FACTORS ASSOCIATED WITH INTRAOPERATIVE ANXIETY AMONG PATIENTS UNDERGOING CONSCIOUS SURGERY FOR CLOSED-LEG FRACTURE

ZHANG XUE

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR MASTER DEGREE OF NURSING SCIENCE
(INTERNATIONAL PROGRAM)
IN ADULT NURSING PATHWAY
FACULTY OF NURSING
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วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรพยาบาลศาสตรมหาบัณฑิต (หลักสูตรนานาชาติ)

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ลิขสิทธิ์เป็นของมหาวิทยาลัยบูรพา

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The Thesis of Zhang Xue has been approved by the examining committee to be partial fulfillment of the requirements for the Master Degree of Nursing Science (International Program) in Adult Nursing Pathway of Burapha University

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ZHANG XUE : FACTORS ASSOCIATED WITH INTRAOPERATIVE ANXIETY AMONG PATIENTS UNDERGOING CONSCIOUS SURGERY FOR CLOSED-LEG FRACTURE. ADVISORY COMMITTEE: NIPHAWAN SAMARTKIT, Ph.D. KHEMARADEE MASINGBOON, D.S.N. 2025.

Patients undergoing open reduction and internal fixation surgery frequently opt for spinal anesthesia, which preserves intraoperative consciousness. This conscious state may trigger significant anxiety during surgical procedures. Despite the clinical relevance of this phenomenon, intraoperative anxiety among conscious patients remains under-recognized in Chinese surgical populations. This knowledge gap motivated the current investigation. This study examined the degree of intraoperative anxiety and the relationship between gender, age, waiting time, surgical time and intraoperative anxiety among patients with closed-leg fracture undergoing conscious surgery. A total 123 participants were recruited during February to April 2025 by selecting samples as per the inclusion criteria and using random sampling. Research instruments include the demographic questionnaire and the visual analog scale for anxiety (VAS-A). Data were analyzed using descriptive statistics, Independence T-test and Pearson correlation coefficient.

The results show that mean intraoperative anxiety was 6.3±2.2, which indicates a clinically-relevant level of anxiety. There was a significant difference in the experience of intraoperative anxiety between female and male patients ($t = -3.922$, $p < .001$). Age, waiting time, and surgical time had a positive correlation with intraoperative anxiety among the patients undergoing conscious surgery ($r = .221$, $p < .05$). $r = .307$, $r = .346$, $p < .001$, respectively).

The findings provide a reference for healthcare providers to better understand the factors contributing to intraoperative anxiety of patients with closed-leg fracture undergoing conscious surgery, allowing for early identification of high-risk individuals, and targeted interventions, thereby preventing and alleviating intraoperative anxiety, reducing anxiety-related physiological response, minimizing complication risk, and promoting postoperative recovery.

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CHAPTER 1
INTRODUCTION

Background and significance of the problems

Bone fractures are a public health problem worldwide and cause serious diseases and economic burdens (Wu et al., 2021). Globally, there were 178 million new fractures in 2019 (Wang et al., 2024). With the modernization construction and the rapid development of the transportation industry, people's sports, outings, and social activities have increased, and various accidental injuries can be seen everywhere, and closed-leg fracture was more common. Data from a survey of trauma patients in Netherlands showed that most injuries were caused by traffic accidents (42.5%), home and entertainment accidents (42.0%) (Smits et al., 2020). In China, electric scooters popular in urban areas, many orthopedic injuries were associated with their used (McNulty et al., 2022). closed-leg fractures were a prevalent clinical condition, which accounted for just over one in four trauma fracture (Shen et al., 2021). These injuries lead to absenteeism, disability, reduced quality of life, and high healthcare expenditures (Wang et al., 2024).

Fractures invariably cause a profound functional dependence in patients, fundamentally impairing their capacity to perform essential activities of daily living (ADLs). The injury and subsequent immobilization or surgical intervention result in a loss of basic functional capabilities, such as independent mobility (walking, transferring), personal hygiene (bathing, dressing), self-feeding, and continence management. (Bello et al., 2023). Under these clinical circumstances, patients demonstrate strong preference for accelerated fracture recovery.

Early surgical intervention is an effective treatment for most closed-leg fractures (Gálvez-Sirvent et al., 2022). The procedure aims to provide anatomical restoration and immediate stability, thereby facilitating earlier mobilization for leg fractures (Dehghan et al., 2016). Especially for elderly patients with femoral fractures, conservative treatment has a higher mortality rate compared to surgical intervention (Merino-Rueda et al., 2021). For surgery of a group of leg fracture patients, most of them received spinal block anesthesia that mean the patient are conscious during

operation. This regional anesthesia technique obviates the need for general anesthesia and helps avoid associated risks, such as airway injuries, postoperative nausea and vomiting, or postoperative pain (Gerges et al., 2006). However, studies have shown that anxiety occurs in one-third of conscious intraoperative surgery patients in the operating theatre (Haugen et al., 2009).

With the development of anesthesiology and the widespread application of local anesthesia continued increase in conscious patients during surgery. Conscious surgery is the use of local anesthesia technology to cause reversible loss of sensation and muscle contraction in a limited area of the body without changing the patient's level of consciousness. The benefits of conscious surgery include decreased operative time, less postoperative opioid usage, decreased recovery time, and better patient satisfaction. (De Biase et al., 2021). A growing number of publications have highlighted the advantages of conscious sedation compared with general anesthesia, including decreased blood loss, fewer medical complications due to general anesthesia and better postoperative pain control (De Biase et al., 2023). Most studies suggest that local anesthesia maybe associated with improved perioperative outcomes, arguing that local anesthesia compared with general anesthesia was associated with a lower risk of perioperative complications and rates of nausea and vomiting, reduced blood loss, related to the length of hospital stay and further reduce the hospital-related costs (Balentine, Meier, Berger, Hogan, et al., 2021; Balentine, Meier, Berger, Reisch, et al., 2021; Desai et al., 2021).

However, Conscious surgery can cause a range of specific fears and anxieties (Hudson, Ogden, & Whiteley, 2015). All the time of operation the patients were conscious and they can perceive everything that occurred during surgical time (Pert ea, M., et al. 2019). Many participants in the operating room reported anxiety related to the narrow operating table, low light conditions, and unsettling noises from drilling, sawing, and cutting (Mitchell, 2008). The unfamiliar environment of the operating room, the alarms of the monitoring device, and the noise related to surgical instruments also cause intraoperative anxiety (Haugen et al., 2009; Jovanovic et al., 2022). The operating room experiences of the patients who underwent surgery under spinal anesthesia were examined, and it was determined that the participants often described the operating room as a scary, bizarre and frightening place and they felt agitated,

anxious, and concerned in the operating room (E. Yilmaz et al., 2020). Anesthesia puncture unsuccessful, where the patient was anxious and unattainable, can have negative consequences on anesthesia. Among orthopedic and trauma patients, intraoperative anxiety was associated with multiple factors, including prolonged surgical time, intraoperative tourniquet use, restrictive postoperative immobilization (e.g., tight bandages, casts, or splints). Additionally, external interventions such as wound dressings, traction, and patient resistance to restricted mobility may further exacerbate discomfort (Gezer & Arslan, 2019).

Intraoperative anxiety refers to acute psychological distress experienced during surgical procedures. Critically, 77% of patients undergoing local or regional anesthesia experience measurable anxiety (Mitchell, 2009). The prospect of being conscious during local anesthetic surgery in particular can be fraught with a range of specific fears and anxieties (Tippelt et al., 2024). Recent studies reported intraoperative anxiety of surgery patients as ranging from 33% to 92% based on various measurements of anxiety (K. Lim et al., 2023).

Physiological effects of anxiety are fluctuating heart rate and elevated blood pressure and patients who show signs of stress can require higher dosages of medication during anesthesia (Bengtsson, Johansson, & Englund, 2016). Intraoperative anxiety exacerbated pain perception and decreases the tolerance to pain (Tapar et al., 2022). Furthermore, empirical evidence confirms that anxiety adversely affects wound healing, with effects being both statistically significant and clinically meaningful (Solowiej et al., 2009). Reduces intraoperative anxiety level can overall control normal blood pressure, heart rate, respiratory rate, and decrease the need for sedative drugs (Kisielewska et al., 2025). Alleviating the intraoperative anxiety of patients may reduce the occurrence of postoperative complications and even shorten the postoperative recovery time (Desai et al., 2021).

Among orthopedic and trauma patients, intraoperative anxiety was associated with multiple factors. Evidence demonstrated that gender differences may significantly influence a patient’s anxiety level during the intraoperative period. The relationship between gender and intraoperative anxiety is a widely researched topic in the academic field. Existing studies indicate that gender differences may significantly influence patients' anxiety levels during the intraoperative period. From the literature review, a

study has shown that state anxiety was found to be higher in females than in males, which indicates the relationship between gender and anxiety (Altinsoy et al., 2020). Fatma Celik made a prospective study, found that anxiety sub-scores of females were found to be significantly higher than the males (Celik & Edipoglu, 2018).

Studies have found that female patients exhibit higher anxiety scores than their male counterparts (Bello et al., 2023; Javaid et al., 2023; Jovanovic et al., 2022). Women are more likely than men to report health-related concerns, as traditional masculinity norms often discourage help-seeking behaviors (Morgan et al., 2022). Female patients tend to experience heightened intraoperative anxiety, exhibit greater pain sensitivity during surgery (X. R. Li et al., 2021), and demonstrate increased concern regarding surgical events. They also show greater preoccupation with postoperative pain and recovery outcomes. This phenomenon may be partly explained by the functional implications of certain procedures, for instance, closed-leg fractures significantly impair mobility, which is essential for both caregiving roles and occupational demands (particularly in physically intensive jobs). Women's heightened awareness of these consequences may exacerbate preoperative and intraoperative anxiety (Ariza-Vega et al., 2019).

Many articles studied the relationship between age and intraoperative anxiety. Young adults typically exhibit heightened fear of the unknown due to limited experience in managing major stressful events. Middle-aged patients, frequently serving as primary breadwinners, experience significant anxiety stemming from potential work incapacity, income loss, and increased family burdens postoperatively. Some studies showed that elderly patients had a greater life experience and coping strategies may moderate these effects (Akutay & Ceyhan, 2023). The actual anxiety level depends on individual psychological resilience, social support, financial status, and occupational characteristics (Y. Jiang et al., 2024).

Among patients with fractures, anxiety and depression were quite common among the elderly (Bello et al., 2023). A hospital in Zhejiang Province conducted a study and discovered that elderly patients undergoing closed-leg fracture surgery commonly exhibit elevated anxiety levels (Zhang et al., 2024). Some studies report the highest anxiety levels among elderly patients, which may be associated with multiple risk factors: progressive cognitive decline, heightened concerns about anesthesia risks

(particularly for those with multiple comorbidities), difficulties in functional recovery (including fears of losing independence, becoming care-dependent, or requiring nursing home admission), and mortality-related apprehensions (Häggström & Brodin, 2024; Ren et al., 2021) . These compounding factors create a unique anxiety profile that differs substantially from younger patient populations.

Research findings that with patients often subjected to both direct and indirect forms of communication, lasting to technical surgical parlance and overhearing team-based interactions among operating room staff can reduce intraoperative anxiety (Emel Yilmaz et al., 2020).

The waiting time before the start of anesthesia can affect the patient's anxiety and discomfort levels (Putri et al., 2023). Putri et al. investigated the relationship between waiting time and anxiety levels in patients receiving spinal anesthesia prior to cesarean section. They found that patients with waiting times exceeding 30 minutes exhibited significantly higher anxiety levels (Putri et al., 2023). It has been found that the longer the waiting time in the operating room, the higher the level of anxiety. Prolonged preoperative waiting time significantly increased patient anxiety levels (Dziadzko et al., 2022). Prolonged preoperative waiting time exhibits a temporal cumulative effect that intensifies patients' rumination on surgical risks—particularly concerns regarding complications, anesthetic efficacy, and postoperative recovery, culminating in a catastrophic thinking cycle. (Carr et al., 2014). Physiological discomforts such as hunger and thirst exacerbate with extended waiting, further triggering anxiety (Kirtil & Aydin, 2025).

The preoperative holding area typically a confined and unfamiliar environment, subjects patients to persistent stressors including medical equipment noises, observable anxiety from other patients, and hurried medical staff behaviors (W. Li et al., 2025). These stimuli continuously activate the sympathetic nervous system, elevating cortisol levels. Prolonged waiting also amplifies information demand, when information provision proves inadequate, anxiety escalates multiplicatively (Lundberg et al., 2024). Research finding that environmental optimization through calming music and medical noise masking, rapid procedural education via animated surgical demonstrations can reduce anxiety (Biddiss et al., 2014). System-level improvements such as smart sequential-case alert systems optimize patient transfer timing to prevent

premature OR arrival, while workflow refinements effectively reduce preoperative anesthesia waiting duration (Mihalj et al., 2022).

Surgical time constitutes a key independent factor triggering intraoperative anxiety, particularly for conscious patients with closed-leg fractures, as prolonged exposure to the surgical environment significantly exacerbates psychological stress responses. A study found that surgery duration on anxiety (71.4%) subjects whose surgery lasted more than 120 minutes showed medium to height anxiety during surgery, in contrast to (16.7%) patient whose surgery lasted less than 120 minutes (Novy et al., 2020). Another article shows that patients requiring thoracic surgery, the longer of the surgical time, the more obvious the intraoperative anxiety (Hasan et al., 2021). Kaur et al. found that as duration of surgery increases, anxiety increases in patients undergoing orthopedic surgeries under spinal anesthesia (Kaur et al., 2022).

