-demographic characteristics of those who received the pre-filled and standard consent forms showed that none of the variables was statistically significant ($p > 0.05$). Thus, it can be concluded that both groups are comparable.

The respondents' mean percentage scores of satisfaction on the endoscopic procedure for the standard consent form was 70.15% ± 12.56 and for the pre-filled consent was 91.31% ±13.72. The comparison of percentage scores of satisfaction of the pre-filled and standard consent forms in between-group based on the respondents' socio-demographic characteristics are shown in Table II.

In the pre-filled consent form group, there were no statistically significant difference in the percentage score of satisfaction between gender ($p = 0.462$), race ($p = 0.114$), age group ($p = 0.627$), educational level ($p = 0.758$), occupation ($p = 0.655$), and procedure ($p = 0.604$). However, there was a statistically significant difference in the percentage score of satisfaction between years of medical officer's experience ($p < 0.001$). In the standard consent form group, there were no statistically significant difference in the percentage score of satisfaction between gender ($p = 0.497$), race ($p = 0.479$), age group (p$p = 0.983$), educational level ($p = 0.713$), occupation ($p = 0.229$), and procedure ($p = 0.495$). However, there was a statistically significant difference in the percentage score of satisfaction between years of medical officer's experience ($p = 0.004$).

The comparison of the percentage score of satisfaction on endoscopic procedure between standard and pre-filled consent form is shown in Table III while controlling for other variables (sex, age (in category), race, education level, occupation, procedure (OGDS and colonoscopy), and doctors' years of experience.

A significant difference in the percentage satisfaction score was observed between the pre-filled and standard consent

Table II: Comparisons of the respondents' percentage satisfaction scores for the pre-filled and standard consent forms based on socio-demographic characteristics

	Consent form					
	Pre-filled			Standard		
	N	Percentage score (Mean ± SD)	*p* value	N	Percentage score (Mean ± SD)	*p* value
Gender						
Male	34	92.43 ± 10.67	0.462	35	71.14 ± 14.70	0.497
Female	31	90.08 ± 14.72		30	69.00 ± 9.59	
Race						
Malay	29	91.03 ± 13.45	0.114	28	70.71 ± 13.52	0.479
Chinese	24	90.04 ± 13.08		23	69.56 ± 11.57	
Indian	9	97.78 ± 6.67		11	67.27 ± 10.09	
Others	3	77.78 ± 4.33		3	80.00 ± 20.00	
Age						
Less than 40	15	93.33 ± 9.75	0.627	13	70.39 ± 15.06	0.983
40–59	35	91.50 ± 14.07		29	69.83 ± 12.57	
60 and above	15	88.83 ± 12.35		23	70.44 ± 11.57	
Educational level						
Primary	10	89.25 ± 13.54	0.758	9	68.89 ± 14.53	0.713
Secondary	43	91.22 ± 13.40		52	70.00 ± 12.52	
Tertiary	12	93.33 ± 9.84		4	75.00 ± 10.00	
Occupation						
Professional	10	96.00 ± 8.43	0.655	4	70.00 ± 11.55	0.229
Non-Professional	23	90.00 ± 14.46		26	69.04 ± 14.97	
Not working	5	90.50 ± 9.42		3	86.67 ± 11.55	
Housewife	27	90.83 ± 13.13		29	69.83 ± 9.77	
Pensioner	0	-		3	66.67 ± 11.54	
Procedure						
OGDS	33	92.12 ± 11.11	0.604	32	69.96 ± 13.22	0.495
Colonoscopy	32	90.47 ± 14.31		33	71.21 ± 11.99	
Doctor's experience						
Less than 1 year	14	85.71 ± 16.51	<0.001*	17	62.35 ± 5.34	0.004*
1–2 years	15	86.83 ± 10.20		18	70.28 ± 12.18	
2–3 years	10	85.25 ± 15.74		16	71.25 ± 10.24	
More than 3 years	26	99.23 ± 3.92		14	78.21 ± 16.60	

Statistical test: one-way ANOVA.
*Statistically significant at $p < 0.05$.

