Ultrasound Guided Bilateral Transperineal Pudendal Nerve Block versus Conventional Blind Technique for Elective Perineal Surgeries: a Randomized Clinical Trial

Aliaa Mohammad El Melegy[1], Anesthesiology[2]

[1]Abdelraheem Mostafa Dowidar, Hoda Al said Ezzand Rehab Said El Kalla
[2]Surgical Intensive Care and Pain Medicine Department, Faculty of Medicine, Tanta University, Egypt

Abstract: Background: Pudendal Nerve Block (PNB) may be associated with reduced length of patient stay in hospital, reduced oral analgesic consumption, and improved patient satisfaction over other methods of analgesia. **Aim:** This study was designed to evaluate and compare the ultrasound (US) guided bilateral transperineal PNB with the conventional blind technique as adjuvant to general anesthesia (GA) for patients scheduled for elective perineal surgeries. **Patients and Methods:** This randomized clinical trial was carried out on 68 patients aged from 18 to 60 years of both gender, 50-100 kg, American Society of Anesthesiology (ASA) class I and II scheduled to undergo elective perineal surgeries and they were randomly enrolled into 2 equal groups; group I: (US guided PNB) and group II: (Conventional blind PNB). After induction of GA, preemptive bilateral transperineal PNB was done either by US or by nerve stimulator guidance. **Results**: Duration of the techniques was significantly longer with US guided technique. Ease of identification of sonographic anatomic structures was good in 73.5%, fair in 17.6 % and poor in 8.8%. Isoflurane consumption was significantly higher in group II. Entropy recording did not show any significant difference between the two groups at any time. Significant hemodynamic stabilization (MAP and HR) was with US group both intra and postoperatively in comparison with group II up to 18 hours. VAS was significantly decreased at 12 and 18 hours postoperatively in US group. Total postoperative morphine consumption was significantly lower in US group. **Conclusion:** PNB either by US or nerve stimulator guidance presented an excellent adjuvant to GA for patient undergoing wide range of perineal surgeries, however the US guidance technique was superior to nerve stimulator one as regard nerve visualization and localization, intra and postoperative analgesic efficacy and reduced postoperative opioid requirements.

[Aliaa Mohammad El Melegy, Anesthesiology. **Ultrasound Guided Bilateral Transperineal Pudendal Nerve Block versus Conventional Blind Technique for Elective Perineal Surgeries: a Randomized Clinical Trial.** *Nat Sci* 2019;17(10):47-58]. ISSN 1545-0740 (print); ISSN 2375-7167 (online). http://www.sciencepub.net/nature. 7. doi:10.7537/marsnsj171019.07.

Keywords: Pudendal Nerve Block- Ultrasound Guided - Conventional Blind - Perineal Surgeries

1. Introduction

Postoperative pain is one of the main complications that extend the patient's stay in the postanesthesia care unit (PACU). For this reason, adequate postoperative management is crucial for achieving effective rehabilitation. Furthermore, effective acute pain management reduces the development of chronic pain.[1]

Perineum is a highly sensitive region and most of the operations performed in the perineum cause significant patient discomfort and often result in a lengthy recovery period [2] and associated with functional disorders of the rectum, bladder and sexual issues which are caused not only by the surgery, but also by the insufficient treatment of postoperative pain.[3]

Pudendal Nerve Block (PNB) was evaluated for many urological procedures such as hypospadias repair and transurethral resection of prostate (TURP) and for gynecologic surgical procedures as repair of cystocele and rectocele and the second stage of labor. The use of this block may be associated with reduced length of patient stay in hospital, reduced oral analgesic consumption, and improved patient satisfaction over other methods of analgesia.[4]

Blind transperineal PNB together with the use of nerve stimulation has mainly focused on providing analgesia for management of pudendal neuralgia.[5, 6] However, this technique has been described for anesthetic purpose in few studies. Use of ultrasound (US) by anesthesiologists performing regional blocks is rapidly gaining popularity.[7] As regard PNB, US may allow direct anatomical landmarks visualization that is in close relationship with the pudendal nerve, such as internal pudendal artery, the ischial spine and the sacrotuberous and sacrospinous ligaments. Furthermore, the spread of the injected solution can possibly be detected and so may improve the precision and safety of the technique and minimize complications.[8]

Our present study was designed to evaluate and compare the US guided bilateral transperineal PNB with the conventional blind technique as adjuvant to general anesthesia (GA) for patients scheduled for elective perineal surgeries. The feasibility of both

techniques of PNB was the primary outcome, while the analgesic efficacy was the secondary outcome.