Moreover, intraoperative apprehension has varying degrees of influence on patients' anxiety during surgery. Apprehension and fear are common emotions interlinked with associated intra-operative anxiety. Nowadays, operating rooms were designed with cleanliness, anti-static properties, and adequate lighting as their main priorities. No consideration was given as to how conscious patients would feel in this environment. About other sensations, feeling hot, cold, dry, or naked, was a problem for patients. For patients, contributory stressors include previous experience, pain, anxiety, the unfamiliar environment and fear (Kelay et al., 2019). Anxiety comes from the surgery itself, fears about lying flat on a narrow bed, the unfamiliar environment, temperature, machines and noise and uncertainty about what to expect. Intraoperative anxiety may be further intensified due to the application of an intravenous cannula, anesthetic injection into the spine, being able to witness the operation, and feeling pain (Bheemanna, Channaiah, Gowda, Shanmugham, & Chanappa,2017). The intravenous infusion, the urinary catheter and the oxygen mask upset some patients (Mitchell, 2009).

This temporal accumulation effect directly extends patients’ exposure to traumatic stimuli, including instrument noises, oscillations of bone drills, and medical staff conversations(Wang & Ozcan, 2024). Conscious patients further develop a sense of loss of control during extended procedures, fostering concerns about unanticipated surgical complexity (e.g., discovery of additional injuries), compromised prognosis, or

elevated complication risks. Prolonged immobilization also precipitates muscle stiffness, aggravated pain, and waning anesthetic efficacy, cumulatively amplifying discomfort and anxiety. Evidence-based interventions indicate that virtual reality simulation of procedural workflows and environmental soundscapes reduces intraoperative anxiety, especially valuable for complex fracture fixation (Wang & Ozcan, 2024). Masking surgical noise via low noise or natural soundscapes suppresses auditory-triggered stress responses. Additionally, optimizing surgical efficiency through accelerated pacing shortens overall procedure time (Mihalj et al., 2022).

Many scholars have conducted extensive research on the preoperative and postoperative anxiety levels of different surgical populations. But the research on the related factors of intraoperative anxiety and the degree of anxiety of patients was still lacking. Healthcare professionals need to understand patients' anxious and should be able to implement strategies to reduce the anxiety, as well as techniques that improve the patient's overall surgical experience and ensure smooth procedures. This study needs to examine the conscious patients' intraoperative anxiety and its related factors, moreover, intraoperative apprehension. This study result can provide a basis for taking effective intervention to relieve anxiety and promote postoperative recovery of patients during conscious surgery. It can helped health care providers to identify and intervene to manage the intraoperative anxiety in patients with closed-leg fracture during conscious surgery, promote the smooth operation of the operation, and improve postoperative recovery of the patients.

Objectives of the research

1. To describe the level of intraoperative anxiety in patients with closed-leg fracture during conscious surgery.

2. To exam the relationship between gender, age, waiting time, surgical time with intraoperative anxiety in patients with closed-leg fracture during conscious surgery.

3. To describe intraoperative apprehension in patients with closed-leg fracture during conscious surgery.

Research hypotheses

1. There is relationship between gender and intraoperative anxiety in patients with closed-leg fracture during conscious surgery in Wenzhou, China.

2. There is the relationship between age with intraoperative anxiety in patients with closed-leg fracture during conscious surgery in Wenzhou, China.

3. There is the relationship between waiting time with intraoperative anxiety inpatients with closed-leg fracture during conscious surgery in Wenzhou, China.

4. There is the relationship between surgical time with intraoperative anxiety inpatients with closed-leg fracture during conscious surgery in Wenzhou, China.

Scope of study

This study was a descriptive correlational research design, the purposes of this study was to describe the degree of intraoperative anxiety and investigate the relationship between gender, age, waiting time and surgical time with intraoperative anxiety inpatients with closed-leg fracture during conscious surgery. The data collected in the operating rooms of The Second Affiliated Hospital of Wenzhou Medical University in Wenzhou, China in February to April 2025.

Research framework

The transactional model of stress and coping developed by Lazarus and Folkman (1984) was used as a conceptual framework to explain relationships between variables in this study. This model focuses on the dynamic interplay among key components within a mutually influential framework, encompassing influencing factors, appraisal processes, coping strategies, and clinical outcomes. Lazarus and Folkman (1984) identified personal factors and situational factors which influenced the coping process. Appraisal refers to the cognitive evaluation of an event (primary appraisal), available coping resources (secondary appraisal), and reappraisal. Coping is the process through which individuals manage demands arising from person-environment interactions that are appraised as stressful, taxing, or exceeding their resources. Coping was the process through which the person manages the demands of the person-environment relationship that are appraisal as stressful, taxing, or exceeding the resources of the individual. Finally, outcomes are produced as a result of the process

when a person cannot cope with the stressor. These outcomes are determined by coping options chosen and can be varied depending on the settings. Problem focused approaches involve attempting to deal with the situation itself, trying to change it into something more exiting– such active coping can be difficult but, if successful, results in a real change in circumstance. In contrast, an emotion focused approach involves changing our relationship with the situation in a way which reduces the stress it causes.

According to Lazarus and Folkman's (1984) defined coping functions as an expression of surgery patients coping process which was a progressive stage of cognitive appraise. Because life changes resulting from trauma that caused them face with closed-leg fracture and need to receive open reduction and internal fixation surgery, was a major source of stress, the patient used coping strategies developed after apprising these stressful changes in their lives (Folkman & psychology, 1984).

As a negative feeling, anxiety was one of the results of the stressors are influenced by various personal factors and situational factors. Gender and age as personal factors, waiting time and surgical time as situational factors influenced the patient's anxiety level. Based on Lazarus and Folkman's model (1984), the strategies undertaken by the patient can be categorized into emotion- and problem-focused coping strategies. For instance, patients can consult medical staff for information about surgery were problem-focused strategies. Abstract themselves when they feel anxious during surgery were emotion- focused coping strategies. Anxiety has a great influence on the surgery outcomes. It could cause hypertension, increase heart rate, and thus, might lead to bleeding (Bedaso & Ayalew, 2019). Besides, it has been shown that high level of intraoperative anxiety was correlated with an increased postoperative pain-relieving requirement. Patients with high levels of anxiety require higher doses of anesthetic induction agents and recover poorly (Strøm et al., 2018). If unrecognized, prolonged anxiety creates stress which may subsequently harm the patient and delay recovery. Therefore, guiding by the transactional model of stress and coping, in this study, gender, age, waiting time and surgical time may correlate with intraoperative anxiety in patients with closed-leg fracture during conscious surgery. Figure1 depicts the relationship between gender, age, waiting time, surgical time and intraoperative anxiety.

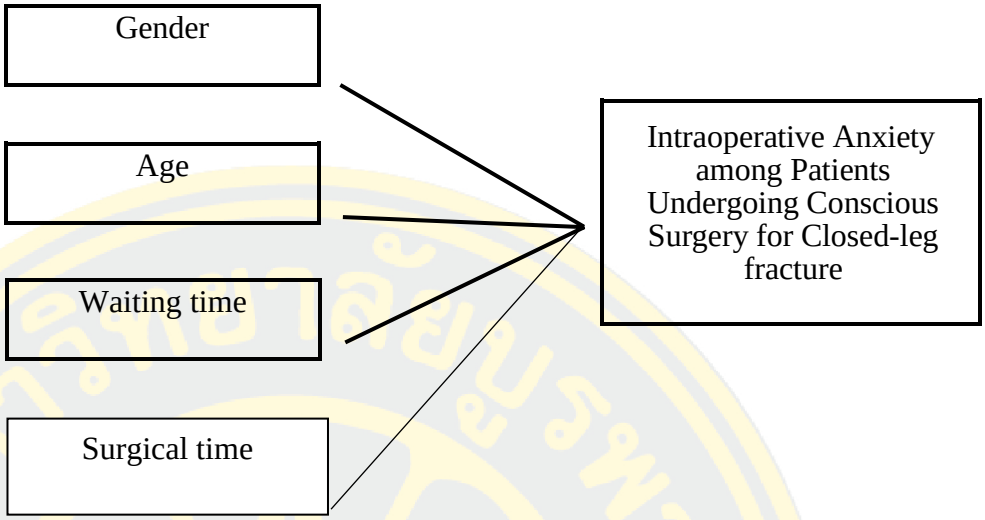

Figure 1 Conceptual framework

Definition of terms

Closed-leg fracture patient refers to trauma patient who has fracture on a leg with non-penetrate wound to outside, include a fracture femur, a fracture tibia, a fracture fibular fracture or both bones who were admitted in the orthopedic ward and receiving open reduction and internal fixation surgery in operation room at The Second Affiliated Hospital of Wenzhou Medical University in Wenzhou, China.

Conscious surgery refers to surgical procedures performed while the patient is awake, typically under local or regional anesthesia. This approach allows patients to remain aware of their surroundings and communicate with the surgical team, but without experiencing pain.

Intraoperative anxiety refers to transitory emotional state experienced perceive by the patient with closed-leg fracture during receiving open reduction and internal fixation surgery, specifically in response to the stressful situation of lying on the operating table and undergoing anesthesia and surgery, spanning from entry into the operating room until discharge from it. In this study intraoperative anxiety measured by visual analog scale for anxiety (VAS-A) (Guerrier et al., 2021).

Age defines as the length of time that a person has lived, measured by years from birth to present time.

waiting time refers to the duration between when a surgical procedure is deemed necessary and when it is actually performed, measure by the interval time between patient entry into the OR and their placement on the operating table prior to anesthetic induction time, which record in operating report.

Surgical time defined as the time from incision to closure of the surgical wound, excluded anesthesia administration and reversal periods, which record in operating report.

Intraoperative apprehension refers to the multiple surgical environmental factors that conscious patients during receiving open reduction and internal fixation surgery are exposed and thereby possibly being susceptible to seeing, feeling, or hearing the surgical procedure that triggering their emotion. It will be measured by The Intraoperative Apprehension Questionnaire (Mitchell, 2009).

CHAPTER 2
LITERATURE REVIEWS

This chapter summarized the patient with closed-leg fracture, the intraoperative anxiety inpatients with closed-leg fracture during conscious surgery, and factors related to intraoperative anxiety in patients with closed-leg fracture during conscious surgery during receiving open reduction and internal fixation surgery are as follows:

The patient with closed-leg fracture

Closed-leg fracture patient refers to trauma patient who has fracture on a leg, include a fracture femur, or a fracture tibia, a fracture fibular fracture both bones of the lower extremities are a common type of fracture in clinical practice and are mostly caused high-energy trauma mechanisms and car accidents. Data from a survey of trauma patients in the Netherlands showed that most injuries were caused by traffic accidents (42.5%) and home and entertainment accidents (42.0%) (Smits et al., 2020). According to the National Bureau of Stochastics of China (2021), more than 250,000 people were injured in traffic accidents in 2020, including orthopedic trauma victims. Lower extremity fractures accounted for 26.45% of the trauma fracture population (Shen et al., 2021).

Definition of closed-leg fracture

Closed-leg fracture was a medical condition in which there was a break in the continuity of a leg bone with overlying skin being intact (Corbett et al., 2021), was common in clinical of lower extremity fracture fixation. Closed-leg fracture includes include a fracture femur, or a fracture tibia, a fracture fibular fracture both bones on a leg. Femoral fractures represent a prevalent orthopedic injury. Fractures of the femur account for 3.41% of all adult fractures (Sun et al., 2014).

Signs and symptoms of closed-leg fracture

Generally, patient had a history of injury, and most of the injured have a history of serious trauma, severe pain in the limbs after injury, movement disorders, local swelling and tenderness, abnormal activities, and shortening of the affected limb.

Fractures are characterized by severe pain, tenderness, swelling, deformity, bone friction, and limb shortening dysfunction. In some parts, large hematomas, skin peeling, and open wounds and bleeding may occur. X-ray pictures can show the fracture site, type and direction of displacement.

Clinical evaluation must include assessment of greater trochanter alignment and knee integrity to identify concurrent injuries like hip dislocations, intra-articular fractures, and potential neurovascular compromise. During the examination, close attention must be paid to the occurrence of co-injury and shock, as well as to the presence or absence of nerve and blood vessel damage in the injured limb.

Treatment of closed-leg fracture

The treatment of closed-leg fracture includes non-surgical treatment and surgical treatment. Which treatment method should be adopted should comprehensively consider the general condition of the patient. More attention should be paid to a comprehensive examination of the functional status of the various organs of the patient's body, to understand the patient's activity status before injury, and to perform a holistic evaluation of the fracture characteristics (e.g., location, stability, comminution) to optimize pain management and enhance postoperative quality of life. Non-surgical treatment was an option for patients with fractures who have no obvious displacement at the fracture site, many comorbidities, and poor systemic conditions who cannot tolerate surgery.

For the elderly, bed rest and immobilization after fracture have many negative effects on their spirit and physique, which further deteriorates the function of various organs with low compensatory function, greatly increases the incidence of complications, and leads to the survival of patient’s quality decline. Therefore, for elderly patients who have surgical indications and whose general physical condition can tolerate surgery, various surgical treatment methods should be actively adopted. Patients whose general physical condition can tolerate surgery should actively take various surgical treatment methods.

Many options are available for the surgical management of closed fractures. These include many variations of intramedullary nails, plates, and external fixators (Hosseini et al., 2024; J. Liu et al., 2023). For the anesthesia provider, the choice of general anesthesia (GA) or regional or neuraxial anesthesia (RA/NA) for lower

extremity fracture patients. Early trials and meta-analyses found significant benefits to RA/NA over GA including decreased rates of all-cause mortality, pulmonary complications, cardiac dysthymias, blood transfusions, venous thromboembolism (VTE), and surgical site infection in vascular, general, and orthopedic surgeries (Brovman et al., 2019). Wideawake anesthesia has gained widespread popularity around the world, as its efficacy was now well documented (Messana et al., 2021).

Conscious surgery patients

Conscious surgery refers to individuals undergoing surgical procedures while maintaining full awareness and cognitive function, typically achieved through regional anesthesia (e.g., spinal/epidural) or monitored anesthesia care (MAC) without general anesthesia. Primarily, it avoids the cardiopulmonary risks associated with general anesthesia, particularly beneficial for elderly patients and those with comorbidities like COPD or heart failure (Fiani et al., 2021). Crucially, conscious surgery mitigates anesthesia-induced delirium (common in geriatric trauma) while allowing patients to participate in early functional assessments, facilitating immediate postoperative rehabilitation planning (Weiqing Li et al., 2025).

