Intraperitoneal Gas Drain to Reduce Postsurgical Shoulder Tip Pain in Gynecological Laparoscopy

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Running Title

Intraperitoneal Drain After Laparoscopy

Abstract

Background : Operative gynecologic laparoscopy has become the preferred method for treating benign gynecologic diseases due to its minimally invasive nature and faster recovery compared to laparotomy. However, post-laparoscopic shoulder pain (PLSP) is a common complaint following laparoscopic surgeries, affecting patients' satisfaction and recovery. Various methods have been proposed to alleviate PLSP, but consensus on their effectiveness remains elusive.

Aim of the Work : This randomized controlled clinical trial aims to investigate the effect of gas drainage by intraperitoneal drain on shoulder pain in women after laparoscopic surgery in comparison to no drain use.

Patients and Methods: A randomized controlled clinical trial involving 120 female patients undergoing laparoscopic surgery was conducted to investigate the effect of intraperitoneal drainage on postoperative shoulder pain. The patients were divided into two groups: the study group (n=60) with intraperitoneal drain placement, and the control group (n=60) with routine technique and no drain use. Visual Analog Scale (VAS) scores were used to assess shoulder and abdominal pain at different postoperative time points.

Results: The study demonstrated that intraperitoneal drainage significantly reduced postoperative shoulder pain in the first 12 hours after surgery compared to the control group ($p < 0.001$ at 3 and 6 hours, $p = 0.038$ at 12 hours). However, no significant difference in shoulder pain was observed between the two groups at 24 hours post-surgery ($p = 0.451$). The need for postoperative analgesia was also lower in the drainage group ($p < 0.001$). These findings align with previous studies suggesting the efficacy of drainage in reducing shoulder pain after laparoscopic surgery.

Conclusion: This study demonstrates the effectiveness of intraperitoneal drainage in reducing post-laparoscop-

ic shoulder pain during the first 24 hours after surgery, consequently reducing the need for postoperative analgesics. These findings support the outcomes of previous investigations, indicating that drain placement may be a valuable strategy to alleviate postoperative shoulder pain in women undergoing gynecologic laparoscopy.

Keywords: Laparoscopy, postoperative pain, shoulder pain, intraperitoneal drainage.

INTRODUCTION

Pain is the most common complaint among patients and a source of concern for medical personnel, and pain management is a significant part of patient satisfaction[1].

With the improvement in medical research, several procedures for treating patients have become accessible, including laparoscopy, which is becoming the gold standard approach for many conditions. [2]In comparison to open surgeries, Laparoscopy caries less complications, better recovery and shorter hospital stay. [3]

It is expected that 30–80% of cases experience shoulder pain following laparoscopic surgery, especially in the first 24 hours [4]. The residual gas causes stretching of the post-distended diaphragm and peritoneum after prolonged surgery in the abdominal cavity, causes shoulder pain [5]. There are many recommended pharmacological agents that has been used to reduce post laparoscopy pain, but due to their side effects, researchers have looked at non pharmacological options. [6]

In some laparoscopic procedures, such as cholecystectomy, the use of an intraperitoneal drain showed conflicting results [7].

For the treatment of shoulder pain after laparoscopy, therapies such as subcutaneous anesthetic injections, regular saline injections into the abdominal cavity, and lowering the pressure of CO2 gas flow are commonly used [8].

Since an intraperitoneal drain is a medical device for emptying and suction, it may be useful for removing gases from the abdominal cavity and eventually reducing post laparoscopy pain. [9].

AIM OF THE WORK

This randomized controlled clinical trial aimed to investigate the effect of gas drainage by intraperitoneal drain on shoulder pain in women after laparoscopic surgery in comparison to no drain use.

PATIENTS AND METHODS

This prospective randomized controlled clinical trial was conducted at operative theatres, Obstetrics and Gynecology Department, Faculty of Medicine, Ain Shams University Hospitals from January until July 2023.

