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Pain and Anxiety During Intravascular Lithotripsy-Assisted Percutaneous Coronary Intervention Compared with Conventional PCI: A Prospective Single-Center Observational Study

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Abstract

Background:

Intravascular lithotripsy (IVL) is an effective treatment for severely calcified coronary lesions during percutaneous coronary intervention (PCI). However, data regarding patient-reported pain and anxiety during IVL are limited.

Objective:

To compare pain and anxiety levels in patients undergoing IVL-assisted PCI with those undergoing conventional PCI.

Methods

In this prospective single-center observational study, 100 patients with chronic coronary syndrome undergoing PCI between 2024 and 2025 were enrolled. Fifty patients underwent IVL-assisted PCI and 50 underwent conventional PCI. Pain was assessed using the Numeric Rating Scale (NRS) and Wong-Baker FACES Pain Rating Scale, while anxiety was assessed using the Subjective Units of Distress Scale (SUDS).

Results

Baseline demographic characteristics were similar between groups. The IVL group had more complex coronary artery disease, including a higher prevalence of three-vessel disease (70% vs. 38%, $p = 0.001$), more previous coronary angiographies ($p = 0.007$), and higher radiation exposure ($p = 0.018$). Despite greater lesion complexity, no significant differences were observed in pain or anxiety scores between groups. The number of IVL pulses was not associated with pain or anxiety.

Conclusions

IVL-assisted PCI was not associated with increased pain or anxiety compared with conventional PCI despite greater procedural complexity. These findings support IVL as a well-tolerated strategy for the treatment of severely calcified coronary lesions.

Introduction

Chronic coronary disease (CKD) is a long-term condition affecting the coronary vessels (coronary arteries), caused by a progressive narrowing of the arteries. Various invasive treatment methods

(performed in the context of an angiography) are available for this purpose. In patients with severe calcification of the coronary arteries, various techniques—such as rotablation, cutting balloons, and intravascular lithotripsy—facilitate successful plaque modification and endovascular revascularization.

Intravascular lithotripsy (IVL) is a treatment method used to eliminate severely calcified vascular stenoses through the use of high-energy shockwaves. IVL is based on lithotripsy technology originally developed for the treatment of ureteral and renal stones; it represents a novel technique for addressing heavily calcified plaque lesions. The procedure utilizes acoustic shockwaves delivered via a balloon-based delivery system. These shockwaves induce calcium fractures, thereby facilitating stent expansion and luminal gain (1).

During the procedure, the IVL balloon must be sized to match the reference vessel diameter (at a 1:1 ratio), advanced into the target calcified lesion, and inflated to up to 4 atm to ensure adequate apposition against the vessel wall; the lithotripsy emitters are then activated to deliver the acoustic pulses by pressing the button on the connecting cable. Once a cycle of 10 pulses has been delivered, the balloon may be inflated to up to 6 atm (nominal inflation pressure) to enhance balloon compliance and assess for symmetrical expansion, thereby confirming calcium modification. The preceding steps must be repeated for each intended IVL cycle; it is recommended to perform at least two IVL cycles to adequately treat the target area. Furthermore, aggressive plaque modification devices—such as cutting or scoring balloons, or atherectomy—could be employed as an adjunctive therapy for challenging lesions to improve outcomes (2).

For most patients, IVL is a pain-free experience, with the only discomfort arising from the catheter insertion. Patients frequently report hearing a faint clicking, ticking, or light tapping sound. But they may also notice a mild tapping or vibrating sensation in the chest area, theoretically, which could lead to increased pain and anxiety compared to other coronary interventions.

Materials And Methods

Study Design and Population

The objective of this scientific study is to compare the pain and anxiety experienced by patients undergoing IVL with that of patients who received a percutaneous coronary intervention without IVL. The study design corresponds to a prospective, cross-sectional, single-center study with a duration of one year with 100 patients undergoing interventional treatment for coronary artery disease in the Cardiology Department, who meet guideline-compliant criteria for a percutaneous coronary intervention either utilizing IVL or, as a comparator group, without IVL (50 patients in each group).