Table III: Multivariate analysis of the percentage satisfaction score between respondents that received the pre-filled and standard consent forms

Source	Type III Sum of Squares	df	Mean Square	F	Sig.[b]	Partial Eta Squared	Observed Power
Corrected model	20454.815[a]	17	1203.224	9.269	<0.001*	0.585	1.000
Intercept	139321.939	1	139321.939	1073.310	<0.001*	0.906	1.000
Consent	9671.450	1	9671.450	74.507	<0.001*	0.399	1.000
Sex	628.919	1	628.919	4.845	0.030*	0.041	0.588
Age	11.006	3	3.669	0.028	0.762	0.001	0.052
Race	207.070	2	103.535	0.798	0.994	0.014	0.055
Education Level	705.155	4	176.289	1.358	0.453	0.046	0.183
Occupation	13.744	1	13.744	0.106	0253	0.001	0.412
Procedure	4884.477	3	1628.159	12.543	0.745	0.251	0.062
Doctor experience	70.907	2	35.453	0.273	<0.001*	0.005	1.000
Error	14538.262	112	129.806				
Total	882262.500	130					
Corrected Total	34993.077	129					

[a]R Squared = 0.585 (adjusted R squared = 0.521)
[b]Significant value is $p < 0.05$
[c]Mean difference of the score of satisfaction between-group: 18.36 (95% CI: 14.15, 22.58)
Statistical analysis: Multifactorial ANOVA (GLM).

Table IV: The comparison of the percentage satisfaction score between respondents that received the pre-filled and standard consent forms based on the significant findings

Variables	Percentage score (95%CI)	Mean difference [a] (95% CI)	*p* value [b]
Sex			
Male	86.35 (78.44, 94.26)	7.47	0.030
Female	78.88 (69.80, 87.95)	(0.73, 14.21)	
Doctor experience			
Less than 1 year	75.03 (66.82, 83.25)	Post hoc test	< 0.05
1–2 years	81.31 (72.81, 89.82)		
2–3 years	81.64 (72.59, 90.69)		
More than 3 years	92.47 (83.75, 99.98)		

[a]Based on estimated marginal means
[b]Adjustment for multiple comparisons: Bonferroni

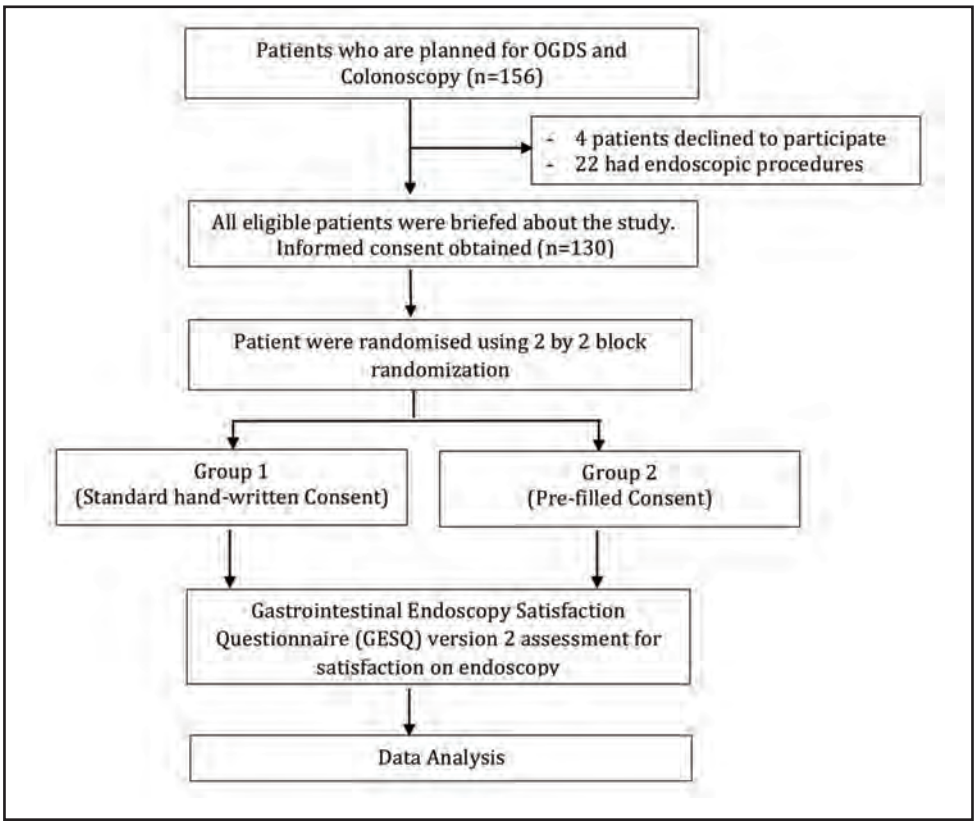

Fig. 1: Flowchart of the study

form groups (F (1,112) = 74.507, $p < 0.001$). The percentage score of satisfaction on the endoscopic procedure using pre-filled was higher than standard form consents (mean difference: 18.36 (95%CI: 14.15, 22.58)). The effect size was large (partial ή = 0.399) and the power was 100.0%. Additionally, two variables were also found to be significant: gender ($p = 0.030$) and years of medical officer's experience ($p < 0.001$). The difference in percentage score of satisfaction was associated with gender ($p = 0.003$) and medical officers' years of working experience ($p < 0.001$).

