Effect of preoperative information about pain on postoperative pain experience and patient satisfaction following orthopaedic surgery: A randomised controlled trial.

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Abstract

Background: Preoperative information about pain has been shown to improve postoperative pain perception and reduce postoperative analgesia requirements. However, there is limited data regarding the effect of preoperative counselling in low resource settings. This study aimed at assessing the effect of preoperative information about pain on postoperative pain experience measured as postoperative pain using a verbal numerical rating scale (VNRS) and patient satisfaction with pain management.

Methods: A randomised, double blind, controlled trial was done in Mulago National Referral Hospital (MNRH), Kampala. We prospectively enrolled 400 participants aged 18years and above scheduled for elective orthopaedic surgery. The consented patients were randomised to either receive the specific preoperative information about pain or not. The primary end points were postoperative pain score and patient satisfaction. A total of 340 were analysed with 170 in either arm. Secondary analyses were done to determine the factors that were associated with postoperative pain and patient satisfaction.

Results: In both arms, the lowest pain score was 0/10 at 0 hours and the highest was 7/10 at 12 hours. A statistically significant difference between the intervention and control arms for the median pain score at 48hours (4/10 vs. 5/10) P-value= 0.029 was seen but none at 0, 12, 24hours. There was no difference in satisfaction with pain management (P value=0.059).

Conclusion: Preoperative information about pain improves postoperative pain experience and may negatively impact patients' satisfaction with pain management due to unmet expectations.

Trial registration: Clinicaltrials.gov, NCT03056521. Registered 17 February 2017 - Retrospectively registered, <https://clinicaltrials.gov/ct2/show/NCT03056521>

Background

Pain is a very common postoperative complication [1-4]. In Mulago National Referral Hospital (MNRH), 100% of patients that had undergone abdominal surgery had pain despite having received drugs to control their postoperative pain [5]. In a systematic review, factors affecting postoperative pain experience were categorised as surgical factors (type of surgery, duration of surgery), psychological factors (anxiety, psychological distress, and coping strategies) and preoperative pain. Sociodemographic factors like tribe, culture, age, gender, socio-economic status, occupation, educational level; if surgery is emergency or elective, type of injury and previous experience of pain have also been documented to affect the perception of pain [6, 7].

The effects of pain go beyond physical delay of recovery to prolonged hospital stay, depression, failure to feed, chronic pain, posttraumatic stress disorder, poor social relations to mention a few. Reliable quantification of pain is necessary for effective pain treatment [8]. Recommended key principles of management include routine assessments of pain and of the effectiveness of interventions using the various available pain scales [9]. Another important criterion for assessing medical service quality is patient satisfaction. This is a conclusion reached by the patient after comparing their feelings during a medical service with their expectations. Patient and hospital factors play important roles with physician care, nursing care and personal concern being the most valued factors to patient satisfaction related to in-patient care [10].

High levels of postoperative pain are still reported even with availability of numerous drugs for postoperative pain management and explanations for this include insufficient education, poor pain assessment by attending clinicians and nurses, and inadequate staffing [11]. Since pain is a multidimensional experience that encompasses physical, emotional, spiritual and behavioural aspects, a multidimensional approach in its management is therefore needed [12].

The American Society of Anaesthesiologists (ASA) emphasises preoperative anaesthesia review for all patients. One of the aims of this review is to provide the opportunity for explanation and discussion, and allaying fear and anxiety [13]. Several studies show that increased anxiety in the preoperative period is associated with increased postoperative pain [14-17]. Postoperative pain control therefore starts before surgery. Behavioural preparation of the individual is pertinent to adequately equip the patients in all possible ways of handling pain beforehand using preoperative information [12].

Preoperative education as a strategy to address said anxiety in the preoperative period is regarded to be an appropriate intervention to decrease postoperative pain and influences patients' postoperative pain experience. Patients who receive preoperative information about pain, experience less pain and require less analgesia [18]. On the contrary, some studies suggest that patient education preoperatively about pain sensitises them to experience more pain [19, 20], while others may fail to understand leading to dissatisfaction with treatment and general care postoperatively [11, 13].

