

The efficacy of a simple single-paged visual illustration on anxiety during pediatric gastroscopy : a randomized clinical trial

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Abstract

Background and study aims: Pediatric gastroscopy is a widely used invasive procedure and causes significant anxiety. In this prospective trial, the efficacy of a new original single-page illustration in reducing anxiety was evaluated.

Patients and methods: One hundred fifty-two consecutive children aged between 7 and 18 years who were scheduled to undergo gastroscopy were randomized to receive a standard consent form plus the new single-page visual illustration (group I) and the usual text consent brochure (group II). The Hospital Anxiety and Depression Scale (HADS) was administered to mothers just before, at the first hour, and at the second week after gastroscopy. Also, Visual Analogue Scale (VAS) scores were obtained from children to measure anxiety at the same time intervals.

Results: The demographic characteristics of the groups were similar. A higher number of cases refused gastroscopy in group II ($p=0.040$). The proportion of mothers with significant HADS-Anxiety scores at the baseline evaluation (≥ 8) was 33.8% in group I, whereas it was 58.1% in group II ($p=0.003$). This remarkable difference in anxiety was also observed at the first hour and second week. Moreover, significant baseline HADS-Depression scores (≥ 8) of the mothers were more common in group II (2.7% vs. 12.7%, $p=0.028$). In addition, overall HADS scores revealed considerably higher values in group II at all time intervals. VAS scores in children revealed significantly less anxiety in group I at both the baseline and the first hour assessment.

Conclusions: Lower anxiety scores were observed in both mothers and children with the incorporation of the single-page illustration. This new modality may provide less anxiety and prevent insufficient comprehension with higher acceptance of gastroscopy. (*Acta gastroenterol. belg.*, 2020, 83, 533-539).

Key words: anxiety, consent, gastroscopy, HADS, VAS.

Introduction

Upper gastrointestinal endoscopy (esophagogastro-duodenoscopy, gastroscopy) is a widespread diagnostic and therapeutic procedure in children. Over the past decades, the number of endoscopies has tremendously increased and endoscopy represents a conventional tool in the daily practice of pediatric gastroenterologists (1,2). However, this procedure was shown to be a source of significant anxiety for children, and preparation before endoscopy was suggested to reduce patients' distress (3). A well-designed multicenter evaluation of the anxiety related to pediatric gastrointestinal endoscopy clearly revealed that approximately 80% of patients experienced anxiety before undergoing endoscopy (4). The authors also strongly suggested a preparatory intervention including an explanation regarding specific concerns before endoscopy to reduce anxiety. Similarly,

parents inevitably experience feelings of anxiety when their child undergoes an invasive procedure such as gastroscopy. Moreover, when an insufficient explanation of gastroscopy is provided, children may experience significant anxiety and may exhibit more disturbed behavior. They may also continue to have negative feelings (5). Therefore, both the child and the family should be adequately informed before the procedure.

It has been reported that children with more knowledge experienced fewer problems and would be less anxious and upset when they had future endoscopies (3). A recent trial proposed a commercial electronic-assisted approach for pediatric endoscopy and demonstrated a significant increase in obtaining informed consent (6). One of the major sources of anxiety may be the 'complexity' of current consent forms because it was shown that current consent forms might be related with suboptimal comprehension in both children and parents (7). Consequently, it is obvious that the innovation of a simple and easy-to-use consent method to decrease anxiety of both children and parents related with endoscopy would be notable. A simplified and illustrated version may also improve the understanding of consent forms. In conclusion, a new straightforward modality would be particularly valuable for busy institutions where significant numbers of endoscopies are performed daily.

For this purpose, we developed a simple, easy-to-use single-page illustration including a brief explanation of pediatric gastroscopy (Appendix 1). Furthermore, in this study, the Hospital Anxiety and Depression Scale (HADS) was used for the first time in the literature to investigate the mothers' situation during pediatric gastroscopy. HADS assesses both anxiety and depression, which commonly coexist (8). It has been validated in many languages and clinical settings. In a large review based on 747 studies, HADS was shown to be effective to detect both anxiety and depression in various conditions including psychiatric cases and somatic problems in primary care settings, and even in the general population (9).