Intraoperative anxiety among patients undergoing conscious surgery for closed-leg fracture

Conscious surgery can cause a range of specific fears and anxieties (Hudson, Ogden, & Whiteley, 2015). Intraoperative anxiety was suggested as being particularly prolonged inpatients undergoing procedures under local or regional anesthesia, as they are awake and aware of the whole surgical procedure. There was limited investigation of the specific anxiety patients experience intraoperatively during awake procedures, the frequency of such anxiety and the implications for health care professionals caring for awake patients in the operating theatre. Anxiety is clearly associated with awake invasive and operative procedures, with potential effect on recovery and outcome, supporting the rationale for further study in the management of intraoperative anxiety.

Anxiety leads to activation of the sympathetic nervous system. It causes release of stress hormones which can cause delayed wound healing and hence delayed recovery (Kaur et al., 2022). Many studies showed that anxiety was affect to the health. Anxiety was now widely accepted as a occur frequently symptom in intraoperative

patients. Anxiety may lead to an increase in the levels of stress hormones, resulting in increased arterial blood pressure, heart rate, and high systemic catecholamine levels (Altinsoy et al., 2020). A study found that 16.3% of the patients had an adverse emotional response to noise, and 52.1% of the patients preferred a quiet surgical environment (Jakobsen & Fagermoen, 2005). Moreover, these physiological changes may cause an increased risk of infection and also an increase in wound healing time (Hudson & Ogden, 2016). The relationship between anxiety and wound healing was not only statistically significant, but also clinically relevant (Gouin & Kiecolt-Glaser, 2011). Anxiety exacerbates pain perception and decreases the tolerance to pain (Altinsoy et al., 2020). Anxiety can ultimately lead to increased pharmacologic interventions and sometimes cancellation of procedures and patient dissatisfaction (Vetter et al., 2015).

From the literature review, a study has shown that state anxiety was found to be higher in females than in males, which indicates the relationship between gender and anxiety (Altinsoy et al., 2020). Another study has shown that a significant difference was found between mean pre-operative state anxiety scores are different in gender (Celik & Edipoglu, 2018).Fatma Celik made a prospective study, found that anxiety sub-scores of females were found to be significantly higher than the males (Celik & Edipoglu, 2018).

The transactional model of stress and coping theory

The transactional model of stress and coping developed by Lazarus and Folkman (1984) was used as a conceptual framework to explain relationships between variables in this study. This model centers on dynamic interactions interaction among each concept in a dynamic and mutually shared relationship, including influencing factor, appraisal, coping and outcomes. Lazarus and Folkman (1984) identified personal factors and situational factors which influenced the coping process. The appraisal was the cognitive evaluation of event (primary appraisal), available coping resources (secondary appraisal) and re appraisal. Coping was the process through which the person manages the demands of the person-environment relationship that are appraised as stressful, taxing, or exceeding the resources of the individual. Finally, outcomes are produced as a result of the process when a person cannot cope with the

stressor. These outcomes are determined by coping options chosen and can be varied depending on the settings.

Problem focused approaches involve attempting to deal with the situation itself, trying to change it into something more palatable – such active coping can be difficult but, if successful, results in a real change in circumstance. In contrast, a emotion focused approach involves changing our relationship with the situation in a way which reduces the stress it causes.

According to Lazarus and Folkman's (1984) definition, coping functions as an expression of surgery patients coping process which was a progressive stage of cognitive appraisal. Because life changes resulting from trauma was a major source of stress, the patient used coping strategies developed after appraisal these stressful changes in her life. As a negative feeling, anxiety was one of the results of the stressors are influenced by various personal factors and situational factors. Gender as personal factors and surgical time and intraoperative apprehension as situational factors influenced the patient's anxiety level. Based on Lazarus and Folkman's model (1984), the strategies undertaken by the patient can be categorized into emotion and problem-focused coping strategies. For instance, patients can consult medical staff for information about surgery were problem-focused strategies. Distract yourself when you feel anxious during surgery were emotion-focused coping strategies. Anxiety has a great influence on the surgery outcomes. It could cause hypertension, increase heart rate, and thus, might lead to bleeding. Besides, it has been shown that high level of intraoperative anxiety was correlated with an increased postoperative pain-relieving requirement. Patients with high levels of anxiety require higher doses of anesthetic induction agents and recover poorly (Strom et al., 2018). If unrecognized, prolonged anxiety creates stress which may subsequently harm the patient and delay recovery.

In this study, the transactional model of stress and coping were sought to seek out the factors and causes that may related to intraoperative anxiety in patients with

closed-leg fracture during conscious surgery during receiving open reduction and internal fixation surgery, and to provide a theoretical reference for relieving intraoperative anxiety in patients with closed-leg fracture during conscious surgery during receiving g open reduction and internal fixation surgery.

Intraoperative apprehension

Intraoperative apprehension has varying degrees of influence on patients' anxiety during surgery. Nowadays, operating rooms were designed with cleanliness, anti-static properties, and adequate lighting as their main priorities. No consideration was given as to how conscious patients would feel in this environment. About other sensations, feeling hot, cold, dry, or naked, was a problem for patients. For patients, contributory stressors include previous experience, pain, anxiety, the unfamiliar environment and fear (Kelay et al., 2019). Anxiety comes from the surgery itself, fears about lying flat on a narrow bed, the unfamiliar environment, temperature, machines and noise and uncertainty about what to expect. Intraoperative anxiety may be further intensified due to the application of an intravenous cannula, anesthetic injection into the spine, being able to witness the operation, and feeling pain (Bheemanna, Channaiah, Gowda, Shanmugham, & Chanappa,2017). The intravenous infusion, the urinary catheter and the oxygen mask upset some Patients.

The study of showed that for some patients, saw such technical equipment and surgical instruments increased their experience of intraoperative anxiety (Haugen et al.,2009). Among orthopedic and trauma patients, the long duration of their operations, tourniquets applied during surgery, tight bandages, dressings, plasters, resistance, traction, and preoperative fear cause postoperative pain and intraoperative anxiety(Gezer & Arslan, 2019) .With patients often subjected to both direct and indirect forms of communication, listening to technical surgical parlance and overhearing team-based interactions among operating room staff can reduce intraoperative anxiety (Yilmaz, Toğaç, Çetinkaya, & Toğaç,2020).

The factors related to intraoperative anxiety among patients undergoing conscious surgery for closed-leg fracture

Gender

From the literature review, a study has shown that state anxiety was found to be higher in females than in males, which indicates the relationship between gender and anxiety (Altinsoy et al., 2020). Another study has shown that a significant difference was found between mean pre-operative state anxiety scores are different in gender (Ertürk & Ünlü,2018). Fatma Celik made a prospective study, found that anxiety sub-

scores of females were found to be significantly higher than the males (Celik & Edipoglu, 2018). Empirical evidence consistently demonstrates significant gender-based differences in intraoperative anxiety responses. Multiple studies confirm that female patients exhibit substantially higher preoperative and intraoperative anxiety levels than male counterparts across surgical contexts (Altinsoy et al., 2020; Bello et al., 2023; Jovanovic et al., 2022).

Anxiety disparities manifest distinctly in female patients, who report heightened health concerns, demonstrate greater procedural pain sensitivity, and express intensified preoccupation with surgical outcomes and recovery trajectories(X. R. Li et al., 2021). These effects are disproportionately exacerbated by closed-leg fracture's functional consequences, particularly mobility impairment that disrupts caregiving responsibilities and occupational functioning, ultimately amplifying anxiety in women. Biologically, this vulnerability may stem from hormonal modulation of the HPA axis and neurobiological dimorphism in pain processing, amplifying sensitivity to surgical stressors. Psychosocially, traditional masculinity norms discourage male help-seeking behaviors (Morgan et al., 2022).

Effective anxiety management requires interventions tailored to these documented gender differences. Non-pharmacological strategies demonstrate particular efficacy for female patients: intraoperative music therapy significantly reduces anxiety levels, as evidenced by systematic review, while structured preoperative anesthesia education mitigates anticipatory distress (Padsala et al., 2023; S. J. Weingarten et al., 2021). These approaches address women's heightened sensitivity to procedural information and sensory stimuli. Concurrently, psychosocial support systems substantially alleviate comorbid anxiety and depression throughout rehabilitation (Chen et al., 2020). For male patients, interventions must navigate masculinity-related reporting barriers through normalized vulnerability framing and discreet assessment methods. Crucially, all strategies should account for gender-specific biological responses: women's neuroendocrine sensitivity to stressors necessitates calibrated pharmacological approaches, while men's tendency to underreport symptoms requires proactive screening. Future interventions should be designed to address gender-specific biological vulnerabilities and gendered coping

patterns, thereby reducing intraoperative anxiety among patients undergoing conscious surgery for closed-leg fracture.

Age

Studies had shown that age was related to intraoperative anxiety. Some author stated that in older adults, anxiety disorders were more prevalent, so that older people were more anxious than younger ones (Erkilic et al., 2017).This finding aligns with evidence indicating a positive correlation between age and heightened anxiety levels (Q. Liu et al., 2023).

Research consistently identifies age as a critical determinant of intraoperative anxiety, with distinct profiles emerging across developmental stages. Young adult patients typically exhibit heightened fear of the unknown, attributable to limited prior experience in managing major medical stressors (Y. Jiang et al., 2024). Middle-aged patients, often functioning as primary breadwinners, demonstrate significant anxiety rooted in socioeconomic consequences - including postoperative work incapacity, income loss, and increased familial caregiving burdens (Batool, 2022).

While elderly patients may possess greater life experience and developed coping mechanisms that theoretically moderate anxiety responses, empirical studies reveal countervailing risk factors that elevate distress in this population. Fracture patients particularly show high anxiety and depression prevalence among the elderly with closed-leg fracture surgery patients in Zhejiang Province exhibiting clinically elevated anxiety levels (Bello et al., 2023; Zhang et al., 2024).

This vulnerability stems from compounding factors: progressive cognitive decline, heightened anesthesia risk perceptions (especially among multimorbid patients), functional recovery concerns (fears of independence loss, care dependency, or nursing home admission), and mortality-related apprehensions (Häggström & Brodin, 2024; Ren et al., 2021). Consequently, elderly patients frequently present the most complex anxiety profiles, fundamentally differing from younger cohorts in both qualitative manifestations and quantitative intensity. The actual anxiety level depends on individual psychological resilience, social support, financial status, and occupational characteristics (Y. Jiang et al., 2024).

Effective anxiety mitigation requires interventions calibrated to these age-specific vulnerabilities. For young adults, technology-enhanced preparatory methods

demonstrate particular efficacy; 3D surgical animations and virtual reality (VR) simulations substantially alleviate fears of the unknown by providing immersive procedural familiarization (Fleet et al., 2025). Communication clarity also proves universally beneficial - patient-centered dialogue minimizing technical jargon while explaining operating room interactions reduces anxiety across age groups (Emel Yilmaz et al., 2020).

For elderly populations, multimodal approaches show greatest promise that anesthesiologist-led preoperative consultations significantly enhance perceived safety when integrated with family-centered communication strategies (Jameson, 2023). Furthermore, structured postoperative care systems specifically addressing geriatric concerns about functional recovery and long-term independence consistently reduce anxiety levels (Karlsson et al., 2022). These findings collectively underscore that successful anxiety management in orthopedic surgery must account for developmental stage-specific stressors - from the anticipatory uncertainty of youth, through the socioeconomic pressures of middle age, to the multidimensional threats perceived by elderly patients.

Waiting time

It has been found that the longer the waiting time in the operating room, the higher the level of anxiety. Prolonged preoperative waiting time significantly increased patient anxiety levels (Dziadzko et al., 2022). Putri et al. investigated the relationship between waiting time and anxiety levels in patients receiving spinal anesthesia prior to cesarean section. Preoperative waiting time operates as a significant predictor of escalating anxiety through multifaceted pathways, with empirical evidence consistently identifying the 30-minute threshold as clinically critical (Putri et al., 2023).

The temporal relationship follows a dose-response pattern, where prolonged exposure amplifies distress through interconnected mechanisms (Benito et al., 2024). Extended waiting activates catastrophic rumination regarding surgical risks and recovery uncertainties, while the preoperative holding environment subjects' patients to sustained stressors including medical equipment noise, observable peer anxiety, and staff haste—all perpetuating sympathetic arousal (W. Li et al., 2025). Concurrently, unmet informational needs during delays multiplicatively heighten distress, creating

self-reinforcing anxiety cycles that intensify with each additional minute of waiting as demonstrated (Dziadzko et al., 2022).

Multimodal interventions effectively disrupt wait-time anxiety pathways through environmental, sensory, and systemic strategies. Environmental optimization demonstrates particular efficacy, where background music masks aversive auditory stimuli and reduces physiological stress markers, though effectiveness varies according to music selection and individual preferences as noted in systematic reviews (Lai & Amaladoss, 2022; Xuan et al., 2021). Complementary sensory approaches include visual distraction through nature scenes or television content, which attenuates time perception by redirecting attention from surgical preoccupations. Integrative Traditional Chinese Medicine (TCM) modalities offer additional mechanisms, with auricular acupressure and acupuncture regulating neuroendocrine pathways to achieve clinically significant anxiety reduction as validated (Hu et al., 2024; Tong et al., 2021). System-level solutions simultaneously target the temporal source, where algorithmic case-sequencing systems minimize premature operating room transfers and shorten wait durations by over one-third according to workflow analyses (Mihalj et al., 2022). This combined approach, addressing psychological responses through sensory modulation while targeting physiological triggers via Traditional Chinese Medicine and fundamentally reducing temporal exposure through operational refinements, embodies the current paradigm for mitigating wait-derived anxiety.

