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Overcoming barriers to postoperative pain management in low resource settings

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Abstract

Background

The annual number of surgical operations performed is increasing throughout the world. With this rise in the number of surgeries performed, so too, the challenge of effectively managing postoperative pain. The study has investigated the quality of postoperative pain management, the barriers and facilitators of effective pain relief after surgery, and the impact of a unique educational intervention package in improving the quality of pain management in Ethiopia; among patients scheduled for major elective orthopedic, gynecologic and general surgery.

Methods

A qualitative descriptive design was used to explore the barriers and facilitators to effective post-surgical pain management. A quasi-experimental, controlled before-after study design, with repeated measures, was used to assess the effectiveness of the educational intervention aiming to improve the quality of care.

Results

Findings indicate that there is a high magnitude of moderate to severe postoperative pain in Ethiopian patients, secondary to inadequate treatment. The contributing factors extended from clinical, and resource-related barriers to cultural related obstacles. As the data suggested, these can be regulated by a proper attention of the health care system; through investment on resources, prioritizing pain and its management on the undergraduate medical and nursing curriculum, and establishing guidelines. The study also hinted that educational interventions that are inclusive of patients, health care professionals and hospital officials might be effective in improving the quality of postoperative pain management in low resource settings. The causal mediation analysis showed that the effect of the treatment was not mediated by patient's participation in decision making.

Conclusion

Many interrelated factors contribute to the high prevalences of untreated postoperative pain in Ethiopia. Low resource countries like Ethiopia would be benefited from future studies that can isolate which specific component of educational intervention is effective in controlling patient's pain after surgery and why.

Key Words Pain; postoperative; patient education; professional education; barriers; facilitators

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Abbreviations

APS	Acute Pain Service
ASA	American Society of Anesthesiologists
ASA-PS	American Society of Anesthesiologists Physical Status Classification
ATE	Average Treatment Effect
ATT	Average Treatment on Treated
CPSP	Chronic Postsurgical Pain
CI	Confidence Interval
QICu	Corrected Quasi-Likelihood Under Independence Criteria
DR	Doubly robust
EU	European Union
EU	European Union
GEE	Generalized Estimating Equations
HCPs	Health Care Professionals
IASP	International Association for the Study of Pain
IPOQ	International Pain Outcome Questionnaire
IPTW	Inverse probability treatment weighting
JUMC	Jimma University Medical Center
LME	Linear Mixed effect
LMICS	Low middle-income countries
NRS	Numeric Rating Scale
PMI	Pain Management Index
PS	Propensity Score
QUIPS	Qualitätsverbesserung in der postoperativen Schmerztherapie
QIC	Quasi-likelihood Under Independence Criteria
RCT	Randomised controlled trial
UK	United Kingdom
US	United States of America
YK12H	Yekatit 12 Hospital
ZMH	Zewditu Memorial Hospital

1. Introduction

1.1 Definitions

In the year 1979, the international association for the study of pain (IASP) defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" [1]. This definition of pain is fairly complex, though it appears simple at the first glance [2]. With the above meaning of pain, one can argue against an oversimplified definitions that posit pain has to necessarily arise from a tissue damage [3]. This careful definition is important as it illustrates the psychological forces of pain [4]. For example, studies involving fMRI (functional nuclear magnetic resonance imaging of the brain), had shown that human negative reactions and sensations (pain) that arise from rejection or losses create a neural stimulation similar to those created by tissue damage [2]. This finding is of great clinical importance because socially outcasted and disturbed persons, in addition to the usual psychological consequences, show high levels of pain that can last even after the stimulus has been removed [4]. So, pain is not necessarily a sequela of tissue trauma and a healed body or tissue does not inevitably cure it. For this reason, it is mandatory to distinguish between two clinical entities when it comes to pain: acute and chronic.

Acute pain is a symptom caused by a particular illness or tissue damage and is usually associated with an important biological duty [5]. It serves as a warning signal of injury or illness and it normally comes on quick and lasts brief [6]. If not treated early and properly, it evolves into chronic pain—a debilitating situation in which, it becomes a disease in its own and stops being a symptom. Chronic pain persists even after the initial injury or illness is healed. It serves no biologic purpose with no recognizable end-point, and it is very calamitous [5]. Chronic pain is a real challenge for many patients, their families, and the medical professionals caring for them. Usually, at this stage—acute pain, changed to chronic pain—it becomes challenging medically and patients look for religious and spiritual solutions to cope [7]. Post-surgical pain or postoperative pain is defined as "pain present in a surgical patient after surgical procedure" [8]. However, if the pain lasts $\geqslant$ 2 months, with no other causes for the pain other than the surgery itself, and if the possibility of malignancy after surgery for cancer or chronic infection, and pain continuing from a pre-existing problem is excluded, it is called CPSP (chronic post-surgical pain), also known as persistent post-surgical pain [9, 10].

1.2 Global history and prevalence postoperative pain

Under a well-established market economy, 5–10% of the population undergo surgery each year [11]. In the year 2012 alone, 266.2 to 359.5 million operations were performed worldwide [12]. Despite containing the worlds' 85% of the population, only less than 4 % of these operations were performed in the low and middle-income countries [13]. As this number of operations performed in the world has risen, so, too, the challenge of managing postoperative pain effectively. Despite sophisticated medical equipment and technologies and advances in medicine, still, the management of postoperative pain is unsatisfactory [14-16]. Starting early in the 1960s, the incidence of postoperative pain together with the challenges has been reported [17]. Since then various investigators reported the proportion of patients suffering moderate and severe intensity of pain from various settings. A study by Sommer et al., after measuring patient's pain intensity over 5 consecutive occasions following surgery, reported that the prevalence of moderate to severe pain was higher (41% on) on day 0, followed by 30% on day 1, and 19%, 16%, and 14% on day 2, 3 and 4 respectively [18]. The Pain Out registry, while validating the International Pain Outcomes (IPO) questionnaire, from 11 medical centers in Europe and Israel, found out that, 70% of patients reported a moderate to severe worst pain intensity (NRS scores of $\geqslant 4$) and about 48% reported a severe pain intensity (NRS $\geqslant 6$) on day 1 after surgery [19]. Recently, a study reported that in the United States (US) alone, 80 % of patients complain of pain after surgery and 88% of those reported extreme pain intensities [20]. In Germany a study after analyzing data from 138 hospitals, revealed that prevalence of severe post-surgical pain in the country was variant across the settings and ranged from as low as 10% to as high as 88% (NRS $\geqslant 5$) on the first day after the surgery [21]. In Spain, the percentage of patients suffering severe postoperative pain was reported to be 39.4% (NRS > 7) [22]. Generally, across Europe, the quality of postoperative pain management is superior compared to the US [23]. One should remember that all these patients (in Europe and US) had been treated according to the standard and evidence-based recommendations [23]. There is hardly any data on the prevalences and predictors of postoperative pain in Africa. However, the reported prevalences of moderate to severe postoperative pain range from 50% to 91% [24]. Murray and Retief from South Africa observed 1231 patients and reported that 62% of patients had a moderate or severe pain at 24 hours. The article further reported that for the time immediately after surgery, 13% of the patients reported a moderate or severe and nearly eighty percent (79%) reported no pain [25].

1.3 Complications of postoperative pain

When postoperative pain is undertreated or left untreated, the resultant physiological and psychological complications are tremendous [26]. It can prolong the length of stay in the hospital [26], pose a threat of an organ damage [15] and causes significant economic burden [27], which all combined together with a potential for a patient morbidity and mortality [28]. For these reasons, untreated postoperative pain remained to be the major burden for the health care system [29]. As defined above, chronic postsurgical pain (CPSP) is also one of the most devastating complications of untreated or undertreated postoperative pain. Next to the degenerative diseases, post-surgical pain was found to be the second largest cause of chronic pain in the world [30]. Yet, in the US alone, the economic burden of persistent pain in adults exceeds the costs for heart disease and cancer combined [31]. Crombie and colleague were the first to isolate and publish previous surgery as a major cause of chronic pain in the year 1998 [32]. The incidence of chronic postsurgical pain (CPSP) varies from one surgery type to the other. For instance, following groin hernia, breast, thoracic, coronary artery bypass surgery, and leg amputation about 10%–50% of patients develop chronic pain, and 2%-13% of these patients would suffer a very intense pain level [33]. Montes and colleagues, also reported that the median time to develop CPSP after surgery was 4.4 months following abdominal hysterectomy and thoracotomy [34]. The major risk factor in developing CPSP is the extent of nerve injury in the intraoperative period [30]. Laparoscopic surgeries are associated with less incidence of CPSP [30, 35]. Further, patients who underwent a very extensive surgery in the hand of experienced surgeons are also associated with less incidence of CPSP [30]. But also, age, gender, genetic predisposition, anxiety, depression and other factors have been also reported as contributing risk factors for developing chronic pain after surgery [30, 33]. How acute postsurgical pain evolve into chronic pain is complex and incompletely understood [36, 37]. Chapman and Vierck propose five classes of hypotheses that describe how acute pain after surgery shifts to chronic pain [37]. They suggested that a persistent noxious signaling combined with enduring maladaptive neuroplastic changes, combined with a compromised inhibitory modulation of noxious signaling and descending facilitatory modulation, results in a maladaptive brain remodeling in function, structure, and connectivity [37]. It is now becoming more clear that the most consistent risk factors for developing CPSP is the presence of preoperative pain and/or its intensity [38]. What is not clear is, however, whether the

relationship between prior pain, early postoperative pain, and chronic postsurgical pain is causal, associative or a combination of the two [38].

1.4 Clinical risk factors for severe postoperative pain

Systematic reviews identified that the most commonly identified predictors of postoperative pain intensity are a pre-operative pain, anxiety, age and the nature of surgical procedure [39]. Some of the risk factors, however, are not predicting the pain and analgesic consumption consistently. Gender, for example, was not found to be a consistent predictor of both pain or analgesic consumption as traditionally believed so [39]. This might be attributed to many reasons. Most importantly recent studies are now emerging claiming age and preoperative pain to be important confounders for the reported association between gender and postoperative pain intensity [40]. However, still, some authors assert gender differences in postoperative pain are due to different socialization process that man and women undergo, hormonal differences and neurotransmitters [39]. A recent review of 58 papers published between the year 2013 and 2015, found that data suggesting higher postoperative pain scores by women were from studies with one type (category) of surgical procedures [41]. The review concluded that gender differences after abdominal and orthopedic surgeries were inconsistent and after oral surgery inexistent [41].

The nature and type of surgery have been found to be a strong predictor of postoperative pain intensity [39]. This is not surprising as different types of surgeries have a varying degree of tissue and nerve damage [30]. For instance, urology patients are 19 times more likely to have severe pain than were ophthalmology patients [42]. Orthopedic procedures are more painful than surgeries involving soft tissue, owing to the fact that the periosteum has the lowest pain threshold of the deep somatic structures [39]. An interesting article by Gerbershagen et al., after comparing 179 surgical procedures from 578 surgical wards and 115, 775 patients in Germany, reported that the extent of tissue trauma and incision size were not related to pain intensity. The article further pointed out that patients after « minor » surgery (such as appendectomy, cholecystectomy, hemorrhoidectomy, and tonsillectomy) ranked among the top 25 painful procedures [43].

Anxiety was found to be an important predictor of postoperative pain, especially in gastrointestinal, obstetrical, and gynecological surgery [39]. The preoperative level of anxiety

has been the most commonly reported predictor of the level of postoperative pain intensity [44]. However, one can still find conflicting results. Rhudy and Meagher argue that the reason for the conflicting results arises from a failure to properly distinguish between the emotional states of fear and anxiety [45]. They found out that a patient expecting (fearing) an unpredictable threatening event will experience enhanced pain. In contrast, a patient that has been exposed to a threatening event will experience a fear state that inhibits pain processing. Interestingly though Absi and Rokke revealed that the type of anxiety itself matters in regulating its relationship with pain intensity. According to the authors, the relationship between anxiety and pain is not always straightforward. This is because if the anxiety is irrelevant to the source of pain, it reduces the experience of pain, whereas if it is relevant to the source of pain it exacerbates it [46]. Others also associate anxiety with patients low expectation regarding the pain relief [47] and previous experiences and stories from family and friends [48]. Preoperative anxiety can also be exacerbated during the preparatory stages of the patient for surgery like changing clothes and lying on trolleys to go to the theatre [48]. For this reason, it has been a while since preoperative visits have been recommended to calm down and ease the patient [49]. While authors for long has been investigating the relationship between psychological factors and post-surgical pain, the impact of depression was sidelined [47]. Though very few studies, which investigated the impact of depression on postoperative pain, it was reported to be associated with a higher level of pain after surgery [47, 50]. Through a transient suppression of the immune function, depression has negative consequences on postoperative pain, which could result in a higher mortality, and a longer convalescence [39]. However, the question whether preoperative depression predicts post-operative surgical pain is not answered yet, as concluded by a recent review [51].

1.5 Socio-demographic risk factors of postoperative pain intensity

Starting the early 1970s the impact of age on the postoperative pain intensity has been reported; recommending HCPs to adjust the dosage of a narcotic analgesic considering the patients' age besides weight and height [52]. Age has been suggested to blunt peripheral nociceptive function, making older patients more susceptive to the effects of opioid analgesia than younger patients [39]. Interestingly though, the type of pain assessment tool used matters to quantify the impact of age on postoperative pain intensity. A study investigating age difference in postoperative pain after radical prostatectomy, using three different pain assessment scales,

reported that visual analog scale is not sensitive enough to identify age differences [53]. The authors concluded that to capture age differences it was better to use verbal descriptions of pain qualities than non-verbal measures of intensity. In contrast a report from China, after comparing three pain measurement scales (Visual analog scale, numeric rating scale, verbal descriptor scale, and the Faces Pain Scale-Revised), in 173 Chinese patients, concluded no significant differences; in terms of gender, age, and educational level [54].

Little is available in the literature, regarding the impact of literacy status on the level of postoperative pain. A study from Greece found out that those with the junior level of educational status experienced more intense pain compared with patients with a higher educational status, [55]. The authors concluded that the low educational status is associated with poor understanding of preoperative information, which, in turn, might cause anxiety, depression, suboptimal use of analgesia [55]. However, Whelan et al., after analyzing 5584 hospitalized patients, found that, patients with higher levels of education reported more significant pain (OR, 1.14; P<.001) and were less satisfied with their pain management (OR, 0.88; P = .02) [56]. These conflicting results should be well investigated in the future.

There are reports that hint towards a lower pain threshold and higher pain sensitivity in a certain ethnic group compared with the other in post-surgical patients [57]. Studies conducted over several decades reported ethnic differences in pain responses and despite advances in pain care, ethnic minorities remain at risk for inadequate pain control [58]. For instance, African–Americans report greater pain and suffering for postoperative pain and other pain types of pain, compared with Whites [59]. It is also difficult to argue that these disparities might be due to some other confounders—socio-economic status, sex, age, literacy, marital status, employment and other factors—as the treatment inequalities persist, even after controlling for these confounders [58]. A study in the 1980s showed that Caucasians and Hawaiians received significantly more analgesics than Filipinos, Japanese and Chinese patients after surgery [60]. Studies in the 1990s also reported disparities in the administration of analgesics when it comes to ethnic per se. For example, Bernardo and colleagues reported that white patients received 22 mg of analgesics per day whereas blacks and Hispanics received 16 mg and 13 mg per day respectively. Further, they have acknowledged that these ethnic treatment disparities were still evident after accounting for possible confounders [61]. In 2006, a systematic review describes that African Americans and Hispanics are more likely to receive less potent analgesics and inadequate treatment of their pain HCPs compared to White patients [62]. Even experimental

studies in the laboratory reported that ethnic difference in pain thresholds and tolerances exist. For example several decades ago, back in the 1940s, Chapman and Jones reported African Americans to have a lower heat pain thresholds and tolerances when compared to non-Hispanic Caucasian [63]. Faucett et al., in 1994, reported postoperative patients of European descent reported significantly less severe postoperative pain than those of black American or Latino descent [64]. It is also believed that African–Americans report a marginally greater number of pain sites with a significantly higher average pain severity compared to non-Hispanic Caucasians [65]. However, it is important to keep in mind that despite all these findings claiming an evidence of ethnic differences in acute clinical pain responses, there are reports that have concluded the opposite [66]. Edwards et al., mentioned the ethnicity of the investigator is rarely documented in most previous works, which might give rise to a very important bias to consider [67]. For example in gender, investigators' sex has been reported to influence results, especially when establishing an association between pain intensity and gender [67].

In addition, the effect of marital status and social support on surgical outcomes remains an area of ongoing debate and controversy [68]. Schade et al., demonstrated that support from the patient's spouse was an independent predictor of long-term postoperative pain relief [69]. In another study of 56 male patients who underwent coronary bypass surgery, married patients recovered more quickly and consumed fewer analgesics than their unmarried counterparts [70]. However, following spinal surgery, Adogwa, et al. reported no significant advantage of marriage (social support) for both short and long-term clinical outcome [68].

1.6 Barriers to effective postoperative pain management

Globally, studies indicate that patients do not receive analgesics when needed most and usually are delayed when administered [71, 72]. Healthcare professionals (HCPs) negative attitudes towards pain [73], fear of drug addiction [74], ignoring patients' pain assessment before and after analgesics [75] are recorded as obstacles to effective pain relief in the surgical patient. Patients' own hesitation to report pain [76] and misjudgments toward postoperative pain management [77] are further obstacles to effective pain management after surgery. The following review of the literature on barriers towards effective postoperative pain management are categorized into three major categories; HCPs', patients' and healthcare systems' related

[48, 78]. The Agency for Healthcare Research and Quality in the US also distinguishes barriers to pain management the same way [48].

1.6.1 Healthcare system related barriers

Healthcare system related barriers [79] are also referred to as "institution or organization" related barriers [48]. Barriers in this category originate from human resource related challenges. These are mostly reported in relation to the nurse-to-patient ratios. Even though this mainly affects the developing countries [4], the developed world also has similar challenges [79]. A limited access to pain specialists is also another challenge for the health care system to effectively manage postoperative pain. Healthcare system-related barriers also encompass challenges associated with resources and regulations [80]. Generally, in most countries' health care system pain is not considered a priority [81]. Most attention and resources are allocated to "important" diseases. Especially, in Africa this is true. While wrestling against poverty to meet United Nations Millennium Development Goals, low and middle-income countries paid little attention to pain management [82]. In Africa, anesthesia service is often characterized by a lack of resources (personnel, drug availability, and basic equipment) which further obstructs adequate pain management [83, 84]. According to the IASP barriers towards adequate postoperative pain management in developing countries, however, are largely associated with lacks of adequate analgesics and education [82]. Institutional lack of commitment to ensure accountability for the management of pain and the complex nature of the patient-professional relationship is also contributing to the inadequate post-surgical pain control [48]. When it comes to pain management the healthcare systems should also create a fair atmosphere of care for every group of patients. In the early 2000s, for example, Todd et al., reported black patients after isolated long-bone fractures, were less likely to be treated with adequate analgesics compared to whites [85].

1.6.2 Healthcare professional related barriers

HCPs' lack of knowledge and skills to effectively halt pain after surgery has been reported for a while. Literature is full of this conclusion starting in the early 90s [86]. The curriculum of medical [87], nursing [88] and pharmacy [89] educations did not give adequate emphasis to equip the graduates with the necessary knowledge and skills to assess and treat pain. A lack of harmonious team spirit between doctors and nurses has been also reported as a health care

professional related barrier [90]. The difficulty of communicating with physicians to discuss patients' pain control has been widely reported by nurses. Teaching the importance of teamwork for doctors and nurses has been suggested as a remedy for this [91]. The barriers related to physicians have a different pattern compared to those related to the nurses. The most frequently reported barriers attributed to the physicians are underestimating the importance of regular and consistent pain assessment. Pain assessments performed by the physicians poorly correlated with those performed by the nurses. Overall the major challenge is not only that physicians' have a knowledge gap, but also that they do not notice it and are neither motivated to fill their gap [79]. It is, however, worthy to note that physicians major reservation arises from the risk of iatrogenic addiction of opioids [92] and analgesics potential of masking important clinical symptoms [79]. But still, authors argue that though barriers to effective pain management are multi-faceted, the greatest concern is related to the clinician [79]. Barriers arising from nurses in addition to the commonly shared barrier; lack of knowledge, there are other limitations that are inherently related to the nurses. One of the major issues is the workload. Because of workload nurses are continuously reporting not being able to both teach patients about the importance of pain management and also use non-pharmacological methods. Incorrect route and time of administration of analgesics, undermining the consequences of untreated pain also arise commonly from high workload. In their day-to-day activities nurses are mainly responsible for patients' continuous care more than any other professional HCPs which puts them in a very unique place to be able to both assess and treat pain [77]. Therefore, it is very essential to focus on increasing nurses' knowledge of pain management [93]. Manias et al. identified four nurses related major barriers to effective pain management, and these include how nurses respond to interruptions of their activities associated with pain, to what extent the nurses are considerate to the patient cues of pain, their varying interpretations of pain, and efforts to address challenging demands of doctors and patients [94]. A decades-old problem of undertreated postoperative pain is not because of lack of effective drugs or techniques but to a lack of an organized, multidisciplinary approach which uses existing treatments. Irrespective of the multidisciplinary approach, teaching programmes to upgrade the role of ward nurses is mandatory [95].

1.6.3 Patient-related barriers

Anthropological studies of pain revealed that despite the universal similarity to the pathophysiology of pain among all human beings, there is a culturally specific expression, perception and coping of pain [96, 97]. When this is coupled with the inherent limitation of pain measurement (subjectivity) the challenge is obvious. Several studies had pointed out that patients, especially the elders, find it difficult to effectively communicate their pain [98]. Patients also believe that it is entirely up to the HCPs to manage their pain, and most are unaware of what is expected of them [99]. Eloise Carr, explained patient-related barriers to effective postsurgical pain by preoperative factors that induce a high level of anxiety in the patients and general factors that prevent patients from reporting their pain [48]. The preoperative period is the most stressful time of one's life which results in a higher anxiety level with subsequent severe postoperative pain intensity [39]. The factors preventing patients from reporting their pain is usually associated with their belief that post-surgical pain is a short-term experience that goes away with time [48]. This, however, is contradictory to established scientific facts [36], even if this patients' view is often approved by the HCPs caring for them [48]. Patients' fear of drug tolerance and inhibition of wound healing, together with the intention to be "a good patient"—by not trying to distract the physician from his work—are also patients related barriers [76]. Plus, illiteracy and lack of medical knowledge is the challenge for patients to comprehend the commonly used pain assessment tools like the NRS or visual analog scale [24, 100]. Moreover, some studies found that patients from different ethnic or cultural backgrounds chose to suffer in silence, either because of their desire to be a good patient or because of their personal philosophy [78].

1.7 Overcoming barriers to postoperative pain management

A lot of quality improvement strategies have been tested for more than 5 decades, hoping that one-day post-surgical patients will have a pain free post-surgical period [101]. These include education to patients [102], professionals [78], cognitive behavioural therapies [103], local anesthetic pharmacological therapies [104], neuraxial therapies [105], policy change [106], implementation of guidelines and protocols [107], the establishment of acute pain service [108], multi-modal analgesia [109] and non-pharmacological methods [105]. However, despite these efforts and sophisticated technologies like patient-controlled analgesia (PCA), pain control after surgery is still unsatisfactory [110]. PCA is a delivery system (machine) that the

patient him/herself uses to administer a programmed amount of analgesics to relieve their pain. Austin et al. in 1980, first described this principle [111]. Its benefit compared with the traditional intramuscular injections include improved pain relief, less sedation and fewer post-operative complications [112]. For instance, a review of published data (extended to nearly 20,000 patients) reported that those who received intramuscular injections of opioids were much more likely to experience a higher level of pain (including severe pain intensity), than those receiving opioids via patient-controlled analgesia [113]. A specially dedicated organization for the management of acute pain, not necessarily after surgery alone, but also for any other type of acute pain is called Acute Pain Service (APS) [114]. The team consists of surgeons, nurses, and anesthetists, where the anesthetist usually assumes a leading role [77, 115]. The first APS was introduced in the US and Germany in the year 1985 [108]. Reports from Individual studies and systematic reviews have consistently proven that this interdisciplinary approach has better results in terms of lowered patients postoperative pain ratings [108]. A German outcome-oriented project known as Quality Improvement in Postoperative Pain Management, also referred as Qualitätsverbesserung in der postoperativen Schmerztherapie (QUIPS), which selects, analyzes, and benchmarks outcomes in postoperative pain management from various settings has also been in progress for a while [101]. Its ultimate purpose is to enhance the postoperative pain management using data that are collected from various settings and provide immediate feedback to the hospitals after analysing the results [116]. It should be noted that even if doctors prescribe the right dose and frequency of analgesics, this does not ensure patient consumption of analgesics [117]. This might explain high prevalence of uncontrolled postoperative pain also observed in settings with a properly functioning acute pain services [23]. A lot of factors determine patients' analgesic consumption, including patients, own philosophies regarding analgesics related adverse effects [117]. Also, evidence-based treatment does not necessarily translate to better treatment outcomes [21]. Overall, inadequate pain management is rooted not in a lack of guidance but in the deficiencies in our current methods of pain education and the best remedy is education [118]. Studies have reported that regular pain assessment and proper compliance of guidelines do not automatically give rise to less pain [21, 23, 119]. This is why one way or the other a proper education of patients [105] and professionals [77] is very important to achieve a high-quality postoperative pain management. In low resource setting, the barriers are mainly related to the financial capacity of the health care system, level of training of the healthcare providers and the ease of access to the necessary resources [120].

1.7.1 A closer look at overcoming barriers to postoperative pain management

The fact that pain is a problem in more than 150 states in the world and for more than 80% of the world's entire population mandates an effective strategy [81]. But, what is an effective strategy is still a question. An evidence-based treatment, modern analgesics, guidelines, for that matter even regular pain assessment is not always associated with lower levels of pain [23, 121]. In the following section, each will be highlighted in detail.

1.7.2 Patient involvement and education

The patient-centered approach is mandatory for effective post-surgical care [77]. It also ensures both patient safety and better quality of care [122]. In order to be able to participate in the decision, patients, however, need to be well informed and provided with relevant information [123]. Relevant information in a sense that it helps them also participate in their treatment. For instance, studies had reported that even if patients possess the necessary knowledge and demonstrate a greater understanding of their role in pain management, they also need to be aware that the reporting is important to avoid complications [124]. Patient information and participation are considered as one of the key factors in postoperative pain management and are seen as quality indicators [125]. Likewise, a preoperative education of patients and their family has been recommended to improve their participation and provide high-quality post-surgical pain management [105]. However, some authors reported no effect of preoperative patient education, in improving postoperative pain outcome, after conducting a randomized controlled trial [126], while others claim a positive effect [127]. Lately, however, the argument whether preoperative patient education is effective or not is starting to materialize in literature [128]. A systematic review and meta-analysis of RCTs on the topic also failed to bring consistent results; while some support [129] and other do not [130]. A lot of factors contribute to these inconsistent results, some are related to methodological issues—lack of blinding, randomization, sample homogeneity and size [131]—whereas the others are because the control group also received some sort of education termed "usual or standard" education [128]. A review of preoperative patient educational intervention to improve postoperative pain after total joint arthroplasty, reviewing 13 RCTs (randomized controlled trials), found out that, only one paper showed a positive effect [132] because of a unique pain science education component of the intervention. From this paper it was evident that; education for patients during

intervention should emphasize pain management, pain communication, and the use of pain assessment tools as well.

1.7.3 Professional education and training

Several studies had reported educational gaps among healthcare providers regarding postoperative pain [133]. A review of literature, also, recommends educational programs to include interdisciplinary professionals and policymakers in addition to patients [78, 134]. In the US, the medical education curriculum failed to emphasize pain and its management [135] and only 3 percent of medical schools had any part of their curricula explicitly devoted to pain education [118]. In Canada, a study reported that from participating institutions only one-third had designated time for teaching mandatory pain content. The study also pointed out that the veterinary respondents reported considerably more hours designated for mandatory formal pain than those indicated in the human health science curricula [136]. Likewise, a similar pattern was observed in Finland, and the authors recommended small-group teaching, case-based learning, and self-learning activities as a solution [137]. In the United Kingdom (UK), a study stated that the minimum median time an undergraduate medical student spends learning pain management was 6 hours whereas the maximum time was 13 hours [77]. The state of pain education in medical curricula further unfolds in another study from Europe. After surveying 15 representative countries, Briggs et al. reported that given the burden of pain the medical schools are not properly teaching pain [138]. In developing countries, there is hardly any data on pain management and pain education at the undergraduate medical level. An investigation that included six developing countries revealed that there was ‘‘no’’ or ‘‘some’’ available education in acute pain management in the surveyed medical, nursing, or pharmacy schools of China, Indonesia, Nigeria, Guatemala, Philippines, and Thailand [137]. From all these, we learn that pain management education for HCPs’ is undoubtedly a necessity. Fortunately, the advantage of augmenting patient’s pain management, by increasing the awareness of pain medicine, among the various HCPs involved in post-operative pain management has been established [77]. For instance, a mandatory training intervention for all HCPs including nurses and surgeons has been implemented and positively influenced pain outcomes [139]. Major HCP-related barriers identified in the literature are inadequate pain assessment and documentation. Educational interventions designed to promote pain assessment and documentation have been also tested [140]. Especially, nurses often have the most frequent

contact with patients, and changes in their knowledge of pain management, attitudes and beliefs are required before optimal pain management can be provided [141]. As well, studies [74] have reported a high percentage of nurses in surgical wards overestimate the risk of addiction and only 25% of them correctly estimated the risk of opioid addiction to be of less than one percent [77]. Traditionally, specific educational programs and practices about postoperative pain have been conducted separately for each healthcare profession [142], however, the impact of such programs was inconclusive [78]. On the other hand, multidisciplinary teams which brought together anesthesiologists, surgeons, nurses, and physiotherapists, while receiving the same educational interventions showed a reduction in their patients' pain and fewer postoperative complications [143, 144]. Aside from the education, an interdisciplinary approach to pain management has been advocated as a means for monitoring the quality of pain management [143].

