Feasibility and clinical benefit of cognitive–behavioral intervention for preparing patients for transesophageal echocardiography

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ABSTRACT

Objective: Despite premedication, anxiety in patients undergoing transesophageal echocardiography (TEE) is prevalent, often causing adverse physiological and psychological effects and contributing to decreased patient compliance. We aimed to evaluate the feasibility of cognitive–behavioral intervention (CBI) in patients undergoing TEE and to assess its impact on the severity of anxiety, patient's and physician's comfort, and administered dose of sedatives.

Methods: Our study was designed as a prospective, single-center, single-blinded, case-controlled pilot study. The study group comprised 49 patients (26 men, 66±8 years old) referred for TEE. Before the examination, 26 randomly selected patients underwent CBI. Sedatives were administered, if necessary. After the examination, patient anxiety and patient's and physician's comfort were evaluated using dedicated questionnaires and scores. Intergroup comparison was performed using Student's t-test for independent variables and Mann–Whitney U test and Pearson's chi-square test or Fisher's exact test for categorical variables.

Results: The mean level of pre-TEE distress and anxiety were significantly lower in patients receiving CBI than in those without intervention (p=0.022). Furthermore, the application of CBI significantly reduced patient's discomfort (p<0.001) and resulted in increased comfort of physician (p<0.001) during TEE. The need of sedative administration (31% vs. 91%, p<0.001) and its mean dose was significantly lower in patients receiving CBI (1.6±0.5 mg vs. 2.7±1.6 mg midazolam, p=0.009).

Conclusions: CBI is feasible in patients undergoing TEE. It decreases patient's anxiety and discomfort and increases physician's comfort. It also results in reduced use of sedatives during the examination. *(Anatol J Cardiol 2016; 16 684-8)*

Keywords: transesophageal echocardiography, anxiety, cognitive therapy, relaxation therapy, conscious sedation, sedatives

Introduction

Transesophageal echocardiography (TEE) is a widely used diagnostic tool in cardiology (1). However, the intolerance of the esophageal probe may limit the duration of the examination and therefore its quality and diagnostic value. In up to 20% of unsedated patients, the quality of acquired images may be not sufficient enough to answer the clinical questions posed by the referring physician (2). Therefore, reduction of patients' discomfort remains one of the main objectives. It involves general anesthesia or administration of sedative drugs. Nevertheless, there are clinical situations when a conscious and active patient's cooperation is necessary to obtain essential information (e.g., Valsalva maneuver in a patient with suspicion of foramen ovale) or the use of pharmacological agents is limited due to patient's safety (3).

Behavioral and psychological procedures, such as hypnosis, self-relaxation training, and cognitive–behavioral intervention (CBI), have been introduced successfully in the reduction of pain and anxiety related to many medical procedures (4). However, the feasibility of CBI before the TEE remains unclear.

The aim of this study was to determine the feasibility of CBI to improve patients' and echocardiographer's comfort during TEE and to assess its impact on the severity of patient's anxiety and the dose of administered sedatives.

Methods

Our study was designed as a prospective, single-center, single-blinded, case-controlled pilot study.

Study population

The study population comprised 49 adult patients referred for TEE to our Echocardiographic Laboratory. The exclusion criteria were a history of psychiatric disorder, hemodynamic or clinical instability, and the need for emergency TEE (e.g., suspicion of aortic dissection or acute complication of infective endocarditis).

Before examination, all patients were randomly assigned to the two subgroups—the intervention group and the control group.

The most common indications for TEE were the following: atrial fibrillation before cardioversion (49%), suspicion of congenital defect (atrial septal defect, patent ductus arteriosus or patent foramen ovale; 22%), and assessment of acquired valvular disease (14%).

The study protocol was approved by the local Bioethics Committee, and all patients signed the informed consent form.

CBI

The control group received standard pre-procedural care. Patients were informed before the procedure about its course and how to cooperate with medical staff during the examination.

In the CBI intervention group, an additional adopted standardized emphatic structured behavior was displayed by the clinician who would perform the TEE examination. CBI is based on the concept of cognitive-behavioral therapy, which connects the elementary theory about how we learn (behaviorism) with the theory about the way we interpret and think about different events in our lives (cognition) (5, 6). In CBI, the therapist and patient work together to set a realistic goal and learn to manage stress and anxiety. Moreover, relaxation techniques such as deep breathing and coping strategies such as refocusing attention using self-statement methods and disseminating information about the medical procedure are being introduced (6). The essentials for intervention success seems to be keeping track of thoughts, feelings, and behaviors to become aware of forthcoming symptoms and to make it easier to control and reduce them.