Study population: Female patients attending Ain Shams University Maternity Hospital for laparoscopic surgery with the following criteria:

Inclusion criteria: Women > 18 years old, women with benign gynecological conditions or indications for diagnostic laparoscopic procedures and laparoscopic duration: minimum 15 minutes and maximum 60 minutes.

Exclusion criteria: Women with chronic abdominal, pelvic and shoulder pain or trauma, women whose laparoscopic surgery changes to laparotomy and women who are not willing to participate in the study or unable to sign consent.

Sampling Method "randomization": Systematic random sampling and women fulfilled the inclusion criteria were randomly assigned to either group. One Hundred Twenty opaque envelopes were numbered serially and, in each envelope, the corresponding letter, which denoted the allocated group, was put according to randomization table. Then all envelopes were closed and put in one box. Randomization was done using computer generated randomization sheet using MedCalc © version 13.

Sample size: The study was conducted on 120 women; they were subdivided into 2 groups. The required sample size calculated based on the following equation: n = required sample size per group = 1.96 (The critical value that divides the central 95% of the Z distribution from the 5% in the tail) n= 0.84 (The critical value that separates the lower 20% of the Z distribution from the upper 80%).

Sample size justification: Using PASS 11 program for sample size calculation, setting confidence level at 95%, margin of error at ± 0.1 and by reviewing results from previous study 9 showed the rate of severe pain among patients underwent female laparoscopic surgery with intraperitoneal drain versus without drain (control) were (2.6% vs. 15.8% respectively); based on that the required sample size will be at least 57 patients undergoing laparoscopic surgery in each group to be sufficient to achieve study objective.

Ethical considerations:

Patient information and informed consent: before being enrolled into the study, all the study procedure was discussed with the patients and an informed consent was obtained from whom who approved to parti consented to participate after the nature, scope and possible consequences of the clinical study had been explained in a form understandable to her.

Confidentiality: only the patient initials were recorded in the case report form, and when the patient's name appeared on any other document, it was kept in a secure place by the investigators. The investigators maintained a personal patient identification list (patient initials with the corresponding patient names) to enable record to be identified.

Protocol approval: before the beginning of the study and any accordance with the local regulation followed, the protocol and all the corresponding documents were declared for ethical and research approval by the council of Obstetrics and Gynecology Department, Ain Shams University.

Concerning safety and efficacy: Complications of laparoscopy.

Study interventions and procedures:

The following data were collected: Women age, BMI, indications of laparoscopy, previous surgical and medical history.

Procedure details including: Number of ports entered the abdomen, amount of gas used during the procedure, findings on entry including: any surgical intervention done during procedure (adhesiolysis, cystectomy, dye test, etc …), any complications during the procedure, time of surgery and postoperative analgesia requirement (according to VAS)

Anesthesia was established after intubation with number 7 or 7.5 tube using anesthetic drugs (1% isoflurane and 50% N2O with 50% oxygen).

Laparoscopic surgery was performed using carbon dioxide gas and three ports will be inserted as follows: A 10 mm port under the umbilical cord to enter the telescope and two 5 mm ports through the outer edge of the rectus muscle to enter the surgical instrument. CO2 gas was entered into the peritoneum with an initial low flow then high flow will be allowed. CO2 gas blower unit was adjusted at gas pressure between 12 and 16 mm Hg during the operation. The same procedure was performed for all the participants of this research. Study population was divided into two equal groups:

Group I (study group): Consisted of 60 women to whom intraperitoneal drain was placed.

Group II (control group): Consisted of 60 women to whom routine technique without drain was used.

In the study group, before closure of the skin, intraperitoneal passive drain (Nelaton catheter size 14) was inserted through any of the side ports without extra incision and placed in RLQ (Right lower quadrant) in pelvis at surgical point through the outer edge of the

rectus. It was entered into the surgical port and then the skin was sutured with 3/0 vicryl thread. In the control group, routine laparoscopic surgical technique without drain was performed. In both groups, the pain in abdomen and shoulder was recorded at 3, 6, 12, and 24 h after the surgery using Visual Analogue Scale (VAS) of pain. As per hospital protocol, analgesia was given at 12 hrs. interval. If extra analgesia was needed a dose of Diclofenac sodium suppositories (Voltaren 100mg, NOVARTIS PHARMACEUTICALS) was given at least 6 hrs. Apart from the previous analgesia if the patient's pain score = or > 4.