2. Patients and Methods

This prospective randomized study was carried out at Tanta University Hospital from May 2016 to September 2018 after approval of ethics and research committee (code: "201604016487"). Every patient received an explanation to the purpose, benefits and potential risks of the study. The study was registered at the Pan African Clinical Trial Registry (registration number: "201608001613798").

The study included 68patients aged from 18 to 60 years of both gender, weight from 50-100 kg, American Society of Anesthesiology (ASA) class I and II scheduled to undergo elective perineal surgeries. Patients who refused to participate in our study, those who had cerebrovascular diseases, coagulopathy (International Normalized Ratio (INR) >1.5, platelets < 80.000), those with history of opioid or drugs abuse and patients who had skin infection at the site of the procedure were excluded.

81 patients were assessed for eligibility and13 were excluded;11 patients did not meet the inclusion criteria and 3 patients refused to participate in the study. Then 68 patients were included in the research (figure1). 68 Patients were randomized into two equal groups (34 patients each) by random selection of envelops, prepared in advance and contained computer-generated random numbers; group I: US guided technique (UST) and group II: conventional blind technique (nerve localization by nerve stimulator) (CBT-NST). In the follow up periods, there was no drop out and all patients were analyzed in each group.

Anesthetic technique & Monitoring

In the operating room, an intravenous (IV) line was established and the patients in both groups were monitored with standard monitoring (Datex-Ohmeda S/5, GE Healthcare, Datex-Ohmeda Division, Helsinki, Finland) including, non-invasive blood pressure, electrocardiogram (ECG) and arterial oxygen saturation through pulse oximetry (SpO_2). Specific entropy sensors composed of self-adhering flexible bands holding three electrodes were placed on the forehead and temple after skin preparation with 70% isopropyl alcohol.

State Entropy (SE) and Response Entropy (RE) measurements were simultaneously displayed on the monitor which automatically recorded two values: SE (only cortical EEG) vary from 0 (suppression of EEG) to 91 (alertness) and RE (also including frontal electromyogram) ranges from 0 to 100.

After preoxygenation with 100% oxygen, GA was induced using IV 1 ug/kg fentanyl, 2 mg/kg of propofol through the IV cannula and after loss of verbal response isoflurane inhalation was started at 1 Minimum alveolar concentrations (MAC) (ranged from 0.9 to 1.4%) maintaining spontaneous ventilation. After adequate depth of anesthesia, confirmed by entropy (regular signal and low values from 40 to 60) and hemodynamic stability, proper size laryngeal mask airway (LMA) was inserted. Anesthesia was maintained using 100% oxygen and isoflurane (ranged from 0.9 to 1.4%), and then patients were positioned in the lithotomy position and proper perineal skin sterilization with povidone – iodine was done.

Groups classification

Group I: US guided technique (UST) (n=34)

Patients of this group underwent transperineally US guided PNB using sterile low frequency (2 to 5 MHZ) curved array US probe (Cx50 extreme edition, Philips, Finland) placed in a transverse plane. US probe was placed at the perineum medial to the ischial tuberosity between the scrotum or clitoris and the anus in the transverse axis of the perineal body to identify the sacrotuberous ligament, the superficial and deep transverse perineal muscles. The probe was moved laterally to visualize the posterior edge of the ischiopubic ramus and the internal pudendal artery could be searched medial to it and below the sacrotuberous ligament and confirmed with color Doppler.

Once structures were identified, color Doppler was used to localize the internal pudendal artery in close proximity to the ischial tuberosity. Under US guidance, a 20-gauge, 120 mm, insulated echogenic needle (Visioplex, Vygon, France), was inserted from the medial aspect of the probe and advanced in plane with the US beam to the medial aspect of the internal pudendal artery. When the final needle position was achieved, 0.15cc/kg of 0.5% bupivacaine was injected at each side with total volume of 0.3cc/kg for both sides not exceeding the maximum dose of bupivacaine which is 3 mg/kg).

The same procedure was applied to the other side. The visualization of the anatomical structures and local anesthetic spread was assessed and the time from probe positioning till the end of the injection was recorded.

Group II: Conventional blind technique (CBT-NST) (n=34)

Conventional blind technique with nerve stimulator for localization of the nerve was done after skin preparation and sterilization, the ischial tuberosity (bony land mark) was palpated, and at the midway between it and the external anal sphincter, a 22-gauge 120 mm nerve stimulator needle (Locoplex, Vygon, France) connected to the nerve stimulator (Plexygon, Vygon, France) with a stimulating current of 1.0–2.0 mA at 1 Hz was perpendicularly inserted.