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Submission date : 03/03/2020

Acceptance date : 26/04/2020

The objective of this prospective randomized study was to compare the efficacy of the addition of this new single-page illustration against the solitary utilization of standard text informed consent form in terms of decreasing anxiety of both the children and the parents.

Materials and methods

Study Population

The study was prospectively conducted in the department of pediatric gastroenterology of a referral university hospital between June 2018 and June 2019. It was performed in accordance with the Helsinki Declaration and approved by the local ethics committee (Institutional review board clinical research protocol number 2018-0511). Informed consent was obtained from all individual participants included in the study. The study complied with the guidelines of Consolidated Standards of Reporting Trials (CONSORT) checklist.

Consecutive patients aged between 7 and 18 years who underwent gastroscopy were included in the study. The exclusion criteria were as follows: severe mental and physical disabilities detected either in patients or mothers, previous history of any type of endoscopy both in the child and the mother, previous history of hospitalization or surgery both in the child and the mother, availability or previous exposure to medical education or occupation in the health sector, and refusing gastroscopy.

Randomization and Procedures

The patients were prospectively randomized into two groups using a simple randomization method. The endoscopy nurse provided the forms to the subjects. Group I received the new one-page illustration together with the usual brochure. The standard brochure was written to obtain consent from the parents, and mainly deals with medico-legal issues. It summarizes the procedure and provides detailed information regarding all possible complications. Parents were asked to read the brochure carefully. Signed consent from the parents was obtained. The new single-page illustration was originally developed to explain the gastroscopy in a simple way by the department of pediatric gastroenterology. An English translation by a native speaker is provided in Appendix 1. This new form contains figures of the gastroscopy instrument including simple anatomic and procedural drawings. Brief explanations are also presented in this form. This information sheet was given to the mothers in group I. Group II received only the standard text informed consent form without any illustration or drawing for gastroscopy. The children's assent for gastroscopy was obtained in both groups. The children in group I received the illustrated form. Apart from this illustrated form, exactly the same steps were followed in both groups.

Demographics were collected including age, sex, education level of mothers, medical history to check

the previous endoscopy, and surgery. HADS and Visual Analogue Scale (VAS) scores were used to evaluate anxiety. HADS aims to measure symptoms of anxiety and depression. It comprises seven questions for anxiety (HADS-Anxiety) and seven questions for depression (HADS-Depression) (8). Anxiety and depression questions are scored separately. HADS-Anxiety concerns mainly the symptoms of generalized anxiety disorder, and HADS-Depression addresses anhedonia as the main symptom of depression. Each item is scored on a response-scale with four alternatives ranging between 0 and 3. A cut-off score of 8 or above is generally advised for both HADS-Anxiety and HADS-Depression (9). Using VAS, the children were asked to score their anxiety from 0 to 10.

In both groups, pre-endoscopy HADS questionnaires were completed just before the child underwent the procedure. Post-endoscopy HADS scores were completed at the first hour and second week after the gastroscopy, respectively. Also, VAS values were simultaneously obtained from children at the same time intervals. All questionnaires and scales were answered in private.

An intravenous line was inserted for all children just prior to endoscopy. All subjects were sedated for endoscopy. A total dose of 0.1 to 0.3 mg/kg midazolam (maximum dose 10 mg) and 1-3 mg/kg meperidine (maximum dose 100 mg) was administered with slow intravenous infusion. The drugs were given in divided doses and were titrated to the desired sedative effect. The same physician performed all gastroscopies. The vital signs, including heart rate, blood pressure, and levels of blood oxygen saturation before and after administration of sedative medication before endoscopy were checked. Heart rate and blood oxygen saturation were monitored during endoscopy procedures.

Statistical Analysis

The collected data were entered and analyzed using the SPSS software version 20 (IBM SPSS Statistics version 20.0, SPSS Inc., Chicago, IL). The Mann-Whitney U test and Fisher's exact test were used to compare demographic characteristics. Percentages were assessed using the Chi-square test. The comparisons of overall HADS and VAS scores were also made using the Mann-Whitney U test between the two groups. The change in HADS subscales and VAS values at different intervals were compared using related-samples Friedman's two-way analysis of variance (ANOVA) by ranks. All these analyses used a significance level of $p < 0.05$.