Study outcomes:

Primary outcome: The severity of shoulder pain in study groups at 3, 6, 12, and 24 h after surgery using Visual Analogue Scale (VAS) of pain. Based on the distribution of pain VAS scores in postsurgical patients who described their postoperative pain intensity as none, mild, moderate, or severe the following cut points on the pain VAS has been recommended: 0 = No pain. 10 = Max. pain. 0 – 3 = mild pain. >4 – 7 = moderate pain. >7 – 10 = severe pain. [10].

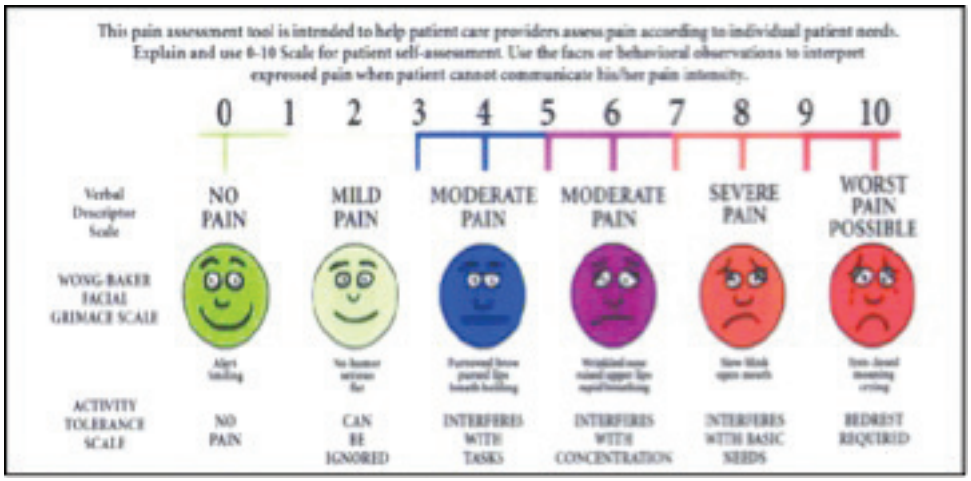

Figure 1: Visual analog scale with corresponding Wong-Baker Faces Scale (WBS) [11]

Secondary outcomes: Severity of abdominal pain, the number of Doses of analgesia, postsurgical adverse events as fever, nausea, vomiting and wound complications, hospital stay and patient satisfaction.

Statistical analysis: Data were collected, coded, revised, and entered into the Statistical Package for Social Science (Rstudio) version 2.3.2. The data were presented as numbers and percentages for the qualitative data, mean, standard deviations, and ranges for the quantitative data with parametric distribution, and median with interquartile range (IQR) for the quantitative data with the non-parametric distribution. **The Shapiro test** was used to verify the normality of the distribution. **The chi-square** test was used in the comparison between two groups with qualitative data and **Fisher exact test** was used instead of the Chi-square test when the expected count in any cell was found less than 5.

Independent t-test was used in the comparison between two groups with quantitative data and parametric distribution and **Wilcoxon Mann-Whitney test** was used in the comparison between two groups with quantitative data and non-parametric distribution.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following: $P > 0.05$: Non-significant (NS), $P < 0.05$: Significant (S) and $P < 0.01$: Highly significant (HS).

RESULTS

Baseline characteristics:

This study was carried out on one hundred and twenty patients (120 patients) divided into two groups. Group (1) consist of 60 patients and Group (2) consist of 60 patients. The comparison between the two groups including age, BMI, parity, mode of previous delivery, past medical and surgical history showed no statistically significant difference as shown in Table (1). Also the indication of laparoscopy was statistically insignificant if compared between the two groups.