The structured intervention included the following components: matching patients' verbal communication patterns, attentive listening, emotional encouragement, emotionally neutral descriptions, assurance of perception of control ("Feel free to let us know if we can do anything for you at any time"), fast response to patient's request and avoidance of negatively loaded suggestions (e.g., "You will feel discomfort in your throat" and "There will be unpleasant swallowing act"), as described previously (4). The CBI intervention was conducted 20±5 min prior to TEE.

In addition, prior to TEE, all CBI patients were provided with a short psychoeducation about relationships among thoughts, emotions, and reactions. Immediately before the examination, patients were also instructed to close their eyes and concentrate on a regular, deep, slow breathing through the nose, connected with muscle relaxation. When a potentially painful stimulus was expected (e.g., probe insertion or probe manipulation), patients were instructed to focus on a competing activity such as regular deep breathing (5).

Pre-TEE anxiety and distress assessment using a visual analogue scale

Before TEE (and after CBI in those who underwent it), all participants were asked to mark the level of their anxiety and distress on a visual analogue scale. The 20-cm vertical scale had scores from 0 to 100, where 0 stood for lowest imaginable level of well-being and highest imaginable distress and anxiety and 100 stood for highest imaginable level of well-being and lowest imaginable distress and anxiety.

Post-TEE patients' and physicians' comfort assessment

After TEE, patient's and physician's comfort during the examination were evaluated using the dedicated questionnaire with a simple three-grade scale: 1, good tolerance/high level of comfort; 2, moderate tolerance/moderate level of comfort; 3, bad tolerance/low level of comfort.

TEE protocol

TEE was performed by the same experienced echocardiographer in all patients using Vivid 9 echocardiograph (GE Healthcare, USA) with a transesophageal probe. All patients had an intravenous access secured. The topical pharyngeal anesthesia (lidocaine spray) was administered at the beginning of the procedure. Sedative drugs were administered if necessary (intravenous (IV) midazolam: initial 1 mg iv bolus, with additional 1 mg iv doses repeated as needed), depending on the course of the procedure (at the physician's discretion). During TEE, patient's ECG and peripheral O_2 saturation were continuously monitored. The blood pressure measurement was taken every 5 min. TEE was carried out according to the current guidelines (1).

Statistical analysis

Data was presented as means±standard deviation or median with interquartile range. Intergroup differences in continuous variables were assessed using Student's-t test for independent variables or nonparametric Mann–Whitney U test depending on the data distribution. Categorical variables were compared using Pearson's chi-square test or Fisher's exact test. A p value of <0.05 was considered statistically significant. All statistical analyses were performed using the Statistica 12.0 software (StatSoft Poland, Kraków, Poland) and MedCalc 9.5 (MedCalc Software, Ostend, Belgium).

Results

The study comprised 49 patients (26 men; mean age, 66±8 years) referred for TEE and randomly assigned to the intervention group (n=27) and the control group (n=22). The demographic characteristics of the study group are presented in Table 1.

The comparison between the studied subgroups according to the indications for TEE is presented in Table 2.

Considering that some medications may alter the anxiety levels, we also analyzed the main groups of medications administered on the day of the procedure, which can significantly modify the anxiety state in studied patients (e.g., beta blockers, thyroid hormones, corticosteroids, anxiolytics, and antidepressants). Overall, most patients were prescribed beta blockers (63%), without significant difference between the intervention and

Table 1. Patients' demographic characteristics

Variable	Overall (n=49)	Intervention group (n=26)	Control group (n=23)	P
Age, years	66 (58–70)	67 (57–70)	66 (59–68)	0.718[1]
Male, n (%)	27 (55)	15 (58)	12 (52)	0.698[2]
Weight, kg	75 (71–89)	75 (71–90)	76 (70–86)	0.732[1]
Height, cm	169 (163–175)	166 (162–175)	170 (164–175)	0.954[1]
BMI, kg/m^2	26.4 (24.6–31.0)	27.4 (24.6–31.2)	26.2 (24.4–29.4)	0.545[1]
EF, %	55 (45–60)	55 (38–59)	52 (46–60)	0.509[1]