Surgical time

Surgical time defined as the time from incision to closure of the surgical wound (Gowd et al., 2020). It affects the occurrence of intraoperative anxiety. Novy et al. found that surgical time on anxiety subjects whose surgery lasted more than 120 minutes showed medium to height anxiety during surgery, in contrast to atient whose surgery lasted less than 120 minutes (Novy et al., 2020). Kaur et al. found that patients experience peak anxiety levels both when entering the operating room and when the surgical time reaches 90-120 minutes (Kaur et al., 2022). Luiz et al. found that they had medium anxiety whose surgery lasted less than 120 minutes ($p=0.08$) (Abu Shosha & Al-Kalaldeh, 2020). Therefore, there was a certain relationship between surgical time and intraoperative anxiety.

Mechanistically, extended exposure intensifies three intersecting burdens: persistent auditory trauma from surgical instrumentation and team communication triggers sensory hyperarousal; progressive loss of control fosters catastrophic thinking about unanticipated complications; and immobilization-induced discomfort compounds physiological strain through stiffness and waning anesthesia.

Contemporary anxiety management strategies directly target these duration-sensitive pathways through sensory, cognitive, and operational modalities. Immersive virtual reality (VR) systems demonstrate dual efficacy—distorting time perception by 31% while reducing anxiety biomarkers including serum cortisol and ACTH levels through procedural simulation (Gao et al., 2023; Singh et al., 2024). A study showed that listening to instrumental music during lower leg fracture surgery caused a reduction in anxiety (de Araújo Azi et al., 2021a). These sensory-cognitive approaches function synergistically with workflow optimization: accelerated surgical pacing protocols minimize exposure duration without compromising safety, while real-time team communication reduces ambiguous auditory triggers (Mihalj et al., 2022). This integrated framework addresses time-dependent anxiety in fracture surgery by concurrently targeting psychological distress through VR immersion, physiological arousal via music/biochemical modulation, and temporal exposure through efficiency gains.

Summary

According to the literature review, knowledge of about the relationship between gender, age, waiting time, surgical time, and intraoperative anxiety. However, existing studies have predominantly concentrated on leg fractures, resulting in limited research on patients undergoing conscious surgery for fractures in other anatomical regions. In addition, there was no specific study on the intraoperative anxiety in patients with closed-leg fracture during conscious surgery during receiving open reduction and internal fixation surgery in Wenzhou. There was a lack of basic understanding of intraoperative anxiety and its related factors in conscious patients in Wenzhou, China.

Therefore, under the guidance of the transactional model of stress and coping, the researchers conducted this study to explore the current situation of intraoperative anxiety in patients with closed-leg fracture during conscious surgery during receiving

open reduction and internal fixation surgery in Wenzhou, China, and to explore factors of intraoperative anxiety inpatients with closed-leg fracture during conscious surgery. This study will provide information for healthcare providers in Wenzhou to develop nursing interventions for intraoperative anxiety in patients with closed-leg fracture during conscious surgery during receiving open reduction and internal fixation surgery, relieve anxiety, improve health outcomes, and improve quality of life. This information will also be useful for nurses and health care providers to guide them to study this population for further research and future intervention studies in this group of patients.

CHAPTER 3
RESEARCH METHODOLOGY

This chapter presents the research methodology including research design, population, and sample, setting of the study, instruments, ethical consideration, data collection procedures, and data analysis was procedures.

Research design

Descriptive correlational research used for this study to describe the degree of intraoperative anxiety in patients with closed-leg fracture during conscious surgery and investigated the relationship between gender, age, waiting time, surgical time with intraoperative anxiety in patients with closed-leg fracture during conscious surgery.

Population and sample

Population

The target population of this study was patients with closed-leg fracture and admitted in the orthopedic ward, moreover, plan for receiving open reduction and internal fixation surgery in an awake state. The data collected from The Second Affiliated Hospital of Wenzhou Medical University in Wenzhou, China in February to April 2025.

Sample

The samples were the patients who had closed-leg fracture and admitted in the orthopedic ward, moreover, plan for during receiving open reduction and internal fixation surgery in an awake state, in The Second Affiliated Hospital of Wenzhou Medical University in Wenzhou, China. The sample follow the inclusion criteria included:

1. Age > 18 years
2. Diagnosed with fracture on a leg, include a fracture femur, or a fracture tibia, a fracture fibular fracture both bones in one leg.
3. No injured in other organs.
4. No history of anesthesia and surgery.

5. Normal hearing and writing skills.

Exclusion criteria included:

1.Patients requiring intraoperative conversion to general anesthesia or deep sedation.

Sample size

The sample sizes in this study were calculated by using the G*Power 3.0.10 program for correlational design. The researcher tested the relationship between the Intraoperative anxiety and each independent variable. In this study, the researcher estimated a medium effect size =.30 and achieved a power of .90 and α = .05 was used for computing the sample size, which leaded to at least 112 participants needed. Add more 10% for incomplete questionnaire, so the total sample size was 123 participants.

Sampling technique

Simple random sampling will be used in this study. The sample randomly selected in this way was unbiased, and each sample has an equal chance to be selected. The researcher randomly selected 50% of these persons as sample by prepare two sheets of paper of the same size and material and wrote down "odd number" and "even number" respectively. The paper was folded and mixed in a prepared bag. In the morning of each day, the researchers randomly selected a piece of paper one by one, if pick up an even number, on that day, data was collected from the closed-leg fracture patients with an even number of appointments. After obtaining the selected patients' consent, the researchers instructed them to sign the consent form and fill in the questionnaire. About 5 patients recruited a day, depending on the number of closed-leg fracture during receiving open reduction and internal fixation surgery people admission to the ward. The sample recruited until the required sample size was reached, and then recruitment stopped for the next phase of the study.

Study Setting

The study conducted in the in the operating room of The Second Affiliated Hospital of Wenzhou Medical University, in Wenzhou, China. The Second Affiliated Hospital of Wenzhou Medical University has a total of five districts. This research conducted in Oujiangnkou district of The Second Affiliated Hospital of Wenzhou

Medical University. There have 23 operating rooms in this district, which are open 5 days a week and have 2,900 surgeries per month, with an average of 10 closed-leg fracture patients planning for receiving open reduction and internal fixation surgery patients need surgery every day.

After the patient's fracture arrived at the ward, the surgeon took the patient's medical history and issued a checklist. The preoperative preparation was performed by the ward nurse. The ward nurse should complete all the examinations required by the operation patients, including laboratory indicators, X-ray, CT, etc., prepare blood before operation, and informed the patients about their diet before operation.

The surgeon made an appointment for the surgery. On the day of surgery, the circulating nurse (CN) notified the patient transporter to retrieve the next patient before skin closure began on the preceding case. Upon receiving notification, the patient transporter verified patient identity and documentation with the ward nurse, transported the patient to the operating theater complex and escorted the patient into the designated pre-operative holding area.

During this time, operating room nurses performed identity checks and information checks, and venous access was established. After the operating room had passed terminal disinfection verification, the circulating nurse escorted the patient into the OR. Upon entering, the nurse conducted the preoperative verification process with both the surgical team and anesthesiologist. Following confirmed agreement among all parties, the patient was safely transferred onto the operating table.

The anesthesiologist chose the appropriate anesthesia method according to the surgical situation, monitored the vital signs during the operation, and gives pain relief. The instrument nurse prepared the instruments and items needed during the operation, assisted the surgeon, passed the blades, needles, and instruments, and cooperated with the surgeon in the operation. Circulating nurses prepared equipment, assisted anesthesiologists and surgeons, and paid attention to patient needs. After surgery, doctors and nurses escort the patient into the resuscitation room. Depending on the patient's condition, the nurse in the recovery room will send the patient back to the ward after 30-60 minutes after post operation.

Research Instruments

Three questionnaires used for collecting data: the demographic questionnaire, visual analog scale for anxiety (VAS-A), the intraoperative apprehension.

The Demographic Questionnaire

The demographic questionnaire developed by the researcher, specific for this study. It includes:

1) General information: gender, age, highest educational level, marital status, religion, occupation, annual family income, living place, healthcare payment scheme.

2) Health information: surgical history, diseases history, fracture site, surgery type, anesthesia method, anesthesia preparation time, surgical time, number of closed-leg fracture.

The Visual analog scale for anxiety (VAS-A)

The visual analog scale for anxiety (VAS-A) was using to measure the intraoperative anxiety level. Cline et al. created this scale. Anxiety was a subjective feeling. VAS-A has become a commonly used instrument for the measurement of these subjective feelings because it was easy to measured, simple for the subject to understand, and can be a valid method for measuring subjective feelings that yield interval level data (Cline et al., 1992). VAS-A is a widely used method for measuring anxiety.

VAS-A comprises a 10 cm line, on which the participants mark their current degree of anxiety with the left end of the line being labelled 0 (no anxiety), and the right end being labelled 10 (maximum anxiety). The participants were asked to indicate how anxious they were feeling by marking the appropriate place on the line (Nielsen et al., 2018). VAS-A is a routinely employed instrument for anxiety assessment in China, with validated and extensive application in measuring intraoperative anxiety (X.-R. Li et al., 2021; Turan et al., 2021).Values around 5 cm are effective indicators of the threshold for a clinically meaningful level of preoperative anxiety (Facco et al., 2013).

The Intraoperative Apprehension

The intraoperative apprehension assessment aspects which patients find anxiety provoking whilst undergoing surgery with local or regional anesthesia.

There are three components or factors were thereby established and referred to as ‘anesthetic information provision’, ‘intraoperative apprehension’ and ‘Health

control'. Questions relating to the nurse and anesthetist providing information and explanations (Q1-Q4) were given the overall title of 'anesthetic information provision'. Questions relating to being awake, seeing, hearing, and feeling (Q6-Q14, Q16) were given the overall title of 'Intraoperative Apprehension'. Questions relating to meal time and feeling 'closed in'(Q5, Q15) were given the overall title of 'Health control' (Mitchell, 2008).

All items on the questionnaire were structured using a Likert Scale format - for example: very anxious, a little anxious, made no difference, a little calm, very calm or never thought about it. With '5'suggestive of very anxious and '1'indicating very calm or never thought about it. This scale ranges from a minimum score of 16 to a maximum score of 80. Scores between 16-40 are classified as Low anxiety, 41-63 as Moderate anxiety, and 64-80 as High anxiety (Mitchell, 2008).

Psychometric property of the instruments

Visual analog scale for anxiety (VAS-A) had already been validated and used in previous studies. VAS-A had been previously validated in clinical studies. VAS-A is a routinely employed instrument for anxiety assessment in China, with validated and extensive application in measuring intraoperative anxiety (X.-R. Li et al., 2021; Turan et al., 2021). But the intraoperative apprehension was currently no Chinese version of this scale. To ensure conceptual equivalence and linguistic accuracy, the original English version of the intraoperative apprehension scale underwent a rigorous cross-cultural adaptation process following international guidelines. This included three sequential phases:

1. Forward translation:

Independent bilingual translator: professor of Nursing School, Zhejiang University of Chinese Medicine. She produced parallel Chinese translations.

2. Back translation:

The Chinese version was blindly back-translated into English by two professors from Wenzhou Medical University who have experience studying abroad, both unfamiliar with the original scale.

3. Expert committee review:

Associate Professor of faculty of nursing, Burapha University compared original, translated, and back-translated versions, confirmed this scale can be used.

The reliability of the intraoperative apprehension scale was assessed using Cronbach's alpha coefficient in a pilot study. Results demonstrated good internal consistency (Cronbach's $\alpha = 0.87$) with 30 participants.

Protection of human rights

The research proposal submitted for approval from the Institutional Review Board (IRB) of Burapha University (BUU) (G-HS129/2567) and Institution Review Board (IRB) of WMU and The Second Affiliated Hospital of WMU, China (2024-K-377-02). Only after that, this research as carried out.

All participants must be fully informed about the study's purpose and participation procedures before data collection. The researcher described the nature of the study and emphasized the individual's right to participate or refuse to participate in the study. Data in this study were collected from participants who agreed to take part and provided informed consent prior to data collection. Consent forms completed prior to data collection. Participants informed that they have the right not to answer any questions and to change their minds and withdraw from the study at any time. All forms collecting data are anonymous and harmless to participants participating in the study. Data will be anonymized to ensure confidentiality, with no personal identifiers disclosed during analysis or reporting. All data on paper files stored in a secure place for research use only, and all electronic data locked with a password that only researchers can access. All data destroyed one year after publication of the study day. In addition, if any individual wanted to know the results of the study, they could contact the researchers.

Data collection procedures

The data collection procedures for this study were conducted by the researchers as follows:

1. After being approved by Graduate school of BUU, the researcher submitted recommendations for ethical review to IRB of BUU and the IRB of The Second Affiliated Hospital of Wenzhou Medical University, China.

2. The researcher requested the Graduate school of BUU to The Second Affiliated Hospital of Wenzhou Medical University, China, for permission to collect data purpose and procedures of the research information.

3. After the researchers obtained permission from The Second Affiliated Hospital of Wenzhou Medical University, China. Investigators explained data collection procedures to, and obtain consent from, staff of operating room.

4. The researcher went to the orthopedic wards or operating rooms department from 8:00 am to 12:00 am and from 1:00 pm to 4:30 pm every weekday (Monday to Friday) for collecting data.

5. The nurse in the orthopedic wards searched the registration to find the clients who meted the inclusion criteria. Patients with closed-leg fracture were asked about their interest in study participation. Those who agreed were referred to the researcher by the orthopedic ward nurses.

6. Researchers met and informed participants and their families of the purpose of the study, ethical issues, and human protection of the study. Written consent signed after the participant understands and wishes. Each participant maintained a one-meter social distance from other participants and researchers.