Procedure details:

As regard of duration of procedure, Table 2 showed equivalent results regarding the time of the laparoscopy between the two groups and the number of ports inserted. The procedure done were similar statistically between the two groups except for the number of cystectomies which was higher with statistically significant difference in group 1 compared to group 2. (Table (2)

VAS score of shoulder pain:

For the VAS score of shoulder pain at 3 hours, 6 hours, 12 hours, the results showed a significant statistical difference between the groups regarding perception of pain with the study group having less pain if compared to the control group.

For the VAS score of shoulder pain at 24 hours, in Group (1) and Group (2), the scores ranged from 0 to 2 and 0 to 3 respectively. The mean & SD for Group (1) and Group (2) were 0.47±0.70 and 0.63±0.90, respectively, so both groups showed equivalent result with no statistically significant difference between them regarding pain perception as shown in Table (3).

VAS score of abdominal pain:

Similar to the shoulder tip pain perception, the VAS score of abdominal pain at 3, 6 and 12 hours, showed statistically significant different scores in study group if compared to the control group with the lower pain scores in the study group while there was no significant difference at 24 hours after the laparoscopy. Table (4)

Need for extra analgesia:

According to the need for extra analgesia, only 16 patients (26.7%) needed extra analgesia in the group (1). However, 40 patients (66.7%) needed extra analgesia in the group (2). There was a highly significant difference in the need for extra analgesia between the two studied groups at ($p<0.001$) as shown in Table (5).

DISCUSSION

Operative gynecologic laparoscopy is becoming the primary approach for the treatment of benign gynecologic diseases, as it is a less invasive procedure, helps shorten the length of hospitalization, and facilitates recovery earlier than laparotomy [12-13]

Most complications of laparoscopic procedures occur during abdominal access or port placement, while other complications arise during abdominal insufflations, tissue dissection, and homeostasis 14. However, post-laparoscopic shoulder pain (PLSP) has been the most common complaint that often occurs following laparoscopic surgeries and has an important impact on patients' satisfaction 15. It was reported that the incidence of PLSP ranges from 35–80%, and the intensity varies from mild to severe [16-17]

Although the exact mechanism of PLSP remains unclear, some studies have suggested that it is caused by the trapping of carbon dioxide (CO2) between the liver and the right diaphragm and subsequent conversion into carbonic acid, which irritates the diaphragm and subsequently generates referred shoulder pain (C4 dermatomal) [18-19]

To reduce the post-laparoscopic shoulder pain, several methods have been suggested including the use of a peritoneal gas drain in the first 4–6 hours following laparoscopy, intraperito-

neal local anesthesia, pulmonary recruitment maneuver, intraperitoneal saline infusion, gasless laparoscopy and reduction in insufflation pressure. It has been suggested that these methods reduce post-operative shoulder pain by decreasing the volume of residual intraperitoneal gas, but there is no consensus among researchers regarding the effectiveness of the above-mentioned methods [20-23]

Herein, this study aimed to investigate the effect of drainage by intraperitoneal drain on shoulder pain in women after laparoscopic surgery in comparison to no drain use. The results as described above showed the reduced VAS scores and need of extra analgesia in the post operative first 12 hours and similar with the control group by 24 hours.

These findings indicate the effectiveness of drainage by an intraperitoneal drain in reducing postoperative pain in the first 24 hours of gynecological laparoscopy to the extent that reduces the need for postoperative analgesics.

These findings support the results of previous studies. Haghoo et al investigated the drainage for peritoneal suction to reduce shoulder pain caused by gynecological laparoscopy. They found at 12 h and 24 h after surgery, the VAS score for shoulder pain was statistically lower in the group with drainage ($P < 0.001$ for both), but not after 48 hours post-surgery ($P = 0.806$). Also, significantly higher postoperative demand for analgesics was observed in the control group ($P < 0.001$). The authors concluded that gas drainage may be useful for preventing postoperative shoulder pain among patients undergoing gynecological laparoscopic surgery and could decrease the need for pain medication [24]

Chauhan and Vaishnav (2016)25, reported that drain insertion increases the duration of procedure and hospitalization, which may be due to the presence of the patients for post-surgical follow-up; meanwhile, the type of drain used was not mentioned in their study.