1.8 Postoperative pain and its management in Ethiopia

In a low resource setting the causes of the poor quality of post-surgical pain management are overlapping with each other; professionals lack awareness, proper education on pain and its treatment, opiophobia of leaders, pain being imminent in the minds of the public, unavailability of drugs in the surgical setting, and institutions' reluctancy to invest in pain management characterize the current situation [145]. Consistent with this, the national pain report—by the Ethiopian Public Health Association, in collaboration with the Federal Democratic Republic of Ethiopia Ministry of Health, and Center for Disease Control—explained that the practice of pain management is very poor throughout the country [146]. The report revealed, 72.1 % of the health professional did not even know Ethiopia has a national pain management guideline. Finally, the report stressed and concluded that the Ethiopian health professionals are not well trained, and do not receive a formal education to prepare them to administer effective pain management [146]. A study conducted on the quality of postoperative care in the Jimma University Teaching Hospital in 2014, reported the incidence of post-operative pain to be 95.2% in the first 24 hours after the surgery [147]. The article further mentioned that about 80% of the patients had their pain undertreated. Except for this article, no other published report was available, at the time of writing this thesis. Above all, the absence of multi-center data that characterize the state of treatment in the country, the already documented poor knowledge and skill of Ethiopian HCPs' to effectively treat postoperative pain [146], and the limited access to

pain management drugs [147] are the characteristics of post-surgical pain management in Ethiopia.

2. Rationale and objectives

Throughout the world, various strategies have been attempted to rescue the patient from suffering undertreated and untreated post-surgical pain, until now [102]. But, still, there are questions left unanswered. What seems clear is that inadequate pain treatment after surgery is not because of ineffective analgesics or lack of guidance and protocols, instead it is rooted in the deficiencies of the necessary knowledge and skills of HCPs [118]. Therefore the best remedy is education and still (in the year 2017) after so many years of education and advancement in medicine, researchers call for further education to optimize postsurgical care [148]. The usual three categories or entities to whom educational intervention is usually directed are HCPs, patient families and the patients themselves. Traditionally, specific educational programs and practices about postoperative pain have been conducted separately for each healthcare profession [78] and predominantly for nurses [142, 149]. However, the impact of such programs was unconvincing and unsatisfying [78]. On the other hand, interprofessional teams which brought together important actors (anesthesiologist, surgeon and nurses) when received the same educational interventions showed a reduction in their patients' pain and fewer postoperative complications [78]. Scholars also argue that education should be provided not only to the clinical staff but also to patients [77] and their families [105]. Starting in the year 1958, an article reported the advantage of preoperative patient educational intervention as one of the strategies to reduce postoperative pain [102, 150]. And following this, many more studies in the field tried to replicate the findings immediately. It took only a decade to spread to Europe [79]. Now about 6 decades later it is still difficult to find similar studies in Africa. However, studies have shown a conflicting result, regarding the impact of patient education on postoperative pain [102]. A systematic review and meta-analysis of RCT on the topic also failed to bring consistent results; while some reported positive outcome after the patient education [129] and others not [130]. This alone calls for more research on the topic to build evidence from a wide array of settings.

In summary previous research on the topic can be viewed as the following. One, educational interventions should be targeted towards not to a single category of professionals, but to also

interdisciplinary teams. Moreover, we have now learned that only educating HCPs or patients separately is not effective, instead, involving and educating patients is also important for the better outcome [151]. In this way, not only effective acute post-surgical pain management is possible, but also the progression of acute post-surgical pain to CPSP can be prevented [152]. A review of literature also concluded that when educational intervention is conducted it should encompass policymakers as well [78].

Moreover, scientific data related to barriers and facilitators to effective postoperative pain management are clearly dominated by investigations conducted in developed countries [153]. For that matter, experimental studies investigating "what works" in the surgical ward, to optimize pain management are hardly available in African literature [78]. So, in plain terms, postoperative pain management in Ethiopia remained an untouched topic for the past several decades. The obvious health care context differences between Ethiopia and the rest of the world, call out studies that have been conducted in the developed world, to be also replicated in the setting. For instance, it can not be assumed that barriers and facilitators of effective post-surgical pain management are similar to the ones reported by the developed countries. Contextual, cultural and political differences mandate the study to be also applied in the low resource settings' of Ethiopia as well. In this way, this study is the first of its type to investigate the barriers and facilitators of effective postoperative pain management in the country. Moreover, no previous published study ever attempted to test any intervention, what so ever, to help improve the quality of postoperative pain management in Ethiopia. It has been almost 70 years since such experimental studies had already surfaced in the US and Europe, during the late 1950s [154]. In addition, this study has also tested the effectiveness of a unique educational intervention package in improving the quality of postoperative pain treatment. Hence, findings contain very important results for policymakers, stakeholders and the health care system of the country in general.

Using a qualitative and quantitative study design this study has explored the following three primary objectives;

1. To determine the ***quality*** of postoperative pain management in Ethiopia

2. To explore the ***barriers and facilitators*** to optimal postoperative pain management

3. To test ***the effectiveness*** of an educational intervention package in increasing the quality of postoperative pain management.

3. Methods

This work was completed using two different research designs (quantitative and qualitative), to answer three specific question : (1) what is the quality of postoperative pain management among Ethiopian orthopedic, gynecologic and general surgical patients? (2) What are the barriers and facilitators to effective post-surgical pain therapy from the patient's, professional's and official's perspective? and (3) how effective is educational intervention in improving the quality of postoperative pain management after elective orthopedic, gynecologic and general surgical procedures, as measured by patient-reported pain outcome measures. To better understand the flow of the study, it is presented in two separate qualitative and quantitative parts.

3.1 Setting

Ethiopia's is located in one of the most unstable regions of the world— the Horn of Africa, close to the Middle East—and it borders Eritrea, Somalia, Kenya, South Sudan, Sudan and Djibouti [155]. In 2012, the Ethiopian population was estimated to be about 83.7 million, estimated to reach 133.5 by the year 2032 [156]. Although it is the fastest growing economy in the region, it is also one of the poorest with gross national income per person of 590 USD in 2016 [157]. In the country, the anesthesia and surgery infrastructure are very limited. For instance, an average Ethiopian hospital, has one to two operating rooms, 4.2 surgeons, one gynecologist, and 4.5 anesthesia providers with a very inadequate access to continuous electricity, and running water [158]. In Ethiopia the hospital-to-population ratios ranges from 1:99,010 to 1:1,082,761, and the overall physician to population ratio ranges from 1:4715 to 1:107,602 [158]. The most frequent surgical procedures performed in the country are emergency procedures, which constitutes about 54% of all surgical cases, including emergency cesarean section and trauma [159]. The studies were conducted at three selected government, referral teaching hospitals. The selected hospitals were Yekatit 12 Medical College Hospital

(Yk 12 MCH), Zewditu Memorial Hospital (ZMH), and Jimma University Medical Center (JUMC). ZMH and YK 12 MC are located in the capital city of the country, Addis Ababa. The town consists of more than 3.3 million inhabitants [160]. Whereas, JUMC, is located 355 KM, south-west of the capital, in Jimma Zone with an estimated to total population of 2.4 million inhabitants [161]. All the three hospitals were built around the same time-periods in the early 1930s (Table 3.1).

Table 3.1: Characteristics of participated hospitals

Name of the hospital	Year of establishment	Location	Catchment Population	Number of beds	Number of professionals in the selected wards	Postoperative pain protocol/Guideline
Zewditu Memorial Hospital *	19 39	Addis Ababa, Ethiopia	600, 000	340	7 Gynecologists, 7 surgeons, 40 nurses	NA
Yekatit 12 Hospital	1922	Addis Ababa, Ethiopia	4 Million	340	6 Gynecologists, 10 surgeons, 3 orthopedicians and 50 nurses	NA
Jimma University Medical Center	1937	Jimma, Ethiopia	15 Million	643	9 Surgeons, 8 gynecologists, 2 orthopedicinas and 76 nurses	NA

* No orthopedic surgery and surgeon is available in the hospital, NA=Not available.

3.2 Designs

3.2.1 Quasi-experimental controlled before after study, with a repeated pretest and posttest measures.

This design was used to assess the effectiveness of educational intervention given to patients and HCPs in order to improve postoperative pain management. The study was conducted in the

setting described above. The two hospitals (ZMH and YK 12 H) were assigned to the control group and one (JUTH) to the intervention. The experimental hospital (group) and the control hospitals (group) were determined by geography. Both groups were pretested simultaneously, before the administration of the educational intervention at the JUTH. At the end of the intervention, a posttest was administered simultaneously to both groups. The study was performed in accordance with ethical standards established in the 1964 Declaration of Helsinki. Details of the ethical statement are explained in the so-named section below. For the illiterate participants (those who could not read and write) their fingerprints were obtained as an indication of their consent after the information sheets and consent forms were read aloud by the data collectors. Patients who provided written consent to participate completed an interviewer-administered baseline questionnaire, prior to the intervention (September to December 2016) and after the intervention (May to August 2017). Patient-reported outcomes were measured at four-time points postoperatively at 6, 12, 24 and 48 hours). After the baseline assessment HCPs and hospital officials of the experimental group were invited to participate in an educational intervention especially designed for the group. Thirteen participants from nursing, physiotherapy, surgery, anesthesiology, gynecology including those in the managerial position participated, following the invitation. Post-treatment assessment was performed 19-20 weeks after baseline assessment (May-August 2017).

3. 2.1.1 Participants

The night before the planned operation we have identified eligible patients from the surgical waiting list. Subsequently, we approached them to explain the study objectives and expected the role of participation. Follow-up was initiated after patients approved participation by signing the informed consent. We have recruited a total of 712 (n=356 before, and n=356 after the intervention) consecutive patients; who were eighteen years or older, scheduled for general, orthopedic and gynecologic surgery. Those having cognitive and mental disabilities (identified from their clinical record files), patients transferred directly to an intensive care unit, those who had emergency surgery including cesarean section and ambulatory procedures were excluded. Details are provided in Figure 4.5 with participants flowchart.

3.2.1.2 Intervention

The contents of all training materials were based on literature review [78, 105, 132, 134], IASP recommendations [162], international recommendations for low resource settings [2], and a

national guideline [163]. Both the HCPs and patients' education (see below), were underpinned by the principle of Learning Sciences. It took into account the conditions, processes, and outcomes of learning [164]. Before the main preoperative patient education, staff members of the intervention hospitals were trained on the effective management of post-surgical pain. Health care providers including those who assumed leading or managerial position, surgeons, gynecologists, nurses, and physiotherapists were invited to participate. A total of thirteen participants (3 anesthetists, 3 surgeons, 2 gynecologists, 1 physiotherapist, and 4 nurses) attended the workshop. For about 13 hours over 3 days, they were trained on topics related to the obstacles to pain management in low-resource settings, the importance of pain assessment, measurement, and tools, use and application of non-pharmacological methods of pain management. In addition to the theoretical lectures, participants were exposed to practical sessions. The hands-on sessions focused on the use of non-pharmacological methods of pain management with emphasis on acupuncture (see Supplementary Table 8.1.3).

After the HCPs education was completed, the night before the surgery, a project team member an anesthetist conducted a one-on-one, individualized education verbally. All patients who met the inclusion criteria were educated and each session lasted for 15 minutes. Voluntary relatives (families) also attended. The table below (Table 3.2.1.3), presents the topics and contents of the patient education given. In brief, each educational session consisted of information regarding why managing postoperative pain is important, non-pharmacological options of pain management, how to take pain medication as directed, report side effects early, participate in the choice of the management of pain with HCPs. Patients were informed that they should not be shy and always be active in the management of their pain. They were also told how to describe their pain using the pain intensity scales. Before concluding the educational session, patients were given chances to ask questions. Once the question and answer session was completed, each patient was asked to repeat what they have learned. Finally, five questions were asked to all patients and if a patient has missed one question education was repeated again.

Patients in the control hospitals received care as usual with no preoperative education. Preoperative education or information for postoperative pain is not part of the care in the setting yet. Also, as a means to standardize the patient education a separate manual was prepared, where experts reviewed it for its appropriateness for the setting.

Table 3.2.1.3 Components of the patient educational intervention

Topic Covered	**Contents and Evidence**
Introductions	Patient and his/her families greeted warmly What is about to be thought introduced and All are asked to sit comfortably.
Overview of post-surgical pain	Definition of post-surgical pain, what causes it and how can it be managed
Goals of management	Why managing post-surgical pain is important and Highlighting the consequences of unmanaged postoperative pain [105]
Patient role in the management	The patient should ask for analgesics and insist if the health care provider is not responding, Patients should not be passive but actively participate in decision [77, 123, 139] How to take medications as directed, manage side-effect early, avoid misconception [165] report side-effect early [166] communicate your pain using instruments [167] How to be relaxed and avoid fear prior to surgery Should believe that unmanaged pain is very harmful [105]
Available options of treatment	Both pharmacological and non-pharmacological methods [105] How to reduce anxiety using various alternatives [47]

3.2.1.4 Recruitment

The night before the operation, the trained data collectors from all sites approached potentially eligible patients. Patients were provided with a detailed information sheet describing the study and their potential involvement. For the majority of the patients (who were illiterate), the written information sheet was read to them aloud. Following completion of the HCPs education, the second group of patients was recruited from both the treatment and control hospital using the same procedure described above. This time, however, in addition to the offer to participate in the interviewer-administered self-reported measures, patients in the treatment group were also given additional information about the planned preoperative education. When the patient agreed to participate, a consent was obtained the same way as described above and the preoperative individualized patient education was conducted. Consequently, using the interviewer-administered questionnaire, patient-reported outcomes were collected after the operation at the four-time points explained above. Patients were aware of their participation in the study but were blind to which condition the hospital was allocated. However, those who administer the interventions and those assessing outcomes were not blind to study allocation. Data collectors were different from those who administered the intervention.

3.2.1.5 Outcome measures

Outcome measures included the IPOQ (International Pain Outcome Questionnaire) — originally developed from the American Pain Society Patient Outcome Questionnaire (APSPOQ) [168]. It has been translated into 15 different languages and validated in 8 European countries and Israel [19]. It includes questions on pain severity, pain interference with physical function and emotions, side effects of pain treatment, and perception of care. Also, it permits to grasp information about the use of non-pharmacological methods for pain relief and the presence of preoperative chronic pain. IPOQ items mostly use 11-point (NRS 0–10) numeric rating scale, but also binary items are included. Patient worst, least and current pain intensity was measured as NRS 0 = “no pain”– 10 = “worst pain possible.” The percentage of time the patient spent in severe pain since surgery was also measured on a NRS with 0% = “never in severe pain”– 100% = “always in severe pain.” The primary outcome of interest was patients’ level of worst pain intensity. Pain interference was measured as functional disability due to

pain (NRS 0 = “did not interfere”– 10 = “completely interfered”), anxiety and helplessness caused by pain (NRS 0 = “not at all”– 10 = “extremely”). Patient perception of care was measured as the degree of pain relief through pain treatment (NRS: 0% = “no relief”– 100% = “complete relief”). Patients wish for more analgesics were recorded as binary (“yes or no”) answers. Satisfaction with the results of pain treatment was measured with NRS 0 = “extremely dissatisfied”– 10 = “extremely satisfied.” The original English version was translated (forward and backward) into two local languages and pilot tested in five steps as per international guidelines [169]. The final version was approved by expert panel to ensure content and face validity. In addition, we retrieved documented analgesics from patients’ clinical record files to calculate the adequacy of pain management (secondary end-point) using the Pain Management Index (PMI). The index is calculated by first categorizing patients worst pain intensity into 0 (no pain), 1 (1–3: mild pain), 2 (4–6: moderate pain), and 3 (7–10: severe pain). The final score is then subtracted from the strength of analgesic prescribed: which is 0 (no analgesic drug), 1 (non-opioids), 2 (weak opioids), and 3 (strong opioids). The final score is between –3 to +3, and negative scores inform inadequate treatment. Originally this was designed to assess the adequacy of cancer pain management; however, its application in surgical patients have been reported [170].

3.2.1.6 Covariates

The covariates considered in this study were the following: time (since surgery), patient’s age and sex, pre-existing chronic pain and patient’s physical condition. We also retrieved demographics (age, sex, marital status, educational status, ethnicity, religion, khat consumption), medical history information (history of previous anaesthesia, surgery, chronic medical illness), physical status, type of surgery, type of anesthesia and pain treatment from the medical records.

3.2.2 Qualitative design

A qualitative description design [171, 172] was used to explore barriers and facilitators to effective postoperative pain management. The HCPs', patients' and hospital officials' perspectives were captured in face-to-face semi-structured interviews, from October 4/ 2016 to December 8/2016. Qualitative description method has been used widely in qualitative health research [172]. It has also been applied to explore pain management practices previously [173]. The study was conducted in the setting described above.

3.2.2.1 Sampling and recruitment

We employed a purposive sampling technique with maximum variation [174]. The sampling framework for maximum variation to select patients was based on baseline pain intensity, type of surgery and gender. HCPs and officials were also invited to participate to increase the validity of the findings [175]. To select HCPs, we considered the background profession, gender and years of work experience. Officials with a managerial or leadership position were recruited if they had assumed their position at least three years ago to make sure adequate exposure to the healthcare environment. All these efforts were to reach data saturation [176], as sampling should consider this a priori and a large sample size does not necessarily provide a saturated data [176, 177]. Consequently, we have defined a minimum of 9 patients, 9 HCPs and 6 hospital officials (officials in a managerial or leading position) a priori. However, we limited the sample to 24 participants because we reached a point of saturation at which completed interviews revealed similarities and no longer a new idea was raised [176].

3.2.2.2 Data collection

Individual face-to-face semi-structured interviews lasting 15 – 30 minutes were conducted. All patient interviews were conducted immediately at 24 hours after surgery in the hospital wards. HCPs and officials were interviewed in the respective offices. Interviews were conducted by the first author (MT), who is a lecturer and anesthetist with experience of working with postoperative patients and took the necessary training in qualitative research, as part of his P.hD curriculum. The interviews were conducted in the local language, Amharic, and were audio-recorded. A semi-structured interview guide (Additional file 8.2.1) was developed based on the literature review and study objectives to assure uniformity [178]. The interview guide for patients covers the following areas: patients' experience of pain after surgery, the perception

of pain treatment options, coping mechanism, perceived barriers for an effective pain management and an evaluation of the professionals help to alleviate pain. Interview guide for HCPs and officials included perceived quality of pain management, barriers, and facilitators for effective pain management. In addition, the interview guide for officials also included questions about monitoring of pain management practice, availability of necessary drugs/human resource for pain management and policy or standards on how the HCPs are expected to manage postoperative pain. The interview guide served only as an outline with the aim of generating discussion that would help to address the research question. Probing questions like "what do you mean by that?" and "can you elaborate this more please," were asked. At the end of each interview, the researcher asked the participants to discuss anything they considered relevant. In line with the proper practice of semi-structured interviewing [178], the interviewer attempted to remain objective during the interview process as much as possible. A good rapport (trust and respect) was maintained throughout the process.

3.3 Datasets and analysis

We have performed three analysis using the qualitative semi-structured interview from the qualitative research, the baseline (pre-intervention) quantitative data from the quasi-experimental study and finally the the pre-intervention and post-intervention data together.

3.3.1 Baseline (pre-intervention) data analysis from the quasi-experimental controlled before after study

The overall goal was to characterize the quality of care provided to patients before the introduction of intervention. For this particular analysis, we employed GEE (Generalized Estimating Equations). The aim was to model the change of outcome measures over time [179]. Further, we applied GEE because of our interest in population-averaged effects instead of subject-specific effects [179]. Throughout the analysis, a manual stepwise backward elimination approach was used to select covariates that influenced the time course of the different outcome measures. The best fitting model and working correlation structure were evaluated by quasi-likelihood under independence criteria (QIC) and corrected quasi-likelihood under independence criteria (QICu); where the one with the lowest possible value was chosen [180]. QIC is the modification of the AIC for the GEE. Consequently, an exchangeable working correlation structure with Huber–White standard error estimates (robust

standard error) were used for all GEE analyses [179]. The linear relationship between outcomes and time was analyzed by adding time squared to the GEE model. In case of a non-linear relationship, time was included as a categorical variable to the model. The equation of the GEE which allows to adjusts for the dependency of observations within one subject is the following,

$$Y_{it} = \beta_0 + \sum_{j=1}^{J} \beta_{1j} X_{itj} + \ldots . + CORR_{it} + \varepsilon_{it}$$

At which Yit is the observed outcome for the subject i, at time t. β0 is the intercept, Xijt is the covariate j for the subject i at time t, β1j is the regression coefficient for covariate j, J is the number of covariates, CORRit is the working correlation structure, and εit is the "error" for subject i at time t. A p-value of 5% was considered significant, and all analyses were executed using the STATA version 13.0 (StataCorp., Texas, USA).

3.3.2 Complete data analysis from the quasi-experimental controlled before after study

The purpose of this analysis was to test whether the implemented intervention was effective or not in improving the quality of pain management, as measured by the patient reported outcomes and other parameters discussed above. The following section presents the sub-section of this analysis conducted in the full data set.

3.3.2.1 Treatment effect

Mean and SD was calculated for normally distributed continuous variables and medians and interquartile range (IQR) in case of skewed distributions. Categorical variables were summarized as numbers (percentage). In order to assess the influence of selection bias, differences in baseline clinical and demographic variables at the baseline were evaluated using univariate generalized linear models and using the Chi-square test. Comparison of changes in the outcomes of interest over time between the control and treatment group were analyzed using a linear mixed-effect (LME) model. All LME models contained time as a categorical variable and the fixed effects of group (treatment Vs control) and their interactions. Interaction terms were used to assess the effect of age, sex, types of surgery, chronic pain severity and types of anesthesia on the treatment effect. If the interaction term was not significant, the model

parameters were re-estimated without the interaction term. Covariates in the final model were selected using backward elimination, which begins with the maximum full model and then deleting variables of limited value. However, age, sex, type of surgery, and chronic pain severity were left in the model despite not having statistical significance, to avoid omitting a significant variable (avoid any Type II errors) and therefore maximize validity and predictive power, which is a good practice [181].

3.3.3.2 Sensitivity analysis using propensity score methods: a brief summary

The gold standard method of estimating treatment effect is using well randomized controlled trials (RCTs) [182]. Random treatment allocation of participants to the treatment and control condition is assumed not to be confounded with either measured or unmeasured baseline confounders [182] [183]. Therefore, treatment effect on outcomes can be estimated by direct comparison of the treated and untreated subject [184]. In non-randomised (quasi-experimental) controlled trials, however, one can not rule out selection bias and internal validity is at risk [185]. In such studies, however, baseline characteristics of treated subjects often differ systematically from those of untreated subjects. Therefore, one must account for systematic differences in baseline characteristics between treated and untreated subjects when estimating the effect of treatment on outcomes. Traditional regression adjustment can account only for differences in measured baseline characteristics, and still, bias from the unmeasured confounders can still be an issue [186]. For such advantages, recently, there has been increasing application of propensity score in estimating treatment effect in medicine [187]

3.3.3.3 Available propensity score methods

The probability of being assigned to the “treatment”, given pre-treatment covariates is called a propensity score (PS) [188]. This sometimes is also referred to as “a balancing score” [186]. The ultimate goal is to create the same propensity score for both the treated and control subjects so that the distribution of covariates for subjects in both groups will be the same [186]. Propensity scores usually are estimated from logistic regression technique [189]. On the other hand, nonparametric methods, such as generalized boosted model (GBM), have been also applied to estimate the PS [190]. Both methods have their own advantages and drawbacks, and it is far beyond the scope of this thesis to discuss in depth. It is recommended to include all the variables (despite their statistical significance or

collinearity) that may be related to the treatment decision to the logistic regression model while estimating the propensity scores [183]. However, variables that are exclusively associated with the treatment decision but not the outcome should not be incorporated [191]. For this reason, marital status, age, sex, educational status, ASA-classification, chronic pain severity, duration of surgery, use of acupuncture, type of surgery, type of anesthesia were incorporated in the PS models used here. Note that all relevant variables remain in the model regardless of their statistical significance. The subsequent use of the estimated propensity score then depends on whether the interest is to estimate the ATET (the average treatment effect on the treated) or ATE (average treatment effect) [188]. In both cases there are four different methods, however, one should bear in mind that the optimal matching for each treated subject is not applicable for estimating ATE [188]. The four methods calculating the ATE using the propensity scores are; propensity score-adjusted regression method, propensity score based stratification, Inverse probability weighted method (IPW) and the doubly robust estimator (DR) [186].

3.3.3.4 Method employed for this particular analysis

Robins et al. in 1994 proposed the DR estimator which is an amendment of the IPW methods [192]. This method brings together both the outcome regression model and the propensity score model. For this reason, the investigator has two opportunities (chances) of specifying the model correctly. Even if either the propensity score model of the outcome regression model misspecified, the DR remains consistent [192, 193]. The usual IPW estimator also shares these attractive properties with the DR estimator, but the "augmentation" that makes this estimator doubly robust also makes it more efficient than the usual IPW estimator [194]. Using a DR approach can compensate for a lack of covariate balance, unlike to other matching techniques of the propensity score. Moreover, with other previously mentioned matching techniques, the dataset can be pre-processed by "trimming" away (removing) individuals with extreme PS, while attempting balance [183]. Therefore, this method of estimation was used in this particular study, to calculate the average treatment effect.

More specifically we have taken the following steps. First, the propensity score was calculated using a generalized linear model for a binary treatment conditional on pretreatment covariates. The average treatment effect—the mean of the individual causal effects in the whole population [188], was used to answer the research questions. For example on average, how would pain

intensity change if everyone in the population of interest had been assigned to the treatment condition relative to if they had not received treatment. Secondly, to estimate the average treatment effect on the population, we calculated weight for the treated patients using, weight= 1/e(X), where e(X) is the propensity score, and weight = 1/1-e(X) for the control group [195]. Finally, to calculate the average treatment effect, the obtained weights were added to the final regression model together with the covariates used to generate the propensity score.

3.3.3.5 Mechanisms of action of the intervention using causal mediation analysis: a brief overview

In addition to testing the treatment effect, we have further explored the mechanisms of actions behind the intervention. Understanding this would certainly help future researchers, in better designing the intervention package, by isolating the responsible part of the educational intervention from the whole package. This is a good practice whether the treatment worked or failed [196].

Recently, there has been an increasing interest in characterizing the mechanism behind health care interventions through a causal mediation analysis [197]. The majority of studies published and worked examples of mediation analysis has focused on the condition where the independent variable (hereafter referred as X), mediator (hereafter referred as M), and the outcome or dependent variable (hereafter referred as Y) come from cross-sectional data [198]. The most highly cited and famous method of causal mediation analysis is Baron and Kenny's approach [199]. They specified a sequence of steps for assessing the presence of mediation, and also popularized Michael E. Sobel's [200] Sobel test. Sobel test is used to confirm or refute the significance of indirect effects. Studies, however, showed that when the sample size is small the causal step approach suffers from loss of power and high type I error [201-203]. Even though it was advised against the causal steps approach one decade ago, it is still in literature and experts warn against this method frequently [204]. Alternatives to this approach include the bootstrapping method [205] and Sobel test [200]. Simulation studies demonstrated bootstrapping—which involves repeatedly sampling from the data and estimating the indirect effect in each resampled data grouping—to be superior because it provides higher power whilst minimizing type I error [206, 207]. However, since the present study was longitudinal we have implemented the within-subject 1-1-1 multilevel mediation (4.9 and 4.10), also known as lower level mediation [198], page 179]. In longitudinal, within-subject mediation, X, M, and Y can

vary either within-subjects (level-1), between-subjects (level-2), or both [198]. Krull and MacKinnon outlined three specific multilevel mediation scenarios: 2 → 2 → 1, 2 → 1 → 1, and 1 → 1 → 1 [208]. Since the mediator (patient participation in decision making) is a level-1 variable and the treatment exposure was also individualized patient education, which is also a level-1 exposure and the outcome variable is also measured at level 1 (patients' worst pain intensity), we have conducted a 1 → 1 → 1, within-subject mediation. We have followed the procedure described by Bolger and Laurenceau [198]. We have performed 1000 sample bootstrap procedure to estimate 95% confidence intervals (CIs) to test the significance of indirect links and CIs are expected not to contain 0 and only then the indirect links are considered to be significant [209]. The mediation analysis was also adjusted for all measured baseline confounders.

3.3.3.6 Within-subject 1-1-1 mediation within the context of this study

Figure 4.6 and 4.7 shows the within-subjects path diagram corresponding to our models, based on the works of Bolger and Laurenceau [198] including the equations used for the mediation model. The treatment condition (treated vs control) is represented by *X*, patients participation in decision making is labeled *M*, and patients' rating of worst pain intensity (*patients' satisfaction for the second mediation model*) is labeled *Y*. The total effect was calculated using the formula from Kenny, Korchmaros, and Bolger [210] which is given by:

$$c = c' + ab + \sigma_{a_j b_j}$$

Here we see that *c*, the relationship between *X* and *Y* for the typical patient, is equal to the sum of (1) *ab*, the product of the *X*-to-*M* and the *M*-to-*Y* coefficients for the typical subject; (2) *c*, the coefficient representing the unmediated portion of the *X*-to-*Y* relationship for the typical subject; and (3) s*ajbj*, the covariance of between-subjects differences in the *X*-to-*M* and *M*-to-*Y* relationships. Including the final covariance term (s*ajbj*) is very important in multilevel mediation and it has an important implications for estimates of mediated effects. It represents that the extent that those patients whose participation in decision making score is most affected by the treatment are the same patients whose pain intensity (patients' satisfaction for model 2) is most affected by their participation in decision making, then the overall mediated effect will be greater than one would expect from the *ab* product alone [198].

3.3.3.7 Software used

All data management, linear mixed model building, and propensity score weighting was done using STATA version 13.0 (StataCorp., Texas, USA). For the multilevel causal mediation analysis, we have used the R function indirectMLM.R, written by Elizabeth Page-Gould [211] in R package version 1.3.4 in R Statistical Software (version 3.4.3; R Foundation for Statistical Computing, Vienna, Austria). Within-subject mediation, by allowing between-subjects heterogeneity in mediated paths, affords a realistic conceptualization of psychological and interpersonal processes.