7. These data collected through a demographic questionnaire in a special private room. It took about 30 minutes for each participant to completed the questionnaires. And the researchers informed and trained the patient how to use the VAS-A. Then, it could be used correctly by patients during the intra-operation procedure. The sample investigated by the VAS-A to measure intraoperative anxiety level while they were in surgical time. Explain the following to the patient:

The VAS-A comprises a 10 cm line, on which the participants mark their current degree of anxiety with the left end of the line being labelled 0 (no anxiety), and

the right end being labelled 10 (maximum anxiety). The participants were asked to indicate how anxious they were feeling by marking the appropriate place on the line.

8. After completed the questionnaire, public goods including pens disinfected by alcohol cotton after using.

9. On the day of surgery, patients received intraoperative anxiety assessment using the Visual Analogue Scale for Anxiety (VAS-A). Upon completion of the surgical procedure, the investigator presented the VAS-A booklet to the patient in the operating room (OR) and queried: 'Please rate your peak anxiety intensity during the surgery on a 0-10 scale, where 0 represents no anxiety and the right end being labelled 10 (maximum anxiety). The researcher then marked the reported score on the scale ruler.

10. The intraoperative apprehension questionnaires collected in the recovery room after surgery. It took about 30 minutes for each participant to completed the questionnaires.

11. The researcher checked that the questionnaire has been completed after the participant has submitted it.

12. This process repeated until the desired sample size is reached.

Data analyses

This study used IBMSPSS26.0 software to analyze the data. The significance level was set at 0.05, and data analysis was included:

1. Descriptive statistics were used to describe the demographic data and frequency, percentage, mean and standard deviation of intraoperative apprehension and intraoperative anxiety in conscious patients during receiving closed-leg fracture during receiving open reduction and internal fixation surgery trauma surgery.

2. T-test was used to examine the relationship between gender and intraoperative anxiety.

3. Pearson's product-moment correlation was used to examine the relationship between waiting time, surgical time and intraoperative anxiety.

CHAPTER 4
RESULTS

The study aimed to describe the degree of intraoperative anxiety of patients undergoing conscious surgery for closed-leg fracture and identify the relationship between gender, age, waiting time, surgical time and intraoperative anxiety in patients with closed-leg fracture during conscious surgery. The data were collected from The Second Affiliated Hospital of Wenzhou Medical University in Wenzhou, China, with 123 participants from February to April 2025. The findings of this study are presented as follows:

1. The description of general information and health information of the participants including gender, age, educational level, marital status, occupation, living place, healthcare payment scheme, annual family income, surgical history, disease history, fracture site, waiting time, surgical time and anesthesia method.

2. The description of the degree of intraoperative anxiety of patients undergoing conscious surgery for closed-leg fracture.

3. The description of the relationships between gender, age, waiting time, surgical time and intraoperative anxiety of patients undergoing conscious surgery for closed-leg fracture.

Part 1 The description of general information and health information of the participants

Description of the general information

The general information about the participants is illustrated in Table 1.

Table 1 Frequency and percentage of demographic characteristics of the patients undergoing conscious surgery for closed-leg fracture (n = 123)

Characteristics	**Number(n)**	**Percentage (%)**
Gender		
Male	70	56.9
Female	53	43.1
Age (years)		
20-40 (early adulthood)	16	13.0
41-60 (middle adulthood)	69	56.1
More than 60 (elderly age)	38	30.9
(M = 54.1, SD = 12.2, Min = 22, Max = 76)		
Educational Attainment		
None	22	17.9
Primary school	18	14.6
Junior / senior high school	59	48.0
Bachelor degree or higher	24	19.5
Marital status		
Married	119	96.8
Single	1	0.8
Widowed	3	2.4

Table 1 (Continued)

Characteristics	Number(n)	Percentage (%)
Occupation		
Employed	90	73.2
Government staff	7	5.7
Healthcare personnel	2	1.6
Commercial staff	36	29.3
Farmer	7	5.7
Labor	38	30.9
Unemployed	33	26.8
Retired	26	21.1
No occupation	7	5.7
Annual family income (1 CNY = 0.14 USD)		
Less than CNY 25,000	46	37.4
CNY 25,000 - CNY50,000	29	23.6
CNY 50,000 - CNY100,000	17	13.8
More than CNY 100,000	31	25.2
Healthcare payment scheme		
Urban residents under the medical insurance system (90% paid by the government)	79	64.2
New rural cooperative medical care system (70% paid by the government)	20	16.3
Out-of-pocket medical (paid by themselves)	5	4.1
Insurance company	19	15.4

According to Table 1, more than half of the participants were male (56.9%), while 43.1% were female. The age of the participants ranged from 22 to 76 years old with a mean age of 54.1 years old (SD=12.2). The largest proportion of participants (56.1%) fell within the 41-59 years age group. Among these participants, nearly half have received an education of junior to senior high school (48.0%), followed by a Bachelor's degree and higher (19.5%). Most of the participants were married (96.8%).

Nearly three-quarters of the participants were employed (73.2%). In terms of annual family income, the proportion of less than CNY 25,000 was the largest (37.4%), followed by more than CNY 100,000 (25.2%). More than half of the participants had a new rural cooperative medical care system to cover their medical expenses (64.2%).

Description of health information

Table 2 showed the health information of the participants containing fracture site, anesthesia method, preoperative preparation time, anesthesia preparation time, duration of anesthesia, surgical time, and comorbidities.

Table 2 Frequency and percentage of health information of the patients with closed-leg fracture during conscious surgery (n = 123)

Characteristics	**Number(n)**	**Percentage (%)**
Fracture site		
Femoral fracture	24	19.5
Tibial fracture	80	65.1
Fracture in both bones (tibia and fibula)	19	15.4
Anesthesia method		
Combined spinal and epidural anesthesia	118	95.9
Spinal Anesthesia	2	1.6
Epidural Anesthesia	3	2.4
waiting time (minutes)		
< 30	53	43.1
＞30	70	56.9
(M = 37.4, SD = 15.2, Min = 9, Max =60		
Surgical time (minutes)		
50-60	13	10.6
61-90	33	26.8
91-120	43	35.0
121-150	25	20.3

Table 2 (Continued)

Characteristics	**Number(n)**	**Percentage (%)**
151-180	4	3.2
＞180	5	4.1
(M = 102, SD = 36.8, Min = 50, Max = 222)		
Comorbidities		
Had comorbidities*	35	28.5
No comorbidity	88	71.5

*=hypertension, diabetes, hyperlipidemia, hepatitis B, osteoporosis

As shown in Table 2, the most common site of fracture among the participants was tibial fracture (65.1%), while femoral fracture was 19.5%. All of the anesthesia method was intraspinal anesthesia, and the most proportion was combined spinal and epidural anesthesia (95.9%). When looking at the waiting time, the largest proportion was more than 30 minutes (56.9%). The largest part of surgical time was between 91 minutes to 120 minutes (35.0%), and 61-90 minutes was followed (26.8%). 71.5% of the participants were healthy, and 28.5% had comorbidities, including hypertension, diabetes, hyperlipidemia, hepatitis B, and/or osteoporosis.

Part 2 The description of study variables

Description of intraoperative anxiety

The Visual Analog scale for Anxiety (VAS-A) was used to measure the level of intraoperative anxiety. It comprises a 10cm line.

Table 3 Range, mean, and standard deviation of intraoperative anxiety of the patients undergoing conscious surgery for closed-leg fracture (n = 123)

Dependent variables	Range	Range	Mean	SD
	Possible score	Actual score		
VAS-A	0-10	0-10	6.3	2.2

Table 3 illustrated that the VAS-A scores of the participants ranged from 0 to 10, with a mean of 6.3 (SD = 2.2), which indicated a clinically relevant level of anxiety.

Description of the gender

Table 4 Number, Percentage, Mean, and Standard Deviation of Intraoperative Anxiety Scores for Patients with Closed-leg Fracture undergoing Conscious Surgery by Gender (n = 123)

Gender	Number(n)	Percentage (%)	Mean of intraoperative anxiety	SD of intraoperative anxiety
Male	70	56.9	5.6	2.2
Female	53	43.1	7.1	1.9

As Table 4 illustrated, the average of intraoperative anxiety of male patients undergoing conscious surgery for closed-leg fracture was 5.6 (SD=2.2). Whereas for female patients, it was 7.1 (SD=1.9), which showed a higher level of intraoperative anxiety than males in this study.

Description of the age

Table 5 Mean and standard deviation of age of the patients with closed-leg fracture during conscious surgery (n = 123)

Age (years)	**Number(n)**	**Percentage (%)**	**Mean of intraoperative anxiety**	**SD of intraoperative anxiety**
20-40 (early adulthood)	16	13.0	6.1	2.4
41-60 (middle adulthood)	69	56.1	6.0	2.2
＞60 (elderly age) (M = 54.1)	38	30.9	6.6	1.9

As Table 5 illustrated, the mean of intraoperative anxiety among patients in different age groups with undergoing conscious surgery for closed-leg fracture was 6.1 (SD= 2.4) (20–40 years old), 6.0 (SD= 2.3) (41–60 years old), and 6.6 (SD= 1.9) (more than 60 years old).

Description of the waiting time and surgical time

Table 6 Mean and standard deviation of waiting time and surgical time in the patients undergoing conscious surgery for closed-leg fracture (n = 123)

Variables	Number(n)	Percentage (%)	Mean of intraoperative anxiety	SD of intraoperative anxiety
waiting time (minutes)				
⩽ 30	53	43.1	5.4	2.2
＞30	70	56.9	6.8	1.9
(M = 37.4)				
Surgical time (minutes)				
50-60	13	10.6	5.1	2.3
61-90	33	26.8	5.4	1.9
91-120	43	35.0	6.2	2.1
121-150	25	20.3	8.0	1.4
151-180	4	3.2	7.3	0.9
＞180	5	4.1	6.2	2.9
(M = 102)				

Table 6 reported that the mean score of intraoperative anxiety among patients undergoing conscious surgery for closed-leg fracture was 5.4 (SD=2.2) when the waiting time was less than 30 minutes, which was much lower comparing with the waiting time exceeding 30 minutes (M=6.8, SD=1.9). Based on the analysis of the surgical time, the mean of intraoperative anxiety was 5.1 (SD=2.3) at 50-60 minutes, 5.4 (SD=1.9) at 61-90 minutes, 6.2 (SD=2.1) at 91-120 minutes, 8.0 (SD=1.4) at 121-150 minutes, 7.3 (SD=0.9) at 151-180 minutes and 6.2 (SD=2.9) at more than 180 minutes respectively.

Description of the intraoperative apprehension

Table 7 Mean and Standard deviation of each item of intraoperative apprehension among patients undergoing conscious surgery for closed-leg fracture (n = 123)

Each item of intraoperative apprehension	Mean	SD
1. How would your anesthetist explaining your anesthetic before going to operation room affect your anxiety?	3.12	1.32
2. How would a nurse explaining your anesthetic on the ward before going to operation room affect anxiety?	2.93	1.23
3. How would being told how long your anesthetic will last affect your anxiety?	3.02	1.27
4. How would being told how soon the numbness will take to wear off affect your anxiety?	3.01	1.24
5. How would being told how soon you will be able to eat and drink again affect your anxiety?	2.80	1.17
6. How would always being told what was to happen next affect your anxiety?	3.12	1.35
7. How did the thought of possibly needing more than one injection to numb your skin affect your anxiety?	3.15	1.16
8. How did the thought of possibly needing a drip (intravenous infusion) affect your anxiety?	3.09	1.16
9. How did the thought of being awake during the operation affect your anxiety?	3.20	1.21
10. How did the thought of possibly hearing what the doctors and nurses were saying in operation room affect your anxiety?	3.07	1.20
11. How did the thought of possibly feeling what the surgeon was doing in operation room affect your anxiety?	3.11	1.25
12. How did the thought of possibly seeing your body ‘cut open’ affect your anxiety?	3.10	1.22

Table 7 (Continued)

Each item of intraoperative apprehension	Mean	SD
13. How did the thought of the operation possibly being more painful because you were awake affect your anxiety?	3.12	1.26
14. How did the thought of the numbness possibly wearing off before the operation was finished affect your anxiety?	3.06	1.22
15. How did the thought of possibly feeling 'closed in' (claustrophobic) during the operation affect your anxiety?	2.89	1.22
16. How did the thought of the pain possibly being worse afterwards because only a part of your body was being made numb affect your anxiety?	3.03	1.21

The table 7 showed that the mean of item 9 "How did the thought of being awake during the operation affect your anxiety?" was the highest among the 16 items in intraoperative apprehension (M=3.20, SD=1.21), while the item 5 "How would being told how soon you will be able to eat and drink again affect your anxiety?" was the lowest (M=2.80, SD=1.17).

Table 8 Frequency, Percentage, Mean, Standard deviation, and level of the intraoperative apprehension among patients undergoing conscious surgery for closed-leg fracture (n = 123)

Intraoperative apprehension score	Number(n)	Percentage (%)	Mean	SD	Level
16-40	35	28.5	28.6	8.2	Low
41-63	65	52.8	51.3	6.6	Moderate
64-80	23	18.7	72.5	6.0	High

As shown in table 8, more than half of the participants reported that their intraoperative apprehension were at the moderate level with a mean score of 51.3±6.6

Table 9 Range, Mean, Standard deviation and level of the intraoperative apprehension among patients undergoing conscious surgery for closed-leg fracture (n = 123)

Variable	Range	Range	Mean	SD	Level
	Possible score	Actual score			
Intraoperative apprehension	16-80	16-80	48.8	16.5	Moderate

As Table 9 illustrated, an average of the intraoperative apprehension among patients undergoing conscious surgery for closed-leg fracture (n = 123) were 48.8±16.5. Overall, intraoperative apprehension of the participants was at a moderate level.

Part 3 the relationship between gender, age, waiting time, surgical time and intraoperative anxiety among the patients with closed-leg fracture during conscious surgery.

An independent samples t-test was conducted to examine the relationship between gender and intraoperative anxiety. The results were presented in Table 10.