Likewise, Tharanon and Khampitak showed that the postoperative intra-abdominal tube drain could be an effective method for improving postoperative pain at nearly all parameters, including decreasing the need for postoperative morphine in long-time operations (> 2 hours)[16]

Hosseinzadeh et al. also agreed with this study findings. They found the severity of shoulder pain was significant between drain and control groups 3, 6, 12, and 24 h after surgery ($p < 0.001$). Consumption of diclofenac after operation was higher in the control group ($p < 0.001$). They suggested the use of a drain in female laparoscopic surgery is beneficial for reducing subsequent shoulder pain [9]

Also, a meta-analysis by Kaloo et al. revealed an association between the intraperitoneal drain and a reduction in the incidence and severity of shoulder pain when compared with no intraperitoneal drain at all time points assessed postoperatively at 3-4 hours, 12 hours, 24 hours, and 48 hours [26]

On the other side, an earlier randomized trial by Abbott et al. studied the effect of drainage use on postoperative shoulder pain after minor gynecological laparoscopic surgery and found that, although drainage use did not change the severity of shoulder pain, its use decreased the incidence of pain. However, the study showed that simply using an analgesic was more cost-effective compared with drainage use and did not recommend routine use of drains to prevent postoperative shoulder pain [27]

Again, contrary to this study results, a meta-analysis conducted by Craciunas et al. 21did not support the routine use of a peritoneal gas drain following gynecological laparoscopy because of very little evidence of an overall benefit from this approach, and in addition, no association with a reduction in the requirement of analgesia and anti-emetics for shoulder pain and total pain when compared to no use of peritoneal gas drain

group. However, the authors recommended future studies to minimize the bias resulting from operating time and the use of the analgesic dosage as an objective measure for pain evaluation.

This was followed by a study that found the VAS scale was similar between the drainage and non-drainage groups ($p = 0.376$ and $p = 0.847$, respectively). They explained this by that drainage use may cause discomfort because of irritation, tissue damage, adhesion, obstruction, or entanglement, suggesting that the increase in postoperative abdominal pain may be because of the presence of the drain itself [28]. Asgari et al., 2018 [29] , also reported no effect of the drain in reducing post laparoscopy pain although they didn't evaluate the first 12 hours post-surgery.

Reduction of pain after pneumoperitoneum was investigated by several studies and different modalities were used. Bogani and colleagues [30]compared low-pressure (8 mm Hg) versus standard-pressure (12 mm Hg) pneumoperitoneum and found that while abdominal pain was similar between groups, the incidence of shoulder tip pain in the early postoperative period was 36% in the standard and 5% in the low-pressure group. Madsen and colleagues demonstrated less shoulder tip pain with lower inflation pressure [31]. When carbon dioxide (CO2) was humidified and heated, postoperative shoulder tip pain scores, but not abdominal pain scores, were lower than when using control gases[32] Lastly, elimination of CO2 with an open umbilical trocar decreased postoperative pain scores, but additional trocar site infiltration did not decrease pain scores or opioid consumption further [33]

Researchers have looked at the effect of the gas drain in different laparoscopic procedures with promising results 34-36. Further studies on larger scales and on lengthy procedures are recommended to validate the use of this simple, available technique to improve patients' satisfaction after surgical laparoscopic procedures.

CONCLUSION

The use of an intraperitoneal gas drain could significantly improve postoperative shoulder and abdominal pain in the first 24 hours resulting from gynecologic laparoscopic surgery. In addition, it reduces the need for postoperative analgesics. It is a cheap option with minimal side effect profile which might increase patient post operative satisfaction.