Inclusion and exclusion criteria

Eligible patients were aged 18 years or older and underwent elective or urgent PCI with documented pain and anxiety scores during or immediately after the procedure. Patients with hemodynamic instability, cardiogenic shock, resuscitation, highly sedated emergency procedures, incomplete scale documentation, or significant cognitive impairment affecting the validity of subjective assessment were excluded.

Data analysis

Cardiac catheterization procedures are performed in the hospital's dedicated cardiac catheterization laboratory using the Allura FD 15 X-ray system (Philips Medical Systems®, Eindhoven, Netherlands) and an intravascular lithotripsy system (Shockwave Medical®, Santa Clara, California, USA).

Coronary angiographies, including intravascular lithotripsy, are carried out by at least one specialist physician in cardiology and at least one specially trained nurse.

Pain and Anxiety Assessment

For the assessment of pain intensity, the use of unidimensional pain scales—such as the Numerical Rating Scale, Verbal Rating Scale, or Visual Analog Scale—is recommended (3). In our study, the Numerical Rating Scale (NRS) and the Wong-Baker Faces Pain Rating Scale (FPS) are employed. The literature contains numerous studies utilizing both scales to assess pain in both adults and children(4) (5).

The Numerical Rating Scale (NRS)

The Numerical Rating Scale is a pain assessment tool that measures pain intensity on a scale from 0 to 10. It is a widely used instrument in medicine and can be administered either verbally or in writing. Patients are asked to select a number that best describes their pain level; 0 signifies "no pain," and 10 signifies "the worst pain imaginable." The NRS can be used to assess pain intensity both at a specific point in time and over the course of time. The NRS demonstrates high correlations with other pain assessment instruments, is practical to use, and enjoys good patient compliance.

Wong-Baker Faces Pain Rating Scale

The Wong-Baker Facial Pain Rating Scale—also known as the Wong-Baker FACES Scale—is a method for the self-assessment of pain. It consists of six faces ranging from "no pain" to "hurts worst."

The Numerical Rating Scale and Wong-Baker FACES Pain Rating Scale.

The Subjective Units of Distress Scale (SUDS)

The intensity of anxiety can be assessed using psychometric scales. When selecting a scale, various factors must be considered, including its reliability and accuracy, the objective of the assessment, the

patient's age and clinical condition, and the nature of the planned surgery (6).

To assess anxiety intensity, our study employs the Subjective Units of Distress Scale (SUDS), which was developed by Joseph Wolpe, which was originally defined as a self-rated measure of current anxiety(7). The SUDS can be used to measure feelings and other internal experiences, such as anxiety, anger, agitation, stress, or other distressing emotions. Furthermore, the emotional scope of the scale has been expanded from subjective anxiety alone to encompass any form of emotional disturbance or negative affect. It has been utilized in cognitive behavioral therapy for anxiety disorders (e.g., in exposure practices and hierarchy construction) as well as for research purposes (8). The SUDS can serve as a benchmark for a clinician or observer to assess the course of treatment.

The Subjective Units of Distress Scale (SUDS).

Statistical Analysis

The objective is to obtain a significant result ($p < 0.05$) with sufficient power (80%) to detect a correlation coefficient of at least 0.4. Therefore, the minimum required sample size for this study is 96. The calculation formula is based on a two-sided test (Hulley et al., 2013). The analysis of the anonymized raw data is performed using the statistical software IBM SPSS Statistics v26.0 (IBM Inc., Armonk, NY, USA). For descriptive analysis, absolute and relative frequencies, means and standard deviations, as well as medians and quartiles are calculated, depending on the data type. Appropriate hypothesis tests for univariate group differences are conducted using chi-square tests, Fisher's exact tests (or Fisher-Freeman-Halton tests), and independent-samples t-tests (or Mann-Whitney U tests) or paired-samples t-tests (or Wilcoxon tests).