In Uganda, there is no standardised pre-operative assessment protocols or information about use of counselling preoperatively about pain to help in guidance of its use in patient management. We sought to understand the role of preoperative pain information on the postoperative pain and patient satisfaction in our setting.

Methods

This prospective, randomized, double-blind, controlled trial was conducted at the Department of Orthopaedics, Mulago National Referral Hospital. The Institutional Review Board of Makerere University Medical School and Mulago National Referral Hospital approved it as part of completion of Master of Medicine in Anaesthesia and Critical Care. The Makerere University School of Medicine Research and Ethics Committee (SOMREC) provided ethical approval for this trial. This study was conducted for 8 months between June 2016 and February 2017.

The trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice and registered at ClinicalTrials.gov. (NCT03056521). A written informed consent was obtained from all patients. The authors have followed the applicable CONSORT guidelines.

For this single centre, we consecutively recruited all patients during the study period who were 18 years and above, scheduled for elective orthopaedic surgery, that consented to participate in the study. We excluded those with surgically unrelated chronic pain, bone cancer and those that were previously recruited but came back for re-surgery for the same/different condition.

Randomization and concealment: Block randomization was used for this study with block size of 5 to ensure equal distribution of patients in each arm. A computer program was used to generate the randomization sequence of patient allocation to either the intervention or control arms by an independent statistician. Arm1 received specific information about pain preoperatively (intervention) while Arm 2 did not receive any information (control). The study numbers were allocated sequentially following the aforementioned codes. The randomization code was sent

to the principal investigator in an opaque carrier envelope by an independent statistician who was not part of the study. They were similar to computer generated number sequence, becoming the patients study number.

Blinding: The study was double-blind with the research assistants, anaesthesia providers and the statistician blinded to the assignment and the arms to which the patients belonged.

Protocol

All patients admitted for elective orthopaedic surgery, were expected to have a pre-operative visit by the anaesthetic provider on the day before surgery. The principal investigator recruited all the patients to ensure consistency. Randomization was based on computer-generated codes.

To conceal allocation, sealed opaque envelopes were opened only shortly before administering the intervention. After consent bedside, they were randomized. Demonstration of the Verbal Numerical Rating Scale (VNRS) and how to indicate the level of pain they experienced was done. The intervention arm privately received specific preoperative information about pain from the principal investigator in addition to the preoperative assessment. A trained assistant assessed the pain scores postoperatively at 0, 12, 24, 48hours or till discharge if less than 48hours.

We used a pretested interviewer administered questionnaire for both the intervention and the control arm. The questionnaire included the patient demographics, vital baseline clinical characteristics, intra operative and postoperative parameters at 0, 12, 24 and 48hours. The patient satisfaction with pain management were also recorded. This was adapted from an unpublished study by Kimenye et al in Mulago National Referral Hospital and adjusted to suit our study [21].

When a patient was found with postoperative pain, the doctor/nurse on duty was informed so as to manage it according to their discretion. All filled data collection tools were checked for completion on a daily basis. Data was entered into EPIDATA-Entry software.

The intervention: Specific preoperative information about pain was given verbally following an order on the leaflet. This information involved the following: emphasis on patient's own role in pain management, benefits of well-treated postoperative pain, role of physiotherapy, use of basic pain medication, disadvantages of poorly controlled pain, practical physical methods of pain management and other facts about postoperative pain. These are based on studies by Gammon et al and Louw et al. methods [22, 23].

Measurements

Socio-demographic data was recorded as well as type of surgery, duration of surgery, type of anaesthesia, pain scores, pulse rate, analgesics given, patient satisfaction and anaesthesia provider.