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Table (1): The Comparison between the two studied groups according to baseline characteristics

		Group (1) (n=60)	Group (2) (n=60)	p-value
Age in years	**Min.- Max.**	19 - 44 years	19 – 41 years	0.962
	Median (IQR)	29.5 (24.0 - 35.0)	30.0 (24.0 - 34.2)	
BMI (Kg/m^2)	**Min. – Max.**	20.8 – 39.5	21.5 – 38	0.362
	Median (IQR)	27.7 (24.7 - 31.0)	26.5 (24.5 - 29.0)	
Parity	**Nulliparous**	36 (60.0%)	37 (61.7%)	0.638
	Multipara	24 (40.0%)	23 (38.3%)	
Indication	**Ovarian cyst**	13 (21.7%)	3 (5.0%)	0.080
	1ry or 2ry infertility	34 (56.7%)	43 (71.7%)	
	Hydosalpinx	7 (11.7%)	10 (16.7%)	
	Ectopic	1 (1.7%)	1 (1.7%)	
	Missed IUCD	5 (8.3%)	3 (5.0%)	
Medical history	**Free**	47 (78.3%)	48 (80.0%)	0.582
	Rheumatic arthritis	1 (1.7%)	1 (1.7%)	
	Rheumatic fever	0 (0.0%)	1 (1.7%)	
	Bronchial asthma	3 (5.0%)	1 (1.7%)	
	Endometriosis	0 (0.0%)	1 (1.7%)	
	TB endometritis	0 (0.0%)	1 (1.7%)	
	FMF on colchicine	0 (0.0%)	1 (1.7%)	
	Hypothyroid on L-thyroxine 50	1 (1.7%)	2 (3.3%)	
	Diabetes	3 (5.0%)	3 (5.0%)	
	HCV	0 (0.0%)	1 (1.7%)	
	Epilepsy	2 (3.3%)	0 (0.0%)	
	HTN	1 (1.7%)	0 (0.0%)	
	TB salpinx	1 (1.7%)	0 (0.0%)	
	Osteosarcoma	1 (1.7%)	0 (0.0%)	
Surgical history	**Abdominal pelvic surgery**	35 (58.3%)	41 (67.8%)	0.272
	No surgery	21 (35.0%)	13 (22.0%)	
	Other non-abdominal surgeries	4 (6.7%)	6 (10.2%)	

Table (2): The Association between the two studied groups according to the procedure details

		Group (1) (n=60)	Group (2) (n=60)	p-value
Duration of procedure	**Min. – Max.**	20-60	20-60	0.094
	Mean±SD	39.83±11.75	36.42±10.38	
Number of ports	**2**	17 (28.3%)	21 (35.0%)	0.432
	3	43 (71.7%)	39 (65.0%)	
Procedure done	**MB +ve tubal patency test**	31 (51.7%)	39 (65.0%)	0.141
	Adhysiolysis	18 (30.0%)	20 (33.3%)	0.699
	Cystectomy	18 (30.0%)	3 (5.0%)	<0.001**
	Tubal disconnection	7 (11.7%)	9 (15.0%)	0.458
	Removal of IUCD	5 (8.3%)	3 (5.0%)	0.470
	Ovarian drilling	2 (3.3%)	5 (8.3%)	0.243
	Salpingectomy	2 (3.3%)	1 (1.7%)	0.576
	Detorsion and plication of ovarian ligament	0 (0.0%)	1 (1.7%)	0.313

Table (3): The Comparison between the two studied groups according to the VAS score of shoulder pain:

		Group (1) (n=60)	Group (2) (n=60)	p-value
VAS score 3 hours	**Min. – Max.**	0-3	0-5	<0.001*
	Mean±SD	2.02±0.77	2.58±0.81	
	Mild (0-3)	60 (100.0%)	56 (93.3%)	
	Moderate to severe (≥4)	0 (0.0%)	4 (6.7%)	
VAS score 6 hours	**Min. – Max.**	0-5	0-6	<0.001*
	Mean±SD	2.33±1.59	3.42±1.68	
	Mild (0-3)	45 (75.0%)	23 (38.3%)	
	Moderate to severe (≥4)	15 (25.0%)	37 (61.7%)	
VAS score 12 hours	**Min. – Max.**	0-3	0-4	0.045*
	Mean±SD	1.58±1.23	2.02±1.21	
	Mild (0-3)	60 (100.0%)	58 (96.7%)	
	Moderate to severe (≥4)	0 (0.0%)	2 (3.3%)	
	Min. – Max.	0-2	0-3	0.260
	Mean ±SD	0.47±0.70	0.63±0.90	
	Mild (0-3)	60 (100.0%)	60 (100.0%)	
	Moderate to severe (≥4)	0 (0.0%)	0 (0.0%)	

Table (4): The Comparison between the two studied groups according to the VAS score of abdominal pain

		Group (1) (n=60)	Group (2) (n=60)	p-value
VAS score 3 hours	**Min. – Max.**	2-3	1-5	<0.001*
	Mean±SD	2.27±0.45	2.85±0.94	
	Mild (0-3)	60 (100.0%)	50 (83.3%)	
	Moderate to severe (≥4)	0 (0.0%)	10 (16.7%)	
VAS score 6 hours	**Min. – Max.**	1-6	2-6	<0.001*
	Mean±SD	3.40±1.11	4.12±1.15	
	Mild (0-3)	45 (75.0%)	22 (36.7%)	
	Moderate to severe (≥4)	15 (25.0%)	38 (63.3%)	
VAS score 12 hours	**Min. – Max.**	1-4	2-4	0.046*
	Mean±SD	2.73±0.63	2.55±0.59	
	Mild (0-3)	57 (95.0%)	57 (95.0%)	
	Moderate to severe (≥4)	3 (5.0%)	3 (5.0%)	
VAS score 24 hours	**Min. – Max.**	1-3	0-3	0.298
	Mean±SD	1.55±0.57	1.67±0.66	
	Mild (0-3)	60 (100.0%)	60 (100.0%)	
	Moderate to severe (≥4)	0 (0.0%)	0 (0.0%)	

Table (5): The Association between the two studied groups according to Need for extra Analgesia:

Need for extra analgesia	Group (1) (n=60)	Group (2) (n=60)	p-value
No	44 (73.3%)	20 (33.3%)	**<0.001***
Yes	16 (26.7%)	40 (66.7%)	

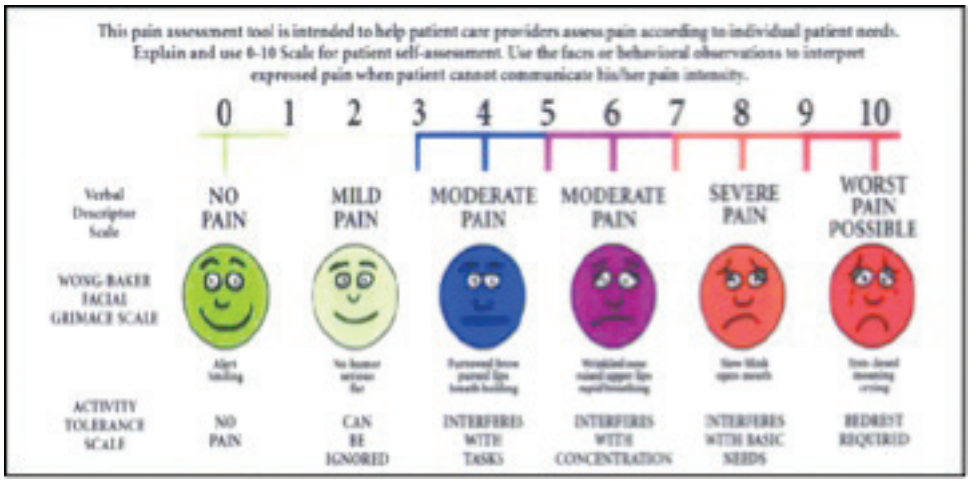

Figure 1: Visual analog scale with corresponding Wong-Baker Faces Scale (WBS) [11]