Table 10 Independent samples t-test analysis of intraoperative anxiety by gender among the patients with closed-leg fracture during conscious surgery (n = 123)

Gender	Number (n)	Percentage (%)	Mean of intraoperative anxiety	SD of intraoperative anxiety	t	p
Male	70	56.9	5.6	2.2	−3. 922	＜. 001
Female	53	43.1	7.1	1.9		

As presented in Table 10, an independent samples t-test revealed a statistically significant difference between gender (t=−3. 922, p＜. 001) and intraoperative anxiety. The analysis indicated significantly higher anxiety in female patients compared with males.

Pearson's product-moment correlation was used to examine the relationship between age, waiting time, surgical time and intraoperative anxiety among the patients undergoing conscious surgery for closed-leg fracture. The normal distribution of the variables was tested through a PP plot. The variables (age, waiting time, surgical time and intraoperative anxiety) conformed to a normal distribution. The results were presented in Table 11.

Table 11 Correlation coefficients between age, waiting time, surgical time and intraoperative anxiety among the patients with closed-leg fracture during conscious surgery (n = 123)

Variables	**Correlation coefficients**	***P*-value**
Age	.221	＜.05
waiting time	.307	＜.001
Surgical time	.346	＜.001

Table 11 indicated that age had a positive and correlation with intraoperative anxiety among the patients undergoing conscious surgery for closed-leg fracture (r = .221, p <.05). waiting time had a positive, significant, and moderate correlation with intraoperative anxiety among the patients undergoing conscious surgery for closed-leg fracture (r = .307, p <.001). Surgical time had a positive, significant, and moderate correlation with intraoperative anxiety (r = .346, p <.001).

CHAPTER 5
CONCLUSION AND DISCUSSION

This chapter presented the conclusion and discussion of the study results according to the research objectives and hypotheses. Implications of the study findings, limitations, and recommendations for future research are presented.

Summary of the study

This study aimed to investigate the relationship between gender, age, waiting time, surgical time and intraoperative anxiety inpatients with closed-leg fracture during conscious surgery. Specifically, the study employed Lazarus and Folkman's Transactional Model of Stress and Coping as the conceptual framework to explain relationships among variables. Using random sampling, 123 participants were recruited from The Second Affiliated Hospital of Wenzhou Medical University. Data were collected using three instruments: 1) The Demographic Questionnaire, 2) the Visual Analog Scale for Anxiety (VAS-A), and 3) The Intraoperative Apprehension Scale. The reliability of The Intraoperative Apprehension Scale was assessed using Cronbach's alpha coefficient in a pilot study. Results demonstrated good internal consistency (Cronbach's $\alpha = 0.87$) with 30 participants, and Cronbach's $\alpha = 0.92$ with 123 participants.

Among the 123 participants, over half were male (56.9%), while 43.1% were female. Participants' ages ranged from 22 to 76 years (mean = 54.1 years, SD = 12.2). The majority (56.1%) were aged 41-59 years. Mean intraoperative anxiety scores across age groups were: 6.1 (SD= 2.4 (20-40 years), 6.0 (SD= 2.3 (41-60 years), and 6.6 (SD= 1.9 (>60 years). Furthermore, 71.5% of participants were healthy, while 28.5% had comorbidities including hypertension, diabetes, hyperlipidemia, hepatitis B, and/or osteoporosis.

Regarding education, nearly half (48.0%) had junior to senior high school education, followed by bachelor's degree or higher (19.5%). The overwhelming majority were married (96.8%), and nearly three-quarters were employed (73.2%). Annual family income distribution showed the largest proportion earning less than

CNY 25,000 (37.4%), followed by more than CNY 100,000 (25.2%). Over half (64.2%) were covered by the New Rural Cooperative Medical Scheme. Tibial fractures were most common (65.1%), while femoral fractures accounted for 19.5%. All patients received intraspinal anesthesia, predominantly combined spinal-epidural anesthesia (95.9%).

Most participants experienced waiting times exceeding 30 minutes (56.9%). Intraoperative anxiety was significantly lower when waiting time was <30 minutes (M=5.4, SD=2.2) compared to >30 minutes (M=6.8, SD=1.9). Surgical time were primarily 91-120 minutes (35.0%), followed by 61-90 minutes (26.8%). Based on the analysis of the surgical time, the mean of intraoperative anxiety was 5.1 (SD=2.3) at 50-60 minutes, 5.4 (SD=1.9) at 61-90 minutes, 6.2 (SD=2.1) at 91-120 minutes, 8.0 (SD=1.4) at 121-150 minutes, 7.3 (SD=0.9) at 151-180 minutes and 6.2 (SD=2.9) at more than 180 minutes respectively.

Overall, VAS-A scores ranged from 0 to 10 (M=6.3, SD=2.2), indicating clinically relevant anxiety levels. Simultaneously, the Intraoperative Apprehension yielded a mean score of 48.8 (SD=16.5, suggesting moderate intraoperative apprehension levels.

An independent samples t-test revealed a statistically significant gender difference in intraoperative anxiety ($t = -3.922$, $p < .001$), with female patients exhibiting significantly higher anxiety levels than males. Furthermore, significant positive correlations were observed between intraoperative anxiety and patient age ($r = .221$, $p < .05$), waiting time ($r = .307$, $p < .001$), and surgical time ($r = .346$, $p < .001$) among patients undergoing conscious surgery for closed-leg fracture.

Discussion

According to the research objectives and hypothesis, the results of this study were discussed. The first objective was to describe the level of intraoperative anxiety in patients with closed-leg fracture during conscious surgery. The second objective was to determine the relationship between gender, age, waiting time, surgical time with intraoperative anxiety in patients with closed-leg fracture during conscious surgery. The third objective was to descript intraoperative apprehension in patients with closed-leg fracture during conscious surgery.

The level of intraoperative anxiety among patients undergoing conscious surgery for closed-leg fracture

Visual analog scale for anxiety (VAS-A) was used to measure the intraoperative anxiety level. It comprises a 10cm line, with the left end of the line being labelled 0 (no anxiety), and the right end being labelled 10 (maximum anxiety). This study illustrated that VAS-A score of the participants ranged from 0 to 10, with a mean of 6.3 (SD = 2.2), which indicated a clinically relevant level of anxiety.

This result is consistent with a study by Saracoglu which found a mean anxiety score for surgery patients under spinal anesthesia of 5.2 (SD = 1.64) (Saracoglu et al., 2021). The findings are also consistent with a study by Mohammed, which found a VAS-A mean score of 3.7 (SD = 1.79) (Mohammed et al., 2022). The elevated intraoperative anxiety scores in this study compared to two studies may be partially explained by demographic variations. In this study, the mean age of patients with closed-leg fracture undergoing conscious surgery was 54.1 years, which is higher than that reported in Saracoglu's study (M = 43.8 years) and in Mohammed's study (M = 39.02 years). This finding aligns with evidence indicating a positive correlation between age and heightened anxiety levels (Q. Liu et al., 2023). Furthermore, our investigation revealed significantly greater anxiety among elderly patients compared to middle-aged individuals. This observation is consistent with established literature demonstrating higher prevalence rates of anxiety in older populations (Javaid et al., 2023). Potential contributing factors include: age-related decline in decision-making capacity and reduced ability to acquire and process health information(Häggström & Brodin, 2024; Ren et al., 2021).

Secondly, gender constitutes a significant factor contributing to intraoperative anxiety. In the present study, females constituted 43.1% of participants, which is distinctly higher than the proportions reported in the studies by Saracoglu (10.6%) and Mohammed (40.0%). This differential distribution may partially account for the observed elevation in intraoperative anxiety scores. This finding is highly consistent with previous research. Numerous studies have systematically confirmed that female patients report significantly higher intraoperative anxiety levels during conscious surgery, compared to male patients (Altinsoy et al., 2020; Bello et al., 2023). Differing norms for emotional expression may lead females to report anxiety more candidly or to

be more susceptible to the influence of health threat information (Farhane-Medina et al., 2022).

In the present research, intraoperative anxiety was higher than found in other similar studies. In this study, the mean surgical time was 102 minutes (SD= 36.8), and that value notably exceeds the finding in the studies by Saracoglu of 45 minutes (SD=33.0) and Mohammed of 35 minutes (SD= 6.3). This suggests that prolonged surgical time is a contributing factor to intraoperative anxiety. This indicated that prolonged surgical time could be a contributing factor to intraoperative anxiety. This observation aligns conclusively with established literature: Bovaira et al. empirically validated that extended surgical time significantly amplifies intraoperative anxiety, particularly during regional anesthesia (Bovaira et al., 2017).

The research has found that income was also one of the factors affects intraoperative anxiety of closed-leg fracture patients. Among the participants, 56.1% were aged from 41 to 60 years old. This Individuals often serve as primary breadwinners or caregivers in their families. And during the investigation that nearly three quarters of the participants were employed (73.2%). Surgery may lead to income disruption. So, during the surgery, patients may ruminate about the surgical outcome, agonizing over whether the fracture will heal properly, whether complications like joint stiffness might arise, whether postoperative rehabilitation will be necessary, and ultimately, how these factors could jeopardize their ability to return to work(Hah et al., 2021). An article indicated at 6 and18 months post- fracture, 34.4% and 56.3% of participants, respectively, and 70.1% had returned to work at 18 months (Masterson et al., 2023). In this article, one third of families have an income of less than 20,000, and the largest group among the participants were labor (n=38, 30.9%). Fracture surgery was unplanned and disruptive, frequently precipitate labor inability to resume occupational duties(Thakore et al., 2015), thereby exposing them to dual socioeconomic vulnerabilities and income attrition risks (Scott et al., 2023).

Among these participants, nearly half (48.0%) had a junior to senior high school education. It indicated that less than college-level education was associated with limited health information (Hoang et al., 2022). This likely occurred because less educated individuals have reduced access to health information and may hold

inaccurate perceptions of surgery, such as overestimating procedural pain (Shahid et al., 2022).

In this study, anesthesiologists did not provide preoperative education to patients, resulting in limited access to anesthesia-related information. This deficiency may contribute to increased intraoperative anxiety, aligning with prior research demonstrating that insufficient anesthesia information heightens patient intraoperative anxiety during conscious surgery (Padsala et al., 2023). As reported in the literature, patients who lacked access to anesthesia information expressed significant anxiety intraoperatively due to fears that anesthesia wearing off might cause pain (Saltalı, 2023). It has been reported that informing patients about surgery and anesthesia in the preoperative period may have a positive effect on anxiety (Kyuhee Lim, Sooah Jung, & Heejung Kim, 2023). Preoperative verbal and written patient education regarding surgical and anesthetic procedures demonstrated a marked reduction in anxiety levels (Kharod et al., 2022).

The relationship between gender, age, waiting time, surgical time with intraoperative anxiety in patients with closed-leg fracture during conscious surgery

In this study, gender had positive significant correlation with intraoperative anxiety, with female patients exhibiting significantly higher anxiety levels than males. In this study, gender, patient age, waiting time, surgical time had positive significant correlation with intraoperative anxiety among patients undergoing conscious surgery for closed-leg fracture. This was consistent with the hypothesis of this study.

Gender

In this study, more than half of the participants were male (56.9%), while 43.1% were female. Gender had a positive significant correlation with intraoperative anxiety ($r = 0.293$, $p < 0.001$). It indicated that there was indicating that there is a significant difference in the intraoperative anxiety values between male and Female. Through research, it was found that gender seems to have the most significant effect on patients' anxiety, with women being more anxious and concerned than men (Vadhanan et al., 2017).

The elevated intraoperative anxiety observed in female patients is mechanistically explained through Lazarus and Folkman's transactional model of

stress. Females predominantly appraise surgery as dually threatening—jeopardizing both personal health and familial caregiving roles—particularly when closed-leg fracture compromise their capacity as primary caregivers. This threat perception intensifies as fracture-induced limitations in activities of daily living (ADLs) trigger systemic household care breakdown, depleting coping resources. Concurrently, 47% increase in domestic conflicts post-injury, directly linking caregiving loss to preoperative distress, and 72% of impacted households demonstrate clinically significant role realignment deficits during the critical 3-month post-fracture rehabilitation window (Ariza-Vega et al., 2019). These dynamics culminate in heightened intraoperative anxiety (Padsala et al., 2023). Therefore, establishing structured family support systems is essential to address dual care challenges: both patient care needs and household caregiving burdens. Social support can help patients in reducing depression, anxiety and comorbid psychological issues throughout rehabilitation (Chen et al., 2020).

This gender disparity may correlate with both biological and psychosocial mechanisms. Biologically, hormonal modulation of the hypothalamic-pituitary-adrenal (HPA) axis and neurobiological dimorphism in pain processing potentially heighten females' sensitivity to surgical stress and anticipatory pain concerns (Heck & Handa, 2019; Osborne & Davis, 2022; Paller et al., 2009). Psychosocially, gender-specific emotional expression norms may facilitate greater openness in reporting anxiety among women, alongside heightened vulnerability to health-threatening information. Consequently, emphasizing the necessity of considering gender factors in perioperative management to achieve individualized anxiety intervention. Preoperative anesthesia education interventions can mitigate intraoperative anxiety levels in female patients. A systematic review and meta-analysis has shown satisfactory results with music therapy for female patients in the reduction of anxiety (Sarah J Weingarten et al., 2021).

Age

In this study, Furthermore, our investigation revealed significantly greater anxiety among elderly patients compared to middle-aged individuals. This observation is consistent with established literature demonstrating higher prevalence rates of anxiety in older populations (Javaid et al., 2023). Potential contributing factors include:

age-related decline in decision-making capacity and reduced ability to acquire and process health information(Häggström & Brodin, 2024; Ren et al., 2021).