3.3.2 Qualitative data analysis

The purpose of this particular analysis was to understand what factors inhibit or promote effective post-surgical pain management and why. After all interviews are completed, first, a complete transcript of each interview in the local language, Amharic, was produced. The transcribed data were read and reviewed to ensure understandability and were compared with the original audio-records for accuracy. Data were analyzed manually by Braun and Clarke's six-step process of thematic analysis [212], using a "bottom-up" approach (inductively), to ensure that important aspects were not missed. Line-by-line coding was performed independently by two authors (MT, DW), one of whom was a medical sociologist with previous experience in qualitative research. Once duplicate codes were removed, and relevant data were extracted, we started searching for themes. In line with the research question, themes were constructed from the codes. Similar themes were collapsed while some were split where necessary. Results of data analysis are presented in Fig 4.4. Emerging concepts and categories were translated into English by two independent translators. The final English version was established upon discussion. A third person (Anesthetist) translated the final English version back into Amharic. Finally, a committee of four individuals, consisting of an expert in English, an anesthesiologist, an expert qualitative research, and the first author settled issues of conceptual and semantic equivalence between the Amharic and the final English version. The two coders finally agreed that the final analysis revealed that data has saturated very well and no new data and themes are generating making extra interviews unnecessary.

3.4 Ethical statement

The study protocol was approved by the Institutional Review Board of the Jimma University (Ref.No RPGC/06/2016; Jimma, Ethiopia) and the Ludwig Maximillian University of Munich Medical Ethics Committee (Ref. No 17-224, Munich, Germany). All participating hospitals also granted permission for the study in response to a support letter written; (Ref.No. ጤምድምማ/ 567/2008, ጤምድምማ/ 568/2008, ጤምድምማ/ 569/2008). During the quantitative phase of the study, before inclusion of participants, the day before the operation, patients were informed about the purpose of the study including their rights to refuse or withdraw at any given time patients'. Patient data were collected only after signed informed consent was obtained. Confidentiality of the individual information gathered was discussed, and additionally, any personal information was anonymized before the final analysis. Also, patients who received preoperative educational intervention were also consulted and detail explanations were given beforehand and only after signed and or verbal confirmation of consent was obtained that the education proceeded. Prior to conducting the semi-structured, audio-recorded interviews, a short explanation of the study including risks and benefits of participation was given. The interview continued only after informed consent was obtained and the participation was voluntary. There was no prior relationship established with any of the participants recruited, during the qualitative interview process. The study was performed in accordance with ethical standards established in the 1964 Declaration of Helsinki.

4. Results

4.1 Results of the baseline (pre-intervention) data analysis from the quasi-experimental controlled before after study

The aim was to describe the quality of pain management in the country, before introducing the intervention. The pre-intervention (baseline) dataset of the quasi-experimental non-equivalent control group trial was selected to answer whether the current quality of post-surgical pain management in Ethiopia is up to the standard.

4.1.1 Demographic and clinical information of participants

During this study period, we had no refusal from eligible participants. There was a slight female predominance (51.1%), with a mean age of 35.4 (± 0.9) years. The majority of participants were Ethiopian Orthodox Tewahido Christians (59.6%). Oromo was the dominant ethnic group (41.3%). Almost all (97.5%) patients had an American Society of Anesthesiologists Physical Status Classification 1 (ASA PS 1). The median (Q1-Q3) duration of the surgery was 1.3 (1-2) hours. Most patients (69.4%) underwent general anesthesia, one-third (29.2%) spinal anesthesia and only five patients (1.4%) ketamine anesthesia. The predominant type of surgery performed was cholecystectomy (15.4%), followed by thyroidectomy and prostatectomy, each constituting 10.1%. (Table 4.1).

Table 4.1 Demographic and clinical characteristics of participants.

Age in years, mean (SD)	39.9 (16.3)	
Duration of surgery in hours, mean (SD)	1.5 (0.73)	
	n	**%**
Women	182	51.1
Physical status classification		
ASA PS 1	347	97.5
ASA PS 2	9	2.5
Educational status		
Illiterate	133	37.6
Elementary school	107	48.0
High school	54	24.2
Certificate	25	11.2
Diploma	26	11.7

Degree and above	11	4.9
Religion		
Orthodox Christian	212	59.6
Muslim	126	35.4
Protestant	18	5.06
Marital status		
Married	253	71.1
Single	82	23.0
Divorced/widowed	21	5.9
Ethnic group		
Amhara	142	39.9
Oromo	147	41.3
Others*	67	18.8
Type of anesthesia		
General anesthesia	247	69.4
Spinal anesthesia	104	29.2
Ketamine anesthesia	5	1.4
Type of surgery		
Cholecystectomy	55	15.4
Thyroidectomy	36	10.1
Prostatectomy	36	10.1
Elective laparotomy	22	6.2
Open reduction internal fixation	22	6.2
Hysterectomy	20	5.6
Herniorrhaphy	14	3.9
Excision	13	3.7
Fistulectomy	11	3.1
Myomectomy	10	2.8
Hemorrhoidectomy	10	2.8
Mastectomy	9	2.5
Other[a]	98	28.1

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[a]Sequestrectomy, Mesh repair, Ligation, Plate removal, K-wire removal, Abscess drainage, External fixation, Fistula repair, Amputation, Debridement, Pyelolithotomy, Lobectomy, Reduction, Biopsy, Colostomy removal, Repair, Appendectomy, Incision, Uterovaginal prolapse repair, Elective colostomy, Tension pad, Screw removal, Urethroplasty, Sistrunk, Examination Under Anesthesia, Nephrolithotomy, Vagotomy, Colostomy, Chest tube Insertion, Bougie dilation, Urethroplasty, Manual vacuum aspiration, Drainage, Thyroid excision, Tension Band Wiring, External Fixation, Herniotomy, Sigmoidectomy, Wound closure, Cystostomy, Bursectomy, Unilateral oophorectomy, Gastrojejunostomy, Modified Bassini's repair, Hemicolectomy.

4.1.2 Adequacy of pain management and perception of care

Time course of PMI scores indicated that during the first 6 postoperative hours 58.4% of patients were inadequately treated using patients worst pain intensity as a reference (Figure 4.1A). Moderate to severe postoperative pain was reported by 88 % of patients at 6 hours and

still by 40 % of patients at 48 hours after surgery (Figure 4.1D). The proportion of inadequately treated patients decreased over time (Figure 4.1A-D). When asked whether they needed more analgesics than prescribed, 57% of the patients replied ‘yes,' at 6 hours after surgery (95% CI: 52.1%, 62.4%) (Figure 2). At the second measurement time-point, still, 55% of patients needed more analgesics (95% CI: 49.5%, 59.9%). This figure dropped to 37% (95% CI: 31.9%, 42.0%) at 48 hours before patient discharge. No patients in our sample received any information regarding options for pain treatment. The patient pain was treated predominantly with Tramadol (92.9%) followed by diclofenac (7%). The most prevalent non-pharmacological methods of pain management was talking to friends or relatives 88.3% (95% CI: 82.5%, 92.4%), 90.6% (95% CI: 85.2%, 94.2%), 90.1% (95% CI: 84.5%, 93.8%) and 94.7% (95% CI: 90.1%, 97.3%) at 6h, 12h, 24h and 48h after surgery, respectively.

4.1.3 Pain intensity :

4.1.3.1 Worst pain intensity

The worst pain intensity ratings had a mean NRS values of 6.5 (SD=1.63) at 6 hours, 5.7 (SD=1.6) at 12 hours, 4.9 (SD=1.6) at 24 and 4.2 (SD=1.4) at 48 hours after surgery. Patient’s current and least pain intensity also declined over time but were not different between both sexes (Figure 4.3). However, it is very worthy to mention that 88% of the participants had moderate to severe pain during the first 6 hours after the surgery. Even in the subsequent measurement, the prevalence of moderate to severe postoperative pain was still high; which is 77% at 12 hours, 63% at 24 hours, and 40 % at 48 hours before discharge (Figure 4.1 D).

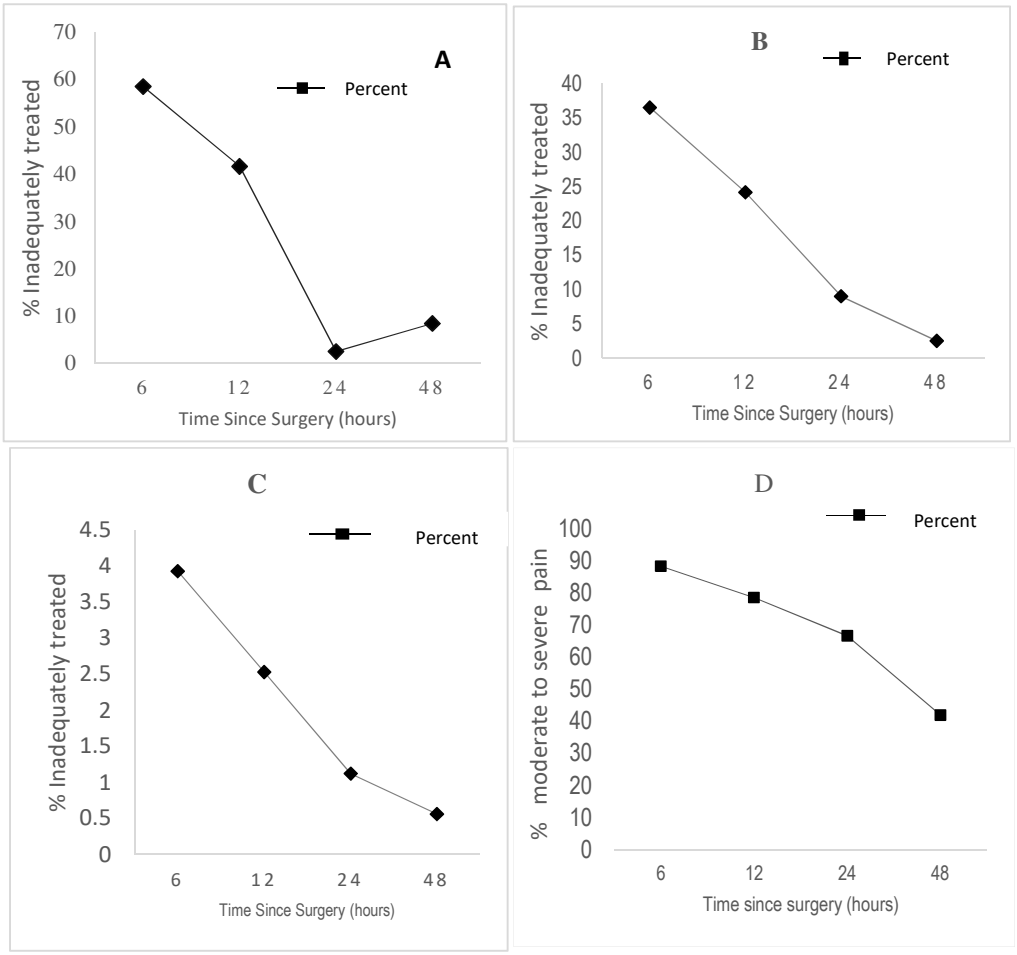

Figure 4.1: Adequacy of pain management: Worst pain intensity as a reference (A); Current pain intensity as a reference (B); Least pain intensity as a reference (C). The percentage of patients with moderate to severe post-operative pain (>4 on NRS) using worst pain intensity as a reference across measurement points (D).

The QIC statistic for GEE model selection suggested age, sex, educational status, type of anesthesia, type of surgery, chronic pain severity and time since surgery as covariates for the final model. Patient's worst pain intensity rating was affected by time since surgery, age, chronic pain severity and educational status. In comparison to 6 hours after surgery, worst pain intensity was significantly lower at each measurement time point with increasing coefficients; 12h (β= -0.66, 95% CI=-0.946, -0.375), 24h (β=-1.49, 95% CI: -1.758, -1.228) and 48h (β=-1.988, 95% CI: -2.315, -1.661).

Table 4.2. Factors associated with worst postoperative pain intensity among adult postoperative patients using linear generalized estimating equations.

	β	SE	P value	95% CI	
Age	-0.018	0.007	0.014	-0.032	-0.004
Sex					
Male	ref				
Female	-0.224	0.193	0.246	-0.602	0.154
Educational status					
Literate	ref				
Illiterate	0.552	0.202	0.006	0.156	0.947
Physical status					
ASA PS 1	ref				
ASA PS 2	0.158	0.556	0.791	-0.943	1.238
Type of anesthesia					
General anesthesia	ref				
Spinal anesthesia	0.223	0.213	0.295	-0.195	0.642
Ketamine anesthesia	-0.440	0.393	0.264	-1.211	0.331
Chronic pain severity	0.346	0.068	<0.01	0.212	0.480
Type of surgery					
General surgery	ref				
Gynecologic surgery	0.271	0.246	0.271	-0.211	0.754
Orthopedic surgery	-0.378	0.265	0.154	-0.897	0.142
Time since surgery					
6 h	ref				
12 h	-0.660	0.146	<0.01	-0.946	-0.375
24 h	-1.493	0.135	<0.01	-1.758	-1.228
48 h	-1.988	0.167	<0.01	-2.315	-1.661

ref= reference group; SE: standard error of the mean; 95% CI: 95% confidence interval.

With increasing years of age worst pain intensity decreases (β=-0.018, 95% CI: −0.032, −0.004). Increase in preoperative chronic pain NRS ratings was associated with a higher worst pain rating after surgery (β=0.346, 95% CI: 0.212, 0.480). Illiterate patients had higher worst pain intensity scores (β=0.552, 95% CI: 0.1562, 0.94731), compared to those with formal education. Sex, type of anesthesia, type of surgery, duration of the surgery and physical status did not affect patient's worst pain experience (Table 4.2).

Table 4.3. Factors associated with time spent in severe postoperative pain among adult post-surgical patients using linear generalized estimating equations..

	β	SE	P value	95% CI	
Age	-0.007	0.011	0.510	-0.028	0.014
Sex					
Male	ref				
Female	-0.239	0.342	0.484	-0.909	0.430
Educational status					
Literate	ref				
Illiterate	-0.071	0.320	0.824	-0.699	0.556
Marital status					
Married	ref				
Single	0.752	0.378	0.046	0.012	1.492
Divorced/widowed	0.453	0.734	0.537	-0.986	1.892
Ethnic group					
Amhara	ref				
Oromo	-0.992	0.368	0.007	-1.714	-0.270
Others**	-0.122	0.398	0.759	-0.902	0.658
Religion					
Orthodox Christian	ref				
Muslim	-1.338	0.347	<0.01	-2.017	-0.658
Protestant	-2.056	0.370	<0.01	-2.781	-1.332
Physical Status					
ASA PS 1	ref				
ASA PS 2	-0.649	0.746	0.384	-2.111	0.812
Type of anesthesia					
General anesthesia	ref				
Spinal anesthesia	-0.226	0.391	0.564	-0.992	0.541
Ketamine anesthesia	1.436	0.633	0.023	0.195	2.677
Duration of surgery	0.968	0.205	<0.01	0.568	1.369
Chronic pain severity	0.239	0.101	0.018	0.041	0.436
Type of surgery					
General surgery	ref				
Gynecologic surgery	0.111	0.336	0.740	-0.547	0.769
Orthopedic surgery	-0.575	0.569	0.312	-1.691	0.540
Time since surgery					
6 h	ref				
12 h	-0.123	0.146	0.401	-0.409	0.163
24 h	-0.760	0.151	<0.01	-1.056	-0.464
48 h	-1.127	0.147	<0.01	-1.414	-0.839

****Tigre, Wolayta, Gurage, Kafa, Silte**
ref = reference group; SE = standard error; 95% CI = 95% confidence interval.

4.1.3.2 Time spent in severe pain

The mean time spent in severe pain based on the NRS ratings was 4.4 (SD=2.0) at 6 hours, 4.2 (SD=1.98) at 12 hours, 3.7 (SD=1.99) at 24 hours and 3.1 (SD=2.3) at 48 hours (Figure 3). In addition to the predictors for worst pain, the QIC statistic informed the inclusion of ethnic group, religion, marital status and duration of surgery. Compared to those who were married, singles reported higher percentages of time spent in severe pain (β=0.752, 95% CI: 0.012, 1.492). Muslims and Protestants reported less time spent in pain when compared to orthodox patients, (β=-1.338, 95% CI: -2.017, -0.658) and (β=2.056, 95% CI: 2.781, 1.332), respectively. The longer duration of surgery in hours, the higher rating of time spent in severe pain (β=0.968, 95% CI: 0.568, 1.369). Preoperative chronic pain (NRS) ratings also predicted how much time the patient spent with severe pain (β= 0.239, 95% CI: 0.041, 0.436). NRS ratings of time spent with severe pain had no statistical difference in the second measurement (12 hours after the surgery), compared to the first 6 hours of the surgery. However, with the subsequent measurements time spent in pain decreased significantly at 24 hours (β=-0.76, 95% CI: -1.056, -0.464) and 48 hours (β=-1.13, 95% CI: -1.414, -0.839). Age, sex, type of surgery, type of anesthesia, educational status and ASA-PS classification were not associated with the time spent in severe pain. (Table 4.3).

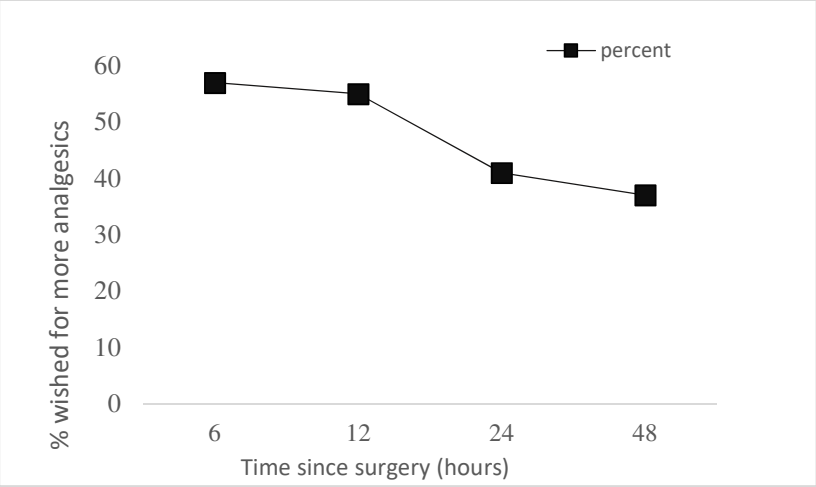

Figure 4.2: The percentage of patients who needed (wished) more analgesics than prescribed across time.

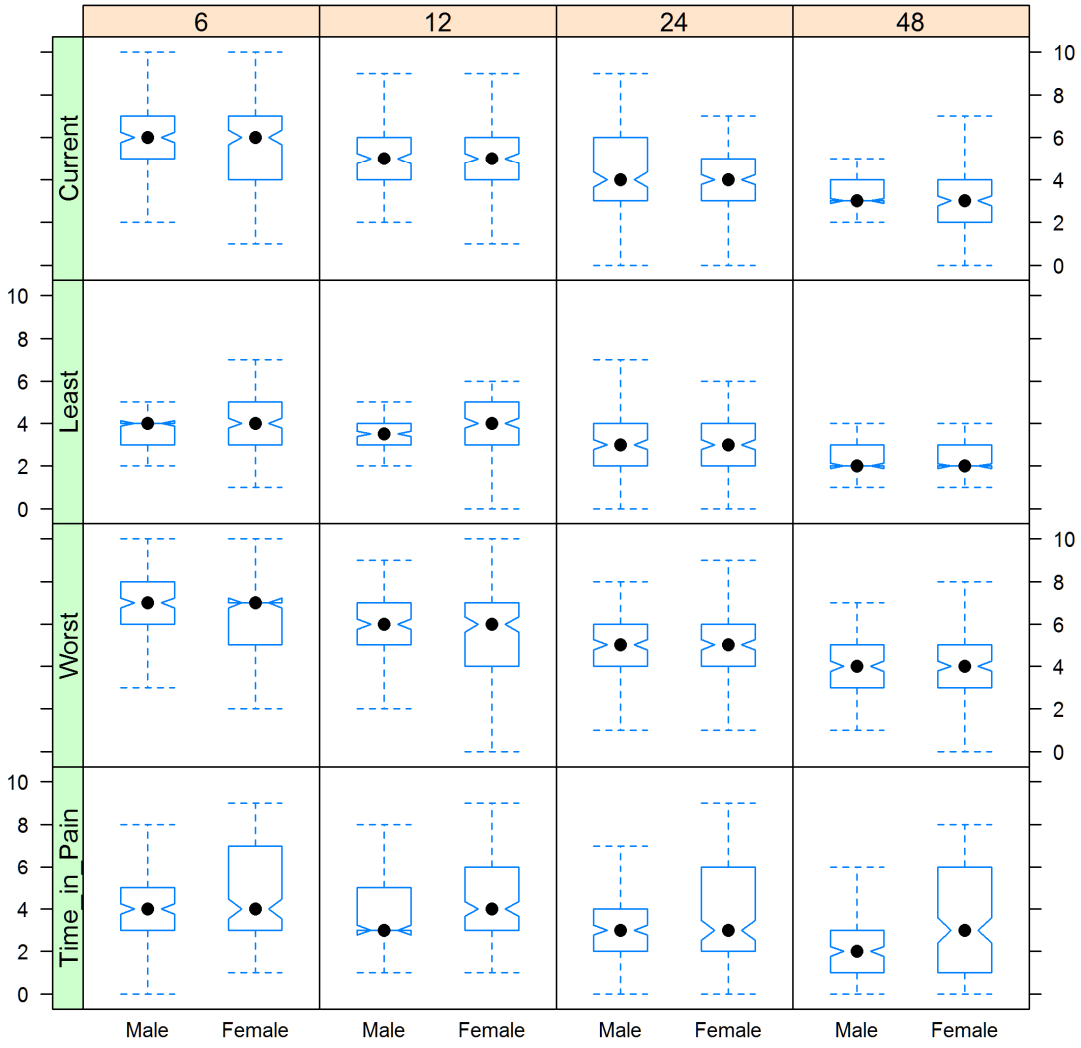

Figure 4.3: Tukey box plots for NRS score of Current, Least and Worst pain intensity at 6, 12, 24 and 48 hours post-surgery. Time in pain shows; the Median NRS score of time patients spent in severe pain (changed to NRS 0-10 from the original 0% -100%) at 6, 12, 24 and 48 hours post-surgery.

4.1.4 Pain interference

4.1.4.1 Interference with movement

Pain interference with the movement was moderate in intensity with mean NRS (SD) of 4.5 (SD=1.9), 4.97 (SD=1.7), 4.54 (SD=1.9) and 3.30 (SD=1.92) at 6h, 12h, 24h and 48h after surgery, respectively. ASA-2 patients reported higher interference (β=0.942, 95% CI: 0.250, 1.633) than ASA-1 patients. Compared to those who underwent general anesthesia with endotracheal intubation those after spinal anesthesia had higher ratings of pain interference with movement (β=0.726, 95% CI: 0.256, 1.23). Patients' rating of worst (β=0.363, 95% CI: 0.225, 0.496) and current (β=0.373, 95% CI: 0.235, 0.511) pain intensity also affected their mobility. When patients perceived pain relieve increased the pain interference with movement decreases significantly (β= -0.027, 95% CI: -0.040,-0.014). This interference of function outside the bed was also affected the by the level of education; illiterate reported more interference, (β=0.503, 95% CI: 0.028, 0.978). Time since surgery, background ethnic group, time spent in severe pain, level of education, religion, chronic pain severity, type of surgery showed no effect (Table 4.4).

Table 4.4. Factors associated with pain interference with movement among adult post-surgical patients using linear generalized estimating equations.

	β	SE	P value	95% CI	
Age	-0.018	0.010	0.074	-0.037	0.002
Educational status					
Literate	ref				
Illiterate	0.478	0.242	0.048	0.004	0.952
Marital status					
Married	ref				
single	-0.670	0.330	0.042	-1.316	-0.023
Widowed/divorced	-0.338	0.348	0.330	-1.020	0.343
Ethnic background					
Amhara	ref				
Oromo	-0.292	0.291	0.317	-0.862	0.279
Others	0.294	0.255	0.248	-0.205	0.793
Religion					
Orthodox	ref				
Muslim	0.392	0.277	0.158	-0.152	0.935
Protestant	0.271	0.401	0.499	-0.514	1.056
Physical Status					
ASA PS 1	ref				
ASA PS 2	0.922	0.352	0.009	0.231	1.613

Type of anesthesia					
General anesthesia	ref				
Spinal anesthesia	0.706	0.235	0.003	0.246	1.166
Duration of surgery	0.179	0.170	0.295	-0.155	0.512
Chronic pain severity	0.161	0.053	0.002	0.057	0.265
Type of surgery					
General surgery	ref				
Gynecologic surgery	0.245	0.228	0.283	-0.202	0.693
Orthopedic surgery	0.571	0.427	0.181	-0.266	1.409
Time since surgery					
6 h	ref				
12 h	0.067	0.416	0.873	-0.748	0.882
24 h	0.255	0.430	0.554	-0.589	1.098
48 h	-0.120	0.432	0.781	-0.968	0.727
Pain intensity					
Worst pain	0.366	0.072	<0.01	0.225	0.507
Current pain	0.390	0.082	<0.01	0.230	0.551
Time in pain	0.008	0.005	0.093	-0.001	0.018
Perceived care					
Relief received	-0.027	0.007	<0.01	-0.041	-0.013

****Tigre, Wolayta, Gurage, Kafa, Silte**
ref = reference group; SE: standard error; 95% CI: 95% confidence interval.

4.1.4.2 Interference with activities on bed

The mean NRS (SD) of pain interference with activities in bed was 5.7 (SD=2.1), 5.0 (SD=1.9), 4.1 (SD=1.9), 3.0 (2.0), from the first to last measurements respectively. The QIC statistic suggested time since surgery, time in pain, pain intensity (worst, current and time in pain) and perceived pain relief as final covariates of pain interference with activities in bed. Worst pain intensity (β=0.319, 95% CI: 0.225, 0.413), current pain intensity (β=0.282, 95% CI: 0.174, 0.390) and the duration of time patients spent in severe pain (β=0.021, 95% CI: 0.015, 0.027), predicted the intensity of interference with activities in bed significantly. As time after the surgery elapses intensity of interference decreases (β=-0.021, 95% CI: -0.027, -0.015). The amount of relief the patient perceived received did not affect (Table 4.5).

Table 4.5. Factors associated with pain interference with activities in bed among adult post-surgical patients using linear generalized estimating equations.

	β	SE	P value	95% CI	
Time since surgery, h	-0.021	0.003	<0.01	-0.027	-0.015
Worst pain	0.319	0.048	<0.01	0.225	0.413
Current pain	0.282	0.055	<0.01	0.174	0.390
Time in pain	0.021	0.003	<0.01	0.015	0.027
Relief received	-0.008	0.005	0.093	-0.01	0.001

SE: standard error; 95% CI: 95% confidence interval.

Table 4.6. Factors associated with pain interference with breathing and coughing among adult post-surgical patients using linear generalized estimating equations.

	β	SE	P value	95% CI	
Sex					
Male	ref				
Female	0.516	0.270	0.056	-0.013	1.046
Educational Status					
Literate	ref				
Illiterate	-0.108	0.257	0.674	-0.611	0.395
Marital status					
Married	ref				
Single	-0.352	0.384	0.359	-1.104	0.400
Widowed/divorced	-0.523	0.630	0.406	-1.759	0.712
Religion					
Orthodox Christian	ref				
Muslim	-0.218	0.276	0.430	-0.758	0.323
Protestant	-0.296	0.369	0.423	-1.019	0.427
Physical status					
ASA PS 1	ref				
ASA PS 2	0.671	0.331	0.043	0.022	1.321
Type of anesthesia					
General anesthesia	ref				
Spinal anesthesia	-1.222	0.335	<0.01	-1.879	-0.565
Ketamine anesthesia	-0.194	0.560	0.729	-1.292	0.904
Duration of surgery	0.225	0.171	0.189	-0.111	0.561
Chronic pain severity	0.253	0.078	0.001	0.100	0.407
Type of surgery					
General surgery	ref				
Gynecologic surgery	0.099	0.294	0.736	-0.476	0.674
Orthopedic surgery	-1.235	0.459	0.007	-2.135	-0.335
Time since surgery	-0.015	0.005	0.006	-0.026	-0.004
Pain intensity					
Worst pain	0.199	0.075	0.008	0.051	0.347
Current pain	0.268	0.063	<0.01	0.145	0.391
Time in pain	-0.008	0.006	0.188	0.019	0.004
Perception of care					
Relief received	-0.020	0.008	0.016	-0.037	-0.004

ref = reference group; SE: standard error; 95% CI: 95% confidence interval. ,

4.1.4.3 Interference with breathing and coughing

Pain interfered with breathing and coughing mildly at 6h, 12h, 24h and 48h with a mean NRS value of 3.0 (SD=2.3), 2.7 (SD=2.1), 2.3 (SD=2.0) and 1.6 (SD=1.8) respectively. Those who underwent spinal anesthesia and orthopedic procedures reported less pain interference with coughing and breathing (β= -1.222, 95% CI: -1.879, -0.565) and (β= -1.235, 95% CI: -2.135,-0.335) respectively. Patients with chronic pain reported a higher interference with breathing and coughing (β=0.253, 95% CI: 0.100, 0.407). This interference with breathing decreased with increasing perceived pain relief (β= -0.020, 95% CI -0.037, -0.004) and time after surgery (β=-0.015, 95% CI:-0.026, -0.004). ASA PS-2 patients reported higher interference of pain with breathing and coughing (β=0.671, 95% CI: 0.022, 1.321) compared to ASA PS-1 patients. Sociodemographic variables like sex, religion, marital status and ethnic background showed no effect. (Table 4.6).

Table 4.7. Factors associated with pain causing anxiousness among adult post-surgical patients using linear generalized estimating equations.