Results

Patient Characteristics

A total of 100 patients with chronic coronary syndrome and calcified coronary lesions were included in the study. The comparison of baseline demographic characteristics between the two groups is presented in Table 1. No significant differences were observed in baseline demographic variables between the groups.

Table 1
Comparison of demographic characteristics of the study population

Variables	IVL group (n = 50)	Control group (n = 50)	P value
Age (years)	72.16 ± 9.14	69.02 ± 12.15	0.148[a]
Sex (F/M)	12 / 38	19 / 31	0.194[b]
Body mass index (kg/m^2)	27.72 ± 4.71	27.3 ± 4.31	0.637[a]
Hypertension, n (%)	37 (74)	32 (64)	0.387 [b]
Diabetes mellitus, n (%)	16 (32)	15 (30)	0.999 [b]
Hyperlipidemia, n (%)	43 (86)	35 (70)	0.090 [b]
Obesity, n (%)	13 (26)	17 (34)	0.513 [b]
Family history, n (%)	29 (58)	27 (54)	0.840 [b]
Smoking status, n (%)			0.750 [b]
Current smoker, n (%)	10 (20)	13 (26)	0.476 [b]
Former smoker, n (%)	26 (52)	23 (46)	0.548 [b]
Never smoker, n (%)	14 (28)	14(28)	0.999 [b]
History of myocardial infarction, n (%)	39 (78)	30 (60)	0.083 [b]
History of percutaneous coronary intervention, n (%)	39 (78)	29 (58)	0.053 [b]
History of psychiatric disease, n (%)	6 (12)	4 (8)	0.741 [b]

[a] = independent-samples T test; b = Chi-Square test

Angiography Findings

Characteristics related to previous coronary angiography and the index coronary angiography procedure are summarized in Table 2. The total number of prior coronary angiographies was significantly higher in the IVL group (p = 0.007). In addition, the prevalence of three-vessel coronary artery disease was significantly greater in the IVL group (p = 0.006) (Fig. 1).

Although fluoroscopy time and contrast volume were numerically higher in the IVL group, these differences did not reach statistical significance. However, the radiation dose exposure was significantly

higher in the IVL group (p = 0.018).

Table 2
Comparison of coronary angiography findings of the study population

Variables	IVL group (n = 50)	Control group (n = 50)	P value
Total number of coronary angiographies	3 (1–8)	2 (1–6)	**0.007**[a]
Number of diseased vessels, n (%)			**0.006**[b]
1-vessel disease	7 (14)	14 (28)	0.086 [b]
2-vessel disease	8 (16)	17 (34)	0.038 [b]
3-vessel disease	35 (70)	19 (38)	**0.001** [b]
Fluoroscopy time (min)	1025.36 ± 633.7	901.44 ± 540.51	0.295 [c]
Contrast volume (mL)	197.24 ± 92.13	183.74 ± 74.7	0.423 [c]
Radiation dose (mGy)	3218.5 (601–8860)	2072.5 (352-10279)	**0.018** [c]

[a] = Mann-Whitney U test; b = Chi-Square test

Pain and anxiety scores

The comparison of pain and anxiety scores between the IVL and control groups is presented in Table 3. Representative distributions of pain and anxiety scores are shown in Figs. 2–4.

No significant differences were observed between the two groups with respect to pain or anxiety levels. The distributions of NRS, Wong–Baker FACES, and SUDS scores are illustrated in Figs. 2, 3A, and 3B, respectively.

No significant correlations were identified between IVL application and pain or anxiety scores. The correlation coefficients and corresponding p values were as follows: Numeric Rating Scale (NRS): r = 0.078, p = 0.442; Wong–Baker FACES Pain Rating Scale: r = 0.047, p = 0.640; Subjective Units of Distress Scale (SUDS): r = 0.033, p = 0.748.