Results

All eligible patients ($n=188$) aged between 7 and 18 years were initially evaluated as consecutive patients who needed gastroscopy. A total of 22 patients were eliminated based on the exclusion criteria (Fig. 1). After randomization, only three mothers (3.8%, 3/79) in

Table 1 a and b. — Demographic characteristics of the groups and their comparisons

a : Continuous variables

	Group I (n=74) (consent form + illustration)				Group II (n=74) (consent form)				p Value**
	Median	Min	Max	IQR*	Median	Min	Max	IQR*	
Children's age (months)	144.50	84	216	89	159.00	84	213	77	0.211
Mothers' age (years)	36.00	28	46	8	38.00	28	49	7	0.163

* Interquartile range. **Mann-Whitney U Test.

b : Categorical variables

		Group I (n=74) (consent form + illustration)		Group II (n=74) (consent form)		Total (n=148)		p Value*
		N	%	N	%	N	%	
Gender of children	Female	36	48.6	41	55.4	77	52.0	0.410
	Male	38	51.4	33	44.6	71	48.0	
Mothers' Education Degree	Primary - Middle School	45	60.8	47	63.5	92	62.2	0.866
	High School - University	29	39.2	27	36.5	56	37.8	

*Fisher's Exact Test

Table 2. — Comparison of two groups with significant HADS subscale scores in mothers

Significant HADS Score ≥ 8		Group I (consent form + illustration n(=74) (N, (%))	Group II (consent form) n(=74) (N, (%))	p Value*
HADS Anxiety	Baseline	25 (33.8)	43 (58.1)	0.003
	60 th min	9 (12.2)	32 (43.2)	<0.001
	2 nd week	5 (6.8)	21 (28.4)	0.001
HADS Depression	Baseline	2 (2.7)	9 (12.7)	0.028
	60 th min	1 (1.4)	4 (5.4)	0.172
	2 nd week	1 (1.4)	1 (1.4)	1

HAD : Hospital and Anxiety. *The chi-square test

Table 3. — Comparison of two groups regarding overall HADS scores in mothers

Mothers' Scores	Group I (consent form + illustration)				Group II (consent form)				p Value**
	Median	Min	Max	IQR	Median	Min	Max	IQR*	
HAD Anxiety, Baseline	6.00	2	11	4	8.00	2	15	4	0.001
HAD Anxiety, 60 th min	5.00	2	9	2	7.00	3	14	3	0.000
HAD Anxiety, 2 nd week	5.00	2	9	2	6.00	3	14	3	0.000
HAD Depression, Baseline	3.00	0	6	3	4.00	0	11	3	0.206
HAD Depression, 60 th min	4.00	0	9	3	4.00	0	12	4	0.036
HAD Depression, 2 nd week	3.00	0	6	2	4.00	0	10	4	0.004

HAD : Hospital and Anxiety. * Interquartile range. **Mann-Whitney U Test

group I (consent form plus new illustrated form) refused gastroscopy for their children. However, 11 subjects (12.6%, 11/87) in group II refused gastroscopy after reading the original text consent form. The difference in the rate of gastroscopy refusal was significant ($p=0.040$). Consequently, a total of 14 cases were then disqualified. We further continued randomization for 14 additional gastroscopy cases to compensate for those who

refused gastroscopy. Finally, a total of 152 consecutive children aged between 7 and 18 years who underwent gastroscopy were randomized. However, three patients were excluded after randomization due to inadequate completion of the forms. Also, another subject was excluded because the mother forgot to declare that she had a previous endoscopy. Finally, 74 children in group I and 74 in group II completed all steps (Fig. 1).

Table 4. — Comparison of two groups regarding VAS scores in children

Children's Scores	Group I (consent form + illustration)				Group II (consent form)				p Value*
	Median	Min	Max	IQR	Median	Min	Max	IQR	
VAS, Baseline	4.00	0	8	3	4.00	2	10	2	0.003
VAS, 60 th min	2.00	1	6	2	4.00	0	8	2	0.007
VAS, 2 nd week	2.00	0	4	2	2.00	0	4	2	0.993

VAS : Visual Analogue Scale. * Interquartile range. **Mann-Whitney U Test

Table 5. — Comparisons of two groups regarding the change in HADS subscale and VAS values at different intervals are provided along with the p values