	β	SE	P value	95% CI	
Age	-0.007	0.009	0.442	-0.024	0.011
Sex					
Male	ref				
Female	0.550	0.284	0.053	-0.006	1.106
Educational status					
Literate	ref				
Illiterate	0.239	0.282	0.396	-0.313	0.792
Marital status					
Married	ref				
Single	-0.957	0.353	0.007	-1.649	-0.265
Widowed/divorced	0.549	0.883	0.535	-1.183	2.280
Ethnic group					
Amhara	ref				
Oromo	0.444	0.322	0.168	-0.188	1.076
Others**	0.026	0.303	0.931	-0.567	0.619
Religion					
Orthodox Christian	ref				
Muslim	0.436	0.244	0.074	-0.042	0.915
Protestant	0.048	0.335	0.886	-0.608	0.704
Physical status					
ASA PS 1	ref				
ASA PS 2	0.625	0.384	0.104	-0.128	1.378
Type of anesthesia					

General anesthesia	ref				
Spinal anesthesia	0.087	0.380	0.82	-0.658	0.831
Ketamine anesthesia	-1.178	0.409	0.004	-1.981	-0.376
Duration of surgery	-0.117	0.251	0.641	-0.609	0.375
Chronic pain severity	0.179	0.089	0.044	0.005	0.352
Type of surgery					
General surgery	ref				
Gynecologic surgery	-1.002	0.348	0.004	-1.685	-0.319
Orthopedic surgery	0.161	0.508	0.752	-0.835	1.157
Time since surgery	-0.004	0.005	0.379	-0.014	0.005
Pain intensity					
Worst pain	0.308	0.066	<0.01	0.179	0.437
Least pain	0.071	0.120	0.555	-0.165	0.307
Current pain	0.253	0.062	<0.01	0.131	0.375
Time in pain	-0.002	0.005	0.684	-0.011	0.007
Perception of care					
Relief received	0.006	0.008	0.41	-0.009	0.021

****Tigre, Wolayta, Gurage, Kafa, Silte**
ref= reference group; SE: standard error; 95% CI: 95% confidence interval, Models estimated with GEE.

4.1.4.4 Interference with mood and emotions

Based on the NRS 0-10 scores, the mean feeling of anxiousness as a result of pain was 2.2 (SD=2.1), 1.9 (SD=1.9), 1.5 (SD=1.6) and 1 (1.4); at 6, 12, 24 and 48 hours respectively. The same way the mean score of pain causing a feeling of helplessness was 1.5 (SD= 1.6) at 6 hours, 1.3 (SD=1.6) at 12 hours, 0.9 (SD=1.3) at 24 and 0.7(SD=1.3) at 48 hours. Singles have less pain interference with anxiousness (β=-0.957, 95% CI: -1.649,-0.265) and feeling of helplessness (β=-0.727, 95% CI: -1.408, -0.046). Muslims scored higher on pain causing helplessness compared to Orthodoxies (β= 0.418, 95% CI: (0.003, 0.833). Patients after gynecologic surgery had less anxiousness (β=-1.002, 95% CI: -1.685,-0.319) and helplessness (β=-0.823, 95% CI: -1.441, -0.206) compared to the general surgery patients. An increase in chronic pain NRS ratings were associated with increased anxiousness (β=0.179, 95% CI: 0.005, 0.352) and helplessness (β=0.188, 95% CI: 0.032, 0.343). A similar trend was noted for worst pain intensity that the more intense the worst pain, the higher the rating of anxiousness (β=0.308, 95% CI: 0.179, 0.437) and helplessness (β=0.240, 95% CI: 0.117, 0.363). Current pain intensity affected pan causing helplessness (β=0.205, 95% CI: 0.112, 0.298), but not anxiousness. Age, sex, level of education and ethnic background showed no effect. (Table 4.7 and 4.8)

Table 4.8. Factors associated with pain causing helplessness among adult post-surgical patients using linear generalized estimating equations.

	β	SE	P value	95% CI	
Age	-0.005	0.009	0.539	-0.022	0.012
Sex					
Male	ref				
Female	0.468	0.279	0.094	-0.079	1.015
Educational status					
Literate	ref				
Illiterate	0.258	0.262	0.324	-0.255	0.772
Marital status					
Married	ref				
Single	-0.727	0.347	0.036	-1.408	-0.046
Widowed/divorced	0.799	0.941	0.395	-1.044	2.643
Religion					
Orthodox Christian	ref				
Muslim	0.418	0.212	0.049	0.003	0.833
Protestant	-0.273	0.278	0.326	-0.817	0.272
Type of anesthesia					
General anesthesia	ref				
Spinal anesthesia	0.280	0.367	0.446	-0.440	0.999
Ketamine anesthesia	-1.494	0.414	<0.01	-2.305	-0.684
Chronic pain severity	0.188	0.079	0.018	0.032	0.343
Type of surgery					
General surgery	ref				
Gynecologic surgery	-0.823	0.315	0.09	-1.441	-0.206
Orthopedic surgery	0.600	0.589	0.308	-0.554	1.754
Pain intensity					
Worst pain	0.240	0.063	<0.01	0.117	0.363
Current pain	0.205	0.047	<0.01	0.112	0.298
Time in pain	0.005	0.005	0.344	-0.005	0.015
Perception of care					
Relief received	0.006	0.006	0.322	-0.006	0.017

ref= reference group; SE: standard error; 95% CI: 95% confidence interval.

4.1.4.5 Pain interference with sleep

The mean NRS (SD) ratings of pain interference with sleep at the four consecutive measurement were; 3.4 (SD=2.2), 3.0 (SD=2.0), 2.4 (SD=1.9) and 1.6 (SD=1.7). Worst pain intensity (β=0.352, 95% CI: 0.211, 0.493), current pain intensity (β=0.302, 95% CI: 0.182, 0.421), time in severe pain (β=0.021, 95% CI: 0.011, 0.030) and relieve received (β=-0.022, 95

CI: -0.033, -0.011) has a strong statistical association. Age, duration of surgery, preoperative pain intensity, and least pain showed no effect (Table 4.9).

Table 4.9. Factors associated with pain interference with sleeping score among adult post-surgical patients using linear generalized estimating equations.

	β	S. E.	P value	95% C.I	
Age	0.011	0.006	0.066	-0.001	0.023
Duration of surgery (hours)	0.139	0.147	0.344	-0.149	0.427
Chronic pain severity	0.098	0.063	0.119	-0.025	0.222
Worst pain	0.352	0.063	0.001	0.23	0.475
Least pain	-0.117	0.102	0.254	-0.318	0.084
Current pain	0.302	0.071	0.001	0.163	0.44
Time in severe pain	0.021	0.007	0.003	0.007	0.034
Relief received	-0.022	0.011	0.044	-0.044	-0.001

SE: standard error; 95% CI: 95% confidence interval.

4.1.5 Satisfaction

The mean patient satisfaction as indicated by the NRS rating between 0 and 10 was 6.8 (SD=1.6) at 6 hours, 7.2 (SD=1.4) at 12 hours, 7.6 (SD=1.3) and 7.9 (SD=1.4) at 48 hours. Ethnic background, pain interference and perception of care had an association with patients rating of satisfaction, in this study. The only pain intensity variable found to have any correlation with the patient's ratings of satisfaction was the time spent in severe pain (β=-0.011, 95% CI: -0.020, -0.001). An increase in pain interference with activities in bed decreases patient satisfaction (β=0.097, 95% CI: -0.392,-0.012). Pain interference with sleep was associated positively with satisfaction (β=0.258, 95% CI: 0.049, 0.468). The degree to which a patient felt relief was also associated with the level of satisfaction (β=0.031, 95% CI: 0.012, 0.051). Time since surgery, sex, marital status, religion, types of anesthesia, preoperative chronic pain, type of surgery, patients' worst, least and current pain intensity had no significant association with satisfaction (Table 4.10).

Table 4.10. Factors associated with pain management satisfaction among adult post-surgical patients using linear generalized estimating equations.

	β	SE	P value	95% CI	
Sex					
Male	ref				
Female	0.475	0.342	0.165	-0.196	1.146
Marital status					
Married	ref				
Single	-0.713	0.519	0.170	-1.730	0.305
Widowed/divorced	-0.241	0.344	0.484	--0.916	0.434
Ethnic group					
Amhara	ref				
Oromo	0.512	0.250	0.040	0.023	1.002
Others**	0.652	0.334	0.051	-0.003	1.306
Religion					
Orthodox Christian	ref				
Muslim	0.413	0.277	0.135	-0.129	0.955
Protestant	0.261	0.304	0.391	-0.335	0.856
Type of anesthesia					
General anesthesia	ref				
Spinal anesthesia	0.393	0.247	0.112	-0.091	0.876
Ketamine anesthesia	-0.176	0.322	0.586	-0.807	0.456
Chronic pain severity	0.036	0.048	0.459	-0.059	0.130
Type of surgery					
General surgery	ref				
Gynecologic surgery	0.178	0.179	0.320	-0.173	0.528
Orthopedic surgery	0.531	0.455	0.243	-0.361	1.423
Time since surgery	-0.010	0.007	0.143	-0.023	0.003
Pain intensity					
Least pain	-0.122	0.119	0.304	-0.355	0.111
Current pain	-0.210	0.149	0.158	-0.503	0.082
Time in pain	-0.011	0.005	0.028	-0.020	-0.001
Pain interference with function					
Activities in bed	-0.202	0.097	0.037	-0.392	-0.012
Movement	-0.036	0.055	0.517	-0.145	0.073
Breathing and coughing	0.053	0.050	0.291	-0.045	0.151
Sleeping	0.258	0.107	0.016	0.049	0.468
Pain interference with emotions					
Anxiousness	-0.063	0.057	0.271	-0.174	0.049
Treatment side effects					
Nausea	0.056	0.055	0.308	-0.052	0.164
Drowsiness	-0.124	0.088	0.159	-0.296	0.048
Dizziness	0.073	0.079	0.359	-0.083	0.228
Perception of care					
Relief received	0.031	0.010	0.002	0.012	0.051
Participate in decision	0.155	0.137	0.259	-0.114	0.425

****Tigre, Wolayta, Gurage, Kafa, Silte**

Ref = reference group; SE = standard error; 95% CI = 95% confidence interval.

4.2 Results of the semi-structured qualitative interview.

The purpose of this analysis was to further understand some aspects of postoperative pain management, that is hardly accessible from the quantitative analysis alone. This second part of the result section presents the barriers and facilitators to effective post-surgical pain management in the country.

4.2.1 Study participants

Emerging themes were classified as HCPs related barriers, patient-related barriers, and health care system-related barriers. These are presented as follows with respective subthemes and example quotes.

4.2.2 Healthcare professional related barriers

The fact that no pain scale measures were used to assess patients' pain intensity, poor availability of opioids and fear of associated side effects, hindered quality postoperative pain management, from the perspective of HCPs' and hospital officials. HCPs' lack of empathy and lack of education were also identified as barriers to effective postoperative pain management from all participants' point of view.

4.2.2.1 Healthcare professionals lack of empathy

The feeling of "I am on my own" was the most commonly shared thought of patients according to the interviews. Patients frequently expressed how they felt neglected by professionals, who paid no attention to their level of pain after the surgery. To them (patients) it seemed as if providers were little interested and not willing to listen or treat pain after surgery.

> *"Professionals should consider themselves in our situation. Whether the wound is big or small- it does not matter, the pain is the same to us. They [professionals] always say its ok; this is small. Doctors should be able to communicate with us…you know…we should be close to them. Professionals should have the attitude of servants, not masters. They [professionals] have to show us compassion". (Hospital 1, patient, prostatectomy, male, 50)*

Also, HCPs and hospital officials admitted a lack of lack of empathy in the care of pain after surgery, because most HCPs had not yet undergone surgical interventions themselves.

"Because we (professionals) never went through the operation, most of us have no idea what it is like to be in pain. What can you do you cannot cut and suture them [professionals]. It is the way it is. Pain is related to experience; they don't have the experience, so they will not manage it". (Hospital 2, HCP, Anesthesiologist, male, 57)

4.2.2.2 Lack of emphasis on pain during education

Most professionals expressed that the undergraduate medical curriculum neglected the topic of pain while it strongly emphasized infection or other medical problems.

"…If one patient did not receive proper pain treatment, they [professionals] don't understand the consequences. Then the patient suffers, develops chronic pain and will be discharged with the pain. He will eventually return with pain as a complaint. Nobody will find the pain because you cannot find it in the laboratory. So most likely he will end up in the psychiatric wards". (Hospital 2, HCP, Gynecologist, male, 44)

Even during in-service training both, the duration and the access to the training were not perceived satisfactory.

"*For example, there are 500 nurses, and for the training, only 50 will be selected. Then it is declared the training has been given to all professionals. Moreover, the trained professional does not share what he or she learned from the training with the rest of the team. It is much better if the training includes all the nurses who are part of the care" (Hospital 2, HCP, Nurse, male, 44).*

4.2.2.3 No use of pain scales

Not applying pain measurement scales was more frequently echoed by HCPs and hospital officials. They expressed that most of them measured pain subjectively, instead of a standard pain rating scale. HCPs mentioned the use of the patients' facial expression and "general condition"—as they put it - to evaluate patients' level of pain and make a decision about administering analgesics.

"We take into consideration the type of surgery to give analgesics. Most of the time, if the patient underwent thoracic surgery or had a bone fracture, we will use strong analgesics if available. If it is an abdominal surgery, these are less painful, so we use less strong analgesics. We then follow the patients to see if they are complaining of pain. This is critical.……this is to identify whether the pain is from the surgery itself

or whether it is something else……like infection development or wound healing……you just have to take patients general condition and facial expression into consideration to decide how severe their pain is. This what we use to measure pain in our setting" (Hospital 3, HCP, Surgeon, male, 35).

How the patient asks for pain medication was also crucial for HCPs to decide whether the patient is in pain or not.

"The way the patient asks for analgesics matters. Some exaggerate the smallest pain, while others bear the unbearable…If the patient nags you the whole day and complains a lot, we then communicate his surgeon and senior physicians to respond". (Hospital 3, HCP, Nurse, female, 37)

4.2.2.4 Fear of side effects and dependence

Professionals were afraid of opioid-related side effects in particular with respect to legal issues. In order to be on the "safe side" and avoid accountability, professional mainly relied on NSAIDs, despite the knowledge about their limited efficacy.

"Narcotics are not available like other analgesics, but even if available there is a worry. This worry of respiratory depression, because of the drugs. Professionals to be on the safe side and avoid legal consequences, they intentionally avoid them. Also because these drugs are prone to abuse (addiction) the chance of these drugs reaching the hand of the professional is also rare" (Hospital 3, HCP, Anesthetist, male, 45).

Also independent of the particular attitude towards opioids, most professionals perceived that it was not wise to give analgesics every time the patient complained due to the risk of side effects.

"The surgery is part of the care, so there will always be a pain. Even when the wound starts to heal, and the skin begins to close naturally, there is a pain. So, every time the patient complains about the pain I don't think it is appropriate to give analgesics. Otherwise, there will be adverse effects" (Hospital 1, hospital official, Nursing unit director, 48, male)

4.2.3 Patient-related barriers

The socially anchored attitude towards pain, the attitude of patients towards analgesics and combating pain rather than asking for relief were identified as barriers related to postoperative pain.

Positive social appraisal of pain bearing behavior

Professionals stated that pain bearing behavior is usually viewed positively by people. Before coming to the hospital disease management commonly included painful techniques such as applying a fire hot sickle to the skin. Such traditions, according to hospital officials, have contributed a lot to undermining and disregarding pain by focusing on the disease.

> *"Our society usually, while suffering from different disease [pain] uses a fire hot sickle to be applied to the skin. Besides, they don't ask for analgesics, even if they wish to, because they feel doctors or the nurses, might not take this behavior positively and might end up affecting their relationship with the professionals and ultimately their care" (Hospital 3, hospital official, medical director, male, 33)*

Most patients perceived post-surgical pain as something simple, temporary and something that would go away with time and healing. They expressed how they were preoccupied with the healing of the wound and returning home as quickly as possible, instead of worrying about the pain.

> *"I have no idea. I let them [professionals] do as they wish to do. Also, they told me its minor pain. So, I didn't care too much. I just want to heal and go back home" (Hospital 2, patient, cholecystectomy, male, 36)*

4.2.3.1 Combating pain

On the other hand, patients also preferred to tolerate and battle even severe pain rather than use analgesics.

> *"When I have pain I forcefully close my eyes and sleep…I don't ask for analgesics...oh…aha… because I don't know…..they [professionals] also told me it is a minor procedure, so I did not pay a heed to it " (Hospital 2, patient, open reduction internal fixation, male, 61)*

This idea was also found in some of the responses given by participating HCPs. They stated that pain was not an alarming sign e.g. as compared to other signs of infection.

> *"Our patients, actually we [professionals] and our people in general, can [try] bear pain. For example, when someone says I have a fever and I have pain, we don't react the same way. When you hear someone has a fever you tremble, if it is a pain you just take it lightly" (Hospital 2, hospital official, deputy, matron office leader, male, 36)*

According to professionals, this kind of tradition has established in the hospital setting a long time ago.

> *"There is an existing trend, for a long time that patient has to be able to beat the pain and professionals will not respond quickly, while the patient is in pain and groaning." (Hospital 1, HCP, Surgeon, female, 40)*

HCPs stated that patients also liked to wait until the pain would go away by itself or would heal completely rather than depend on the analgesics.

> *"Sometimes they withstand the pain and say it will go away by itself. They don't want to take drugs especially those with previous surgery history. They prefer to cope with it in their own way". (Hospital 1, HCP, Gynecologist, female, 36)*

4.2.3.2 Analgesics do not heal the wound

To some patients, analgesics were not any help in healing the injury. They didn't take analgesics because it would only take away the pain but would not cure the disease (wound).

> *"They give me analgesics; I feel ok then, after a while I will again feel pain. Pain will not go away with drugs. You feel better when the wound heals." (Hospital 3, patient, myomectomy, female, 35)*

4.2.3.3 Fear of side effects and dependence

Just as HCPs, patients were afraid of side effects of analgesics. Many would prefer not to take any drug because of concerns about developing dependence, addiction or other side-effects. To most of the patients, analgesics have many complications and side effects, which is why it is better to recover without the help of drugs.

"I don't want my body to depend on drugs to heal, at all. It is better to move around and forget about the pain, than taking drugs every time you feel pain". (Hospital 1, patient, mastectomy, female, 50)

Professionals also ascertained that the patient's fear of side effects was sometimes a significant challenge for them to treat the patients' pain accordingly.

"There are occasions were; we offer pain medication and the patient themselves, refuses because of fear of addiction and side-effects……even while the patient is in severe pain, they refuse to take drugs because of fear of side effects" (Hospital 2, HCP, nurse, male, 44)

4.2.4 Healthcare system-related factors

Low physician-and nurse-to-patient ratios, a lack of resources, insufficient follow-up and absence of regulations by hospitals were identified as healthcare-related obstacles to effective postoperative pain management.

4.2.4.1 Healthcare professional to patient ratio

The physician- and nurse-to-patient ratios were among the most frequently mentioned barriers. Both hospital officials and HCPs pointed out that in the wards only a small number of providers was available for a large number of patients.

"In the ward, there might be 40, 50 patients, and there are only 5 or 4 nurses. Imagine, how could you give a better care …because of work overload you feel weary. When you work for many years, this leads to exhaustion and wearing." (Hospital 1, HCP, Nurse, female, 37)

4.2.4.2 Availability of resources

The high costs of narcotics and the lack of opioid supply were further significant challenges mentioned by HCPs and hospital officials.

"Take pethidine. It's around 16 ETB inside the hospital pharmacy, but outside in the pharmacy shop it costs about 80 or 90 ETB. Especially morphine, it's unthinkable, it's the cheapest analgesics in most other countries, from my experience, but in Ethiopia, a single injection ampule costs about 107-115 ETB. (Hospital 2, HCP, Anesthesiologist, male, 57)

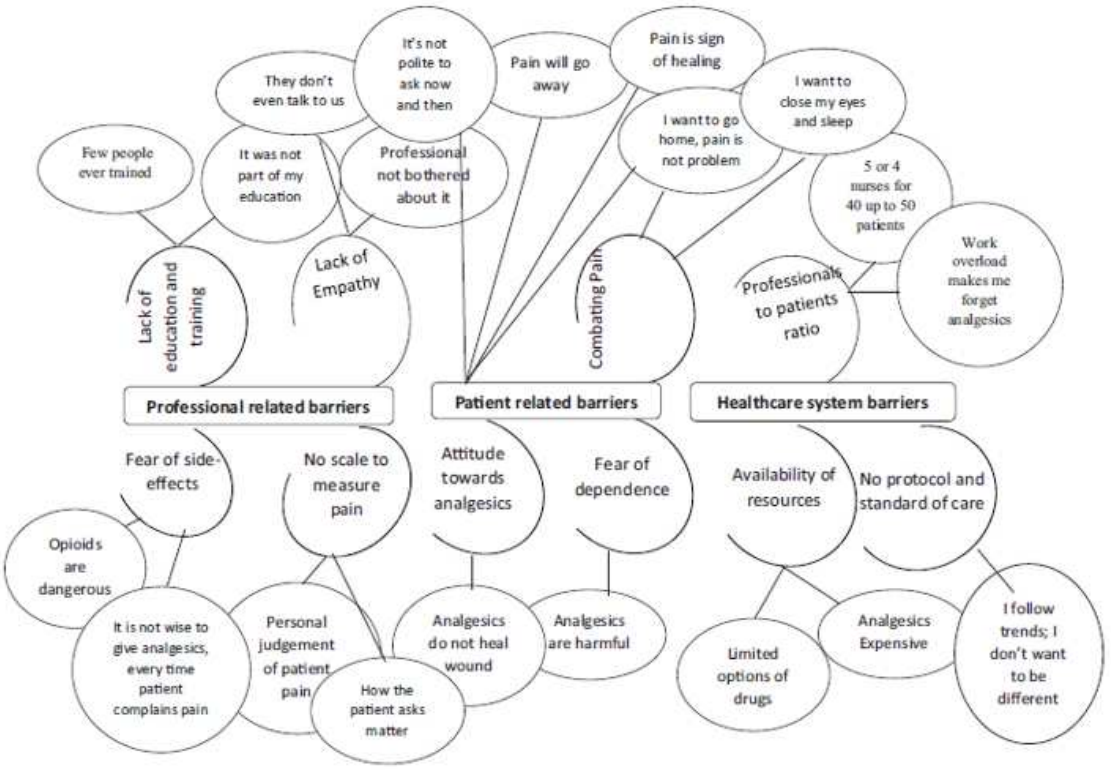

Figure 4.4: Lists of emergent themes that influence effective postoperative pain management

4.2.4.3 Healthcare priority

Hospital officials mentioned that the health policy of the country should pay the same attention to postoperative pain as it pays on anti-microbial and other infectious diseases.

> *"There is a pain-free initiative just initiated by the ministry of health. This should be strengthened and continued. The commitment shown to the infectious disease should be extended to pain also" (Hospital 2, hospital official, general dean, male, 34)*

4.2.5 Facilitators of postoperative pain management

HCPs and hospital officials gave insights into how to overcome the above-mentioned barriers. We have categorized emerging themes into HCP and patient level solutions in contrast to health care system level solutions. Subthemes within each of these themes are described on the following pages without any specific hierarchy/order.

4.2.5.1 Healthcare professional and patient-level solutions

A continuous education to professionals and patients were identified as facilitators of the provision of adequate post-surgical pain treatment. According to them, the HCPs' knowledge, skills, and attitudes are the starting points. HCPs stressed that the education should be carefully designed to improve their communication skills, cultural competency, and ethical norms in order to help them to provide a respectful and compassionate care. Hospital officials, on the other hand, recognized adequate supply of analgesics, continuous supervision, the establishment of policies, and standards of care to be crucial.

4.2.5.1.1 Providing in-house/on-job training for healthcare professionals

They [HCPs and hospital officials] argued that the lack of emphasis (if not ignorance) on pain and its management in the undergraduate medical and nursing curriculum can be addressed by the hospitals themselves when training young HCPs.

> *"If possible, we need to intervene in the pre-service education. In the same way we teach them to give anti-malarial drugs for malaria patients, they should be able to manage patient's pain after the operation. Especially during their internship period a lot can be done. We need to start regarding pain as a disease" (hospital 1, hospital official, clinical director, male 35)*

4.2.5.1.2 Enhance the ability of healthcare professionals to create favorable rapport with patients

Patients and some professionals felt a lack of harmonious relationship between professionals and patients, which affected patient's psychology and emotions. Providers and officials believed that in order to create a favorable caring environment for the patient education of HCPs should be extended by ethics and psychology in addition to physiology and pharmacology of pain.

> "*Patients are not a mere bone and flesh. They have psychology and emotions. I think pain management should start with this attitude. They are in pain. You don't have to be an additional cause. You need to be considerate, and the best way to achieve this is to teach medical professionals about ethics, norms and compassionate care in addition to the usual anatomy and physiology*" (*Hospital 2, HCP*, *Anesthesiologist, male, 57*).

4.2.5.1.3 Increase the cultural competence of professionals

HCPs and hospital officials recommended modifying the pain education curriculum by cultural competency since the society in Ethiopia consists of many different ethnic groups.

> *"We need to increase the cultural competency of professionals. They have to know in detail for whom they are caring and who they are trying to cure. They should be familiar with their way of life, how they perceive, react and treat pain. We are so diverse in culture and language, what…aha…about 83 different languages and 200 different dialects" (Hospital 3, hospital official, Medical director, male, 33).*

4.2.5.1.4 Patient education

It was the typical response given by HCPs that patient education was import to improve postoperative pain management. For most of all, the patient should consider pain management as their right and should be demanding and insisting on anti-pain, without any hesitation.

> *"Patients should say, "anti-pain is my right!". They need to be trained [modern], should be familiar with pain assessment scales and encouraged to tell his/her feelings without any hesitation. Since most of them [patients] believe this to be part of the care they tend to beat/bear the pain, we should first and foremost discourage such behavior" (Hospital 1, HCP, Surgeon, female, 40).*

4.2.5.2 Healthcare system level Solutions

Strong supervision of post-surgical pain management, provision of adequate supply of drugs and establishment of protocol and standard of care were major recommendations, by the HCPs and hospital officials.

4.2.5.2.1 Rigorous supervision of apprentices to practice postoperative pain management

There was an urge for clear, even legal consequences of neglected postoperative pain management. Those responsible should be held accountable. Someone should be held responsible. One suggestion was to establish task force.

> *"We need to have a clear policy of pain management in the hospital. This way you can influence professionals to be serious about it. And then you can hold responsible anyone who is not abiding…..there should also be a multi-*

disciplinary task force who shall research the issue in detail and develop a guideline" (hospital 2, hospital official, general dean, male, 34).

4.2.5.2.2 Provision of adequate drugs

Improvement of the provision of analgesics both regarding type and quantity was the most frequently suggested prerequisite to adequate postoperative pain management by HCPs and hospital officials. The latter also suggested a financial and budgetary support, which explicitly should aim at establishing a standard quality postoperative pain management.

"There are drugs even not available on the market. They should be available. The country should also make sure these drugs are in the essential drug list…..some drugs are not being brought in by the ministry of health. We don't have easy access to these drugs; we should" (Hospital 1, HCP, surgeon, female, 40).

4.2.5.2.3 Establishment of a guideline for postoperative pain management

HCPs and hospital officials suggested that the health care system should be involved with postoperative pain management, as it directly affects the outcome of surgical patients. There should be a clear guideline stating explicitly how postoperative pain should be managed in the hospital.

"….Advocacy is the most important thing, but as a health system we should be able to develop a protocol and establish a policy…." (Hospital 1, hospital official, clinical director, male, 35)

4.3 Results of complete data analysis from the quasi-experimental controlled before after study

4.3.1 Reliability and validity of the instrument used

In order to test whether the intervention is effective or not, it was deemed appropriate to test first, whether the instrument demonstrated an acceptable reliability and validity. First, assessed the psychometric properties of the IPOQ in terms of construct validity, internal consistency, and factor structure. Before exploratory factor analysis, the Kaiser-Meyer-Olkin (KMO) test

and Bartlett's test of sphericity were calculated to evaluate the factorability of the correlation matrix. The KMO measure of sampling adequacy was 0.8587 and the significance of Bartlett's test of sphericity was less than 0.001, confirming the suitability of the respondent's data for EFA [213]. Principal component analysis with varimax rotation was used. The factor analysis generated a four-factor solution (Eigenvalue >1.0), explaining a total variance of 64.8 %. The factor loadings per item are displayed (See Supplementary Table 8.1.1). The overall internal consistency of the IPOQ in our sample, based on Cronbach's alpha among all items, was 0.86. Regarding IPOQ sub-scales, all four present acceptable values. The pain intensity and physical interference scale achieved Cronbach‟s alpha (r=.87), followed by "affective emotions‟ (r=.89) and "adverse effect (r=0.73) "perceptions of care‟ (r=.62). All the above parameters were consistent and very much comparable with the reports of the original authors [214], except for the four-factor solution where the original authors reported 3-factor structure. However, the phase-one data of the original authors reported four-factor solution with a total explained variance of 60.78% [214, page=1368], which is consistent with our findings. As it is a common practice in the field to do so [19], discriminant validity was assessed by comparing surgical category of patients. Mann-Whitney U tests and chi-square tests were used to compare groups. Because of the small proportion of orthopedic and gynecologic patients, the two were combined together and compared with the general surgical patients. Except for least pain intensity, pain interference with sleeping, pain interfering with activities out of bed, patient perceived pain relief, and patient satisfaction, for all 12 NRS items a significant difference between the general surgery and comparative (orthopedic and gynecologic patients combined) groups was observed (see Supplementary Table 8.1.2). Almost all (except the percentage of time patient spent in severe pain) pain intensity items, both items on affective impairment and 2 interference items, were significantly higher in the group where orthopedic and gynecologic patients were combined. All 4 adverse effects measures were also increased in the same group of patients.

4.3.2 Participants' Characteristics

Figure 4.5 shows the study flowchart. No baseline measures were balanced across the treatment and control groups. Rather, patients in the treatment group were significantly older, more illiterate, Muslim, married, Oromo by ethnicity, underwent spinal anesthesia, had an orthopedic and gynecologic surgery, had a less duration of surgery, and lower chronic pain intensity (Table 4.11).

Table 4. 11: Baseline characteristics of the sample by condition (Intervention and Control Group).