Table 3
Comparison of pain and anxiety scales of the study population

Variables	IVL group (n = 50)	Control group (n = 50)	P value
Numeric Rating Scale (NRS)	2 (0–9)	2 (0–9)	0.439 [a]
Wong–Baker FACES Pain Rating Scale (GBS)	2.5 (0–9)	2 (0–10)	0.637 [a]
Subjective Units of Distress Scale (SUDS)	20 (0–80)	20 (0-100)	0.746 [a]
[a] = Mann-Whitney U test			

During IVL procedures, balloon sizes ranging from 2.5 mm to 4.0 mm were used. The median number of IVL applications was 10 (minimum 3, maximum 15). The relationship between the number of shockwaves delivered during IVL and pain and anxiety scores was also evaluated. No significant correlations were found between the number of shockwaves and the pain or anxiety scales (NRS: r = 0.084, p = 0.562; Wong–Baker FACES Pain Rating Scale: r = 0.039, p = 0.790; SUDS: r = 0.039, p = 0.789).

Upon examining the responses provided by patients to the open-ended questions, the majority reported that the procedure did not cause any unusual sensations, apart from the sounds produced during the IVL process and the longer procedural time compared with previous interventions. Nevertheless, some patients described experiencing additional pressure in the chest, particularly when hearing the IVL sounds. One patient reported feeling the impulses in his brain and skull with each pulse, describing the sensation as: “It felt like a lightning bolt in my head every time.” Two other patients described the IVL pulses as small electric shocks that were perceptible all the way to the back of the head, even more prominently than in the chest. Three patients reported pricking and tingling sensations in the neck area. Interestingly, several patients noted sensations resembling small electric shocks that were perceived more strongly in the head and neck than in the chest. Patients who experienced symptoms in the breast area reported mild electric shock-like sensations and tingling during the IVL procedure.

Discussion

Principal findings

This prospective single-center observational study showed that IVL-assisted PCI was not associated with increased pain or anxiety compared with conventional PCI. This was observed despite significantly greater coronary disease complexity in the IVL group, including a substantially higher prevalence of three-vessel disease and a greater number of previous coronary angiographies.

Interpretation of pain findings

Chest discomfort following PCI is not necessarily a manifestation of myocardial ischemia. Several mechanisms may contribute to post-procedural symptoms, including transient ischemia, coronary spasm, and mechanical effects on the treated vessel. Previous studies have also reported differences in the frequency of non-ischemic chest pain according to the type of coronary intervention, with a higher incidence reported after stent implantation than after balloon angioplasty (9). One proposed explanation is the persistent mechanical interaction between the implanted stent and the vessel wall. In our study, the absence of greater pain in the IVL group may be related to effective lesion preparation, the full expansion of the stent and the optimal results achieved through IVL; however, this interpretation remains speculative and cannot be established from our observational data.

In the prospective multicenter, single-arm post-approval Disrupt CAD study conducted at 15 hospitals in 9 countries, the authors showed that IVL was safely performed with high procedural success and minimal complications and resulted in substantial calcific plaque fracture in most lesions by 120 patients. Severe CAC was present in 94.2% of lesions. Successful delivery and use of the IVL catheter were achieved in all patients. There was no procedural abrupt closure, slow or no reflow, or perforations. In 47 patients with post-percutaneous coronary intervention optical coherence tomography, calcium fracture was identified in 78.7% of lesions (10). IVL, which offers a remarkably high procedural success rate, can prevent the onset of peri- and post-procedural ischemic pain.

The absence of a measurable increase in procedural pain with IVL may be compatible with the technical characteristics of the treatment. Balloon-based coronary interventions can produce transient symptoms through temporary impairment of coronary flow and mechanical distension of the treated vessel. IVL modifies calcified plaque by delivering acoustic pulses while the balloon is maintained at a relatively low inflation pressure, with the therapeutic effect primarily directed toward calcified components of the vessel wall (11). This mechanism may limit the mechanical stress associated with aggressive balloon-based lesion preparation and could contribute to the favorable tolerability observed in our cohort. Nevertheless, the present study was not designed to investigate the mechanisms underlying procedural pain, and this explanation should therefore be regarded as hypothesis-generating.