BMI - body mass index; EF - left ventricular ejection fraction
[1]Mann–Whitney U test; [2]Pearson's chi-square test

Table 2. Indications for transesophageal echocardiography

Indication	Intervention group (n=26)	Control group (n=23)
Atrial fibrillation, n (%)	13 (50)	11 (48)
Congenital defect, n (%)	5 (19)	6 (26)
Valvular disease, n (%)	4 (15)	3 (13)
Infective endocarditis, n (%)	4 (15)	2 (9)
Intracardiac mass, n (%)	0 (0)	1 (4)

control groups (62% vs. 65%, p=0.790). Similarly, no intergroup difference was found between thyroid hormone supplementation (8% vs. 22%, p=0.230). None of the patients were prescribed corticosteroids, anxiolytics, or antidepressants.

The mean level of pre-TEE distress and anxiety was significantly lower in patients receiving CBI than in the group without intervention (p=0.022). Furthermore, we observed that the application of CBI significantly reduced patient's discomfort (p=0.002) and resulted in increased comfort of physician (p<0.001) during the TEE. Moreover, in the intervention group, patients were three times less likely to be prescribed a sedative (p<0.001); also, its mean dose and indexed (to the body weight) dose was significantly reduced after the intervention (0.5 mg vs. 2.4 mg of midazolam, p<0.001). Due to suspicion of intra-cardiac shunt, the Valsalva maneuver was performed in 10 patients (20%), and successful cooperation during this maneuver was achieved more

frequently in the intervention group (75% vs. 50%), but this difference was not statistically significant (p=0.571) (Table 3).

The calculated posthoc study power (with alpha = 0.05) for measured different outcomes were as follows: 99.9% for the observed difference in frequency of sedatives administration (31% vs. 91%, p<0.001), the posthoc study power was and 88.6% for measured mean difference in administered midazolam dose (1.6±0.5 mg vs. 2.7±1.6 mg, p=0.009).

Discussion

The results of our pilot study clearly indicate that a simple CBI can significantly reduce pre-procedural anxiety and improve patient's and echocardiographer's comfort during TEE. Also, it reduces not only the dose but also the frequency of sedative administration in patients undergoing TEE. Particularly noteworthy was that finally only 8 of 26 (31%) patients in the intervention group needed sedatives.

TEE, in contrast to conventional transthoracic echocardiography, is a semi-invasive procedure. It is associated with

Table 3. Values of assessed end-points in the studied groups

Variable	Intervention group (n=26)	Control group (n=23)	P
Mean level of pre-TEE well-being+	64.81±16.15	55.0±12.25	0.022[1]
Mean level of patients' comfort during TEE*	1.27±0.45	1.83±0.65	<0.001[1]
Good tolerance, n (%)	19 (73)	7 (30)	0.006[2]
Moderate tolerance, n (%)	7 (27)	13 (57)	
Bad tolerance, n (%)	0 (0)	3 (13)	
Mean level of echocardiographer's comfort during TEE*	1.19±0.40	1.78±0.60	<0.001[1]
High level of comfort, n (%)	21 (81)	7 (30)	0.001[2]
Moderate level of comfort, n (%)	5 (19)	14 (61)	
Low level of comfort, n (%)	0 (0)	2 (9)	
Midazolam administration, n (%)	8 (31)	21 (91)	<0.001[2]
Mean midazolam administered dose, mg	1.6±0.5	2.7±1.6	0.009[1]
Mean indexed midazolam administered dose, µg/kg	17.9 (11.0–26.2)	27.8 (25.0–33.3)	0.011[3]
Successful Valsalva maneuver, n (%)	3/4 (75%)	3/6 (50%)	0.571[4]

TEE – transesophageal echocardiography
+ - scale from 0 to 100: 0–lowest imaginable level of well-being, highest imaginable anxiety,
100-highest imaginable level of well-being, lowest imaginable anxiety
* - three degree scale: 1–good tolerance/comfort, 2–moderate tolerance/comfort, 3–bad tolerance/comfort of examination
[1]Student's-t test for independent variables; [2]Pearson's chi-square test; [3]Mann–Whitney U test; [4]Fisher exact test

discomfort for the patient and risk of complications, especially when patient cooperation is poor (6). A multicenter survey has proven that the commonest reason of probe insertion failure is lack of patient cooperation, and that the interruption of TEE is mainly caused by the intolerance of the TEE probe (6). The study on patient tolerance of TEE performed by De Belder et al. (2) using dedicated questionnaire indicated that although TEE was well tolerated by 50% of patients, nearly 73% of all inpatients preferred to be sedated. Here, we proved that a simple CBI may significantly increase the tolerance and comfort of examination, thereby improving its feasibility and diagnostic value.