Age constitutes a pivotal demographic variable, in this study found that elevated anxiety in younger (mean=6.1, SD= 2.4) and elder adults (mean=6.6, SD= 1.9), with lower levels in middle-aged individuals (mean=6.0, SD= 2.3). This might be related to factors such as people's physiological decline, cognitive alterations, and psychosocial factors. It revealed significantly greater anxiety among elderly patients compared to middle-aged individuals. This observation is consistent with established literature demonstrating higher prevalence rates of anxiety in older populations (Javaid et al., 2023). Elder adults experienced age-related decline in decision-making capacity and reduced ability to acquire and process health information (Häggström & Brodin, 2024; Ren et al., 2021). Therefore, the elderly need the support of their family and friends to help communicate with doctors and make decisions during their hospital stay (Chiu et al., 2016). Medical staff should offer more care and more health education support to help patients better understand fracture surgery and prognosis (Griffiths et al., 2021). The synergy between anesthesiologists and surgeons fosters effective communication and cooperation, aiding in the selection of optimal anesthesia and surgical plans (Jameson, 2023). These behaviors can enable elderly patients to receive more assistance and a greater sense of trust, thereby reducing intraoperative anxiety.(Fu et al., 2025; Shen et al., 2023)。Elderly individuals, due to the decline in their physiological functions, exhibit greater concerns regarding postoperative care systems compared to younger people (Partridge et al., 2022). Establish a sound post-hospital care system to provide better care for elderly patients and prevent the occurrence of postoperative complications (Karlsson et al., 2022).

Waiting time

In this study, the largest proportion of waiting time was more than 30 minutes (56.9%). The mean score of intraoperative anxiety among patients undergoing conscious surgery for closed-leg fracture was 5.4 (SD=2.2) when the waiting time was less than 30 minutes, which was much lower comparing with the waiting time exceeding 30 minutes (M=6.8, SD=1.9). waiting time had a positive, significant, and moderate correlation with intraoperative anxiety among the patients undergoing conscious surgery for closed-leg fracture ($r = .307$, $p < .001$).

The waiting time before the start of anesthesia can affect the patient's anxiety and discomfort levels (Putri et al., 2023). In this study found that the largest proportion of waiting time was more than 30 minutes (56.9%), the mean score of intraoperative anxiety was 6.8 (SD=1.9). This result is consistent with Putri et al. study. Putri et al. investigated the relationship between waiting time and anxiety levels in patients receiving spinal anesthesia prior to cesarean section. They found that patients with waiting times exceeding 30 minutes exhibited significantly higher anxiety levels (Putri et al., 2023). It has been found that the longer the waiting time in the operating room, the higher the level of anxiety (Dziadzko et al., 2022). Similarly, the study found that waiting time had a positive and moderate correlation with intraoperative anxiety among the patients undergoing conscious surgery for closed-leg fracture ($r = .307$, $p < .001$). Studies concluded that preoperative waiting area existed some evidence to support an anxiety-reducing effect of background music on patients, though studies vary widely in methodology and music selection (Lai & Amaladoss, 2022; Xuan et al., 2021). Part of the healthcare environmental psychology strategy to reduce stress used televisions in waiting rooms, with the intent to distract the viewer and make waiting easier (Fryburg, 2021). In China, many researchers have explored Traditional Chinese Medicine (TCM) therapies—such as acupuncture and auricular acupressure—to reduce anxiety during waiting periods. The results demonstrated that these interventions significantly reduced the incidence of anxiety (Hu et al., 2024; Tong et al., 2021).

Surgical time

Observe the results of the surgical time, The largest part of surgical time was between 91 minutes to 120 minutes (35.0%), the mean was 6.2 (SD=2.1). This result was consistent with Kaur et al. study. Kaur et al. found that patients experience peak anxiety levels when the surgical time reaches 90-120 minutes (Kaur et al., 2022). Patients among the patients undergoing conscious surgery for closed-leg fracture whose surgical time the range of 121 to 150 minutes showed the highest level of intraoperative anxiety (mean=8.0, SD=1.4). This result was consistent with Novy et al. study. Novy et al. found that surgery duration on anxiety (71.4%) subjects whose surgery lasted more than 120 minutes showed medium to height anxiety during surgery (Novy et al., 2020). Research on the correlation between surgical time and intraoperative anxiety levels indicates that prolonged surgical time may significantly impact patients'

intraoperative anxiety (Bovaira et al., 2017). The research results findings were consistent with Bovaira et al. reported. Contrary to expectations, the data revealed a paradoxical reduction in intraoperative anxiety among patients with prolonged surgical time (more than 150 minutes). This finding should be the limited sample size (n=9). Many researchers have explored the effectiveness of intervention measures in reducing the occurrence of intraoperative anxiety during conscious surgery. A study showed that listening to instrumental music during lower leg fracture surgery caused a reduction in anxiety (de Araújo Azi et al., 2021a). VR glasses create immersive environments to distract patients from various stress factors (Gao et al., 2023). Investigating the use of VR/music on serum cortisol and adrenocorticotropic hormone (ACTH) levels in knee replacement surgery under combined spinal epidural anaesthesia can improve intraoperative anxiety (Singh et al., 2024).

Although these interventions effectively mitigate anxiety in patients during both the pre-anesthetic waiting period and intraoperative phases, optimizing workflow efficiency to minimize waiting times and surgical duration should remain a priority.

Descript intraoperative apprehension in patients with closed-leg fracture during conscious surgery.

This study illustrated that an average of the intraoperative apprehension of the patients with closed-leg fracture during conscious surgery were 48.8 (SD=16.5. Overall, intraoperative apprehension of the participants was at a moderate level. Intraoperative apprehension can occur in specific situations, for example is a common feeling experienced by many patients who are going to be operated (A. Jiang et al., 2024). The main reasons for this problem are the lack of knowledge and information, not only about surgical intervention, but also about anesthesia (Ruiz Hernandez et al., 2021). As identified in the study, healthcare providers' failure to deliver anesthesia-related information preoperatively resulted in significant uncertainty among patients regarding anesthetic procedures. This study found that most anesthesiologists failed to provide anesthesia-related information to patients, and ward nurses' preoperative education did not include anesthesia-related content.

Orthopedic surgeries generate the highest noise levels due to instrument usage (e.g., hammers, drills), which significantly contributes to intraoperative patient anxiety (Simpson & Hamer, 2017). Our closed-leg fracture surgery observations demonstrated

concordance with these findings. Critically, this investigation revealed that surgical teams' failure to provide anxiety-related communication directly elevated patient anxiety levels—contradicting evidence that continuous information delivery and question-opportunities reduce intraoperative anxiety (Haugen et al., 2009).

With the predicted rise in the volume of conscious surgery, the importance of interventions designed to resolve such issues cannot be underestimated. Generalized anxiety and depression prior to surgery should be identified to implement nursing interventions to reduce anxiety in the operating theatre (Haugen et al., 2009). The results of this study showed that listening to selected music reduces intraoperative anxiety (Jiménez-Jiménez et al., 2013; Kaur et al., 2022). Delivering music is the most frequently used as non-pharmacological intervention by researchers (de Araújo Azi et al., 2021b). In the preoperative stage, providers can offer educational content to explain the procedure to their patients. Whether it be through telephone calls, educational videos, or utilization of visual models, educating the patient regarding their procedure may reduce their anxiety. Intraoperatively, there are multiple methods that can be used such as music, guided imagery, coloring books, medications, hypnosis, and distraction techniques (Yousif et al., 2023). In addition, dry cupping method, progressive muscle relaxation (PMR) exercise and virtual reality (VR) goggles were used in included studies (Kyuhee Lim, Sooah Jung, & Heejung %J Journal of Clinical Nursing Kim, 2023).

Conclusion

This study found a mean intraoperative anxiety score was 6.3±2.2, which indicates a clinically-relevant level of anxiety. In addition, there was a significant difference in intraoperative anxiety between female and male patients ($t = -3.922$, $p < .001$). Females had higher intraoperative anxiety than their male counterparts. Age, waiting time, and surgical time had a positive correlation with intraoperative anxiety among the patients undergoing conscious surgery ($r = .221$, $p < .05$). $r = .307$, $r = .346$, $p < .001$, respectively). These factors can help medical staff more specifically develop interventions to reduce intraoperative anxiety.

Implication for nursing practice

The findings of the current study might be useful in the following areas:

Nursing Practice

The findings of this study provide a reference for healthcare providers to better understand the factors contributing to intraoperative anxiety of patients with closed-leg fracture undergoing conscious surgery, allowing for early identification of high-risk individuals and targeted interventions. Additionally, the results should assist medical staff in tailoring intraoperative nursing strategies based on individual patient differences, thereby preventing and alleviating intraoperative anxiety, reducing anxiety-related physiological responses, minimizing complication risks, and promoting postoperative recovery.

Nursing Education

For nursing educators, this study highlights the importance of guiding students to recognize and address intraoperative anxiety issues, as well as providing specialized training for practicing nurses to update their knowledge and skills in anxiety management. By examining the factors of intraoperative anxiety of patients with closed-leg fracture during conscious surgery, which important to make nursing students aware of the significance of intraoperative anxiety. Furthermore, the analysis of intraoperative anxiety factors, enhancing students' awareness and practical competence in psychological care.

Recommendations for future research

This study aimed to describe the degree of intraoperative anxiety of patients with closed-leg fracture during conscious surgery and identify the relationship between gender, age, waiting time, surgical time and intraoperative anxiety in patients with closed-leg fracture during conscious surgery. But this study was conducted only on patients undergoing closed-leg fracture, which may limit the generalizability of the findings. Future research could expand the scope of investigation and increase the sample size. Additionally, the specific characteristics of significant intra-operative anxiety require further investigation in order to potentially develop more effective intraoperative anxiety management techniques.

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APPENDIX

QUESTIONNAIRES

The questionnaires include three parts as follows:

1. The Demographic Questionnaire with 16 items
2. Intraoperative apprehension with 16 items
3. Visual analog scale for anxiety (VAS-A)

มหาวิทยาลัยบูรพา BURAPHA UNIVERSITY

The Demographic Questionnaire

Instruction: Fill in the blank or select option most related to you by marking √

NO.	
I. General information	
Gender	☐ Male ☐ Female
Age	_____years old
Education level	☐Never go to school ☐Primary School ☐Junior to senior high school ☐Bachelor's Degree ☐Master's Degree or higher
Marital status	☐Married ☐Single ☐Divorced ☐Widowed
Occupation	□Government staff ☐Healthcare personnel ☐Commercial staff □Farmer ☐ Labor (e.g. builder, factory worker, sanitation worker) ☐Retired ☐No occupation
Annual family income	□Less than CNY 25,000 ☐CNY 25,000 - CNY50,000 □CNY 50,000 - CNY100,000 ☐ More than CNY 100,000
Healthcare payment scheme	☐Urban residents under the medical insurance system □New rural cooperative medical care system □Out-of-pocket medical □Others
2) Health information:	
Comorbidities	☐No comorbidity ☐Hypertension ☐Diabetes ☐Hyperlipidemia ☐Osteoporosis ☐Others
Fracture site	☐Femoral fracture ☐Tibial fracture ☐Both bone (tibia and fibular)
Surgery date	
Operation	☐Internal fixation ☐Others
Anesthesia method	☐ Combined spinal and epidural anesthesia ☐Spinal Anesthesia ☐ Epidural Anesthesia
Preoperative preparation time (waiting area: outside the operating theater)	☐less than 10min ☐11-15min ☐16-30min ☐31-45min ☐46-60min ☐more than 60min

Preoperative preparation time (inside the operating theater)	☐less than 10min ☐11-20min ☐21-30min ☐more than 30min
Surgical time	☐less than 30min ☐31-60min ☐61-90min ☐91-120min ☐121-150min ☐151-180min ☐more than 120min

Intraoperative apprehension

Instruction: Select option most related to you by marking √.

Items	very anxious	a little anxious	made no difference	a little calm	very calm or never thought about it
1. How would your anesthetist explaining your anesthetic before going to operation room affect your anxiety?	5	4	3	2	1
2. How would a nurse explaining your anesthetic on the ward before going to operation room affect anxiety?	5	4	3	2	1
3. How would being told how long your anesthetic will last affect your anxiety?	5	4	3	2	1
4. How would being told how soon the numbness will take to wear off affect your anxiety?	5	4	3	2	1
	5	4	3	2	1
	5	4	3	2	1
	5	4	3	2	1
	5	4	3	2	1
	5	4	3	2	1

Items	very anxious	a little anxious	made no difference	a little calm	very calm or never thought about it
	5	4	3	2	1
	5	4	3	2	1
	5	4	3	2	1
	5	4	3	2	1
14. How did the thought of the numbness possibly wearing off before the operation was finished affect your anxiety?	5	4	3	2	1
15. How did the thought of possibly feeling ‘closed in’ (claustrophobic) during the operation affect your anxiety?	5	4	3	2	1
16. How did the thought of the pain possibly being worse afterwards because only a part of your body was being made numb affect your anxiety?	5	4	3	2	1

Visual analog scale for anxiety (VAS-A)

Dear patient：

Please use the following visual analog anxiety scale to measure your anxiety level. 0 means no anxiety at all and 10 means maximum anxiety you can imagine. Please mark the scale according to your actual feelings of anxiety. Thank you for your help!

No anxiety Maximum anxiety

Participant information sheet and consent forms

Research Title: Factors related to intraoperative anxiety in patients with closed-leg fracture during conscious surgery in Wenzhou, China.

Dear participants

I am Xue Zhang, a student in Master of Nursing Science (International Program) Faculty of Nursing, Burapha University Thailand. My study is "Factors related to intraoperative anxiety in patients with closed-leg fracture during conscious surgery in Wenzhou, China". This study is descriptive correlational research design, the purposes of this study is to describe the degree of intraoperative anxiety and investigate the relationship between gender, surgical time, and intraoperative apprehension with intraoperative anxiety in patients with closed-leg fracture during conscious surgery in Wenzhou, China.