In particular, psychological factors may play a role in the genesis of pain. Higher baseline depression and anxiety scores are significantly associated with nonischemic chest pain (12) (13). We tried to avoid this situation by excluding all patients with substance use disorders, known mental illnesses or disorders that may impair self-assessment and judgment.

In our study, we utilized two different pain scales, and no statistically significant difference was observed in patients who underwent IVL on either scale. Similar to our study, it has been demonstrated in the literature that these scales are correlated with one another. Bielewicz et al. concluded that pain intensity measurements by NRS and VAS mutually correlate although assessing different aspects of pain (14). Similarly, in a cross-sectional study performed on 100 patients with chronic low back pain, there was a significant positive correlation between VAS and NRS ($r = 0.92$, $p < 0.001$) with high agreement as detected by Bland-Altman method (mean difference = 0.33) (15).

Interpretation of anxiety findings

No significant difference in anxiety was observed between the two groups. Anxiety during invasive cardiology procedures is known to depend on multiple factors, including prior experiences, expectations, perceived control, and operator-patient communication (16).

Although IVL is accompanied by acoustic and mechanical sensations that could theoretically increase distress, our data suggest that these do not translate into higher measured anxiety. This is consistent with broader literature emphasizing that procedural distress is strongly shaped by patient-specific psychological factors rather than the intervention itself (17).

Coronary interventions themselves constitute a significant source of anxiety for patients. In their largest cohort to date, Delewi et al., included patients undergoing CAG or PCI between April 2009 and April 2010 (18). Anxiety levels were measured using the self-reported Visual Analogue Scale (VAS). VAS anxiety scores were obtained at hospital intake, pre- and post-procedure, and at hospital discharge. Multivariate linear regression analyses were performed to assess correlations between baseline characteristics and anxiety levels at the different time points. In total 2604 patients included, VAS anxiety scores were highest pre-procedure (44.2 ± 27.0mm). Female patients reported a significantly higher pre-procedure VAS anxiety score (50.4 ± 26.5) compared to males (41.5 ± 26.8, p = 0.02). Other factors associated with higher levels of anxiety at different time points were age<65years, low level of education and an acute primary PCI.

Ashour et al. studied a convenience sample of patients undergoing first-time elective PCI (N = 165) (19). The patients completed the Generalized Anxiety Disorder Scale at baseline (discharge time) and 6 months later. Six months after PCI, the anxiety level scores decreased significantly; mean scores for the baseline versus follow-up were 10.84 ± 5.98 versus 4.29 ± 6.02, respectively (P = .001). Only 18.2% of the patients had normal levels of anxiety at the baseline compared with 71.5% 6 months later. Although coronary interventions themselves appear to be a significant source of anxiety, we demonstrated that IVL did not cause additional anxiety during the procedure.

Patients with coronary heart disease often experience anxiety. The dynamic changes of peri-procedure anxiety, status and its influence on quality of life and readmission rate after PCI were studied in a total of 220 patients who underwent elective PCI (20). Statistical analysis showed that the anxiety scores at hospitalization appointment (T1) (P = 0.002) and 3 days before procedure (T2) (P = 0.024) were independent risk factors for treatment satisfaction at 3 months after PCI. In this study, by demonstrating that IVL does not alter patients' anxiety levels, we suggest that treatment satisfaction is likewise preserved.

Disease complexity and clinical relevance

A particularly important finding of the study is that IVL was preferentially used in patients with more advanced coronary disease burden. Despite this, no increase in pain or anxiety was documented. This

supports the interpretation that IVL can be applied in more challenging anatomical scenarios without compromising patient comfort. The higher prevalence of extensive CAD in the IVL group reflects contemporary clinical practice, where IVL is reserved primarily for heavily calcified and technically demanding lesions.