Primary outcomes were postoperative pain experience and patient satisfaction. Postoperative pain experience was measured as pain score using the VNRS. The assessed pain using the VNRS was classified as no pain (1-3), pain (4-10) but also as no pain (0), mild (1-3), moderate (4-6) and severe pain (7-10).

We also assessed patient satisfaction with pain management which was a yes or no answer. Those that were not satisfied with the management were requested to give reasons.

Sample size calculation and statistical analysis

Sample size calculations for our trial were based on the study of Sjöling et al [12]. Power analysis determined that a sample size of at least 165 subjects per arm would achieve 80% power to detect a difference in VNRS scores between the two arms, with a significance level α of 0.05.

Arms were primarily compared for balance in patients’ demographic data, intra-operative characteristics and postoperative variables.

Data was analyzed using STATA version 12.0. Continuous variables were summarized using means, standard deviations, medians, and ranges. Categorical variables were summarized using frequencies, proportions, and percentages. Box and Whisker plots were drawn to also present the continuous variables. The differences between arms were regarded as being statistically significant if the P-value was less than 0.05.

To assess the effect of preoperative information about pain, the outcome was dichotomized as yes (VNRS 4-10) and no (VNRS0-3). Bivariate analysis was performed for each of the independent variables to determine association with outcome. The association was assessed using logistic regression and its strength was summarized using odds ratios and 95% confidence intervals. Variables with a P-value of ≤ 0.2 at bivariate analysis were considered for multivariate model. Multivariate logistic regression was performed to determine how preoperative pain information as a main predictor is associated with the outcome. Interactions between the variables which remain in the model were assessed using the Chunk test followed by assessing for confounding using a difference of $\geq 10\%$ between the crude and adjusted measure of effect (OR) for the variables that would have gone out at each step.

Results

A total of 400 patients were screened and 398 were enrolled for the study, 198 were enrolled to the intervention arm while 200 to the control arm, 170 were analysed in each arm as shown in the consort flow diagram (Figure 1).

The baseline patient characteristics in both arms were as shown in Table 1. The mean preoperative pain score of patients in the intervention arm was 3.52 SD (2.45) and 3.59 SD (2.63) in the control arm.

Table 1: Demographic characteristics

	Intervention n (%)	Control n (%)	P value
Characteristic			
Gender			
Male	115 (67.6)	110 (64.7)	0.567
Female	55 (32.4)	60 (35.3)	
Education level			
No formal education	3 (1.76)	12 (7.06)	0.003*
Primary	46 (27.06)	65 (38.24)	
Secondary	78 (45.88)	63 (37.06)	
Tertiary / university	41 (24.12)	25 (14.71)	
Missing	2 (1.18)	5 (2.94)	
Type of surgery			
Major	148 (87.06)	144 (84.71)	0.533
Minor	22 (12.94)	26 (15.29)	
Preoperative assessment			
Not done	149 (87.65)	146 (85.88)	0.631
Done	21 (12.35)	24 (14.12)	
ASA classification			
ASA class I	148 (87.06)	138 (81.18)	0.304
ASA class II	21 (12.35)	29 (17.06)	
ASA class III	1 (0.59)	1 (0.59)	
missing	0 (0)	2 (1.18)	
History of drug/ alcohol abuse			
Yes	55 (32.35)	66 (38.82)	0.145
No	115 (67.65)	99 (58.24)	
Missing	0 (0)	5 (2.94)	
Preoperative analgesia			
Yes	56 (32.94)	62 (36.47)	0.494
No	114 (67.06)	108 (63.53)	
Occupation			
Employed	22 (12.94)	28 (16.47)	0.358
Unemployed	148 (87.06)	142 (83.53)	

*P value based on the Fishers exact test

The highest pain score was noted to be at 12 hours and the lowest at 0 hours in both arms. The median pain scores at 0, 12, 24hours had no statistically significant difference in both arms. At 48 hours, there was a statistically significant difference between medians of the intervention and control arms with P-value= 0.029 (Table 2).