	Control	Treated	p-value
Age, mean (SD)	40.52 (15.9)	37.69 (17.2)	<0.001
Sex			
Male, n (%)	241 (58.3)	123 (43)	<0.001
Educational Status			
Literate, n (%)	324 (69.7)	125 (53.2)	<0.001
Religion			
Orthodox, n (%)	349 (75.1)	77 (32.8)	<0.001
Marital status			
Married, n (%)	331 (71)	177 (75.3)	0.015
Ethnicity			
Oromo, n (%)	112 (24.1)	156 (66)	<0.001
Types of Surgery			
General, n (%)	378 (81.3)	113 (48.1)	<0.001
Types of Anesthesia			
General, n (%)	350(75.7)	158(67.5)	<0.001
ASA-Physical Status			
I, n(%)	459 (98.7)	212 (90.2)	<0.001
Duration of surgery in hours, mean (SD)	1.85 (0.9)	1.47 (0.9)	<0.001
Chronic pain severity, mean (SD)	4.9 (2.7)	2.5 (2.4)	<0.001

Total n=700 ; Treated n=231 ; Control n=469

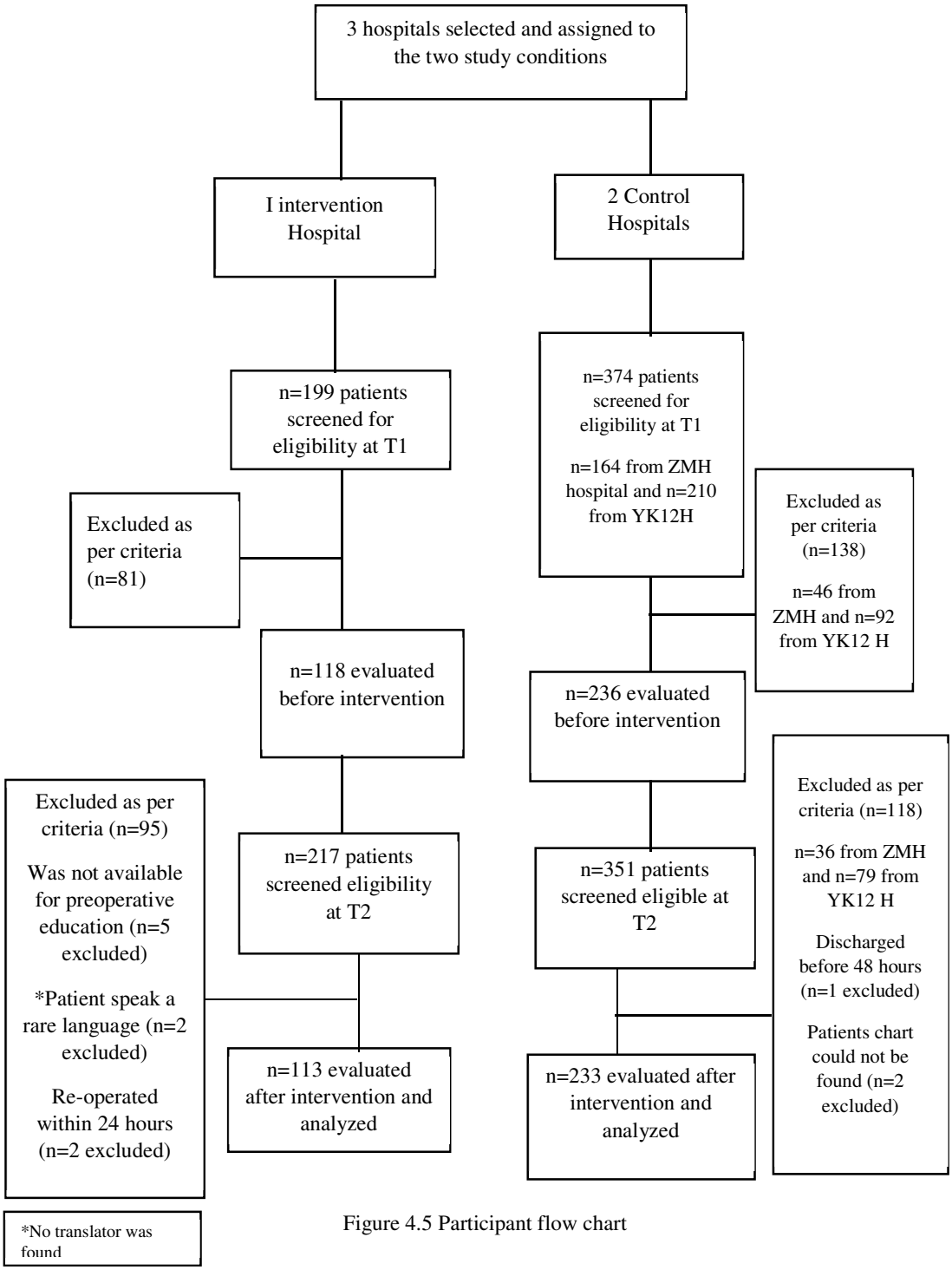

Figure 4.5 Participant flow chart

4.3.3 The effectiveness of the intervention

Generally, both the weighted and unweighted models gave consistent results for all pain intensity measures except for patients' worst pain intensity and for all the pain interference measures except for pain interference with sleeping and pain causing the feeling of anxiousness. The interaction Group (treatment vs. Control) × Time (6, 12, 24 and 48 hours) was significant for most outcome measures, implying the groups differed in rate and manner of change over the course of the study. Patients in the treatment group had scored lower worst pain intensity score at the second (β=-1, 95% CI (-1.649, -0.359)), third (β=-1.553, 95% CI : (-2.23, -0.875)) and fourth (β=-2.000, 95% CI :(-2.822, -1.178)) measurement points respectively (Table 4.12). However, in the weighted model, significant changes were observed at the third and fourth measurement points. Both weighted and unweighted model revealed that patients in the treatment hospital had a lower score of the percentage of time patient spent in severe pain at the last measurement point (β=-0.80, 95%CI : (-1.25,-0.35)). The same consistent results were obtained between the weighted and unweighted models for both least and current level of pain at the fourth measurement points (β=-0.73, 95% CI= (-1.21, -0.24) and (β=-1.34, 95%CI : (-2.38,-0.31)) respectively. The treatment group had lower pain interference with activities in bed score at the second (β=-0.90 95%C. I : (-1.46,-0.34)), third (β=-1.00, 95%C. I : (-1.75, -0.25)) and fourth (β=-1.89, 95% C.I (-2.78, -1.01)) time points. Pain interfere with movement was improved in the treatment compared to the control (β=3.13, 95% CI : (-4.63, -1.63)), (β=-3.14, 95% CI : (-3.94, -2.35)), (β=4.19, 95% CI : (-5.22, -3.17)) at the second, third, and fourth measurement points respectively. Pain interference with breathing and coughing was also significantly lower in the treatment group at the third and fourth measurement points (β=-0.73, 95% CI : (-1.30,-0.15)), (β=-1.26, 95% CI : (-1.87, -0.64) respectively. However pain interference with sleeping was not significantly different between the two groups in the weighted model, and only at the last measurement point in the unweighted model (Table 4.12). The treatment also lowered pain causing the feeling of anxiousness at the last measurement point (β=-0.94, 95% CI : (-1.59, -0.28)) in the weighted model and in the second and last measurement point in the unweighted model. Consistent results were observed for the score patients' feeling of helplessness, where the treatment group has lower score at the last measurement points (β=-0.84, 95% C.I : (-1.43, -0.25)). Patient participation in decision-making was significantly higher in the treatment group at the second measurement points only (β=3.81, 95% C.I : (2.69, 4.93)). Patients' satisfaction with the treatment remained unaffected by the treatment. The proportion of patients in the intervention group who were inadequately

treated declined over time except at 48 hours before the intervention. Before the intervention, about 87% of patients were inadequately treated, however, after the intervention 55% of patients were inadequately treated at 6 hours after the surgery in the treatment group. The same way before the intervention about 72% of patients were inadequately treated in the treatment group and it dropped to 46% after the intervention. However, the proportion of patients inadequately treated increased from 30% to 41% and from 1% to 23% at the 24 and 48 hours after the surgery respectively. The same trend was observed in the control group that patients inadequately treated increased at the 24 hours and 48 hours. Both before and after the treatment patients in the treatment group were inadequately treated. After the treatment, about 70% of patients also received acupuncture treatment for postoperative pain in the intervention group.

Table 4.12 Doubly robust and unweighted analyses of change from baseline in outcome measures

		Linear Mixed Effect					
		Weighted			Unweighted		
Worst pain		β(SE)	95% C.I		β(SE)	95% C.I	
	Treatment	2.19(0.29)**	1.63	2.75	2.42(0.23)**	1.96	2.87
	Time (h)						
	12 h	-0.43(0.10)**	-0.62	-0.24	-0.45(0.10)**	-0.65	-0.24
	24 h	-0.82(0.10)**	-1.02	-0.62	-0.86(0.10)**	-1.06	-0.66
	48 h	-0.85(0.12)**	-1.09	-0.62	-0.91(0.10)**	-1.11	-0.70
	Treatment x Time (h)						
	Treatment x 12 h	-0.22(0.26)	-0.72	0.28	-0.54(0.21)*	-0.95	-0.12
	Treatment x 24 h	-0.66(0.31)*	-1.26	-0.05	-1.06(0.21)**	-1.48	-0.64
	Treatment x 48 h	-1.68(0.23)**	-2.13	-1.22	-1.82(0.21)**	-2.24	-1.41
Least pain							
	Treatment	0.77(0.24)**	0.30	1.25	0.80(0.20)**	0.40	1.20
	Time (h)						
	12 h	-0.26(0.08)**	-0.41	-0.10	-0.24(0.09)*	-0.41	-0.07
	24 h	-0.73(0.09)**	-0.90	-0.56	-0.74(0.09)**	-0.91	-0.56
	48 h	-0.76(0.10)**	-0.95	-0.57	-0.78(0.09)**	-0.95	-0.60
	Treatment x Time (h)						
	Treatment x 12 h	-0.15(0.17)	-0.47	0.18	-0.22(0.18)	-0.57	0.13
	Treatment x 24 h	-0.12(0.22)	-0.56	0.32	-0.28(0.18)	-0.63	0.07
					-0.78(0.18)**	-1.13	-0.43
Current pain							
	Treatment	1.88(0.33)**	1.24	2.52	1.82(0.22)**	1.38	2.26
	Time (h)						
	12 h	-0.50(0.10)**	-0.69	-0.31	-0.48(0.11)**	-0.69	-0.27
	24 h	-1.13(0.10)**	-1.34	-0.93	-1.14(0.11)**	-1.35	-0.94
	48 h	-1.40(0.12)**	-1.63	-1.16	-1.41(0.11)**	-1.62	-1.20
	Treatment x Time (h)						
	Treatment x 12 h	-0.17(0.27)	-0.70	0.35	-0.30(0.22)	-0.72	0.13
	Treatment x 24 h	-0.59(0.39)	-1.35	0.17	-0.62(0.22)**	-1.04	-0.19
	Treatment x 48 h	-1.34(0.53)*	-2.38	-0.31	-1.15(0.22)**	-1.57	-0.72
Time spent in severe pain	Treatment	-0.77(0.28)*	-1.32	-0.22	-0.88(0.26)**	-1.32	-0.26

	Time (h)						
	12 h	-0.22(0.09)*	-0.41	-0.04	-0.28(0.09)*	-0.38	-0.02
	24 h	-0.67(0.10)**	-0.86	-0.48	-0.62(0.09)**	-0.80	-0.43
	48 h	-0.59(0.10)**	-0.52	-0.39	-0.58(0.09)**	-0.75	-0.38
	Treatment x Time (h)						
	Treatment x 12 h	-0.16(0.18)	-0.52	0.21	-0.02(0.19)	-0.48	0.27
	Treatment x 24 h	0.01(0.20)	-0.38	0.39	-0.03(0.19)	-0.41	0.34
	Treatment x 48 h	-0.80(0.23)**	-1.25	-0.35	-0.77(0.19)**	-1.16	-0.41
Activities on bed							
	Treatment	1.99(0.33)**	1.34	2.64	2.19(0.27)**	1.67	2.71
	Time (h)						
	12 h	-0.09(0.12)	-0.32	0.15	-0.08(0.13)	-0.33	0.16
	24 h	-0.56(0.13)**	-0.83	-0.30	-0.59(0.13)**	-0.84	-0.35
	48 h	-0.97(0.14)**	-1.24	-0.70	-1.00(0.13)**	-1.24	-0.75
	Treatment x Time (h)						
	Treatment x 12 h	-0.90(0.29)**	-1.46	-0.34	-1.23(0.26)**	-1.73	-0.73
	Treatment x 24 h	-1.00(0.38)*	-1.75	-0.25	-1.30(0.26)**	-1.80	-0.79
	Treatment x 48 h	-1.89(0.45)**	-2.78	-1.01	-2.12(0.26)**	-2.62	-1.61
With movement							
	Treatment	4.57 (0.40)**	3.79	5.36	4.54 (1.28)**	2.03	7.06
	Time (h)						
	12 h	0.10 (0.26)	-0.42	0.62	0.14(0)	-0.32	0.60
	24 h	-0.53 (0.27)	-1.06	0.01	-0.51(0)*	-0.97	-0.05
	48 h	-0.78 (0.28)*	-1.34	-0.23	-0.66(0)*	-1.12	-0.20
	Treatment x Time (h)						
	Treatment x 12	-3.13(0.77)**	-4.63	-1.63	-3.01(1)*	-5.53	-0.49
	Treatment x 24	-3.14(0.40)**	-3.94	-2.35	-2.89(1)*	-5.39	-0.39
	Treatment x 48 h	-4.19(0.52)**	-5.22	-3.17	-4.28(1)*	-6.78	-1.78
Breathing & coughing	Treatment	1.56 (0.32)**	0.94	2.19	1.62(0.30)**	1.04	2.21
	Time (h)						
	12 h	-0.29(0.12)*	-0.53	-0.05	-0.31(0.12)*	-0.54	-0.08
	24 h	-0.52(0.12)**	-0.76	-0.29	-0.57(0.12)**	-0.80	-0.35
	48 h	-0.93(0.12)**	-1.18	-0.69	-0.95(0.12)**	-1.17	-0.72
	Treatment x Time (h)						

	Treatment x 12 h	-0.07(0.39)	-0.84	0.69	-0.31(0.24)	-0.77	0.15
	Treatment x 24 h	-0.73(0.30)*	-1.30	-0.15	-0.82(0.24)**	-1.29	-0.36
	Treatment x 48 h	-1.26(0.31)**	-1.87	-0.64	-1.37(0.24)**	-1.84	-0.91
Sleeping							
	Treatment	0.80(0.34)**	0.13	1.47	0.94(0.29)*	0.37	1.50
	Time (h)						
	12 h	-0.25(0.12)*	-0.49	-0.01	-0.24(0.13)*	-0.49	0.01
	24 h	-0.87(0.13)**	-1.13	-0.61	-0.89(0.13)*	-1.14205	-0.64
	48 h	-1.09(0.14)**	-1.37	-0.82	-1.08(0.13)**	-1.34	-0.83
	Treatment x Time (h)						
	Treatment x 12 h	-0.18(0.22)	-0.61	0.25	-0.40(0.26)	-0.91	0.12
	Treatment x 24 h	-0.48(0.35)	-1.17	0.20	-0.47(0.26)	-0.99	0.04
	Treatment x 48 h	-0.67(0.40)	-1.47	0.12	-1.06(0.26)**	-1.57	-0.54
Anxiousness	Treatment	1.92(0.37)**	1.20	2.65	1.89(0.36)**	1.18	2.59
	Time (h)						
	12 h	-0.12(0.11)	-0.33	0.10	-0.10(0.11)	-0.32	0.11
	24 h	-0.57(0.12)**	-0.80	-0.34	-0.56(0.11)**	-0.78	-0.35
	48 h	-0.82(0.12)**	-1.06	-0.58	-0.81(0.11)**	-1.02	-0.59
	Treatment x Time (h)						
	Treatment x 12 h	-0.43(0.25	-0.92	0.07	-0.64(0.22)**	-1.08	-0.21
	Treatment x 24 h	-0.43(0.26	-0.95	0.09	-0.39(0.22)	-0.83	0.05
	Treatment x 48 h	-0.94(0.33)**	-1.59	-0.28	-0.83(0.22)**	-1.27	-0.39
Helplessness	Treatment	1.38(0.36)**	0.68	2.09	1.32(0.36)**	0.62	2.03
	Time (h)						
	12 h	-0.15(0.11)	-0.36	0.06	-0.13(0.10)	-0.32	0.06
	24 h	-0.48(0.11)**	-0.69	-0.27	-0.47(0.10)**	-0.66	-0.28
	48 h	-0.66(0.11)**	-0.89	-0.44	-0.64(0.10)**	-0.83	-0.45
	Treatment x Time (h)						
	Treatment x 12 h	-0.22(0.20)	-0.62	0.18	-0.27(0.20)	-0.66	0.12
	Treatment x 24 h	-0.31(0.21)	-0.73	0.10	-0.28(0.20)	-0.67	0.11
	Treatment x 48 h	-0.84(0.30)*	-1.43	-0.25	-0.74(0.20)**	-1.13	-0.36
Relief received	Treatment	0.16(0.24)	-3.11	0.63	0.19(0.21)	-0.23	0.60

	Time (h)						
	12 h	0.33(0.14)*	0.06	0.60	0.28(0.13)	0.03	0.54
	24 h	0.72(0.16)**	0.41	1.03	0.63(0.13)**	0.38	0.88
	48 h	0.73(0.17)**	0.39	1.06	0.64(0.13)**	0.38	0.89
	Treatment x Time (h)						
	Treatment x 12 h	0.08(0.26)	-0.44	0.60	0.05(0.26)	-0.47	0.57
	Treatment x 24 h	-0.20(0.25)	-0.70	0.30	-0.19(0.26)	-0.70	0.33
	Treatment x 48 h	0.26(0.30)	-0.33	0.85	0.13(0.26)	-0.39	0.64
Participate in decision							
	Treatment	0.13(0.32)	-0.51	0.77	0.36(0.29)	-0.20	0.93
	Time (h)						
	12 h	-0.05(0.08)	-0.20	0.11	-0.04(0.19)	-0.42	0.33
	24 h	1.96(0.24)**	1.48	2.43	2.32(0.19)*	1.95	2.69
	48 h	-0.08(0.08)	-0.22	0.07	-0.07(0.19)	-0.45	0.30
	Treatment x Time (h)						
	Treatment x 12 h	-0.42(0.24)	-0.88	0.05	-0.21(0.39)	-0.97	0.55
	Treatment x 24 h	3.81(0.57)**	2.69	4.93	2.60(0.39)**	1.84	3.37
	Treatment x 48 h	-0.32(0.23)	-0.77	0.13	0.03(0.39)	-0.74	0.79
Satisfaction	Treatment	0.26(0.21)	-0.15	0.68	-0.05(0.25)	-0.53	0.44
	Time (h)						
	12 h	0.20(0.11)	-0.01	0.41	0.18(0.14)	-0.09	0.45
	24 h	0.54(0.13)**	0.29	0.79	0.53(0.14)**	0.27	0.80
	48 h	0.37(0.17)*	0.03	0.71	0.36(0.14)*	0.10	0.63
	Treatment x Time (h)						
	Treatment x 12 h	-0.15(0.17)	-0.48	0.18	0.03(0.28)	-0.52	0.57
	Treatment x 24 h	-0.32(0.25)	-0.81	0.18	0.04(0.28)	-0.51	0.58
	Treatment x 48 h	0.20(0.26)	-0.31	0.70	0.51(0.28)	-0.04	1.06

Weights are inverse propensity scores. Multivariate models included age, indicators for being female, ASA classification, types of surgery, types of anesthesia, duration of surgery in hours, chronic pain severity. Standard errors are robust in weighted models. Time (h) reffers to the time points after surgery. All models assume the control group and 6 hours after the operation as a reference group. **p<0.01 ; * p<0.05.

4.3.4 Mechanism of the intervention

4.3.4.1 Path a, of both figure 4.6 and 4.7

The purpose of the first mediation analysis was, to examine the role of the educational intervention (X) on postoperative pain intensity (Y) through the mediating pathway of patient participation in decision-making (M). The indirect, direct and total effects of each of the model are given in Figure 4.6. For the typical patient in the treatment group, there is clear evidence that the treatment (X) predict greater participation in decision-making (M). Compared to the control group patients in the intervention group had a predicted 3.07 unit higher participation in decision making, 95%CI:(2.69, 3.46). Even after adjusting for measured covariates including age, sex, type of surgery, type of anesthesia, baseline worst pain intensity and duration of surgery, path a, remained significant and treatment predicted 2.4 units higher participation in decision making 95% CI : (1.972, 2.707).

4.3.4.2 Patients' participation in decision making on pain intensity: Path b, of figure 4.6

The patient participation (M) to postoperative pain intensity (Y) slope for the average patient is -0.06 95% CI:(-0.19, 0.08), indicating that, for patients in the treated group for each additional unit increase in decision making, it did not predict reduced postoperative pain intensity.

4.3.4.3 Patients' participation in decision making on satisfaction: Path b, of figure 4.7

The unadjusted patient participation (M) to patient satisfaction (Y) slope for the average patient is 0.227, 95% CI :(0.125, 0.369), indicating that, for patients in the treatment group with each additional unit of patient participation in decision making, it predicted a higher satisfaction. However, when adjusted for baseline confounders the result is insignificant 0.018 95% C.I (-0.293, 0.267).

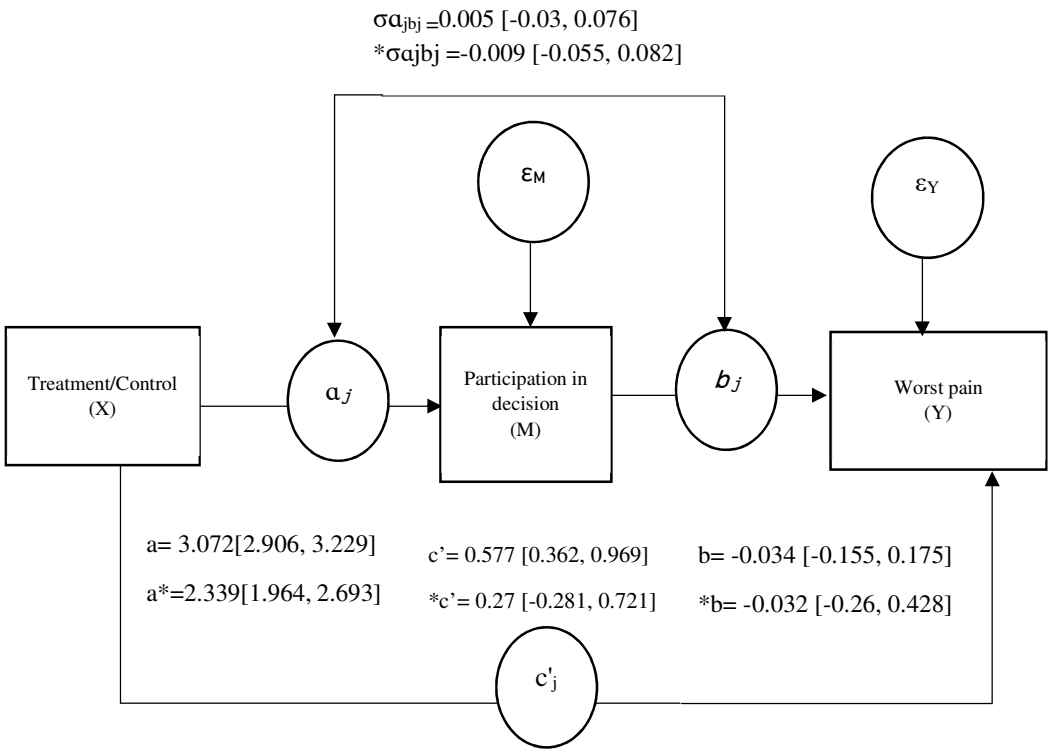

Figure 4.6 Within-subjects mediation for pain intensity (see Bolger and Laurenceau, 2013 [186]): To reduce confusion, we have omitted time as a predictor and we treat X, M, and Y as varying within-subjects only. These are the essential features of an actual within subjects mediation analysis. *Adjusted for age, sex, preoperative pain, type of surgery, type of anesthesia, baseline worst pain intensity and duration of surgery.

4.3.4.4 The indirect effect Path a*b, for Figure 4.6

The indirect effect (Path a*b) of treatment on postoperative pain intensity, with patient participation in decision making as the potential mediator, was not statistically significant for both, the unadjusted ab=-0.106, (95% CI: (-0.491, 0.538) and adjusted analysis ab=-0.075, 95% C.I (-0.592, 0.968). This means that if everyone in the study had the intervention and patient's participation in decision making increased by the mean difference between the control and intervention group, postoperative pain intensity would not change significantly from baseline.

4.3.4.5 The indirect effect Path a*b, for Figure 4.7

As expected from the results of Path a and Path b analysis results, the unadjusted path model, gave a significant indirect effect ab= 0.696 [0.385, 1.112]. That means, the indirect effect, of treatment on patient satisfaction, with patient participation in decision making as the potential

mediator, was statistically significant. Had everyone had the intervention, the patient satisfaction would have increased significantly from baseline when patient's participation in decision-making increases by it's the mean difference between the control and intervention group. However, the adjusted analysis showed an insignificant indirect effect 0.006, 95% C.I (-0.709, 0.601).

4.3.4.6 Covariance of Path a and Path b estimates: Figure 4.6

One of the most interesting aspects of multilevel mediation unlike to the usual between subject mediation is the presence of, the covariance of Path a and Path b estimates in the estimation of the indirect effect (see σαjb in Figure 4.6 and 4.7). Both the unadjusted and adjusted estimates were not significantly different from zero, with an estimate of σαjbj =0.005, 95% C.I (-0.03, 0.076) and αjbj =-0.009, 95% C.I (-0.055, 0.082) respectively. This indicates that those who had a higher participation in decision making, as a result of the education also do not have a lower worst pain intensity consequently.

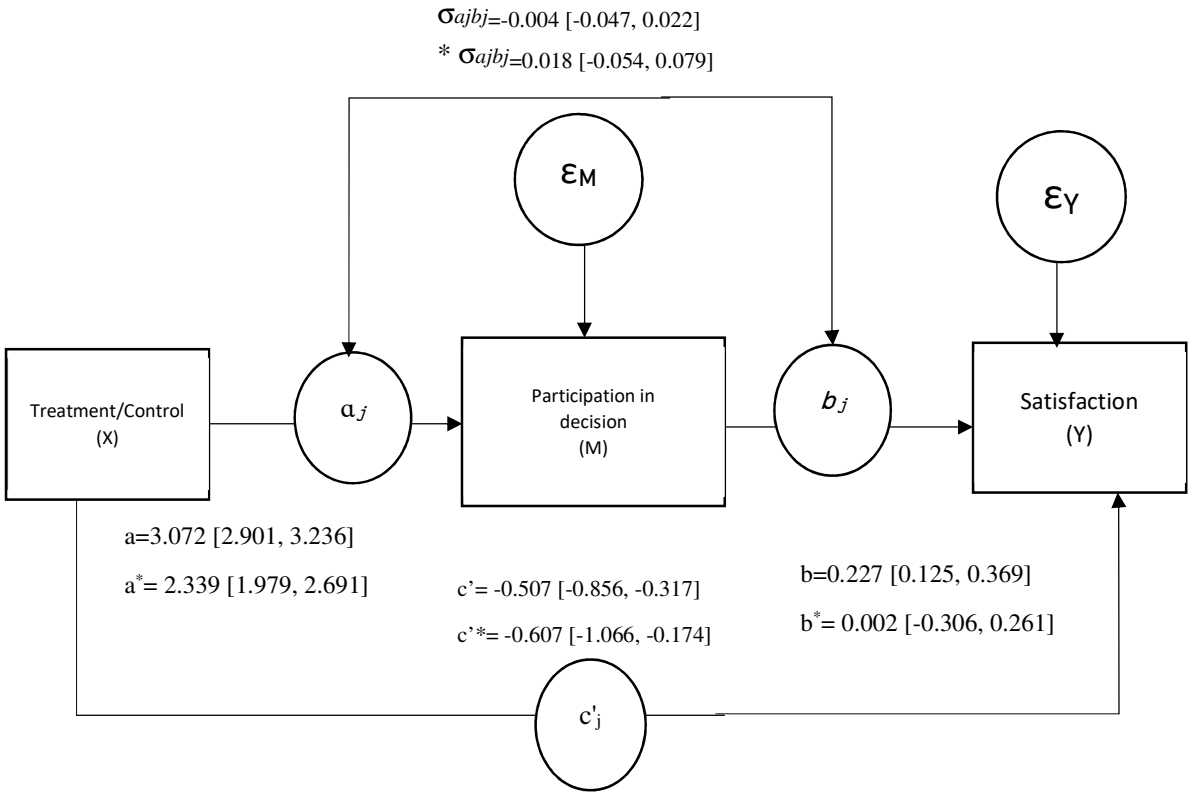

Figure 4.7 Within-subjects mediation for satsfaction (see Bolger and Laurenceau, 2013 [186]): To reduce confusion, we have omitted time as a predictor and we treat X, M, and Y as varying within-subjects only. These are the essential features of an actual within subjects mediation analysis. *Adjusted for age, sex, preoperative pain, type of surgery, type of anesthesia, baseline worst pain intensity and duration of surgery.

Covariance of Path a and Path b estimates: Figure 4.7

The population variance for this second mediation model was also insignificant. Both the unadjusted σαjbj=-0.004 [-0.047, 0.022] and adjusted σαjbj =0.022, 95% C.I (-0.051, 0.082) estimates were statistically insignificant. This means that those who had a higher participation in decision making, because of the education also do not have a higher reported satisfaction.