Tolerance of TEE is strongly dependent on the prior anxiety and patient's perception of the examination (7). Many different non-pharmacologic approaches to patients' preparation of the various invasive medical procedures have previously been described. Eren et al. (8) in recent prospective single-blinded study on patients scheduled for TEE have shown hypnosis to be associated with positive therapeutic outcomes in comparison to the traditional sedation in TEE (intravenous midazolam). They have shown lower level of post-procedural anxiety and better maintenance of vigilance in the hypnosis group. Moreover, similar to our results, both cardiologists and patients rated the probing significantly higher when the non-pharmacological approach was applied (8). In the randomized trial of Lang et al. (4), the structured attention and self-hypnotic relaxation has been proven to be beneficial during invasive medical procedures, resulting in pain and anxiety reduction. These results are consistent with our findings, where patients receiving CBI had lower anxiety state levels. Schupp et al. (9) also showed that a similar non-pharmacological analgesia adjunct is particularly effective in patients with high state anxiety levels.

Midazolam is the most frequently chosen sedative drug to facilitate TEE (10). As a short-acting benzodiazepine, it has amnestic and anxiolytic effects, and besides sedative action, provides pain reduction and muscle relaxation (3). However, it can also increase the number of potential complications and may result in oversedation, disorientation, confusion, discoordination, and dizziness (3, 11) and induce significant hemodynamic and respiratory depression (12). Moreover, the decisional capacity and cooperation with a sedated patient is limited, which may reduce the diagnostic value of the examination (3). Furthermore, the effective dose of midazolam is dependent on many different factors, such as patient's age and LV systolic function (13). Despite being commonly used, it has not been finally clarified whether sedative administration decreases or increases the percentage of unsuccessful endoscopic procedures (14). In our study, CBI resulted in a significantly lower administered dose of midazolam, thus decreasing the risk of side effects and providing a more rapid post-procedure recovery with a potentially earlier discharge time. In a study by Lang et al. (4), the use of self-hypnosis and other techniques of stimulation in patients undergoing radiological procedures under sedation and analgesia the non-pharmacological adjunct had a positive effect on the comfort level of patients, although the lower

doses of midazolam were administered in the intervention group. The same paradoxical effect was observed in our study, where despite significantly lower midazolam dose in the CBI group, the patients reported better examination tolerance. Similar results describing decrease in the duration of procedure with the use of self-hypnosis and complementary techniques, and showing them as cost-effective approaches have been reported by other authors (15,16). These findings are especially important in the light of the fact that only a minority of echocardiographers receive formal training in sedation, although many use it during TEE (10). Thus, introduction of non-pharmacological methods of patient preparation to TEE may improve its safety by reducing sedative use.

Study limitations

The major limitation of our study was that the echocardiographer involved in the study was aware to which group the patient was assigned. This could have potentially biased the results. Another limitation was lack of pre-CBI anxiety level assessment. We did not perform it, because we believed that test–retest interval would affect study results. However, without this assessment, it cannot be ruled out that baseline anxiety levels were different between the study groups. Basic hemodynamic parameters (heart rate, blood pressure, and blood oxygen saturation) and TEE duration were not compared between the study groups. These parameters were directly related to indications for the TEE, and because these indications varied between the study groups, we believe that comparing hemodynamic parameters and TEE duration would reflect rather the differences in indications for TEE than the influence of CBI. Finally, we did not assess the education level and socioeconomic status of patients, which can affect the level of anxiety and also modify the response to CBI and general cooperation during TEE. However, our study was originally planned as a pilot study to gather preliminary data for a randomized blinded study at a later stage, including collection of previously mentioned missing variables.

Conclusions

CBI is feasible in patients undergoing TEE. It decreases patient's anxiety and discomfort and improves echocardiographer's comfort. It also results in reduction in the frequency of sedatives use and its administered dose during the examination.

Conflict of interest: None declared.

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