Table 2: Postoperative pain scores using the VNRS

Postoperative								
s)	0		12		24		48	
	Intervention (n= 169)	Control (n=170)	Intervention (n= 169)	Control (n=169)	Intervention (n= 168)	control (n= 168)	Intervention (n=146)	Control (n=147)
an pain	0	0	7	7	5	5	4	4
quartile	0—1	0—1	4—8	6—9	3—6	4—8	2—5	3—6
ie	0.421		0.673		0.251		0.029	

The individual postoperative pain scores at 12, 24 and 48 hours were generally less in the intervention compared to the control arm. This becomes more noteworthy with increasing time postoperatively (Figure 2).

Patients who had surgery longer than 120 minutes had an adjusted odds ratio for postoperative pain of 2.06 (CI 1.28-3.30; P= 0.003). Patients who had major surgery had an adjusted odds ratio for postoperative pain of 2.59(CI 1.33-5.04; P= 0.003) (Table 3).

Table 3: Comparing pain perception and patient variables

Variables	Pain perception* n (%)	Pain perception** n (%)	Unadjusted OR,95% CI	Adjusted OR,95%CI	P value
Arms					
Control	107 (51.4)	63 (47.7)	1	1	
Intervention	101 (48.6)	69 (52.3)	1.16(0.75,1.79)	1.16(0.73,1.86)	0.523
Gender					
Male	135 (64.9)	90 (68.2)	1		
Female	73 (35.1)	42 (31.8)	1.16(0.73,1.82)		0.534
Education level (n=333)***					
No formal education	9 (4.4)	6 (4.7)	1	1	
Primary	68 (33.4)	43 (33.3)	1.05 (0.35-3.17)	1.21(0.39-3.79)	0.741
Secondary	78 (38.2)	63 (48.8)	0.83 (0.28-2.44)	0.86(0.28-2.69)	0.808
Tertiary / university	49 (24.0)	17 (13.2)	1.92 (0.59-6.20)	2.08(0.61-7.07)	0.242
Technique					
Regional	158 (76)	113 (85.6)	1		
General	50 (24)	19 (14.6)	1.88(1.05,3.36)		0.084
Intraoperative analgesia					
No	15 (7.2)	9 (6.8)	1		
Yes	193 (92.8)	123 (93.2)	1.06(0.45,2.50)		0.89
Age(n=338)					
<=35 years	111 (53.9)	68 (51.5)	1		
> 35 years	95 (46.1)	64 (48.5)	0.91(0.59,1.41)		0.67
Type of surgery					
Minor	17 (8.2)	31 (76.5)	1	1	
Major	191 (91.8)	101 (23.5)	3.45(1.82,6.53)	2.59(1.33,5.04)	0.003
Duration of surgery					
<=120	100 (48.1)	87 (65.9)	1	1	
>120	108 (51.9)	45 (34.1)	2.09(1.33,3.28)	2.06 (1.28,3.30)	0.003
History of alcohol /drug abuse					
No	133 (65.2)	81 (61.8)	1		
Yes	71 (34.8)	50 (38.2)	0.86(0.55,1.36)		0.532
Preoperative analgesia					
No	138 (66.3)	84 (63.6)	1		
Yes	70 (33.7)	48 (36.4)	0.89(0.56,1.40)		0.609

*patients who perceived pain (VNRS 4-10)
missing data

**patients who did not perceive pain (VNRS 0-3) ***7

Patients who received preoperative information about pain had an adjusted odds ratio for satisfaction with pain management during hospital stay of 0.601 (95% CI: 0.36-1.01 P=0.059) (Table 4).