After appropriate stimulation of the pudendal nerve which was visualized as ipsilateral contractions of the external anal sphincter, the position of the needle's tip was optimized by preserving muscle contractions while at the same time reducing the stimulating current to 0.5–0.6 mA. If anal sphincter continued to contract at a stimulating current below 0.5 mA, the needle was readjusted backwards till disappearance of contraction below 0.5 mA to avoid intraneural injection then the injection was performed.

After exclusion of bleeding by aspiration, 0.15cc/kg of 0.5% bupivacaine was injected at each side with total volume of 0.3cc/kg for both sides (not exceeding the maximum dose of bupivacaine which is 3 mg/kg), while noticing disappearance of the external anal sphincter contractions visually.

The same procedure was applied to the other side, and the time was recorded from identification of ischial tuberosity till the injection was finished.

For both groups

Skin incision was started (15 to 30 min) after the end of the injection (average onset of bupivacaine) and after achieving Entropy values from 40 to 60 (proper depth of anesthesia) through titration of isoflurane concentration. Changes in heart rate (HR) or mean arterial blood pressure (MAP) were recorded in response to skin incision indicating the success of the block. Along the time of the surgery, isoflurane concentrations were adjusted either increased or decreased (ranging from 0.9 to 1.4) according to Entropy values and hemodynamic changes, and the total isoflurane consumption at the end of surgery was recorded.

After recovery from anesthesia and on arrival in recovery room, evaluation of pain intensity was educated to patients by visual analogs scale (VAS) ranging from 0 (no pain) to 10 (worst pain imaginable). Rescue analgesia was given if inadequate nerve block was suspected by IV morphine titration which was given when VAS is >3 as a bolus of 2mg if body weight less than 60kg and 3mg if body weight more than 60kg with 10 min lockout interval between each bolus with no upper limit guided by the complications until VAS is <3.

Measurements:

Demographic data of patients (age, sex, weight, duration and type of surgery) were recorded. In US group only, ease of identification of anatomic structures (visualization of the pudendal artery, pudendal nerve, local anesthetic spread, ischiopubic ramus, sacrotuberous ligament, deep and superficial perineal muscles and ischial spine) was rated as good (structures were easily detectable), fair (structures were detectable on US after few attempts), or poor (structures were not detectable). Duration of the technique began from when the US probe was applied till the injection was finished for US technique and from identification of ischial tuberosity till the injection was finished for the Nerve Stimulator technique.

Entropy values were recorded as: pre-induction (baseline reading), post induction, at time of skin incision, and at end of surgery. Intraoperative Isoflurane consumption "Usage of Isoflurane (ml) = Dialed concentration × Fresh gas flow × Duration at that concentration × Molecular weight (184.5g/mol) divided by 2412 × Density".

Intra operative hemodynamic changes (MAP and HR were recorded as: pre-induction (baseline reading), post induction, at time of skin incision and at end of surgery then at 2h, 4h, 8h, 12h, and 18h post operatively.

VAS scores at 2h, 4h, 8h, 12h, and 18h after recovery. Postoperative morphine consumption was assessed during the first 18 hours postoperatively. IV morphine titration was given when VAS is >3 (rescue analgesia).

The sample size was calculated considering 95% confidence limit, 80% power of the study, the expected outcome ranging between 55-85% of ideal analgesia required and based on previously established studies, which investigated the efficacy of the PNB technique as a primary outcome, at least 30 patients were required in each study group to detect a significant difference in the intra and post-operative analgesia. To compensate for possible dropouts, we increased the sample size by 10 % to be 34 patients in each group.

The collected data were organized, tabulated and statistically analyzed using SPSS (IBM, USA) software statistical computer package version 25. Parametric data (age, weight, duration of surgery, Entropy, duration of the technique and isoflurane consumption) were presented as mean ± SD and analyzed using independent T test for comparison between two groups. Non-parametric data (VAS and morphine consumption) were presented as median and interquartile range and analyzed using Mann-Whitney test for comparison between the two groups. Categorized data (sex, type of surgery, ease of anatomic structure identification) were presented as number and percentage (%) and analyzed using Chi-square test for comparison between the two groups. The level of significance was adopted at P value < 0.05.

3. Results

There was no statistically significant difference between the two groups as regard to demographic data (Age, weight, gender) and type and duration of surgery. Duration of the techniques was significantly longer with US guided technique than nerve

stimulator guided one with mean time of (19.44 ± 4.9) min and (8.67 ±2.57) min respectively (Table 1). As regards ease of identification of sonographic anatomic structures in US group; US images was rated as good in 73.5% (n = 26), fairin17.6 % (n=5) and considered poor in 8.80% of patients (n=3) with significant increase in good images (P <0.001).

Isoflurane consumption was significantly higher in nerve stimulator group than US one (Table 1). Entropy recording did not show any significant difference between the two groups at any time (Table 2).