4. 3. 5 Summary of the results

Before the introducing the intervention, about 88% of postsurgical patients suffer moderate to severe postoperative pain at 6 hours after the operation. Patients also wished for more analgesics than prescribed for the most part of the postoperative periods. For example, 57% of the patients wished for more analgesics at 6 hours after the operation. Patients also did not receive any type of information regarding their options of postoperative pain management in all hospitals surveyed. The patients' pain was treated predominantly with tramadol (92.9%) and diclofenac (7%). The most prevalent non-pharmacological methods of pain management were talking to friends or relatives 88.3%. We have also observed that with increasing patients' years of age, the worst pain intensity decreases and with increasing in preoperative chronic pain ratings, worst pain intensity increases. Illiterate patients reported higher worst pain intensity scores than those with formal education. Sex, type of anesthesia, type of surgery, duration of the surgery and physical status did not affect patient's worst pain experience after surgery. Pain interference with the movement was moderate in intensity and ASA-2 patients reported higher interference than ASA-1 patients. As expected, compared to those who underwent general anesthesia with endotracheal intubation those after spinal anesthesia had higher ratings of pain interference with movement. The only pain intensity measure found to have a correlation with the patient's ratings of satisfaction was the time patient spent in severe pain. Also, an increase in pain interference with activities in bed decreases patient satisfaction. As the qualitative data suggest, HCPs' lack of empathy, the absence of pain education on most medical and nursing curricula, the fact that HCPs are not using pain scales to assess and document pain, together with the fear of side effects of the analgesics prevented the setting from providing high-quality postoperative pain management. Patients' positive social appraisal of pain bearing behavior, their tendency to combat pain and the deep rotted idea that "analgesics do not heal the wound" being prevalent in the minds of the patients further inflamed the

observed poor quality of pain treatment in the setting. Enhancing the ability of healthcare professionals to create favorable rapport with patients, increasing the cultural competency of professionals, regular patient education, rigorous supervision of apprentices to practice postoperative pain management, provision of adequate drugs and establishment of a guideline for postoperative pain management were the solutions proposed by the participants. Consequently, the the implemented intervention (patient and HCPs education) had showed a positive result for most of the quality indicators. Patients in the treatment group had scored lower worst pain intensity score at 12, 24 and 48 hours after surgery. In addition, patients in the treatment hospital had a lower score of the percentage of time patient spent in severe pain at 48 hours after the surgery. The treatment group had a lower score of pain interference with activities in bed and movement at all measurement points after the surgery. Pain interference with breathing and coughing was also significantly lower in the treatment group at 24 and 48 hours after the surgery. Interestingly patients' perceived pain relief and satisfaction remained unaffected by the intervention at all measurement points. Patient participation in decision-making was significantly higher in the treatment group only at 24 hours after the surgery. The proportion of patients in the intervention group who were inadequately treated declined over time except at 48 hours before the intervention. Before the intervention, about 87% of patients were inadequately treated, however, after the intervention 55% of patients were inadequately treated at 6 hours after the surgery in the treatment group. There was a very high use of non-pharmacological pain management options after the intervention in the treatment group (70%) received acupuncture treatment for postoperative pain relief.

5. Discussion

This discussion section is divided by the most important findings from each study. It is also followed by methodological considerations that a reader should bear in mind while interpreting the findings.

5.1 The quality of postoperative pain management in Ethiopia

The (pre-intervention) baseline analysis of the quasi-experimental controlled study, revealed that majority of participants (88.2%), had moderate to severe pain during at 6 hours after the

surgery. Such high prevalence might be comparable to studies conducted in the early 2000s; where a prevalence up to 86% has been recorded in the USA [215]. However, the percentage presented in our study is unacceptably high compared to recent studies from both developed [18] and developing countries [25], which reported the prevalence of 34% and 62% respectively. Even after two days of surgery (48 hours), 40% of patients were in moderate to severe pain, which is still higher compared to other settings in Africa [216]. Since most prevalence studies in the world are cross-sectional and employed non-uniform NRS cut-off point comparison is difficult. However large sample cross-sectional studies from Germany, for example reported ranged from 10% to 88% (NRS $\geqslant$ 5) [21], Spain to be 39.4% (NRS > 7) [22]. There is hardly any data on the prevalences and predictors of postoperative pain in Africa. However, the reported prevalence of moderate to severe postoperative pain ranges from 50% to 91% [24]. The observed large magnitude of pain could originate from reciprocation of heterogeneous, but interrelated factors. The first is poor knowledge and attitude of Health Care Providers (HCPs) towards pain; there is already an established evidence to support this argument [217]. Secondly, a lack of organizational commitment, resources and supervision could also inflame high prevalence of pain in hospitalized patients [29]. Thirdly, some authors argue, high pain scores to be an aftermath of inadequate doses of analgesics administered [218]. In connection with this, maybe the high frequency of negative scores we have observed from the calculated pain management index contributed partly. Tramadol alone was used predominantly (92.9%), followed by diclofenac alone (7%); which is again contrary to international recommendations [219]. This study also uncovered a mismatch between patients' pain intensity and strength of analgesics prescribed. The calculated PMI indicated, 58.4% of participants received sub-optimal pain treatment at the first 6 hours after the surgery; a study from China reported almost similar results [220]. A previous report from Ethiopia reported XX% of patients are inadequately treated [147]. No patients in this study received information regarding pain treatment options. One can not be surprised with this result, as there was no supervision of the HCPs practice of pain management or Acute Pain Services (APS) in the country [146]. In fact, a study conducted in Iceland reported, 70% of patients did not receive information regarding pain treatment options [221]. This is very much low compared to other settings. In Spain for example 63.3% received pain information [22]. In Europe by the year 2008, patients receiving pain information were reported to be 48.5% [222]. Nowadays, it is strongly recommended to give preoperative information to patients to improve acute post-surgical pain [105].

We have noted a link between intensity of pain and physical function interference. However, patient activities in bed were hindered to a higher degree of intensity than patient physical movement out of bed, because of the pain. It might be because patients will not move around out of their bed unless the pain drops down to a certain tolerable level to make mobility easier. Plus, this is affected by the nature of the surgical procedures; as orthopedic patients resume movement a bit later than non-orthopedic patients early in the postoperative period. This finding is similar to previous studies, which reported a positive correlation between intensity and interference of pain [223]. In line with other investigations, preoperative pain contributed to higher postoperative pain ratings [43, 224-226] . As no longer brain is considered adynamic organ, the effect of chronic preoperative pain on postoperative pain intensity can be interpreted by the principles of neural plasticity [227]. Using a transcutaneous electric sensation; previous researchers have reported preoperative back pain to be associated with central neuroplasticity in surgical patients [227]. We have detected a higher pain intensity ratings in the younger ages. The relationship between age and pain intensity is not new [40]. Previous, researchers have observed a decreased pain-related caudate and putamen activities of the brain among the healthy older compared to the younger adults [228]. Nevertheless, conclusive evidence is needed to determine whether older individuals underreport pain or lower pain sensitivity exists [226]. A blunted peripheral nociceptive function with increasing age [229] and the reduced influence of specific gene has also been reported [230]. In keeping with pain intensity, according to our results, it seems as if sex does not matter. A very recent study, affirm this by showing how age and preoperative pain could be confounders, instead of a real association [40, 41]. In a recently published review, sex differences in pain were found to be contradictory after orthopedic and abdominal procedures, and absent after oral surgery [41].

How ethnicity [58] and spirituality [231] affect patient post-surgical pain intensity has been examined, to the extent, pray and meditation intervention to be on the lists of non-medicine intervention [231]. Coming to our results both religion and ethnicity did not exhibit an association with patient's worst pain intensity. Nonetheless, those who are Oromo by ethnicity spent relatively less time with severe pain. The same for Muslims and Protestants, however, the information at hand neither confirm nor deny this finding; accordingly a larger nationwide cohort should explore to what extent these factors play a role.

Though it is puzzling, patients in this study despite high levels of pain intensity, reported a higher level of satisfaction. This “the severe pain-high satisfaction paradox” [232] seems a

regular finding [233, 234]. Interpretation of this paradox has been many-sided, and HCPs are caring attitudes towards patients was one possible explanation. It is to mean that HCPs compassionate care might cloud patient's pain experience and result in a better satisfaction [234]. From our qualitative study it seems quite the opposite (more on this later); as our patients criticize their respective HCPs for lack of empathy, when it comes to pain treatment. Also, postoperative pain might be unavoidable in the minds of patients, and there is a possibility to perceive it as something normal. Then, this, in turn, might affect how a patient perceives satisfaction [233].

Coherent with previous finding [56], neither age nor sex affected the patient's rating of satisfaction. Our results support previous reports which reported a negative correlation between satisfaction and time spent in severe pain and a positive relationship with that of perceived relief received [168]. A positive association between ratings of satisfaction and pain in interference with sleep was observed in the study. First, the overall level of pain interference with sleep in our sample was quite low, and so would not have the strength to negatively affect a larger number of patients' reports of satisfaction. Second, though not directly with pain interference with sleep, such unexpected findings are not uncommon when it comes to patient satisfaction with postoperative pain management. For example, a positive correlation between satisfaction and adverse events were observed previously [168]. Moreover, some believe the measure of satisfaction is not a reliable indicator of quality postoperative pain treatment and should not be used [235]. Although satisfaction with pain management currently is used as a measure of institutional quality, satisfaction with pain management is no longer recommended as a quality indicator for pain control. [143, 236]. This is because patient satisfaction findings are difficult to interpret. In their review of 20 quality improvement studies conducted between 1992 and 2001, Gordon and colleagues [237] noted 15 studies reported high satisfaction with pain management despite many patients experiencing moderate to severe pain during hospitalization. Thus, patient satisfaction data should be cautiously interpreted and, if used, used in conjunction with other quality indicators. Because of the current focus on report cards for healthcare organizations, patient satisfaction data are routinely collected and easily obtained for review [236]. Nevertheless, future investigations who pursue the matter— the relationship between pain interference and satisfaction, requires populations who have higher ratings of pain interference with sleep.

Lastly, the relationship between satisfaction and background ethnicity has been explored in previous investigations [223]. Though we have observed some link, we would not go far to resonate the same conclusion given our sample size. This study could not hint any association between the patient rating of satisfaction and worst, current, and least pain intensity; the result is similar to previous investigations [238] [234]. Hence, the findings contribute to growing data on the experience of pain treatment after surgery in low-resource countries; where absence research on the topic is one barrier towards upgrading the quality of pain treatment.

5.2 Why poor quality of pain management is observed

In the following sections, the results of the qualitative analysis are discussed. It will help the reader have a better perspective on the matter in detail. It explains the underlying causes that lead to high prevalence of moderate to severe postoperative pain, and inadequate treatment in the setting. It uniquely brings together the perspectives of HCPs', hospital officials', even patients' themselves. In general, patients felt that HCPs lack of empathy is the main reason for under-treatment of postoperative pain. HCPs agreed with these patients' emotion and associated with the lack of empathy with the low professionals to patient ratio in the wards. Professionals believe this lack of empathy is because of burnout, owing to the low professionals to patient ratios in the wards. Indeed, a recent systematic review of cross-sectional studies has confirmed a negative correlation between burnout and empathy [239]. However, the authors argue it is still difficult to establish causality from such an observational study. Rather a previous report, from the same setting, which reported a low emotional and cognitive empathy scores of medical students [240]; supports patients' point of view. This obviously might block HCPs from internalizing the patients' pain, which the patients are exactly stating. One should also bear in mind that whether burnout causes a lack of empathy or whether a lack of empathy causes burnout is still unclear [241]. For that matter, there are even studies which reported, a medical professional, if highly motivated, dedicated and emotionally involved in the work, might develop lack of empathy [242]. Given all these, it is difficult to ascertain that the lack of empathy is the reason for the observed poor quality pain management. For that matter, studies had reported that those professionals who are at risk for burnout are those who are emotionally over-involved and difficulty in recognizing one's own emotional state [243]. This means it is minimal empathy that is important [244] and burnout is only to happen if only professional is highly motivated, dedicated and emotionally involved in the patient care [243]. Hence,

professionals should ask themselves whether the reason for ignoring patients' pain is burnout or lack of empathy or it is just that they are now senior and become desensitized for others pain [244]. The bottom line is that patient should be listened, and an appropriate timely response is needed from the HCPs when patient are expressing their pain. In part, it also seemed as if patients were not convinced of the danger of untreated/undertreated postoperative pain themselves. Patients perceived postoperative pain as a natural consequence of surgery. They regard it as a minor phenomenon that goes away with time and tissue healing, without any damage. The patients' belief that pain is "not harmful" has been identified as a significant barrier previously [48]. Since HCPs not only supported but also endorsed this idea, the attitude became benevolent among patients. Surprisingly other studies confirmed that HCPs have the perception of postoperative pain being short-term and decipitating with time and tissue healing [48]. This contrasts the substantial evidence for long-lasting adverse effects of postoperative pain caused by sensitization of the peripheral and central nervous system [227]. This for that matter might be the main reason for the increasing incidence of CPSP in the world [32]. All these fallacious thoughts are borne out of a poor knowledge, skills, and attitude of HCPs towards postoperative pain. A lack of education and training is the most common barrier identified from previous studies and is of great concern for professionals from low-income countries [4]. Hospital officials also felt that this gap in education is due to a lack of emphasis on pain education inherent to the Ethiopian medical and nursing curriculum. Furthermore, hospital officials stressed that most of the undergraduate and even postgraduate medical and nursing curriculum focused on infectious and other "important" diseases while the pain was not treated fairly. The absence of pain education in medical, pharmacy and nursing curriculum has been highlighted previously as an obstacle to effectively manage pain [81]. Especially this is true in Ethiopia where a nationwide study confirmed HCPs in the country are not ready to assess and treat pain in general [146]. Data are available in the world, and the developed nations have already identified to what extent the undergraduate medical curriculum suffers from a lack of emphasis on pain and it's management [87]. Studies from the US, Canada, Finland and the UK already calculated the extent of damage and has been already a decade since, remedial actions in place [118, 138]. Even in India and Nigeria such studies exist [118]. In Ethiopia, the extent the disastrous omission of this important topic, as participants explained, has not been determined yet, and no published data is available. However, participants have stressed this lack of exposure to the topic in their both undergraduate and post-graduate training, and have admitted, the knowledge gap they have. Also, patients are not surprised when encountering

pain after the surgery, instead attempt to cope with it in their own way without the help of analgesics. For them, analgesics are the last options, should the pain becomes very much unbearable. To patients, it seems a better decision to avoid painkillers as much as possible and remain in pain. This "pain by choice" seems also a socially desirable behavior. Avoiding analgesics has been reported previously in post-surgical patients two decades ago [245] and is, in fact, a barrier worldwide [246]. For these reasons, it has been a while since preoperative education has been recommended as part of routine care to improve postoperative pain management [48] and, in fact, had been successful [245]. Sadly preoperative patient education was not part of the routine care in all the participating hospitals of this study. Furthermore, professionals confessed that they do not use standardized pain scales to determine whether the patient is in pain or not. HCPs only consider the patients' facial expression, the nature and type of surgery to assess the level of pain. Early studies highlighted that relying on patients' self-report or the HCPs' personal judgment of facial expressions, crying/moaning, were significant barriers to postoperative pain management in both developed [247] and developing countries [83]. Lack of pain assessment was one of the most problematic barriers to achieving good pain control and it has been reported consistently [237]. The most critical aspect of pain assessment is that it is done on a regular basis (e.g., once a shift, every 2 hours) using a standard format [248]. Similarly, many studies have reported an infrequent assessment of postoperative pain, and even when assessed the values are not properly documented [77]. This might even be the factor contributing to patients' perception of HCPs' lack of empathy. The reason is that use of standardized instruments can improve physician/patient communication, offer an opportunity for greater understanding into patients' pain and even inform the level of pain relief patient consider as acceptable [249].

On top of all these, resource-based limitations like the absence of strong analgesics like opioids, which are preventing them from effectively managing postoperative pain. Especially in Africa, a lack of resources has chocked the health care system from delivering quality postoperative pain management [250]. Globally, there is an enormous, increasing gap between the need for, and availability of, opioid analgesics, and this is increasingly skewed against people living in poverty [251]. There are two pictures of opioids crisis in the world. The opioid epidemic has claimed more than 300,000 lives in the United States since 20001 and the majority of persons with opioid addiction started with prescribed painkillers [252]. The too few opioids in LMICS is the other face of the problem, exposing patients to unnecessary sufferings, despite bearing

80% of the global burden of non-communicable diseases [253]. Of the 298.5 metric tonnes of morphine equivalent opioids distributed in the world per year, only 0.1 metric tonnes is distributed to low-income countries [254].

5.2.1 What can be done to improve the quality of care

5.2.1.1 In-house education

Regarding factors that facilitate effective postoperative pain treatment, providing in-house/on-job training for health professionals was proposed as first step measures by participants. Hospital officials also felt that the education should include topics that could enhance HCPs cultural competency and skills that enable providers to create a good rapport with patients. Good physician/patient communication is an essential component of the patient-centered approach, in order to achieve a common understanding of the patient's condition and expectations, as well as the proposed therapy and achievable treatment goals [249]. Participating HCPs also expressed that patient education should be part of the intervention. A most recent randomized controlled study recommended preoperative patient information as a tool to decrease patients' postoperative pain intensity and increase satisfaction [255].

5.2.1.2 Establishing Protocols and Guidelines

The most common facilitator suggested by participating HCPs and hospital officials were the establishment of guidelines, protocols, and accountability. The global evidence is in favor of the development and implementation of guidelines for high-quality health care [256]. Especially for low resource settings establishing policies, guidelines and protocols have been recommended for improving postoperative pain management [2]. Previous studies already confirmed that guidelines can help to hold HCPs accountable for inadequate care [257]. The absence of guideline created a favorable environment for HCPs to ignore postoperative pain management, as there are no consequences for under-treating the pain. Hence, hospital officials believe rigorous supervision of apprentice to practice postoperative pain management, provision of adequate drugs are also critical. All participants believe that protocols and guideline regarding postoperative pain should be established. Professionals also state that those who are in a managerial or leading position should make analgesics available, forming and investing policies reward the desired behavior regarding praise and recognition. Our findings suggest that in order to achieve sustainable improvement in postoperative pain management, a

fundamental rethink of the whole society is necessary. Systematically changing the social norm in which the professionals are interacting with, i.e., the setting can be changed by educating patients and their families. This is to mean that, when professionals are facing a demanding and aware patient, they will be forced to change their behavior because of the overwhelming social persuasion [258].

5.2.1.3 Understanding the barriers and facilitators using a theoretical framework

The above-discussed barriers and facilitators could be understood best using Albert Bandura's reciprocal determinism theoretical framework [259]. Reciprocal determinism is a theory which posits that any human behavior is determined by external environmental factors through social stimulus events and internal personal factors through the cognitive processes [260]. These factors affect the personal behavior in an unequal strength. Bandura [261], defined the environmental factors as social influences which include social persuasion, instruction, and modeling. Also, the personal factors are explained as internal factors which include thinking, believing, and feeling of people [261, 262]. Moreover, the personal factors include cognitive, affective and biological events [258]. In this model, the major relations that determine the actual practices are the relationship between the personal factors and the actual behavior, and the relationship between the environmental factors and the actual behavior. Figure 1.3 demonstrates the reciprocal determinism model [263].

According to reciprocal determinism, any human behavior is the result of external environmental factors (via social stimulus events) and internal personal factors (through cognitive processes) [259] . The internal personal factors, for example, include HCPs lack of empathy, lack of education on pain assessment and treatment, fear of side effects and dependence. Whereas the environmental factors include the social (patients) milieu with which HCPs are continually interacting with (e.g., patient attitude towards pain and analgesics) and the surrounding surgical ward environment (e.g., availability of resources, protocols, guidelines, regulation, professionals to patient ratio). Therefore, the poor practice of HCPs with regard to postoperative pain management is affected by these personal and environmental factors reciprocally (bi-directional) as shown in Fig 4.11.

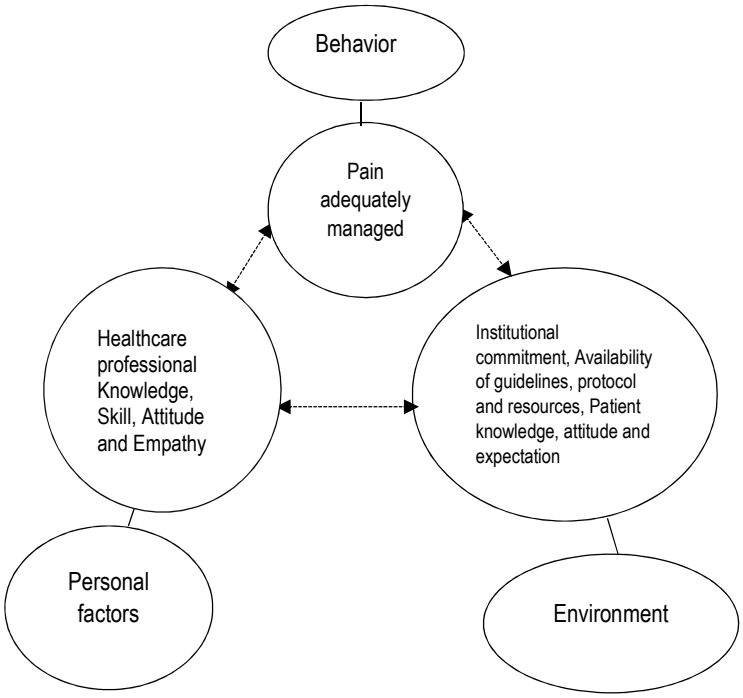

Figure 4.11 when conceptualizing postoperative pain management using Reciprocal determinism

Findings of this study demonstrated the social environment like; patients' willingness to suffer pain by avoiding analgesics, the inclination to combat pain and under-estimation of pain, in general, are likely to encourage HCPs to disregard patients' pain. In the same manner, the absence of a protocol and guideline have also removed the sense of accountability from HCPs. Hence, the environment is friendly to those HCPs who lack empathy, ignore postoperative management and had a negative attitude; which in turn creates a suffering patient. Coming to the personal factors; the inherent lack of training in pain management might have created an imperfect knowledge, skill, and attitude, which in turn led to having wrong beliefs and at the end a poor practice, again creating a suffering patient Fig 4.11. Thus, future intervention as well should be designed in the same manner carefully considering these SCT perspectives. For example, if an intervention only targets HCPs, it might be neutralized by barriers which are external to HCPs (like a patient and the environment). This is to mean barriers and facilitators of postoperative pain management are continually interacting with one another. A multi-

faceted intervention that aims at HCPs, patients and the organization as a whole, is more likely to be successful.

5.3 How effective is an education in improving the care

Here the discussion focuses on the results of the complete data analysis from the quasi-experimental controlled before-after study, which tested whether the implemented intervention was effective or not. A significant difference was observed between the treatment and control group, at least at one measurement point for all outcome measures, except for patients' satisfaction, perceived pain relief and pain interference with sleeping. For these outcomes, no significant difference were observed between the groups. In addition for almost all outcome measures, both the linear mixed effect regression and the doubly robust estimation demonstrated consistent results. The exceptions are only for worst pain intensity, pain interference with sleeping and pain causing the feeling of anxiousness. This is expected as the double robust technique is robust for model misspecification compared to linear regression methods [192]. Also, when covariate imbalances between the treated and control group are large, linear regression is expected to produce a biased estimate, especially when such covariates are also non-linearly associated with the outcome [264].

The other important result observed was that patients' worst pain intensity and pain interference with breathing and coughing were lower at 24 and 48 hours after surgery in the treatment group. Whereas, pain interference with activities on bed and with movement were lower in the treatment group at all measurement points. Outcome measures like patients' least and current level of pain, time spent in severe pain and patient participation in decision making were lower only at 48 hours after surgery. Observing significant effects at later postoperative periods compared to the early time-points could arise from the natural surgical ward contexts in the low resource settings, the nature of preoperative information itself and complex psychological phenomena.

There is a limit to what extent pain management can be successful without the use of strong analgesics. No matter how effective an education is, it is an adjunct treatment [105] and can not replace effective analgesics. At the time of this study, no opioids were available for the surgical patient and Ethiopia is classified as a country with nil morphine per capita [265]. Also, giving patients specific information about the importance of good postoperative analgesia might improve their understanding, however, this does not translate necessarily to better

postoperative pain outcome. Psychologists explain this by the difference between automatic and planned behavior [266]. Automatic processes, or habits, enable behaviors to be carried out with a little or no demand for cognitive effort, and they make behavioral changes very complicated [148]. Education, therefore, can lead to improved knowledge; however, this does not necessarily change old beliefs and habits. And it might be possible that patients can have increased knowledge of pain treatment and increases participation, without the desired changes in their beliefs or behaviors in accepting analgesics after surgery [148]. The results of this study should encourage HCPs, or researcher that even without opioids with education and non-pharmacological options of pain management, this study demonstrated that improvement can be achieved at least after 12 hours of the surgery.

The difference between patients' worst level of pain with that of current level of pain and, least level of pain, could be associated with the fact that these intensity measures (least and current) are not as sensitive as worst pain intensity in detecting treatment effects, and authors have been recommending against [267]. A clinical trial in Taiwan also reported no effect of the treatment when the outcome was current level of pain and the average level of pain, instead of worst pain intensity [268]. It is also worthy to mention that a recent RCT from Germany, reported no superiority of preoperative patient education over the standard of care for most of the outcome measures authors used, including postoperative pain intensity [269]. Patients' participation in decision making was notably higher in the treatment group compared to the control at 24 hours after the surgery. This is expected as we have encouraged patients in the treatment group not to be passive and shy, rather to participate actively in the choice and manner of pain management. The goal of encouraging patients to participate in decision-making is to increase satisfaction and better health outcomes. Studies have also hinted this even can reduce the patient report of pain intensity [77, 270] and randomized controlled trials are also currently investigating the topic [122].

Our results from the mediation analysis, however, revealed insignificant indirect effect, for both pain intensity and patient satisfaction, and patient participation in decision did not mediate the treatment with both outcome measures. Still, our result should not be over-emphasized. The absence of statistically significant mediating effects identified could be due to the study being underpowered to detect these effects, as the mediation analysis was secondary and was not powered for this analysis [271]. However, we have measured the most important predictors of severe postoperative pain as identified from systematic review except for preoperative anxiety

level. These also were appropriately tested if the addition of such measured confounder covariates—(age, chronic pain, types of surgery, types of anesthesia and duration of surgery) —affected the mediation and the results were the same. A previous study also showed that higher patient-driven participation in decision-making was associated with lower odds (OR, 0.82; 95% CI, 0.75–0.89) of frequent pain, but was not significantly associated with severity of pain. Interestingly they have found no significant association with either frequency or severity of pain when the patient participation was physician-driven [272]. Despite, our reported insignificant indirect effect, we encourage patient participation in decision making, as insignificant indirect effect does not mean, no evidence of indirect effect at all. Even statistics aside patient participation in decision making is justified on humane grounds alone [123]. Nevertheless, it is unquestionable that the question how does preoperative education is expected to lower postoperative pain intensity and increase patient satisfaction, should be the focus of future researches. Maybe this will pave the way towards consistent results, when it comes to the impact of preoperative patient education on postoperative pain, and also explain conflicting results on the topic. The focus of the mediation analysis was to test whether our theory of how the intervention worked was correct rather than test a more complex mediation model. Hence, future research could test a more complicated model that includes multiple potential mediators in a single pathway, to show a process of change in several variables as part of the treatment process. Simply testing, whether patient educational intervention is associated with a decreased postoperative pain intensity is not enough and future studies should also establish the causal mechanisms by which educational intervention improves postoperative pain. In this way, others would be benefited in designing their intervention by including the mediating variable responsible for reducing patient pain intensity.

5.4 Strengths and limitations of the study.

There are several strengths of this study, which gives credence to the findings in many ways. First no previous author from Ethiopia used either quasi-experimental controlled group before after study or qualitative study to characterize the postoperative pain management of the country. Further, we employed modern and advanced statistical analysis methods which are recommended by experts in the subject [273]. Third, we have included a relatively representative population by including three major teaching and referral hospitals in Ethiopia. In addition the qualitative study, which evaluated the barriers and facilitators to postoperative

pain management, was unique in providing information from patients', HCPs' and hospital officials' perspective together. Findings from such multi-perspective, can inform the design and implementation of strategies to improve the delivery of pain management services for the surgical patients. The study has also tested the impact of the educational intervention, in decreasing postoperative pain intensity. No previous study reported patient educational intervention to improve the quality of pain management in Ethiopia. The strength of this particular experimental study, was the large study sample (n = 700), with repeated measures, very few missing values and high adherence to treatment. Selection bias as appropriately controlled by powerful statistical methods. Using causal mediation analysis, the study also attempted to further understand the mechanism behind the intervention. Causal mediation analysis is of an interest when mediators are modifiable by an experiment and a study is longitudinal. This study takes the later advantages as patient-reported outcomes were measured repeatedly. Since the conclusions were also based on multilevel mediation models, from an experimental dataset, it further gives weight to the results. Generally speaking, the advantage of this report is that unlike other reports, we have studied the research questions of the study in a sequential manner by first identifying the magnitude of the problem (analysis of baseline pre-intervention data), explore the reasons behind the problem (qualitative explortation) and finally testing proposed solution (effectiveness of developed intervention package) for the problems already identified.

However, each individual steps and analysis could suffer from the following limitations. One, during the pre-intervention (baseline) data analysis from the larger cohort of patients, the established models are prone to biases as any other observational studies. For example, it is impossible to entirely rule out the possibility of other confounders and or other explanatory models in determining the association between chronic pain and postoperative pain intensity, or for that matter age and postoperative pain intensity. As well, we have only assessed a limited set of variables that could explain their relationships. The identified risk factors and predictors are not the only models that could be used to examine the link between clinical and sociodemographic characteristics and postoperative pain intensity. Alternative models (e.g., adding preoperative anxiety, intraoperative analgesics consumption) could be used to explore other relationships.

Second, the qualitative study also might not be generalizable for all surgical patients in all parts of Ethiopia, given the fact that we have included only elective surgical, gynecologic and

orthopedic patients. Still cultural, religious and contextual difference in multi-ethnic countries like Ethiopia, could influence the findings. Also, since transcripts were not returned to the participants it might have compromised the validity. We also would like to state that while we employed the reciprocal determinism theory to explain the reciprocal influence of the environment and personal factors on the practice of HCPs pain management, we did not specifically examine the individual constructs of SCT, neither have we measured performance of HCPs. These limitations aside, this qualitative work presented here attempted the first multi-center exploration from the multi-perspective point of view in the country, with better potential for generalizability of findings and future reference. To date, there are only a few qualitative studies which used reciprocal determinism for explaining barriers and facilitators to effective postoperative pain management, hence future studies in the field might benefit from this.

Third, in the experimental study, there was a clear a baseline imbalance between the control and treatment groups, as expected. However, these were appropriately dealt with during the treatment effect estimation. Nonetheless, it is still of a concern for the internal validity of the study. Heterogeneous samples from different surgical categories might also affect internal validity. This has been also raised previously as a concern from previous trials dealing with the same topic [274], but it could contribute positively to external validity and generalizability of the study. Aside from this, there are known threats to internal validity when one is implementing a quasi-experiment study design. We have tried to control for most threats using various methods. In this regard, the use of two control groups adequately controlled for what is called the “history effect” [275]. Maturation also seems not to affect the trial as the duration of the study was short [276]. Patients were the only one who were blinded so there is a threat of the Hawthorne effect [275]. Lastly, because HCPs were also targeted during the intervention phase, the independent effect of the HCPs might compromise the effect of preoperative patient education and the independent effect could not be estimated.