Table 4: Comparing patient satisfaction with pain management

	Not satisfied n (%)	Satisfied n (%)	Unadjusted OR(95% CI)	Adjusted OR(95% CI)	P- Value
ntion	124 (47.2)	46 (59.7)	1	1	
	139 (52.8)	31 (40.26)	0.601(0.359,1.006)	0.607(0.362,1.019)	0.059
	53 (68.8)	172 (65.4)	1		0.534
	24 (31.2)	91 (34.6)	0.856(0.496,1.476)		
ion level)***					
al education	13 (5.0)	2 (2.7)	1		
r	86 (33.3)	25 (33.3)	1.89(0.39-8.94)		0.422
ary	110 (42.7)	31 (41.3)	1.83 (0.39-8.55)		0.441
r / university	49 (19.0)	17 (22.7)	2.25 (0.46-11.03)		0.315
que					
al	206 (78.3)	65 (84.4)	1		
l	57 (21.7)	12 (15.58)	0.667(0.337,1.320)		0.245
ative analgesia					
	177 (67.3)	45 (58.4)	1	1	
	86 (32.7)	32 (41.6)	1.462(0.869,2.465)	0.694(0.411,1.172)	0.172
338)					
ears	138 (52.9)	41 (53.3)	1		
ears	123 (47.1)	36 (40.7)	0.952(0.592,1.639)		0.954
'surgery					
	40 (15.2)	8 (10.4)	1		
	223 (84.8)	69 (89.6)	1.547(0.691,3.462)		0.288
n of surgery					
	149 (56.7)	38 (49.4)	1		
	114 (43.3)	39 (50.6)	1.34(0.806,2.232)		0.258
of alcohol /drug					
	169 (65.2)	45 (59.2)	1		
	90 (34.8)	31 (40.8)	0.773(0.458,1.306)		0.336
erative analgesia					
	21 (8)	3 (3.9)	1		
	242 (92)	74 (96.1)	0.467(0.136,1.610)		0.228

***7 missing data

Discussion

Our randomised, double blind, controlled trial demonstrated that preoperative information about pain improves postoperative pain experience at 48 hours, but had low patient satisfaction with pain management at MNRH orthopaedic ward.

The individuals in the two arms of the study had comparable demographics for age, preoperative analgesia, history of drug and alcohol abuse, and ASA classification. However, there were statistically significant differences in the education level of participants with people in the intervention arm more educated than those in the control arm. In a prospective study among general surgery patients, it was discovered that patients with lower level of education were prone to experiencing higher pain scores than the more educated and could be mainly due to the poor understanding of the preoperative information, the level of anxiety and depression caused by that and the suboptimal request and use of analgesia [24]. This could also contribute to skewing of our final results in this study. Level of education has been also found to have an impact on patient satisfaction with the less educated being more satisfied [25]. At multivariate analysis however we did not realise any significant difference in effect of level of education on patient satisfaction and pain experience which is contrary to what is already known in high income countries. This could be attributed to the cultural and social setting in low income countries where healthcare is usually taken as a privilege by majority of patients.

Postoperative pain experience:

Patients in both arms experienced pain the least immediately after surgery and it increased to highest recorded pain score at 12 hours in this study. This may be because inflammatory mediators have been found to be highest 6-8 hours post-operatively and reflects the acute phase response peak that occurs in the first 24 hours following surgery [26, 27].

Our study showed that there were no overall significant differences between the arms regarding the overall perception of pain at 0 and 24 hours. This finding is in agreement with two systematic reviews which both concluded that preoperative education for orthopaedic surgery has no statistically significant effect on postoperative pain experience [23, 28]. This may also be due to the fact that the type of intraoperative and postoperative analgesia for the patients was not controlled for in our study and the use of the one-on-one method of educating the patients. A study comparing the effect of individual and group preoperative teaching on postoperative outcomes, showed group education to be just as effective as, and more efficient than individual education [29].

At 48 hours post-surgery, the patients in the intervention arm had lower VNRS pain scores compared to the control arm and this was statistically significant. These findings imply that postoperative pain experience improved progressively with time and was influenced by the individual preoperative education. A similar study in Sweden noted that postoperative pain declined more rapidly for patients in the intervention arm [17]. Studies done in both high income and low income settings agree with our study findings that preoperative patient education improves postoperative pain experience [17, 30]. It may be concluded from the above published data that as pain due to actual injury to tissues reduces, the effect of preoperative counselling about pain has a more profound positive influence on the postoperative pain experience.