	Group I (consent form + illustration)				Group II (consent form)			
	Baseline vs 60 th min #	Baseline vs 2 nd week#	60 th min vs 2 nd week#	p Value*	Baseline vs 60 th min #	Baseline vs 2 nd week#	60 th min vs 2 nd week#	p Value*
Mothers', HAD Anxiety	<0.001	<0.001	1	<0.001	<0.001	<0.001	1	<0.001
Mothers', HAD Depression	0.001	<0.001	1	<0.001	0.088	0.026	1	0.003
Children's, VAS	0.014	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001

VAS : Visual Analogue Scale. HAD : Hospital and Anxiety. * Related Samples Freidman's Two-Way Analysis of Variance by Ranks. # p values of the Pairwise comparison (adjusted significance)

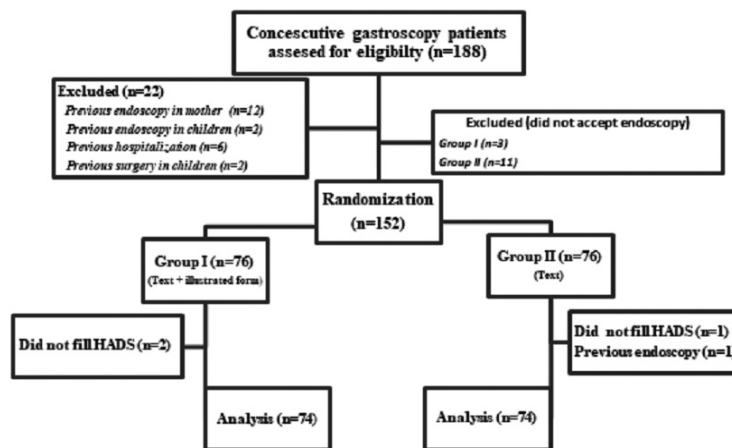


Fig. 1. — The flowchart of the study participants

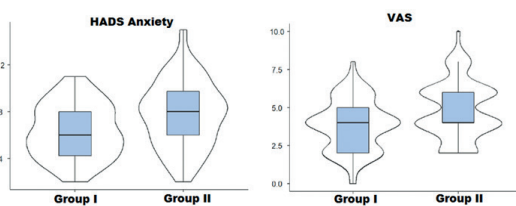


Fig. 2. — Violin plots of baseline values regarding mothers' HAD anxiety and children's VAS measurements in both groups are given to visualize the distribution of the data and its probability density.

The demographic characteristics of the groups are shown in Table 1 including the median age and ranges of the groups. The age comparison was similar between the groups. Sex distribution was also comparable. Furthermore, the mothers' age and education level showed similar values in both groups.

The HADS-Anxiety scores clearly demonstrated that pediatric gastroscopy caused significant anxiety (≥ 8 HADS) in mothers. Almost 1 in 3 mothers in group I, and more than half of the mothers in group II developed significant anxiety. The proportion of mothers with significant HADS-Anxiety scores (≥ 8) was 33.8% (25/74) in group I, whereas it was 58.1% (43/74) in group II according to baseline evaluations (Table 2). The difference was significant ($p=0.003$) suggesting less anxiety with the use of the illustrated form. This remarkable difference in the ratio of significant anxiety was also observed at the first hour and the second week assessments (Table 2). Moreover, significantly high baseline HADS-Depression scores (≥ 8) among the mothers were more common in group II (2.7% vs. 12.7%, $p=0.028$, Table 2). On the other hand, the comparison of the two groups regarding the overall HADS subscale scores in the mothers revealed considerably higher values

in group II at all time intervals (Table 3). Similarly, VAS values in the children revealed significantly less anxiety in group I at both the baseline and the first hour assessment (Table 4). This observation suggested that the visual instrument also prevented anxiety in children. In particular, the baseline comparison of HADS-Anxiety and VAS scores revealed a significant improvement in group I through the use of the visual form (Fig. 2).

Interestingly, the evaluation of two groups regarding the change in overall scores at different intervals demonstrated that the mothers' baseline HADS-Anxiety scores were significantly higher than both the first hour and the second week assessments (Table 5). HADS-Depression scores, on the other hand, presented a tendency to decrease by time. It can also be concluded that both HADS subscale scores reached a stable level after the procedure, because the first hour and the second week values were similar. Correspondingly, the children's VAS scores were highest in the baseline evaluation. However, these VAS scores showed a remarkable improvement during each evaluation, indicating that the level of anxiety in children diminished by time (Table 5).