Regarding the mediation analysis, the results presented in this report need to be interpreted with caution. Preoperative level of anxiety was not accounted for in this mediation analysis and might affect the findings. Temporality, or the sequence in which change occurred, is a major concern in mediation analysis [196]. Regardless of the mediation analysis used, all assume that X happens before M, and M happens before Y, and if X causes M and M, in turn, causes Y, then X must temporally precede M, which, in turn, must precede Y [277]. It is unlikely that this affected our analysis as we have investigated change between 4-time points and the

treatment modified M. However, no matter how unlikely it is, it is not entirely impossible. Even though no significant mediation was observed, it is tempting and possible to test if lowered worst pain intensity could have enabled the patient to have an increased patient participation, rather than increased patient participation leading to a change in worst pain intensity. One way of testing this is through reversing the mediation arrows and check if they hypothesized mediation model is superior to the reversed mediation [278], this is also known as the reverse Mediation Testing [279]. This technique involves interchanging the mediator and the outcome and see if results are different from the mediational pattern [279]. However, this technique has been proven to be inaccurate and authors are now encouraging researchers to abandon this technique [278]. Simulations show that it often fails, especially when the mediator is less reliable than the dependent variable [279]. Thus, it was perceived inappropriate to do so here.

The other important source of bias in mediation analysis is if the variables measured are with error [280]. This especially true in the case of self-reported measures [281]. Our study made use of experimental data. Although we adjusted for major confounders and baseline differences, regarding the association between the treatment and outcome, the results may still be subject to unmeasured confounding by the preoperative level of anxiety, genetic predisposition, or other clinical factors. A higher percentage of participants underwent orthopedic procedure in the intervention group compared with the control group, which could have reduced the statistical power of tests of the analysis. Consequently, the results should be interpreted with caution.

6. Conclusion

In Ethiopia, postoperative pain is not well managed and there is unacceptably high prevalence of moderate to severe postoperative pain. There is also an evidence reflecting a severe interference of pain with patients' functional activities in bed, which could result in many complications. This study, without doubt, has demonstrated that pain treatment after surgery to be a huge problem for the Ethiopian healthcare system. Additionally, postoperative patients are more satisfied with the care provided to them, despite a higher pain intensity scores. This should not trick HCPs and hospital officials, to believe the care is ideal for postoperative pain management. Satisfaction is poorly correlated with pain intensity measures in this study, and other studies as well. There are previous reportes which suggested against this indicator when measuring the quality of postoperative pain management. The pain management index also

showed that a huge proportion of patients were treated inadequately. Among all the other factors, unavailability of strong analgesics like opioids in the setting were the causes. Health care leaders in Ethiopia have a better opportunity to learn from the world, and their own experience (this study for example), to find the balanced care for those who are in pain. We advocate a reasonable use of opioids, by being vigilant to early signs of epidemics of opioids, and also removing exaggerated opiophobia. How to find the balance should be the focus of future studies.

Ethiopian patients also have many distorted views about pain after surgery and the HCPs should teach them routinely before the operation. Using other alternative ways like electronic media or other suitable channel health care leaders should attempt to change this patients' distorted view, as it might persist even after education given at the hospital. Establishing the necessary rapport between clinician and patient should be facilitated, by increasing the cultural competency of professionals during their pre-licensure education. Assessment of pain intensity using a standardized measuring instrument should be the culture in the wards both before and after administering analgesics. With the current attention of the medical and nursing curriculum towards pain and it's management the situation is unlikely to change. All participating professionals from most parts of the medical and nursing discipline acknowledged this. The next step should be to accept this terrible omission of an important topic and improve the curriculum as soon as possible. Only educating HCPs about pain physiology, pharmacology and management the current situation is unlikely to improve. Patients should also be educated and the environment also should be modified to bring high-quality postoperative pain management. However, while designing the patient education intervention, future investigators should consider which specific patient education ingredient is hypothesized to have a positive outcome. In this study, patient participation in decision making not mediated the treatment with pain intensity. By strengthening the limitation of this study, future authors should attempt to answer this, for example using experimental-causal-chaining—also called double randomization design [282, 283].

7. References

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8. Annex

8.1 Supplementary Tables

8.1.1 Rotated Component Matrix of Factor Loadings for NRS Items

Variable	Pain intensity and physical Interference	Emotional Impairment	Perception of care	Adverse effects
Pain intensity: worst pain	0.781*	0.036	0.055	0.096
Pain intensity: least pain	0.678*	0.188	-0.100	-0.092
Pain intensity: current pain	0.783*	-0.049	-0.157	0.168
Pain intensity: time spent in severe pain	0.636*	-0.021	0.272	-0.268
Pain interference: with activities on bed	0.780*	-0.127	0.175	0.168
Pain interference: with breathing and coughing	0.671*	0.070	-0.067	-0.033
Pain interference: with sleeping	0.585*	0.159	0.087	-0.050
Pain interference: with activities out of bed	0.792*	-0.181	-0.078	0.317
Emotional impairment due to pain: anxiousness	0.036	0.877*	-0.049	0.071
Emotional impairment due to pain: helplessness	-0.098	0.983*	-0.096	-0.006
Adverse effects: nausea	0.053	0.412	0.011	0.464*
Adverse effects: drowsiness	0.031	0.359	0.346	0.499*
Adverse effects: itching	0.099	-0.053	-0.429	0.647*
Adverse effects: dizziness	0.132	0.030	0.120	0.804*
Perception of care : perceived pain relief	-0.412*	-0.214	0.003	0.333
Perception of care : participate in decision making	-0.128	0.081	-0.887*	0.060
Perception of care : satisfaction with pain treatment	-0.086	-0.035	0.974*	0.112

*shows items loading in a single factor. Except percived pain relief all items loaded in a single factor.

8.1.2 Significant Differences of 16 Items for Type of Surgery (General Versus Orthopedic and Gynecologic surgery combined)

	Orthopedic and Gynecologic			General Surgery			Mann Whitney U test
Scale and Items	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	P value
Pain Intensity							
Worst pain	209	5.157	2.243	491	4.798	2.209	<0.001
Least pain	209	3.780	1.532	491	3.695	1.542	0.553
Current pain	209	4.761	1.936	491	4.319	1.862	<0.001
Ttime spent in severe pain	209	4.638	2.324	491	4.931	2.331	<0.001
Pain interference with							
Activities in bed	209	4.522	2.582	491	4.156	2.338	<0.001
Breathing and coughing	209	2.244	2.075	491	2.666	2.212	<0.001
Sleeping	209	2.758	2.250	491	2.704	2.140	0.866
Activities out of bed	209	4.237	1.990	491	4.162	1.892	0.542
Emotional impairment due to pain							
Anxious	209	2.319	2.204	491	1.548	2.134	<0.001
Helpless	209	1.815	2.043	491	1.188	1.911	<0.001
Adverse effects							
Nausea	209	2.243	2.306	491	1.588	1.981	<0.001
Drowsiness	209	2.026	1.993	491	1.542	1.834	<0.001
Itching	209	1.161	1.666	491	0.684	1.456	<0.001
Dizziness	209	2.258	1.939	491	1.744	1.957	<0.001
Perception of care							
Perceived pain relief	209	7.114	1.622	491	7.046	1.645	0.140
Participation in decision making	209	2.953	3.556	491	2.346	3.425	<0.001
Satisfaction with pain treatment	209	5.196	2.920	491	5.377	2.971	0.163

8.1.3 Topics and contentes of educational intervention given to interdesciplinary health care professionals

Outcomes	**Objectives**	**Assessment Methods**	**Teaching Learning Strategies**	**Time allocated**
Professionals will adequately manage postoperative pain according to the national and International standards.	After the training Professionals recognize what pain really is and how it is regarded in the scientific community.	Pre-Posttest (written knowledge test)	30 min Interactive presentations 10 min Group discussions	Day 1
	After the training the ***professional*** applies acupuncture, local anesthesia infiltration and principles of correct analgesic prescription	1 - does it in a simulation 2 - does it on a patient after surgery	Learners do it on a simulated limb or on each other under supervision 40 min Presentation 3 hours practical demonstration and simulation	Day 1
	After the training ***professionals*** apply the positive experience from other role models provided to them	Pre-Posttest (written knowledge attitude test)	Listening to peer role models experience.	Day 2
	Professionals recognize consequences of effective postoperative pain management	Pre-Posttest (written knowledge test)	Interactive Presentation using case vignettes	Day 2
	After the training professionals ***do apply*** techniques of non-pharmacological methods for adequate pain relief postoperatively	Does in a patient after surgery	Learner do it on each other under supervision Group work	Day 2
Stake-holders will invest, regulate and monitor postoperative pain management	After the training ***stake holders*** will have ***implemented feed-back mechanisms*** to assist professionals behavior of performing adequate pain relief	Simulated feedback conversation with a learner	Simulated feedback conversation with a learner	*Day 3*

	After the training sessions ***stake-holders will propose*** a suitable environment (resource and policy) for adequate pain	Submission of a developed action plan.	Project-based learning. participants develop an action plan in a group exercise	*Day 3*
	After the training ***stake-holders*** will value the importance of effective postoperative pain management in the setting	Submission of position statement regarding postoperative pain management in the institution.	Interactive Presentation using case vignettes	*Day 3*
Patients will call for professional's attention to their postoperative pain and will change their unhelping attitudes	After preoperative individual teaching sessions ***patients will recognize their postoperative pain and ask*** professionals to manage their pain when not treated or undertreated	Verbal questions and answers sessions after the surgery (using 0-10 NRS rating scale)	Preoperative individual verbal and video instructions	10 min verbal and video persuasions (For consecutive 2 months)
	After preoperative individual teaching sessions ***patients will evaluate and change*** the behavior of disregarding the importance of adequate pain relief postoperatively	Verbal questions and answers sessions after the surgery (using 0-10 NRS rating scale)	Preoperative individual verbal and video instructions	10 min verbal and video persuasions (For consecutive 2 months)
	Patients will appreciate consequences of effective postoperative pain management.	Verbal questions and answers sessions after the surgery (using 0-10 NRS rating scale).	Preoperative individual verbal and video instructions	10 min verbal and video persuasions (For consecutive 2 months)

8.2 Additional files

8.2.1: Semi-Structured Qualitative Interview Guide

8.2.1.1 Professional interview Topic Guide

ለጤና ባለሙያዎች የተዘጋጀ የቃለምልልስ መምሪያ

1. Would you be kind enough to tell me what you are doing to manage pain after surgery for the surgical patient ?
   እባክዎትን እሰኪ ከቀዶ ህክምና በኋላ በሚከሰተው የህመም ስሜት ለሚቸገር ህመምተኛ ምን እያደረጉ ይገኛለ እስኪ እነደው ድርሻዎትን ቢያካፍሉኝ ?

   Subsequent questions will be asked to clarify and further explore barriers influencing postoperative pain management.

   ከዚህ ጋር ተያይዘ ተከታታይ የሆኑ ጥያቆዎች ይጠየቃሉ። እነዚህ ጥያቆዎች ለህመም ስቃይ ህክምናው ማነቆዎችን ለመረዳት የታለሙ ናቸው።
2. Would you please share an example of a time when your efforts to manage a patient in postoperative pain?
   እስኪ እባክዎትን ምሳሌ በመጥቀስ ከቀዶ ህክምና በኋላ ህመም ውስጥ የነበረን ህመምተኛ ያከሙበትን ሁኔታ ይገልጹልኛል

   Was it successful or unsuccessful? How or Why?'

   የተሳካ ነበረ ወይንስ አልተሳካም እንዴት ልምን
3. What are the barriers against proper management of pain for postoperative patients in your opinion?
   እሰከ እነደው በእርስዎ አስተሳሰብ ከቀዶ ህክምና በኋላ የህመም ስሜትን ለመቆጣጠር እንቀፋት ይሆናሉ የሚሏቸውን ምክንያቶች ቢያስረዱኝ
4. What are the solutions in your opinion for adequate/satisfactory pain management?
   Probe questions, such as "What do you mean by that?" and "can you elaborate this more?" will be asked. All interviews will be tape-recorded and lasted between 15 and 20 min.

   የበለጠ ለመረዳት እናዲያመች ምን ማለትዎ ነው፣ እስኪ በደንብ ሊያብራሩልኝ ይችላሉ እና የመሳሰሉ የ ማነቃቂያ ጥያቄዎች ይጠየቃሉ።ሁሉም ቃለ ምልልሶች ከ 15-20 ደቂቃ ይቆያሉ እንዲሁም በድምጽ መቅረጫ ይቀዳሉ።

8.2.1.2 For Patients -Interview Guide,

ለህሙማን የተዘጋጀ መምሪያ

1. Tell me about your postoperative pain and pain relief experiences
2. እባክዎትን ከቀዶ ህክምና በኋላ ስለነበርዎት የህመም ስሜት እና የ ህመም ማስተገሻ ቢንገሩኝ
3. Tell me about a specific pain situation: what happened? (How do they describe their pain)
4. ለመረዳት እንዲያመች ስለነበርዎት አንድ አጋጣሚ (ከህመም ስሜቱ ጋር/ ከቁስሉ የህመም ስሜት) በተያያዘ ማለቴ ነው እስኪ ምን ሆነ ምን ተሠጥዎት
5. Their perception of pain management (Is it important to treat it, in your opinion? how do you cope with it?)
6. ከቀዶ ህክምና በኋላ ህመምን ለማከም የተለያዩ ዘዶዎችን መጠቀም እንዴት ነው በእርስዎ አስተሳሰብ ጥሩ ይመስልዎታል እርስዎ እንዴት ተቋሙት
7. What relieved or increased your pain?
8. ምን አሻልዎት/ ምን አባሰብዎት
9. What was the barrier in your opinion? How?
   በእርስዎ እይታ እንቅፋት/ አዳጋች የሆነብዎት ምንድን ነው እንዴት
10. Was anything done to relieve your pain? Who offered you help with your pain
    የህመም ስሜትዎን ለማስታገስ የተደረገልዎት ነገር አለ ማን ነው የረዳዎት
11. If there was an option other than drugs for your pain, will you be happy to use it…like massage, acupuncture?
    ከህመም የማስተገሻ መድሃኒቶች ውጪ ፣ ማለትም የሚዋጡም ሆነ በመርፌ ከሚሰጡ ውጪ እንደመታሸት እና የደረቅ መርፌ ህክምና አማራጭ ቢቀርብልዎት ለመጠቀም ፍቀደኛ የሚሆ ይመስልዎታል

    Probe questions, such as “What do you mean by that?” and “can you elaborate this more?” will be asked.
    All interviews will be tape-recorded and lasted between 15 and 20 min.

የበለጠ ለመረዳት እናዲያመች ምን ማለትዎ ነው፣ እስኪ በደንብ ሊያብራሩልኝ ይችላሉ እና የመሰሰሉ የ ማነቃቂያ ጥያቄዎች ይጠየቃሉ።ሁሉም ቃለ ምልልሶች ከ 15-20 ደቂቃ ይቆያሉ እንዲሁም በድምጽ መቅረጫ ይቀዳሉ።

8.2.1.3 Interview guide- stakeholders (Leaders)

በስልጣን እና የሃላፊነት ድርሻ ላይ ላሉ የጤና ባለሙያዎች የተዘጋጀ መምሪያ

1. What is your position in the hospital/university or college? And your role?
   በሆስፒታሉ ወይንም በዮኒቨርሲቲው ያለዎት የሃላፊነት ቦታ ምን ይባላል
2. What is most important in your opinion for surgical patients?
   ለቀዶ ህክምና በሽተኞች በእርስዎ እይታ በጣም አስፈላጊው ምንድን ነው

3. What is postoperative pain in your opinion and do you think in your ward/hospital patient's pain is managed.
   ከቀዶ ህክምና በኋላ የህመም ስቃይ ስሜትን እንዴት ይገልጹታል

   እርስዎ በሚሰሩበት በዚህ ሆስፒታል ወይንም ዋርደ ውስጥ በደንብ የሚታከም ይመስልዎታል
4. If yes….what are the strategies? Like guidelines? Protocols?
   አዎን ካሉ እስኪ የሚከተሉትን የትገበራ ሂደት ወይንም ዘዴ፣ እንዲሁም የሚጠቀሙትን

   መመሪያ እና ሳይንሳዊ ቀመር ቢያስረዱን
5. Some people say pain management is a fancy concern and we have a lot to do first than worrying about patient's pain after surgery. Do you agree or not? Give reasons?
   አንዳንዶች የቀዶ ህከምናው ነው እንጀ ዋናው ከዛ በኋላ የሚከሰተው የህመም ስሜት ቀላል እና

   ሊካበድ የማይገባው ነው። ሌሎች ልናደርጋቸው የሚገቡን ብዙ ነገሮች አለ እርሱ ብዙም

   አያሳስብም ይላሉ። እርስዎ በዚህ ሀሳብ ይስማማሉ ወይነስ አይስማሙም እስኪ ምክንያተዎን

   ዘርዘር አድርገው ያስረዱን
6. Do you continuously monitor professionals to manage pain after operation? If not why? If Yes How?

   በሃላፊነት ቦታ ላይ እንደመሆንዎ፣ ባለሙያዎች ከ ቀዶ ህክምና በኋላ በትክክል ህመሙን

   መቆጣጠር ወይንም አለመቆጣተራቸውን በሚገባ እና በማያቋርጥ መልኩ ይከታተላሉ።
7. Why do you think pain management **is** important? / Why do you think pain management **is not** important?
   ለምን ይመስልዎታል የህመም ህክምና ጠቃሚና አስፈላጊ ነው የሚባለው/ ለምን

   ይመስልዎታል የህመም ህክምና ጠቃሚና አስፈላጊ አይደለም የሚባለው/
8. In your opinion what is the best **strategy/ approach** to adequately manage post-surgical pain?
9. እንደው እንደረስዎ ከሆነ በተገቢው መልኩ የህመም ስቃይን ለመቆጣጠር እና ለመቀነስ ጥሩ የትግበራ ዘዴ ወይንም የሃሳብ ቀመር ምን ይመስልዎታል
10. Do you think all the necessary drugs/human resource/ for pain management are available? And if not why? If yes can you give example?
    ሁሉም ግብአቶች ማለት የሰውም፣ የንብረትም፣ የመድሃኒትም ሆነ ሌሎች ይህን የህመም

    ስቃይ ለመቆጣጠር የተሟሉ ይመስልዎታል አልተሟሉም ካሉ ቢያብራሩልኝ

    Probe questions, such as "What do you mean by that?" and "can you elaborate this more?" will be asked. All interviews will be tape-recorded and lasted between 15 and 20 min

የበለጠ ለመረዳት እናዲያመች ምን ማለትዎ ነው፣ እስኪ በደንብ ሊያብራሩልኝ ይችላሉ እና የመሳሰሉ የ ማነቃቂያ ጥያቄዎች ይጠየቃሉ።ሁሉም ቃለ ምልልሶች ከ 15-20 ደቂቃ ይቆያሉ እንዲሁም በድምጽ መቅረጫ ይቀዳሉ።

8.2.2 Questionniare Used

Identification **Date_____**

1. Patient name_____ _____2. Age_____ 3. sex____ 4. Card. No _____

5. Educational Status: ☐ Illiterate ☐ Literate

If literate: ☐ Elementary ☐ High school ☐ Certificate ☐ Diploma ☐ Degree and above

7. Marital Status: ☐ Married ☐ Divorced ☐ Single ☐ Widowed

8. Ethnicity_____

9. Religion: ☐ Orthodox ☐ Muslim ☐ Protestant ☐ Catholic ☐ Jehovah Witness
Others _____

10. Occupation _____ Ethnicity_____

Part-II Clinical Profile

11. Diagnosis at Admission _____12. ASA classification _____

13. ASA classification _____14. Types of Surgery_____

15. Types of Anesthesia_____ 16. Hours since surgery_____

17. Past Medical history_____18. Duration of surgery_____

19. Past Surgical History_____

20. History of Alcohol use _____ 19. History Dug use_____

21. History of Khat Consumption_____

22. Analgesic ordered for postoperative pain? ☐ Yes ☐ No

23. If yes, who ordered? ☐ Surgeon ☐ Anesthetist / Anesthesiologist ☐ Nurse ☐ Medical Intern ☐ Surgical resident ☐ Anesthesia Resident

24. Who administered it? ☐ Surgeon ☐ Anesthetist / Anesthesiologist ☐ Nurse ☐ Medical Intern ☐ Surgical resident ☐ Anesthesia Resident

25. Drug name_____ dose_____ Route _____ frequency _____

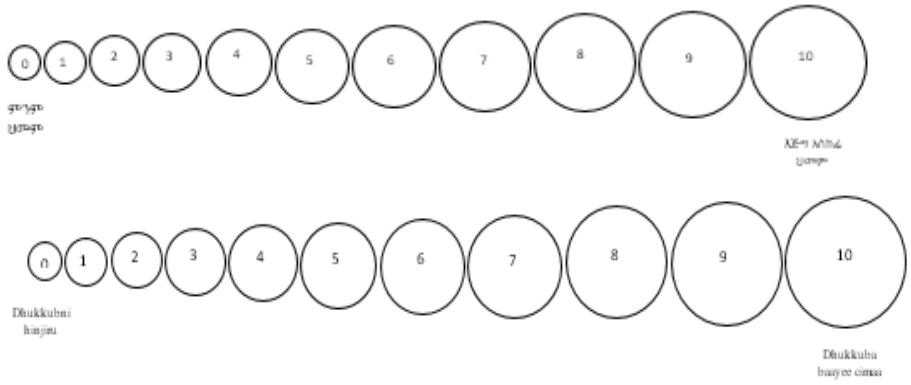
26. Local anesthesia used for postoperative pain relief? Yes No

27. If yes, drug name_____ dose_____ Route _____

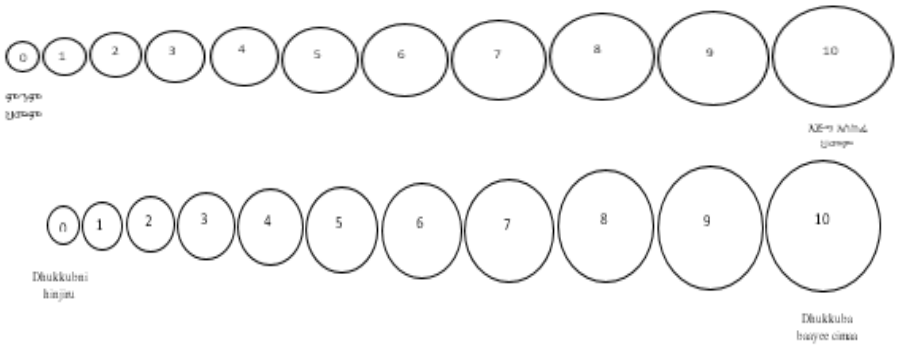
28. Acupuncture used? ☐ Yes ☐ No

29. If yes, type of acupuncture technique_____

1. በዚህ መለኪያ መሰረት ቀዶ ሀክምና ካደረጉ በኋላ የተሰማዎትን **እጅግ ከፍተኛ የህመም** ስሜት ያመልክቱ
   1. Yaalii baqaqsanii hoduu kana booda dhukkubbii akka malee sitti dhagahame madaallii kanarratti argisiisime

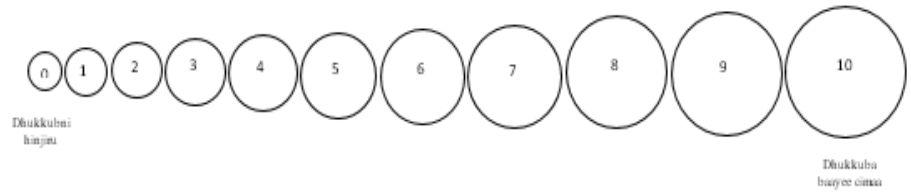


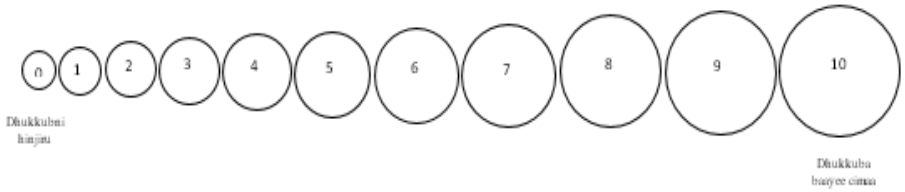
2. Yaalii baqaqsanii hoduu kana booda dhukkubbii xiqqoo sitti dhagahame madaallii kanarratti argisiisimee
   2. በዚህ መለኪያ መሰረት እባከዎትን ከቀዶ ሀክምና በኋላ የተሰማዎትን **አነስተኛ የህመም ስሜት** ያመልክቱ



   3. አሁን በዚህ ሰአት ያለዎት የህመም ጫና ምን ያህል ነው?

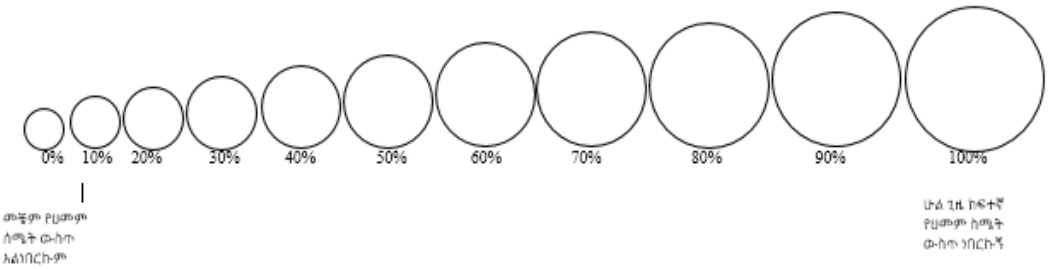
   3.Amma dhukkubni kun hammam sitti cimeera?

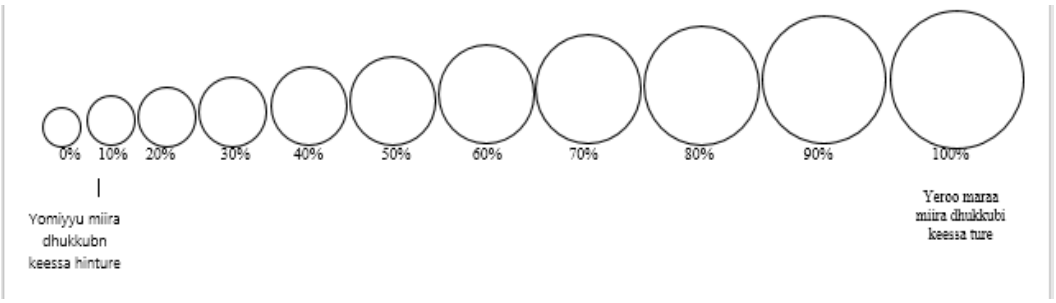




4. Baqaqsanii yaaluu kana booda si’a meeqaaf dhukkubbiin kun sitti hammaate? Maaloo mee tilmaamakee dhibbeentaan si’a meeqaaf dhukkubbiin hamaa kun akka simudate itti marimee

4. ቀዶ ጥገና ካደረጉ ጀምሮ **ለምን ያህል ጊዜ ከፍተኛ ህመም ስሜት ነበረዎት** እባክዎትን በጠቅላለው ለምን **ያህል ጊዜ** ህመሙ ይሰማዎት እንደነበር በመቶኛ ይጠቁሙ





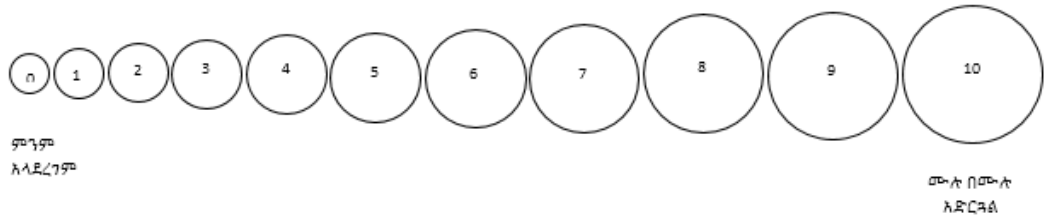
5.Erga baqaqsanii yaaluun siif raawwatamee booda dhukkubbiin kun si’a meeqaaf akka sirakkise ykn maal irraa akka sidhorke kan sirriitti ibsu lakkofsa armaan gadii keessaa tokko itti mari

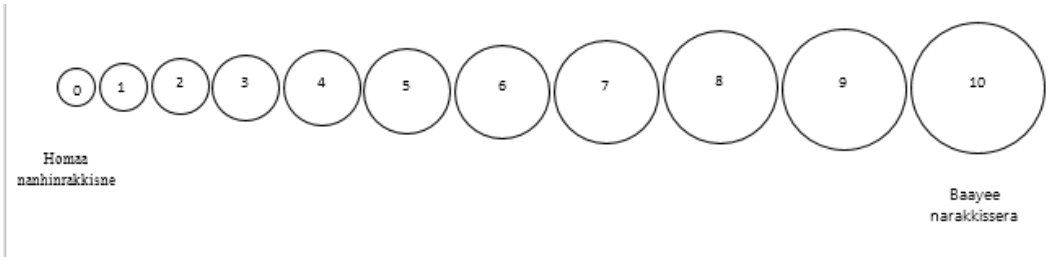
A. Siree irratii sosocho’uu kan akka gaggaragaluu, oljedhee taaa’uu, cinaacha geeddarachuufaa

5. ከታች ከተዘረዘሩት ቁጥሮች አንዱን በመምረጥ ቀዶ ሕክምና ካደረጉ ጊዜ ጀምሮ ከተነሳብዎ የህመም ስቃይ የተነሳ ያጋጠምዎትን ችግሮች መጠን ይጠቁሙ ለምሳሌ የህመሙ ስቃይ ምን ያህል