The comparison of the percentage of satisfaction on the endoscopic procedure between standard and pre-filled consent forms for the significant findings is shown in Table IV. There was a significant difference for the gender group ($p = 0.03$). The percentage satisfaction score of males was significantly higher than that of females (mean difference = 7.47; 95% confidence Interval [CI]: 0.73, 14.21). The medical officer with working experience of 3 years and above recorded a higher percentage satisfaction score compared to those with less than 1 year [mean difference = 17.44; 95% CI: 9.65, 25.23), $p < 0.001$], those with 1–2 years [mean difference = 11.16; 95% CI: 3.52, 18.80), $p = 0.001$], as well as respondents with 2–3 years working experience [mean difference = 10.83; 95% CI: 2.78, 18.89, $p = 0.003$].

In the comparison between unadjusted and adjusted analysis, the difference in the percentage satisfaction score

decreased from 21.15 (95% CI: 16.76, 25.54) to 18.36 (95% CI: 14.15, 22.58). Likewise, the effect size decreased from 41.6% to 39.9%. However, in terms of respondents' satisfaction, the impact of giving the pre-filed consent was large enough compared to administering a standard consent form.

DISCUSSION

In this study, the pre-filled consent form enhanced patients' satisfaction significantly when compared to the standard consent form ($p < 0.001$). Based on the socio-demographic characteristics, gender and the medical officer's years of working experience have a significant impact on patients' satisfaction with the pre-filled against standard consent forms.

It also showed that males had higher satisfaction scores compared to females ($p = 0.030$). It could be that the female patient required more information and explanation before they can be satisfied. The nature of females is that they will usually ask more questions than the male patient.[18] It also depends on the doctor's gender in giving the informed consent. On meta-analysis review done by Roteret al.[19] found that female doctors have better communication skills, disclose more information, and more engagement in between female patients. A study carried out by Wolosker et al.[20], found that there was no significant difference in a predicting factor for procedure satisfaction observed in both genders. However, few studies have reported that satisfaction may affect a gender if the procedure is executed by the same gender. For example, a female endoscopist working on a female patient[21] or in a single-gender environment where all the staff is of the same gender.[22] As the study only evaluated patient satisfaction based on validated GESQ questionnaire, other factors that influence patient's satisfaction, such as the language used when obtaining consent, the use of medical jargon, the patient's privacy when obtaining consent and the standardization of how doctors obtaining the consent, were not explored.

In this study, the medical officers' working experience had a significant impact on patient satisfaction with informed consent ($p < 0.001$). Studies have shown that patients are more satisfied when they are attended by an experienced doctor.[23] This is supported by a study conducted by Shiwani and Gosling[24] demonstrated that consent information differs depending on one's level of experience. Senior doctors usually will have better explanation in disclosing information while obtaining informed consent because of the experience they have in communication with patients which involves their role in paying full attention, listening, allowing questions, affirming concerns, a sense of shared responsibility, and trust than the junior doctors have.[25]

There was no statistical difference found for the race in both consent forms. A similar conclusion was also reached in a study by Spodik et al.[26] in the association between race and satisfaction in endoscopic procedures. The researchers concluded that there was no evidence of racial prejudice or a difference in cultural knowledge between the pre-filled and standard consent forms. The age group also found no significant difference in the satisfaction scores in both forms. However, previous studies showed that younger generations are more prone to feel unsatisfied with the informed consent forms than the older generations.[27] Borello et al.[28] reported that age has no effect on a patient's understanding and satisfaction concerning informed consent. The level of education also did not affect the difference in the satisfaction scores ($p = 0.453$). This result was consistent with a previous study in which education level did not influence patients' satisfaction with informed consent.[29] Additionally, a high educational degree is not predictive of effective health literacy.[30]

The patient should be informed before he or she decides, as those procedures may involve risks and complications that are unpredictable to the patient.[31] In addition, the patient may experience anxiety and mental symptoms, which is a natural human reaction when confronted with such life-or-death decisions.[32] The pre-filled consent form must contain complete information for patients to exercise their rights and autonomy according to their best interests. To justify a patient's autonomy in decision-making, the doctor must establish that the patient fully understands and acknowledge the consent completely. According to the study, patients failed to recall all of the information presented. Patients tended to be more focused on high expectations in the outcome rather than comprehension of other anticipated complications. Akkadet al.[33] demonstrated that most patients in their study interpreted consent as a legal and administrative necessity, not knowing that they had rights to other treatment options.