Procedural complexity and radiation exposure

Radiation dose was significantly higher in the IVL group, most likely reflecting greater procedural complexity. Similar associations between lesion complexity and procedural burden have been described in studies of calcified lesion PCI and atherectomy-assisted procedures (21) (22). However, the higher radiation exposure observed in the IVL group did not translate into greater pain or anxiety, suggesting that subjective procedural burden is not directly determined by technical complexity alone.

No meaningful relationship was observed between IVL cycles and subjective outcomes. This finding is clinically relevant, as it indicates that additional IVL pulse delivery, when required for optimal lesion preparation, does not appear to increase patient discomfort. Mechanistic studies suggest that IVL acts selectively on calcium and spares surrounding soft tissue to a large extent, which may explain this favorable tolerability profile (23).

The present findings suggest that IVL is not only technically effective but also well tolerated. This is particularly relevant in elderly patients and those with complex calcified lesions, where procedural burden and sedation requirements are important practical considerations. These results may facilitate patient counseling and support broader confidence in IVL as a patient-friendly technology. In the context of current PCI guidelines and patient-centered care frameworks, these observations support the integration of IVL into routine contemporary practice.

Limitations

Several limitations should be considered. First, this was a single-center observational study with a modest sample size. Second, group allocation was not randomized and was based on clinical indication, which explains the higher disease complexity in the IVL group. Third, pain and anxiety are inherently subjective measures and may be influenced by interindividual variability. Finally, the exploratory design did not include adjustment for multiple testing.

Conclusion

In conclusion, IVL-assisted PCI was not associated with increased pain or anxiety compared with conventional PCI, despite more complex coronary disease in the IVL group. These findings support IVL as a safe, effective, and well-tolerated lesion preparation strategy for calcified coronary stenoses.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was obtained from the Ethik-Kommission der Universität Witten/Herdecke e.V., Alfred-Herrhausen-Str. 50, 58448 Witten, Germany. Written informed consent was obtained from all participants before enrollment in the study. Data were collected and analyzed in pseudonymized form

Consent for publication

Not applicable.

Data availability

The datasets generated and/or analysed during the current study are not publicly available due to privacy and ethical restrictions but are available from the corresponding author on reasonable request.

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Authors' contributions

All co-authors have made substantial scientific contributions to this work, approved the final version, and agree with its submission.

Cetiner MA and Gjapi A wrote the main manuscript text, Özderya A prepared statistics and tables, Vorpahl M, Seyfarth M and Turan RG reviewed the manuscript.

Clinical trial number

Clinical trial number: not applicable.