Discussion

Gastroscopy can be regarded as a routine investigation for pediatric gastroenterologists. Consequently, the number of gastroscopies in the pediatric population has increased tremendously (1, 2). This creates a significant burden for referral hospitals where sometimes only one pediatric gastroenterologist works. Particularly in these busy centers, obtaining consent from patients can be regarded as a supplementary step. The physician may not spend sufficient time for the consent procedure, and it may be considered as just a mandatory legal issue for gastroscopy. Currently, a 2-3 paged written text form that particularly focuses on possible complications is given to parents in certain centers. The parents are asked to read this form and then they are anticipated to give permission for gastroscopy. On the other hand, current consent instruments may require a high reading level, and even a seventh/eighth-grade reading level may be required for certain consent forms regarding pediatric endoscopy (6). It was also shown that just two patients and 12 parents out of 88 pairs of patients-parents demonstrated comprehensive understanding of the consent form for pediatric endoscopy (7). It was postulated that about 60% of parents overestimated their understanding of the informed-consent discussion (10). Therefore, it is required to simplify the original consent forms in order to increase the level of understanding.

One of the straightforward ways to improve the comprehension of such forms is to add simple pictures or drawings. For this purpose, we developed a single-page outline including simple drawings about gastroscopy (Appendix 1). The addition of this new illustrated page improved the rate of approval for gastroscopy. About

4% of the mothers in group I refused gastroscopy, and this ratio increased to 13% in group II ($p=0.040$). This observation suggested that this one-page illustration improved the understandability of the consent form. This issue is also crucial for young patients because children should also participate in the consent process. The American Academy of Pediatrics suggested that youth should be incorporated into healthcare decision-making (11). Therefore, this new modality may prevent suboptimal comprehension of the consent process for adolescents because it is well-accepted that, providing pictures, simplifying written materials, and using an appropriate font size can improve health literacy (12). In a randomized trial, a video intervention in the consent process was shown to improve parental and youth comprehension of consent (13). However, such modalities based on technology would be somewhat difficult for busy referral centers where a limited number of health personnel work.

On the other hand, the complexity or suboptimal comprehension of consent forms would be a significant source of anxiety for both children and their parents. It is self-evident that anxiety is a major concern for invasive procedures, particularly in the pediatric population. Endoscopy has been reported to be associated with significant anxiety in both children and their parents. In a study of 100 children aged 8 to 17 years, almost 20% of patients reported some memory of the procedure, even at the end of the day (3). The authors also showed that children with greater recall reported greater aversion and a more negative attitude toward subsequent endoscopies. A multicenter trial clearly demonstrated that approximately 80% of the patients and 60% of the parents were anxious before gastrointestinal endoscopy (4). Therefore, all efforts are required to reduce the anxiety of children and their parents. It was demonstrated that psychological preparation before endoscopy significantly decreased anxiety in both pediatric patients and their parents (14). It was also shown that children with greater knowledge about endoscopy would be less anxious (3). Accordingly, a brief and clear form would also decrease the anxiety of pediatric patients. However, common practice throughout the world is focused on obtaining consent from the parents of patients aged less than 18 years to avoid legal problems. Therefore, the target of existing consent forms is predominantly the parents. However, children and adolescents in particular should have the opportunity to provide approval for the procedure (11, 15). The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) Endoscopy and Procedures Committee also advised to obtain proper informed consent from the parent/legal guardian, along with assent in the case of older adolescent patients (16). A shorter and uncomplicated consent form is also needed to obtain assent at least of older adolescents. Our new form would also address the issue of consent by the child and also help to reduce the anxiety of children and their parents.