For a patient to decide, he must rely on the doctor who gives the information he believes. If the pre-filled informed consent is more structured with the complete information needed for the patient to decide, it will make the patient feel more secure and comfortable with the doctor. This also promotes the doctor to patient's relationship.[34] It will lead to firm decision-making without any hesitation and coercion. Also, the patient will be certain that his or her autonomy is secured from any form of abuse, deception, or mistreatment.[35] From the doctor's view, it will lead to a good impression and motivation to perform any procedure without hesitation. However, it might also lead to medical paternalism if the patient has too much trust in the doctor's decision. Informed consent can protect the patient from any harm and preserve confidentiality.[36]

It is necessary to consider a patient-specific approach when obtaining comprehensive informed consent. It integrates clinical and socio-cultural information about patients. Additionally, these approaches vary in terms of the complexity of the procedure. The riskier the procedure, the more complicated the informed consent process becomes. However, it should act as a guide on how informed consent should be obtained. By using the pre-filled consent form, all the standard information regarding the procedure will be available. This will make the informed consent process more systematic and comprehensive. Also, the pre-filled consent form should comply with MMC guidelines.[37] It includes the patient's capacity, the use of comprehensive language, voluntary participation without coercion, adequate time for discussion, the opportunity for a second opinion, and the presence of a witness or someone who can translate into the patient's native language.

The pre-filled consent form should comply with MMC guidelines[38] and may protect the doctor from liabilities in medical malpractice, provided the standard of care and duty of disclosure which is consistent with the acknowledged body of medical opinion and case law. Following the MMC consent guidelines 2016, under provision 12, all doctors are not authorised to get consent from patients unless they have the credentials and have been granted privileges by the head of the department.[37] This is to ensure that only qualified and experienced doctors have the authority to get permission and execute any operation. Consequently, it will safeguard the doctors from medical malpractice due to their competency in obtaining informed consent.

Experts across several subspecialties prepared it to standardise the inadequacy of consent processes in Malaysia. It also obligates the disclosure of information and warning of any particular material risk before obtaining consent.[38] No treatment can be performed without the patient's valid informed consent.[31] The disclosure should be made easy to enable the patient to make a final decision. Four preconditions are to be met before any doctor can take the consent include : i) the establishment of the doctor–patient relationship where the doctor who is performing any invasive procedure must meet the patient before the procedure; ii) all information regarding the nature of the procedure, benefit, alternative procedures, and complication must be explained to the patient; iii) the estimated duration of hospitalization must be made known to the patient, and iv) the prerequisite must be satisfied so that valid informed consent can be obtained from patients. Failing of any disclosure may be interpreted as a failure in the standard of care. This guideline also permits the use of any prepared information such as a pre-filled consent form for improved understanding and patient satisfaction on informed consent.

It is recommended to use the pre-filled consent form in other invasive procedures. The usage of this form can be forwarded to high authorities such as the Ministry of Health and Malaysian Medical Council so that it can be legally applied across Malaysia. Future studies could explore the satisfaction of doctors and the legal implications in using this pre-filled consent form, as well as assess if the information content is in line with the legal standard of informed consent.

Some limitations were found in this study. This study only focused on the pre-filled consent form for the endoscopy procedure as this procedure is routinely performed and easy to recruit the required number of participants. Other factors such as understanding and recalling information were not discussed. Secondly, the study was conducted using quantitative methodology only. It would be recommended to proceed with a qualitative approach to understand further the benefit of a pre-filled consent form.

CONCLUSION

The pre-filled consent form fulfills the ethical and legal aspects of the informed consent process and should be used as a standard consent form in endoscopic and other invasive procedures in Malaysia. It is suggested that a formal training, exposure to course in communication skills, breaking bad news on patient consent among junior doctors need to be taken to improve patients' satisfaction of the endoscopic procedure.

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CONFLICT OF INTEREST

All authors declare that there is no conflict of interest.

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