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Figures

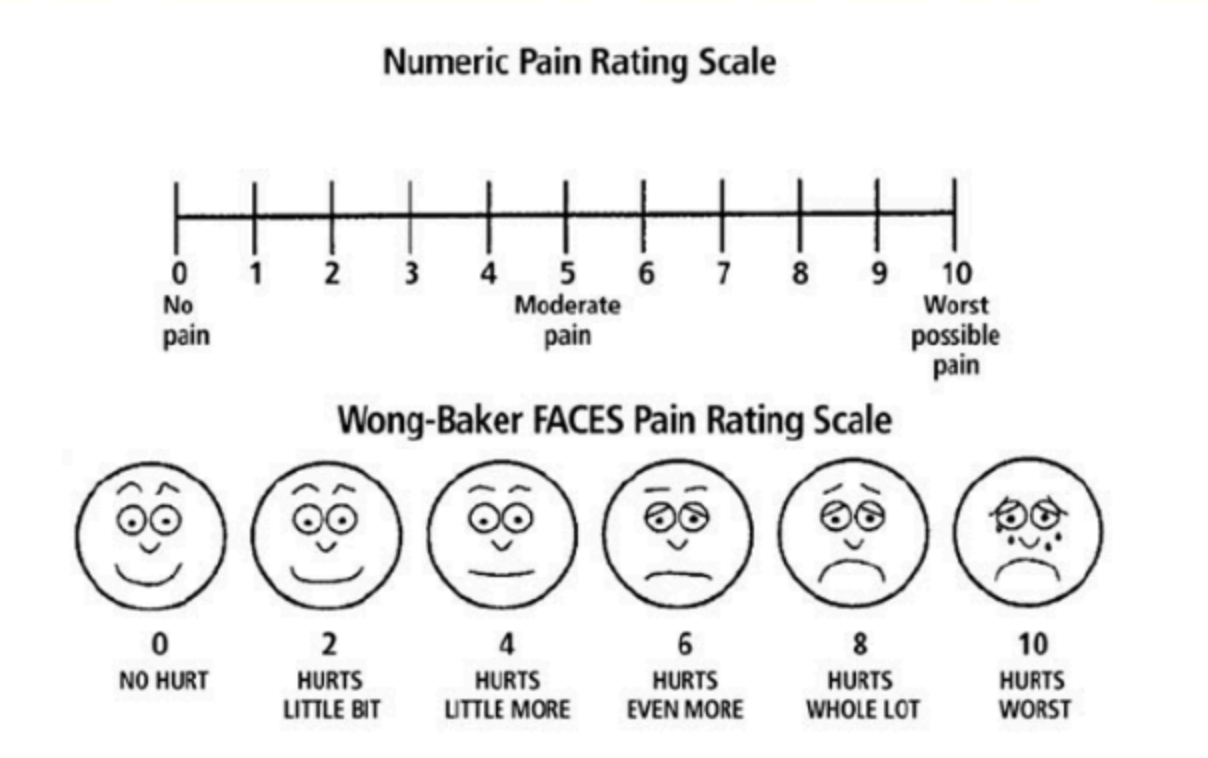


Figure 1

Prevalence of three-vessel coronary artery disease in IVL and control groups. The IVL group demonstrates a significantly higher disease burden (70% vs 38%, p = 0.001).