According to a review article by Rawal, a pain score ranging from 4-10 on VNRS is considered to be inadequately treated pain [31]. In our study, 61% of all the patients experienced pain of four or more on the VNRS, a pattern similar to Pavlin et al in USA [32]. Our findings are however lower than those from a study done in MNRH by Kiswezi et al whose finding was 100% postoperative pain after laparotomy [5]. The differences between the two studies is rooted in the type of surgeries considered (laparotomy Vs orthopaedic surgery) and methodology.

Long surgery time and major surgery were found to significantly influence pain experience irrespective of the counselling about pain preoperatively. This is similar to what has been found in other studies that included

duration of surgery and type of surgery as being significant determinants of the postoperative pain experience [33, 34].

Patient satisfaction:

In both arms of our study, there was no difference in patient satisfaction with pain management. This contrasts literature indicating that specific preoperative information improves patient satisfaction [12, 35]. In our study population, the outcomes of patient satisfaction maybe more related to the varied nursing care received [12, 36]. Additionally, those in the intervention arm could have had raised expectations which were not met making them less satisfied than expected.

Provision of analgesia in our study was not significantly related to patient satisfaction and this was more pronounced in the control arm than the intervention arm. Equivalent studies showed that patient satisfaction was more related to the nursing care than actual analgesia provision. It was only related to analgesia provision as long as pain was well controlled [37, 38]. Provision of analgesia in our study was left to the discretion of the clinical care team. A study in MNRH stressed challenges in pain management such as widely spaced analgesic prescriptions, irregularities in timing of analgesic doses, and sometimes unavailability of the prescribed analgesics [5]. The highlighted issues were still present at the time of our study and could have contributed to our findings in relation to patient satisfaction.

This was a pragmatic randomized clinical trial with a large sample size to show the effect of this information. Our study was done at a national referral hospital which receives patients from all over the country making our findings generalizable.

Limitations in our study included ascertainment bias and lack of control for analgesia regimen. Ascertainment bias in this study may have arisen from the study participants in the control arm being given additional preoperative information by the unknowing anaesthetic providers during pre-anaesthesia assessment as this was a double blind study. Analgesia regimens was not controlled for which could have affected the results.

Conclusion

Patients that received preoperative information about pain experienced lower and sharp declines of postoperative pain scores, but had a lower satisfaction than expected mainly due to unmet expectations with nursing care.

Therefore, the use of preoperative information is vital in pain management postoperatively for patients and should be used together with the other standard postoperative pain management protocols in order to have good outcomes.

We also recommend that it is vital to have nurses directly involved in educating patients while on ward about surgery and postoperative pain as satisfaction was found to be much more related to nursing care.

We recommend future studies looking at the effect of preoperative pain information on pain experience with established/similar analgesic regimes, nursing involvement and continued counselling postoperatively.

Abbreviations

MNRH   Mulago National Referral Hospital

Declarations

Ethics approval and consent to participate

Permission to carry out the study was sought from Mulago National Referral Hospital and Makerere University College of Health Sciences School of Medicine Research Ethics Committee with reference #REC REF 2016-055. Each participant provided written informed consent.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on request.

Competing interest

There are no competing interests.

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Author's contributions:

MO the principal investigator designed the research, sought ethical approval, trained the data collectors and data entrants and wrote the report. JM, EA, CL, AW and PM were co- investigators. They helped in designing the study and obtaining ethical approval and JM helped with randomisation, cleaning and analysing the data. CS helped with designing the protocol and writing the final report. All the authors helped with writing the final report.

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Figures

Figure 1

Consort Flow Diagram

Yes= intervention   No= control

Figure 2

post operative pain scores comparing the two arms

Supplementary Files

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