In this study, we used HADS to measure anxiety for the first time in a pediatric endoscopy procedure. HADS is a universal tool used to evaluate anxiety simultaneously with depression (8, 9). HADS is an ideal simple instrument for such clinical situations because anxiety and depression commonly coexist. Cut-off scores of HADS are also described for quantification. A score of 8 or more for anxiety has a specificity of 0.78 and a sensitivity of 0.9, and for depression a specificity of 0.79 and a sensitivity of 0.83 (8, 9). In our study, HADS-Anxiety scores clearly demonstrated that approximately 60% of the mothers had significant anxiety (HADS-Anxiety ≥ 8) when only a text consent form was used. Also, almost 13% of the mothers of group II even had significant depression (HADS-Depression ≥ 8). This observation confirms that gastroscopy is a stressful procedure for parents. The rate of this significant anxiety decreased to nearly 30% just by adding the visual form. Moreover, the significant HADS-Depression ratio was also decreased from almost 13% in group II to 3% in group I by using the illustrated form.

VAS scores also proved that anxiety in children was prominent in group II at all assessments in this study. Incorporation of a simple visual instrument significantly decreased the level of anxiety in children based on VAS scores at all time points. According to a similar trial, the mean VAS anxiety scores of parents before and after providing systematic information via a set of real photograph-based technical illustrations were 3.89 and 1.90, respectively ($p < 0.001$) (17). These values for the anxiety of children aged over 5 years before and after providing systematic information were 4.38 and 3.36, respectively ($p = 0.143$). The authors reported that systematic visual illustration of technical procedures in children undergoing gastrointestinal endoscopy could significantly reduce the parents' anxiety, confirming our trial results.

In this study, we established that pediatric gastroscopy was a relatively stressful procedure for both children and their mothers based on VAS and HADS scores. This procedure was even associated with depression in mothers. An interesting study on 20 children aged 4 to 15 years undergoing endoscopy indicated that all children and their parents considered the preparation necessary (18). The researchers used salivary chromogranin A levels as a sensitive indicator of mental stress and a marked elevation in all children was observed before endoscopy. The authors also noted that a psychological preparation was necessary to reduce fear, misunderstanding, and other psychological stress in children undergoing endoscopy. However, this process would be impossible for busy centers where a many endoscopies are performed daily. Therefore, there exists a great variation among institutions as to the consent methods and styles for pediatric gastroscopy. Many of these differences are in the large part caused by legal requirements. The load of institutions also plays a significant role in daily practice, and anxiety may be ignored. According to the

randomized prospective trial, just the incorporation of a new illustrated single-page form into the standard consent brochure offers an effective and easy way to decrease anxiety of both children and their parents. The current study also suggests that adding simple pictures or drawings may improve the understandability of consent forms, and may increase the approval rate for the procedure.

In conclusion, we employed a randomized prospective study to evaluate the role of a new single-page illustration in an attempt to offer an effective easy way to decrease anxiety of both children and their parents. The results confirmed a remarkable decrease in anxiety scores of both children and their parents based on HADS and VAS values. This new modality may prevent suboptimal comprehension and increase the approval ratio of the consent procedure. It is easily transferable to other languages and even other areas of daily medical practice. Nevertheless, additional research is needed to standardize and improve pediatric consent forms for gastroscopy.

Ethical approval

The study was reviewed and approved by the Local Institutional Ethics Committee of the University Hospital.

Conflict of interest

No financial or nonfinancial benefits have been received or will be received from any party related directly or indirectly to the subject of this article.

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APPENDIX 1 - PEDIATRIC GASTROSCOPY

1. Gastroscopy is a procedure used to inspect the esophagus, stomach, and the first part of the small bowel by using a long, thin flexible tube (gastroscope) with a light and a camera on the end (Figure 1a,b,c).



Figure 1a, b, c : Gastroscope

2. Reflux, ulcer, bleeding, and abdominal pain are possible conditions that require gastroscopy (Figure 2). Sometimes small samples (biopsies) of tissue from the stomach may be taken during gastroscopy.

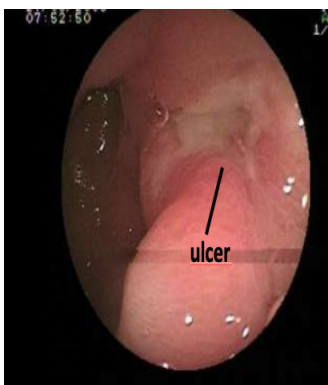


Figure 2: Ulcer

3. Gastroscopy is performed under sedation through a sedative drug by an injection into a vein. You will be asleep during the procedure.