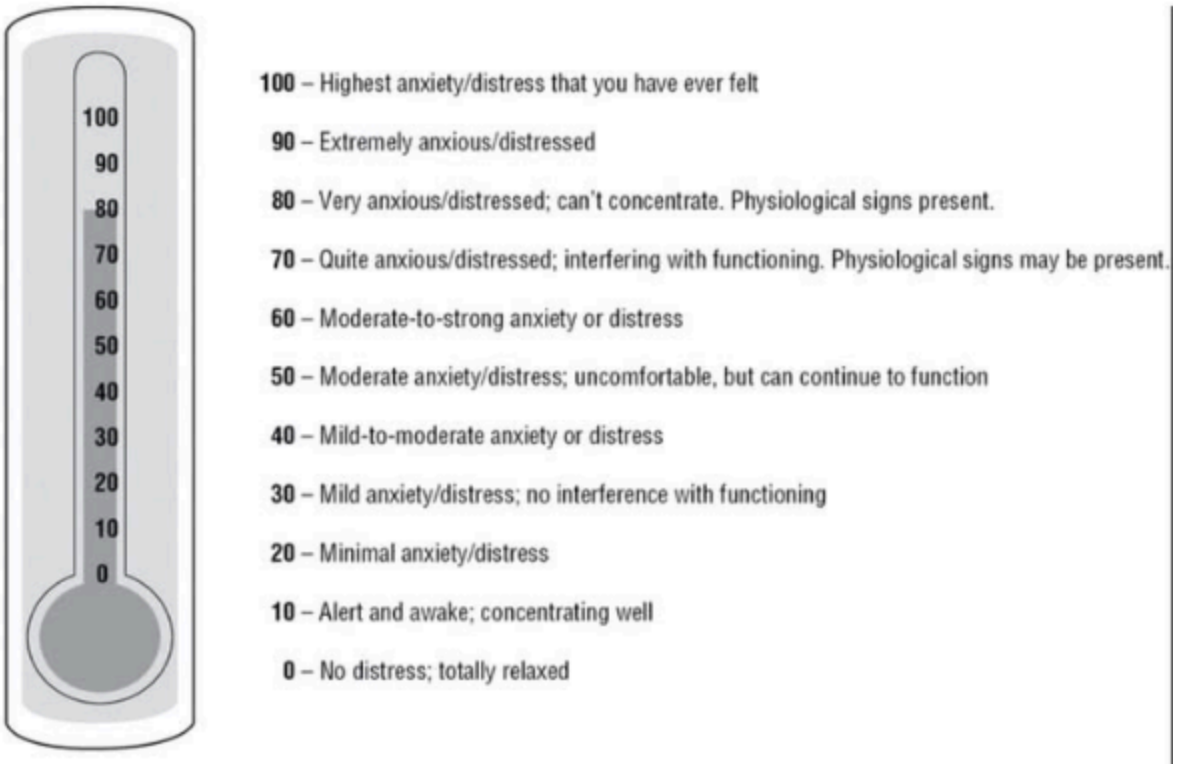


Figure 2

Boxplot showing distribution of Numeric Rating Scale (NRS) pain scores in IVL and control groups. No significant difference was observed (p = 0.439).

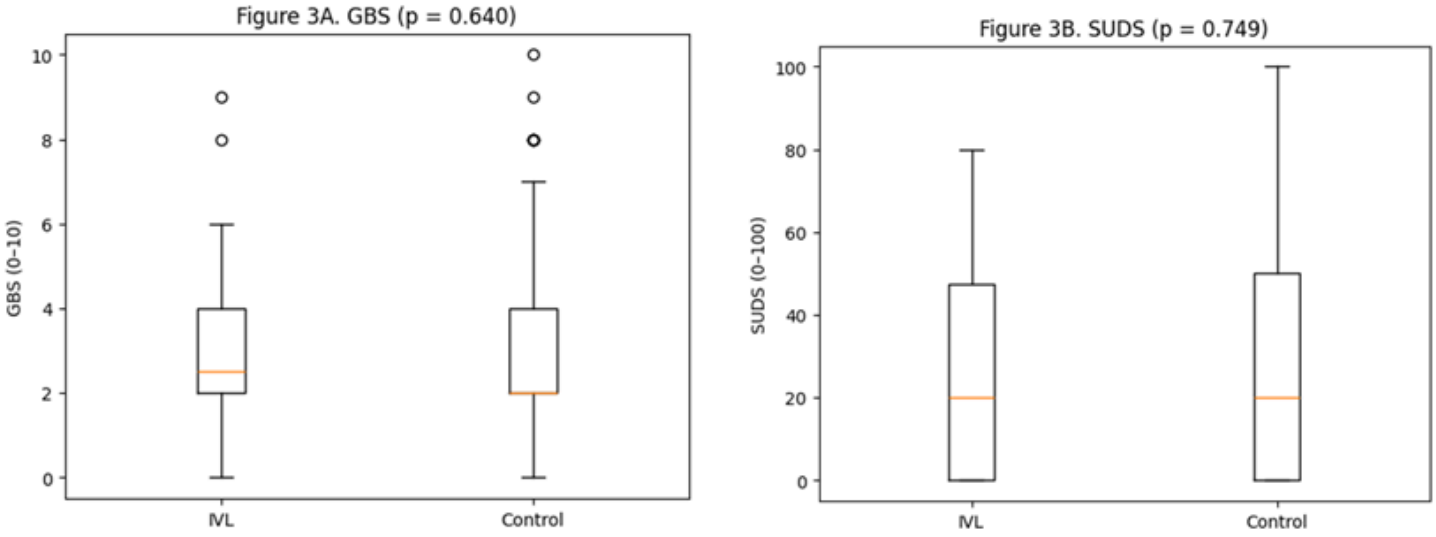


Figure 3

A. Boxplot showing distribution of facial pain scale (GBS) scores. No significant difference between groups (p = 0.637).

B. Boxplot showing distribution of Subjective Units of Distress Scale (SUDS) anxiety scores. No significant difference was observed (p = 0.746).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CentralIllustrationIVLAnxietyPain.pdf
- PlainLanguageSummary.pdf
- AuthorContributionStatement.pdf