This study will be a survey study. Participating in this study is voluntary. If you agree to participate in this study, you will answer the following questionnaires, which will take approximately 10-minutes. During the data collection period, the researcher will clarify any questions posed by the participants for clarity regarding the language or content. You will not get any direct benefits by participating in this study. However, the results of this study will help health care provider's better understanding of intraoperative anxiety in conscious surgical patients. The information obtained in this study will further identify factors influencing to intraoperative anxiety in conscious surgical patients, guidance, and effective interventions to prevent and help patients relieve their anxiety during the operation and promote postoperative recovery. This research result will also help health care providers to conduct future research and intervention to reduce intraoperative anxiety among this group of patients.

During the study, you have the right not to answer questions, and you also have the right to change your minds and refuse to participate in the project at any time, and the refusal would not affect the medical services you received. Any information collected from this study, including your identity, will be kept confidential. A coding number will be assigned to you and your name will not be used. Findings from the study

will be presented as a group of participants and no specific information from any individual participant will be disclosed. All data will be accessible only to the researcher which will be destroyed one year after publishing the findings. You will receive a further explanation of the nature of the study upon its completion, if you wish.

The research will be conducted by Xue Zhang under the supervision of my major-advisor, Associate Professor Dr. Niphawan Samartkit. If you have any questions, please contact me at mobile number: + 8613868881695 or by email 37378693@qq.com and/or my advisor's e-mail address nsamartkit@gmail.com. Or you may contact Burapha University Institutional Review Board (BUU-IRB) telephone number 038 102 620. Your cooperation is greatly appreciated. You will be given a copy of this consent form to keep.

Xue Zhang

Consent Form

Research Code: ……..

(Given by the Research Ethics Committee at Research and Innovation Administration Division, Burapha University **)**

Research Title: Factors related to intraoperative anxiety in patients with closed-leg fracture during conscious surgery in Wenzhou, China

Date ……..

Before signing the consent form for this research participation, I was provided the information about the purposes and the processes of the research in the participant information sheet, which the researcher has given to me. I have fully understood the preceding explanation and the researcher has undertaken to answer my questions willingly and without concealment to my satisfaction.

I voluntarily agree to participate in this research project. I understand I can withdraw from the research project at any time without giving a reason, without it affecting any benefits that I am entitled to.

I have been given the explicit guarantees that my information and identity will be kept confidential and will be shared only in the summary of research results. Disclosure of my information to the relevant authorities requires my permission.

I have read and fully understood the above statements in all respects and have signed this consent document willingly.

In the case that I cannot read or write, the researcher has read the statement in the consent form to me until I fully understand it well. Therefore, I willingly signed or stamped my thumb on this consent form.

Participant's signature ……..……..

(…….)

Researcher's signature …….……..…..

(…….…….)

Note: If the participant gave thumbprint as their consent, witness signature will be needed.

知情同意书

研究代码:

（由泰国东方大学人类伦理委员会办公室发布）

研究题目: 中国温州地区缺血性脑卒中后患者康复依从性的影响因素

签署同意：日.....月.....年.....

在签署本次研究参与同意书之前，我在研究员黄诗婷女士给我的参与者信息表中了解了本次研究的目的和过程。我已经完全理解了前面的解释，研究人员已经承诺愿意毫不隐瞒地回答我的问题，令我满意。

我自愿同意参加这个研究项目。我明白我可以在任何时候退出研究项目，而不需要给出任何理由，也不会影响我应得的任何利益。

我已经得到明确的保证，我的信息和身份将被保密，只会在研究结果总结中被分享。向有关部门披露我的个人信息需要得到我的许可。

本人已阅读并完全理解上述各项声明，并自愿签署本同意书。

在我无法阅读或书写的情况下，研究者黄诗婷女士已经为我朗读了同意书中的声明，直到我完全理解为止。因此，我自愿在这份同意书上签字或盖章。

参与者签名:

研究人员签名:

注:如参加者按手印表示同意，则需证人签名。

สำเนา

ที่ IRB3-009/2568

เอกสารรับรองผลการพิจารณาจริยธรรมการวิจัยในมนุษย์

มหาวิทยาลัยบูรพา

คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา ได้พิจารณาโครงการวิจัย

รหัสโครงการวิจัย : G-HS129/2567

โครงการวิจัยเรื่อง : Factors related to intraoperative anxiety in patients with closed leg fracture during conscious surgery in Wenzhou, China

หัวหน้าโครงการวิจัย : MRS.XUE ZHANG

หน่วยงานที่สังกัด : คณะพยาบาลศาสตร์

อาจารย์ที่ปรึกษาโครงการหลัก (สารนิพนธ์/ งานนิพนธ์/ วิทยานิพนธ์/ ดุษฎีนิพนธ์) : รองศาสตราจารย์ ดร.นิภาวรรณ สามารถกิจ

หน่วยงานที่สังกัด : คณะพยาบาลศาสตร์

อาจารย์ที่ปรึกษาโครงการร่วม (สารนิพนธ์/ งานนิพนธ์/ วิทยานิพนธ์/ ดุษฎีนิพนธ์) : ผู้ช่วยศาสตราจารย์ ดร.เขมารดี มาสิงบุญ

หน่วยงานที่สังกัด : คณะพยาบาลศาสตร์

วิธีพิจารณา : ☐ Exemption Determination ☐ Expedited Reviews ☑ Full Board

BUU Ethics Committee for Human Research has considered the following research protocol according to the ethical principles of human research in which the researchers respect human's right and honor, do not violate right and safety, and do no harms to the research participants.

Therefore, the research protocol is approved (See attached)

1. Form of Human Research Protocol Submission Version 2: 6 January 2025
2. Research Protocol Version 1: 17 October 2024
3. Participant Information Sheet Version 2: 3 January 2025
4. Informed Consent Form Version 2: 3 January 2025
5. Research Instruments Version 1: 17 October 2024
6. Others (if any) Version -: -

วันที่รับรอง : วันที่ 10 เดือน มกราคม พ.ศ. 2568

วันที่หมดอายุ : วันที่ 10 เดือน มกราคม พ.ศ. 2569

สำเนา

ลงนาม *Assistant Professor Ramorn Yampratoom*

(Assistant Professor Ramorn Yampratoom)

Chair of The Burapha University Institutional Review Board

Panel 3 (Clinic / Health Science / Science and Technology)

** หมายเหตุ การรับรองนี้มีรายละเอียดตามที่ระบุไว้ด้านหลังเอกสารรับรอง **

涉及人的生物医学研究伦理审查批件

Ethics Committee Approval Letter of Biomedical Research Involving Humans

批件号 Approval NO.：伦审(2024-K-377-02)

项目名称 Study Title	腿部闭合性骨折术中清醒患者术中焦虑的相关因素分析		
项目来源 Source	自选课题		
受理号 Acceptance Number	2024-K-377-02		
主要研究者 Principal Investigator	张雪	承担科室 Responsible Department	瓯江口手术室
审查类别 Category of Review	复审	审查方式 Type of Review	快速审查
审查日期 Date of Review	2025 年 01 月 21 日	审查地点 Location of Review	线上审查
审查文件清单 Items Reviewed	1. 复审申请表 2. 临床研究方案（版本号：V2.0；版本日期：2025.01.15） 3. 知情同意书（版本号：V2.0；版本日期：2025.01.15）		
审评意见 Evaluation	批准		
审查决定 Decision	委员会对该项目的审查决定为：☑批准 (Approval)		
主任委员签字 Chair Signature			
签发日期 Date of issue	2025 年 01 月 21 日		
医学伦理委员会 Stamp of EC	医学伦理委员会盖章		
批件有效期 Period of Validity	自本医学伦理委员会初始审查批准之日起一年内，本临床研究应在本院启动。逾期未启动的，本批件自行废止。		
年度/定期跟踪审查 Continue Review	审查频率为该研究批准之日起每 12 月一次，首次请于 2026 年 1 月 20 日前 1 个月递交研究进展报告。 医学伦理委员会有根据实际进展情况改变跟踪审查频率的权利。		
声明 Statement	本医学伦理委员会的职责、人员组成、操作程序及记录遵循《涉及人的生物医学研究伦理审查办法》、《涉及人的健康相关研究国际伦理准则》、《赫尔辛基宣言》、GCP 和 ICH-GCP 等国际伦理指南和国内相关法律法规。		

注意事项：

1. 请遵循我国相关法律、法规和规章中的伦理原则。
2. 请遵循经本医学伦理委员会批准的临床研究方案、知情同意书、招募材料等开展本研究，保护受试者的健康与权利。对研究方案、知情同意书和招募材料等的任何修改，均须得到本医学伦理委员会审查同意后方可实施。
3. 在本院发生的 SAE/SUSAR 以及研发期间安全性更新报告须按照 NMPA/GCP 最新要求及时递交本医学伦理委员会，国内外其它中心发生的 SAE/SUSAR 需定期汇总、评估后递交本医学伦理委员会。
4. 根据报告情况，本医学伦理委员会有权对其评估做出新的决定。
5. 自今日起，无论研究开始与否，请在跟踪审查日到期前 1 个月提交研究进展报告。
6. 申办方应当向组长单位医学伦理委员会提交中心研究进展报告汇总；当出现任何可能显著影响研究进行或增加受试者危险的情况时，请申请人及时向本医学伦理委员会提交书面报告。
7. 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止研究规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益或健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办方、监查员或研究者提交违背方案报告。
8. 申请人暂停或提前终止临床研究，请及时提交暂停或终止研究报告。
9. 完成临床研究，请申请人提交结题报告。
10. 凡涉及中国人类遗传资源采集标本、收集数据等研究项目，必须获得中国人类遗传资源管理办公室批准后方可在本中心开展研究。
11. 凡经本医学伦理委员会批准的研究项目在实施前，申请人应按相关规定在国家卫健委、药审中心等的临床研究登记备案信息系统平台登记研究项目相关信息。

医学伦理委员会

MHESI 8137/293

Graduate School, Burapha University
169 Longhaad Bangsaen Rd.
Saensuk, Muang, Chonburi
Thailand, 20131

February 18th, 2025

To Director of the First Affiliated Hospital of Wenzhou Medical University

Enclosure: 1. Certificate ethics document of Burapha University
2. Research Instruments (Try out)

On behalf of the Graduate School, Burapha University, I would like to request permission for Mrs. Xue Zhang to collect data for testing the reliability of the research instruments.

Mrs. Xue Zhang, ID 63910207, a graduate student of the Master of Nursing Science program (International Program) in Adult Nursing, Faculty of Nursing, Burapha University, Thailand, was approved her thesis proposal entitled: "Factors related to intraoperative anxiety in patients with closed leg fracture during conscious surgery in Wenzhou, China" under supervision of Assoc. Prof. Dr. Niphawan Samartkit as the principle advisor. She proposes to collect data from 30 patients who have closed leg fracture and admitted in the Orthopedic Ward, moreover, plan for receiving open reduction and internal fixation surgery in an awake state at the Operating Room of the First Affiliated Hospital of Wenzhou Medical University.

The data collection will be carried out from February 15, 2025 - March 15, 2025. In this regard, you can contact Mrs. Xue Zhang via mobile phone +86-1386-8881-695 or E-mail: 37378693@qq.com

Please do not hesitate to contact me if you need further relevant queries.

Sincerely yours,

มัณฑนา รังสิโยภาส
(Asst. Prof. Dr. Montana Rungsiyopas)
Vice-Dean for Academic Affairs
Acting of Dean of Graduate School, Burapha University

Graduate School Office
Tel: +66 3810 2700 ext. 705, 707
E-mail: grd.buu@go.buu.ac.th
http://grd.buu.ac.th

เอกสารนี้ลงนามด้วยลายเซ็นอิเล็กทรอนิกส์ ตรวจสอบได้ที่ (https://e-sign.buu.ac.th/verify)

MHESI 8137/295

Graduate School, Burapha University
169 Longhaad Bangsaen Rd.
Saensuk, Muang, Chonburi
Thailand, 20131

February 18th, 2025

To Director of the First Affiliated Hospital of Wenzhou Medical University

Enclosure: 1. Certificate ethics document of Burapha University
2. Research Instruments

On behalf of the Graduate School, Burapha University, I would like to request permission for Mrs. Xue Zhang to collect data for conducting research.

Mrs. Xue Zhang, ID 63910207, a graduate student of the Master of Nursing Science program (International Program) in Adult Nursing, Faculty of Nursing, Burapha University, Thailand, was approved her thesis proposal entitled: "Factors related to intraoperative anxiety in patients with closed leg fracture during conscious surgery in Wenzhou, China" under supervision of Assoc. Prof. Dr. Niphawan Samartkit as the principle advisor. She proposes to collect data from 125 patients who have closed leg fracture and admitted in the Orthopedic Ward, moreover, plan for receiving open reduction and internal fixation surgery in an awake state at the Operating Room of the First Affiliated Hospital of Wenzhou Medical University.

The data collection will be carried out from March 16, 2025 - May 10, 2025. In this regard, you can contact Mrs. Xue Zhang via mobile phone +86-1386-8881-695 or E-mail: 37378693@qq.com

Please do not hesitate to contact me if you need further relevant queries.

Sincerely yours,

มัณฑนา รังสิโยภาส
(Asst. Prof. Dr. Montana Rungsiyopas)
Vice-Dean for Academic Affairs
Acting of Dean of Graduate School, Burapha University

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เอกสารนี้ลงนามด้วยลายเซ็นอิเล็กทรอนิกส์ ตรวจสอบได้ที่ (https://e-sign.buu.ac.th/verify)

BIOGRAPHY

NAME	MRS.ZHANG XUE
DATE OF BIRTH	23 December 1984
PLACE OF BIRTH	Wenzhou, Zhejiang, China
PRESENT ADDRESS	Room 704，Building 5，Tongren Block, Lucheng District, Wenzhou city, Zhejiang Province, China
POSITION HELD	2007-Present Clinical Nurse The second affiliate hospital of Wenzhou medical university, Wenzhou, China
EDUCATION	2003-2007 Bachelor of Nursing, Wenzhou medical University, Wenzhou, China 2020-2025 Master of Nursing Science (M.N.S.) in Adult Nursing Faculty of Nursing, Burapha University, Chonburi, Thailand