U. በአልጋዎ እንቅስቃሴዎችን እንዳያደርጉ ማለት ተዘዋውሮ መተኛት፣ አልጋ ላይ መቀመጥ ፣

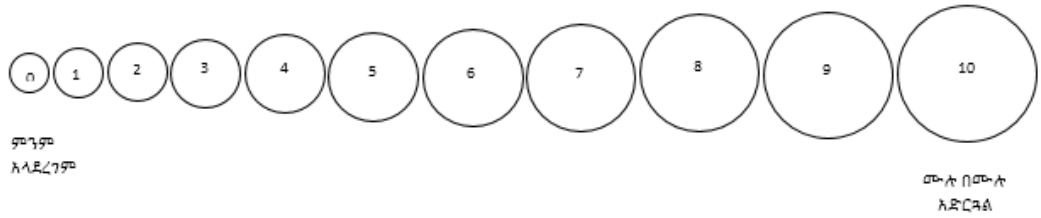
መቀመጫ መቀየር፣ መገላበጥ እንዳይችሉ አድርጓል

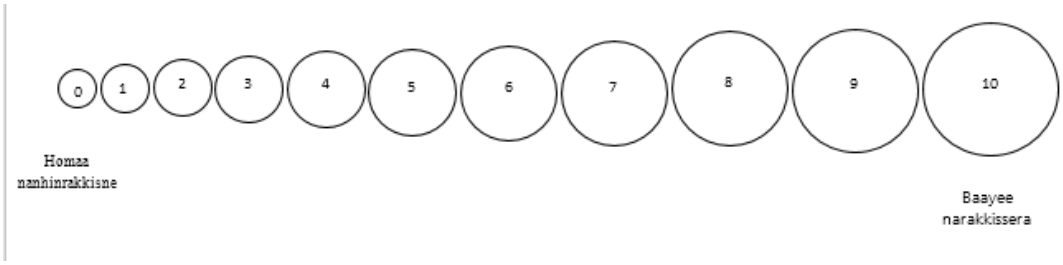




B. Afuura bareechanii baafachuu ykn qufa’uu

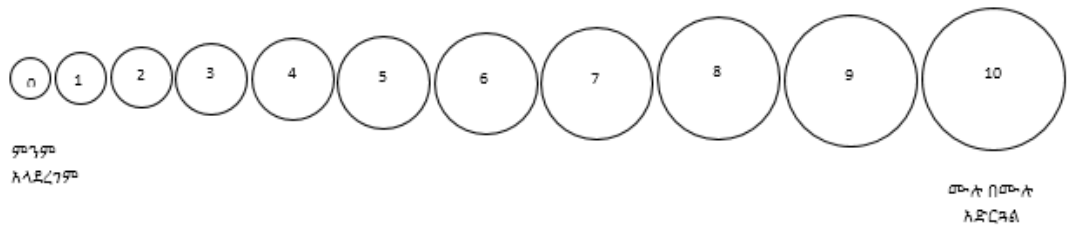
ለ. በደንብ እንደልብዎ እንዳይተነፍሱ ወይንም እንዳያስሉ አድርጓል

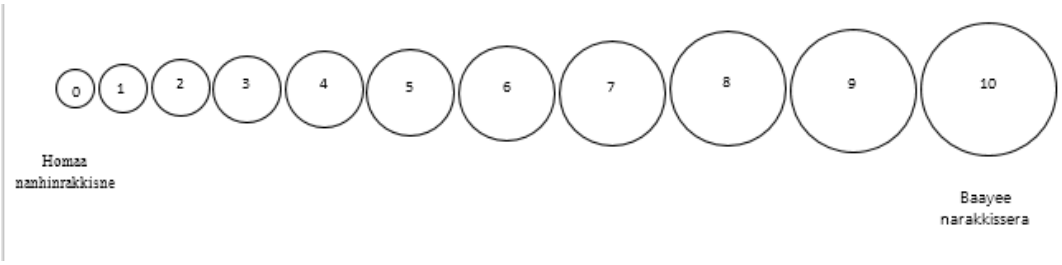




C. Hirriba

ሐ. እንቅልፍ እንዳይወስድዎ አድርጓል





D. Erga baqaqsanii yaaluun kun siif rawwatamee sireerraa kaatee beektaa

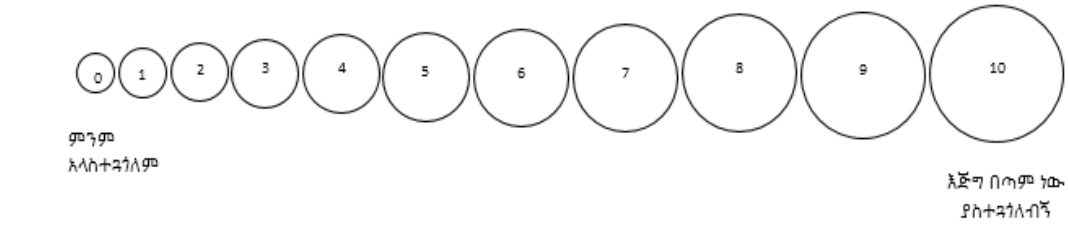
A) **Eeyee** B) **lakki**

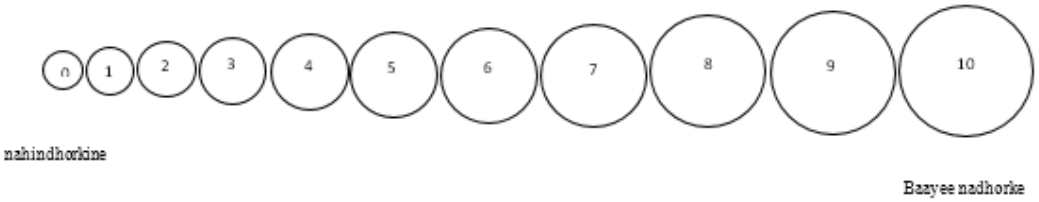
Yoo eeyee ta'e, dhukkubbiin kunoo si'a meeqaaf si rakkise ykn hammam akka ati sireerraa buutee hujii hin hojjenne si dhorke fkn deemuu, teessoorra taa'uu, xuruurtoorra dhaabbachuu

መ ከቀዶ ህክምና በኋላ ከአልጋዎ ወርደው ያውቃሉ

ሀ) አዎን ለ)አልወረድኩም

ካልጋ ወርደው ከነበር ወርደው የሚያደርጓቸውን እንደ ርምጃ፣ ወንበር ላይ መቀመጥ፣ መታጠቢያ ጋር መቆም የመሳሰሉትን እንቅስቃሴዎች ሕመምዎ ምን ያህል አስተጓጉልብዎ



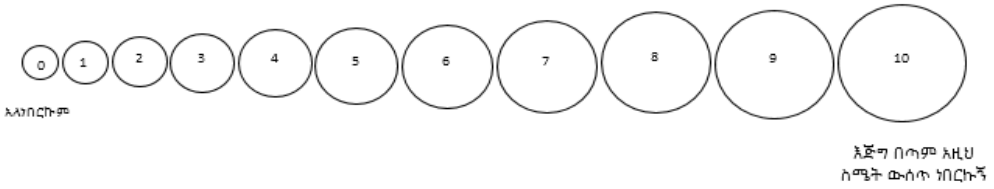


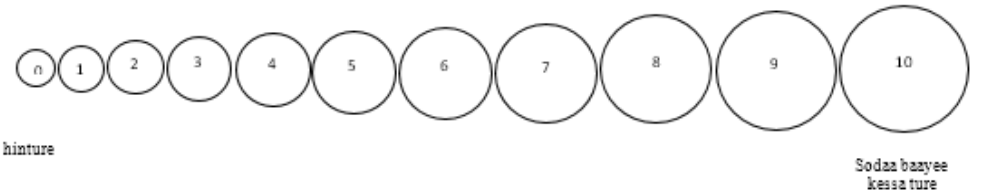
6.Dhukkubbiin miiraa fi kaka'umsa keenya ni miidha Erga baqaqsanii yaaluun kun siif hojjetamee sababii dhukkubbii kanan waan sitti dhagahame kan ibsu mee iskeelii kanarratti tokko itti marii argisiisi

A. Yaaddoo/ sodaa

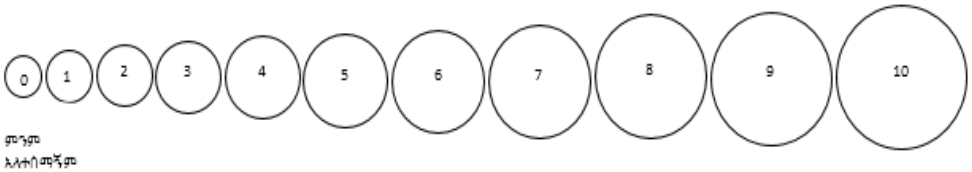
6. ህመም የውስጥ ስሜትዎን አና የውጭ ስሜቶቸን ሊነካ ይችለላል በዚህ መለኪያ እባክዎን ቀዶ ህክምና ካደረጉ ጀምሮ ምን ያህል የህመም ስቀዩ ለሚከተሉት ስሜቶች እንዳደረገዎ ይጠቁሙ

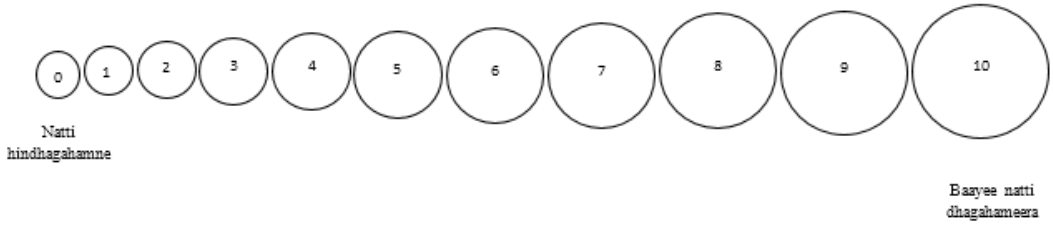
ሀ. የስጋት/የመሸበር ስሜት ውስጥ





ለ. ተስፋ ቢስ የመሆን ስሜት
B. Gargaarsa dhabuu



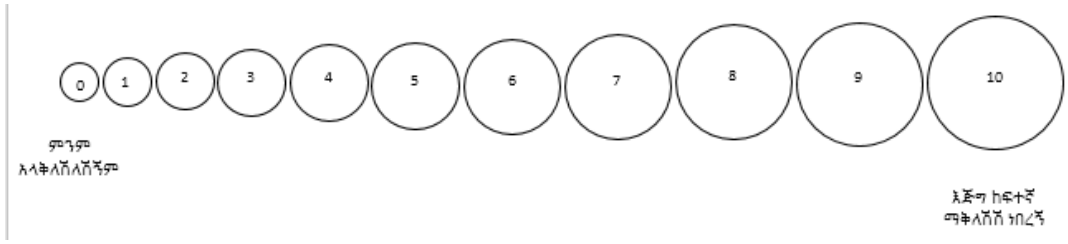


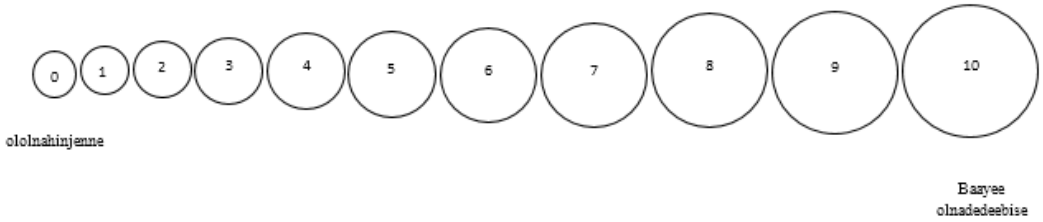
7.Baqaqsanii yaliin booda rakkoon armaan gadii kun simudatee beekaa?

Yoo lakki jette ‘’0’’ ti mari, yoommoo eeyyee jette ta’e lakkoofsa kana gadii keessaa hammeenyasaa ibsuu danda’a jettu tokko filadhu itti mari
Ol-ol jechuu/ garaa hammeessuu

7. ከቀዶ ህክምናው በኋላ የሚከተሉት የጎንዮሽ ተጓዳኝ ገዳቶች አግኝቶዎታልን ካለገኘዎት “0” ን ይምረጡ፣ ካገኘዎት ግን ላገኘዎት የጎንዮሽ ተጓዳኝ ገዳት መጠኑን ይገልጽልኛል የሚሉትን ቁጥር ይምረጡ

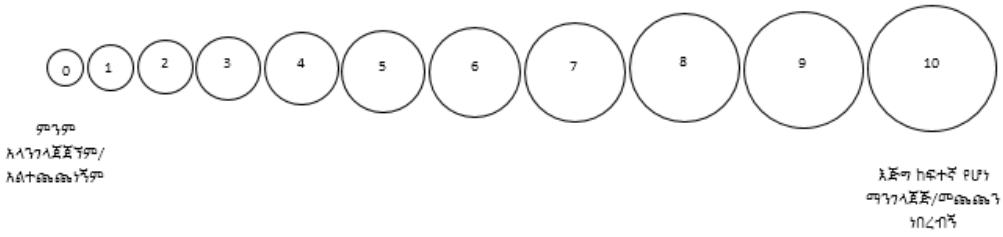
ሀ. ማቅለሽለሽ

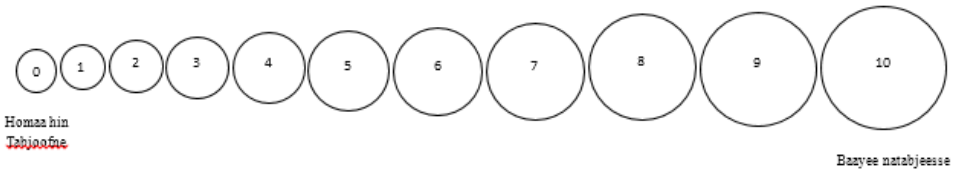




B. Tabjaa'uu/dukukaa'uu

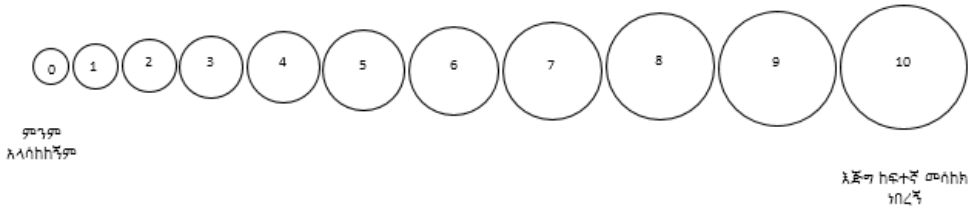
ለ. ማንገላጀጅ/መጫጫን

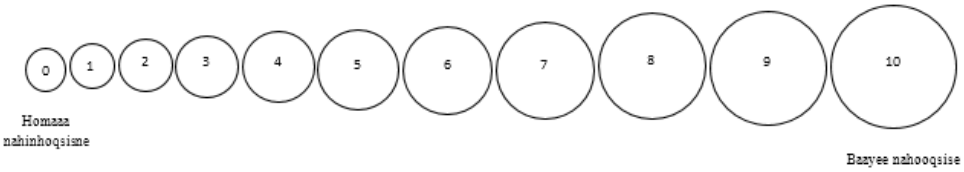




C. Dhaqna nyanyaachuu/ hoqsisuu

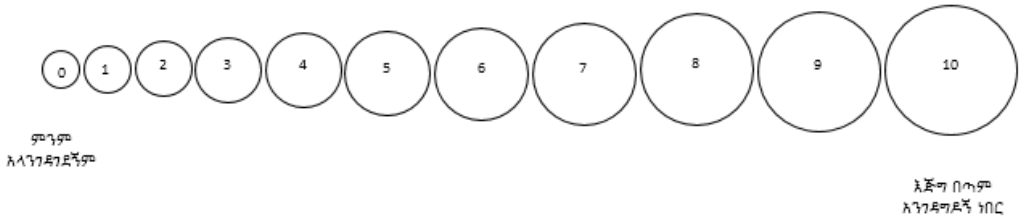
ሐ. ማሳከክ

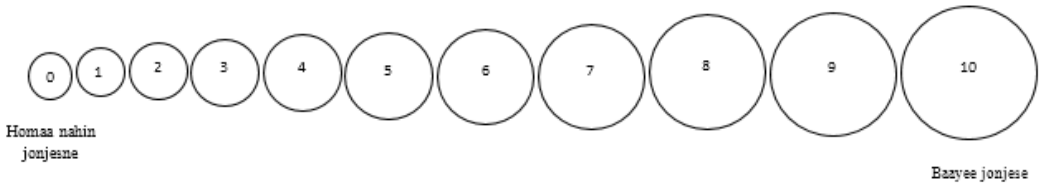




D. Jonja'uu/ mataa offii baachuu dhadhabuu

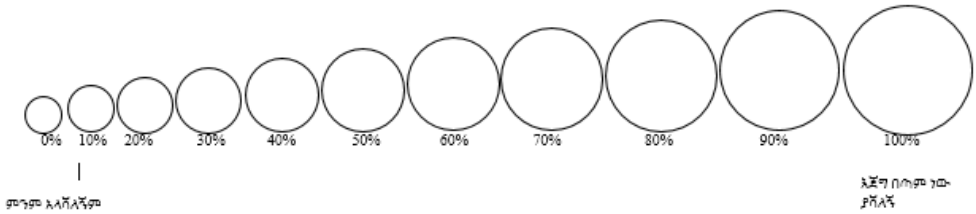
መ. ማንገዳገድ

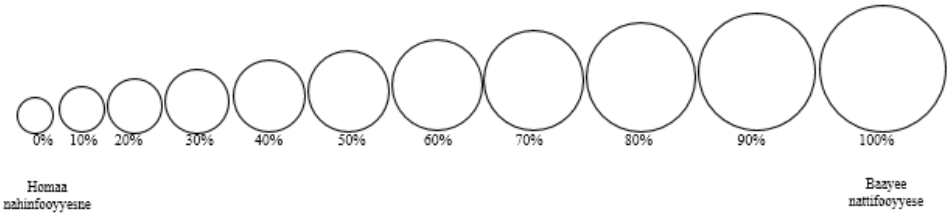




8.Erga baqaqsanii yaalamtee booda si'a meeqaaf dhukkubbii kanaaf qoricha fudhatte? Guutummmaa yaalii dhukkubbii kana keessa walitti makinsaan (qorichaafi qorichaan ala) siif taasifame sirritti dhibbeentaadhaan kan ibsuu danda'u itti marimee

8. ከቀዶ ሕክምናዎ በኋላ ምን ያህል የህመም ማስታገሻ ተሰጥዎት? እባከዎትን የተሰጠዎ ማስታገሻ (ኪኒን እና መርፌም ይሁን ወይንም ኪኒን እና መርፌ አልባ) ህመምዎን ከመቶ ምን ያህል እንዳስታገሰልዎ/ እንዳሻለዎ ያመልክቱ





9. ተጨማሪ የህመም ማስታገሻ ቢጨምርልዎ/ቢሰጥዎ ይፈልጉ ነበር ?

ሀ) አዎን እፈልግ ነበር ለ) አላስፈለገኝም ነበር/በቅቶኝ ነበር

9. Silaa otuu siif ta'ee kan amma yaalamteen ol dhukkubbii kanaaf si yaalini ni barbaaddaayyuu?

A) Eeyee B)Lakkii

10. ስለህመምዎ የማስተገሻ ህክምና አማራጮች መረጃ ተሰጥቶዎት ነበርን
ሀ) አወን ተሰጥቶኝ ነበር

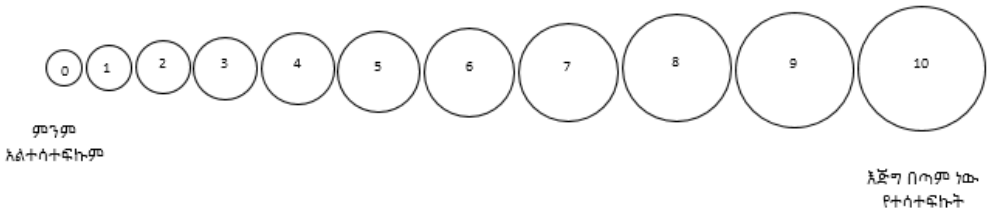
ለ) ምንም አልተሰጠኝም ነበር

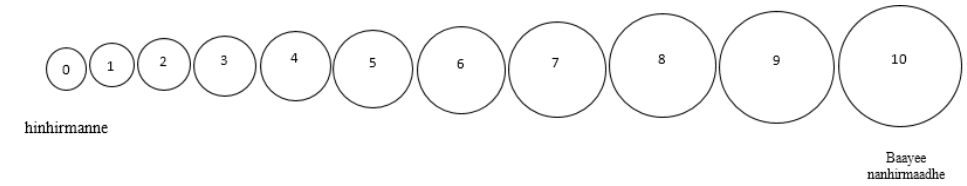
10. Gosa wallaansaa dhukkubbiikeef si barabachisu irratti odeeffannoo fudhatteettaa?

A) Eeyee B)Lakkii

11. Akka barbaaddetti murtee wallaansa dhukkubbiikeef barbaachisu irratti godhamu keessatti hirmaachuuf carraa argatteettaa?

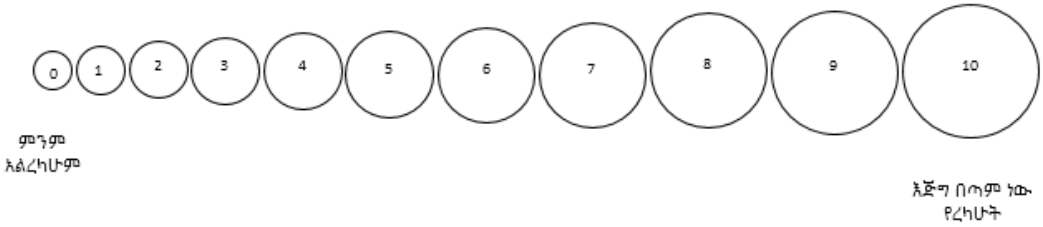
11. እርስዎ እንደፈለጉት ሥለህመምዎ የማስታገሻ ህክምና በሚደረገው ውሳኔ ላይ አብረው ተሳትፈው ነበርን / ያማከረዎ አለ።

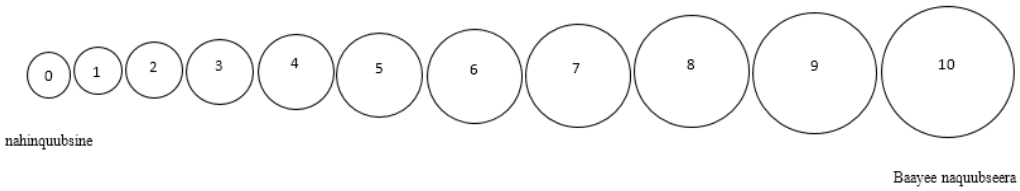




12.Erga wallaansa baqaqsuu argattee kaasee bu'aa wallaansa dhukkubbiikeef gadhame ilaalchisee itti quufinsakee sirriitti kan argisiisu lakkoofsa armaan gadiitti mari.

12. በህመምዎ የማስታገሻ ህክምና ምን ያህል እርካታ ይሰማዎታል ተብለው ቢጠየቁ ከመቶ ስንት ይመርጣሉ





13. ኪኒን ወይንም መርፌ አልባ የህመም የማስታገሻ ህክምና ተደርጐሎዎት ነበርን.? **ሀ) አዎን**

ተደረጎልኝ ነበር ለ) ምንም አልተደረገልኝም

13. Dhukkubbiikee irraa fooyya'uuf qorichaan ala mala biraa gargaaramteettaa ykn fudhatteettaa?**A)**

Eeyee)Lakkii

ሀ. አዎን ከሉ የተደረገልዎትን ከነዚህ ውስጥ ይምረጡ

ሀ) ቀዝቃዛ በረዶ ለ) ተመስጦ ሐ) በጥልቅ መተንፈስ መ) ሙቀት ሰ) የደረቅ መርፌ (አኩፓንክቸር) ቀ) ጸሎት በ) ከጤና ባለሙያዎች ጋር ማውራት ተ) ዞር ዞር ማለት ቸ) መታሸት ኀ) ከጓኞች እና ጎረቤቶች ጋር ማውራት ነ) ዘና ፈታ ማለት ኘ) ትኩረትዎን ለመቀየር (እንደ ቴሌቪዝን ማየት, ሎሙዚቃ መስማት, መጽሀፍ ማንበብ) ዐ) ሌሎች ካሉ (እባክዎን ይግለጹ

A. Yoo "eeyee" ta'eef , kan gargaaramte hunda agarsiisi ykn fili:
Cabbii, Meediteeshenii, gadifageenyaan arganuu, ho'a, lilmoo gogaan waraannachuu(acupuncture), kadhachuu(duwaayii), ogeessa fayyaa mari'achiisuu, sosochohu, sukkuumamuu (massage), hiriyyaa ykn fira mari'achiisuu,

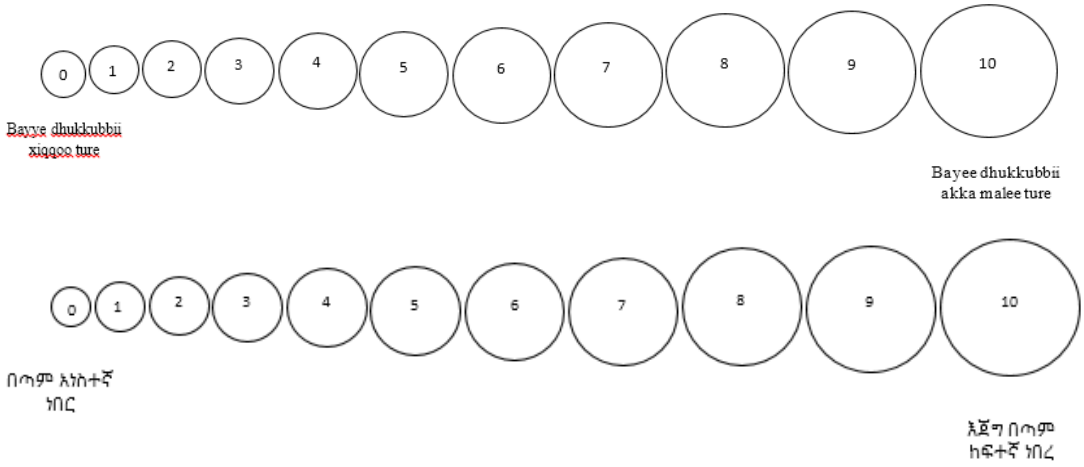
14. Utuu wallaansa baqaqsuuf gara hospitaalaa hin dhufin dhukkubbii addaan hin citne baatii 3 ykn isaa oliif ni qabda turte?

A) Eeyee B)Lakkii

A. Yoo eeyee ta'e, ciminni dhukkubichaa yeroo hedduu akkam ture?

14. ለዚህ ቀዶ ህክምና ወደ ሆስፒታሉ ከመምጣትዎ በፊት ለ 3ት ወራት ያህል የቆየ እና እረፍት የሌለው የማያቋርጥ የህመም ስሜት ነበርዎት **ሀ) አዎን ለ) አልነበረኝም**

ሀ. መልስዎ አዎን ከሆነ የህመሙ ጫና ብዙውን ጊዜ ምን ያህል ነበረ? እባክዎትን ይህን የሚያመለክተውን ቁጥር ይምረጡ



B. Iskelli lakkoofsa sirriitti ibsutti maruun agarsiisi Yoo eeyee ta'e, bakki dhaabbataan si dhukkubu sun bakka kami?

1) Bakkan baqaqfadhe, 2) bakka biraa, 3) lamaanuu (bakka baqaqee fi bakka biraa)

ለ. መልስዎ አዎን ከሆነ የዚህ ህመም ስሜት ምንዎ ጋር ነበር

ሀ) የቀዶ ህክምናው ቦታ ለ) ሌላ ቦታ ሐ) ሁለቱንም (የቀዶ ህክምናውም ቦታ እንደገናም ሌላ ቦታ)

8.2.3 Statement on pre-release and contribution

Parts of this monographic thesis have been previously submitted and is under review in PLOS ONE journal with the title "Quality of postoperative pain management in Ethiopia: a multi-center longitudinal study". My contribution to the pape includes: conceived, designed, collected data, analyzed the data and wrote the first draft of the manuscript. I am also the first author of this manuscript. The second manuscript with the title "Barriers and facilitators of postoperative pain management in Ethiopia: A multi-center, multi-perspective study" was also submitted for publication to the PLOS ONE Journal and is currently under review. I have contributed to the manuscript on design, data collection supervision, analysis of the data, interpreting the data and writing the first draft of the manuscript. Also, in this study I am the first author. The last paper which is part of the thesis is currently completed and will be submitted to the journal, with the title "Educational intervention for effective for postoperative pain management in low resource settings: Evidence from Ethiopia". I am also the first author of this manuscript. My contribution to this study are: during the conception of the study, intervention and data collection stage. I have also analysed the data, interpreted and wrote the first draft manuscript.

8.2.4 Acknowledgments

First and for most, Glory to God, for his unspeakable gifts and support throughout my life, it keeps counting and counting; and I have nothing to give back, except acknowledging it.

I feel pleasure to have the opportunity to thank my direct LMU supervisor, Priv.-Doz. Dr. med. Dominik Irnich. I will always remember how he made himself of no reputation to listen to my ideas. For the time and attention he gave to me—even during his very occupied schedule, for the trust he had shown me, and for the lessons, he thought me, I thank him so much and wish him all the best life could give. I will always keep mind the extra miles he went to support me, including flying to Ethiopia, just to support my research!. His compliment and encouraging words have been an analgesics for me through the sometimes painful experience of studying pain in Ethiopia.

I think myself happy, to meet someone like my habilitated supervisor Prof. Dr. med. Matthias Siebeck. My very special thanks go to him. He cared so much about my work and supported me in many ways as he could. He never turns down any of my queries, throughout this Ph.D. program, even when my queries were stupid and unreasonable. Thank you very much for all the things you taught me both consciously and unconsciously. I always remember his decency and humbleness, to show up at our meeting, after those long hours of surgery he have been performing the whole day. Dear Prof. Dr. Siebeck, it is an honor to be your P.hD. student and thank you very much.

My sincere gratitude is reserved to Prof. Markos Tesfaye, my local supervisor. He is the only one who believed in me, many years back, before even I completed my master's degree. He trusted my potential and skills more than I trusted mine. I thank him so much for answering all my calls even when I call late in the night. Thank you very much, for the flawless professionalism and mastery you showed me. I would not have been where I am now, if you had not supported me, and thank you.

I would like to express my deepest gratitude, to Dr. rer. biol. hum. Petra Bäumler. I have learned a lot from her notes on my research papers than I did from any of my statistics and research methodology classes. I am indebted to her tremendous support and insightful advice during my study, and will always be grateful. She always managed to bring everyone together during all

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