Significant hemodynamic stabilization (MAP and HR) was recorded with US group both intra and postoperatively in comparison with nerve stimulator group up to 18 hours (Figure 2, 3).

VAS ranged from no pain to mild pain in US group and from mild to moderate pain in nerve stimulator group along 18 hours postoperatively with significant decrease at 12 and 18 hours postoperatively (Table 3). Total postoperative morphine consumption was significantly higher in nerve stimulator group than the US one (Table 1).

Neither complications due to the block as hematoma, inadvertent sciatic nerve block and local anesthetic toxicity nor due to the rescue analgesia (morphine) as respiratory depression nausea and vomiting occurred were found.

Table (1): The demographic data and patient characteristics in the two studied groups:

Demographic data			**Group I (n = 34)**	**Group II (n = 34)**	**Test**	**P value**
Age (years)	**Range**		23 - 60	23 - 59	t = 0.022	0.98
	Mean ± SD		40.9 ± 10.1	40.8 ± 11.9		
Weight (Kg)	**Range**		54 - 95	56 - 98	t = 0.55	0.58
	Mean ± SD		76.12 ± 12.08	74.56 ± 10.83		
Gender	**Male**	**N**	15	18	X^2 = 0.53	0.47
		%	44 %	53 %		
	Female	**N**	19	16		
		%	56 %	47 %		
Type of the surgery	**Anal fissurectomy**	**N**	5	5	X^2 = 15.5	0.42
		%	15%	15%		
	Hemorridectomy	**N**	7	6		
		%	21%	18%		
	Perianal fistula excision	**N**	3	4		
		%	9%	12%		
	Perianal abscess	**N**	1	0		
		%	3%	0		
	Perianal wound repair	**N**	0	2		
		%	0	6%		
	Scrotal mass excision	**N**	0	1		
		%	0	3%		
	TURP	**N**	8	9		
		%	23%	26%		
	Urethroplasty	**N**	2	3		
		%	6%	9%		
	Urethrolithotomy	**N**	1	0		
		%	3%	0		
	Vaginoplasty	**N**	3	2		
		%	9%	6%		
	Vulvar mass excision	**N**	2	2		
		%	6%	6%		
	Bartholin gland excision	**N**	2	2		
		%	6%	6%		
Duration of the surgery (Min)	**Range**		45 - 90	35 - 90	t = 1.11	0.27
	Mean ± SD		71.9 ± 15.2	67.1 ± 20.2		
Duration of the PNB technique (Min)	**Range**		11-30	5 -15	t = 11.3	0.001*
	Mean ± SD		19.44 ± 4.9	8.67 ± 2.57		
Isoflurane consumption (mL)	**Range**		15-28	18-32	t = 3.9	0.001*
	Mean ± SD		20.9 ± 3.6	24.6 ± 4.1		
Post-operative morphine consumption (mg)	**Median**		3	6	U = 268	<0.001*
	IQR		0-3.75	6 - 9		

SD: Standard deviation, X^2: Chi-square test, t= Student's t test. TURP: transurethral resection of prostate, N: Number. PNB: Pudendal nerve block, IQR: Interquartile range, U: Mann-Whitney test * statistically significant as P value <0.05

Table (2): Comparison of the Entropy values between the two studied groups

Entropy			Group I (n = 34)	Group II (n = 34)	t	P value
Pre-induction		**Mean ± SD**	93 ± 2	95 ± 3	2.76	0.07
Post-induction	**State**	**Mean ± SD**	45 ± 6	46 ± 5	0.956	0.343
	Response	**Mean ± SD**	44 ± 5	46 ± 6	1.175	0.244
Skin Incision	**State**	**Mean ± SD**	44 ± 5	47 ± 5	1.328	0.189
	Response	**Mean ± SD**	45 ± 5	47 ± 5	1.393	0.168
End of surgery	**State**	**Mean ± SD**	45 ± 5	46 ± 5	1.051	0.273
	Response	**Mean ± SD**	45 ± 5	47 ± 6	1.429	0.158

SD: Standard deviation, t: Student's test

Table (3): Comparison of Visual Analogue Score (VAS) between the two studied groups

Time	VAS	Group I (n = 34)	Group II (n = 34)	U	P value
2H	**Median**	1	1	1149	0.777
	IQR	0-1	0 -1		
4H	**Median**	2	1	1226	0.5196
	IQR	1 – 2	1 – 2		
8H	**Median**	2	2	1126	0.5684
	IQR	1.75– 2	1 – 3		
12H	**Median**	2	3	860	<0.001*
	IQR	2.75 – 3	3– 4		
18H	**Median**	3	5	690	<0.001*
	IQR	3- 3	4- 6		

U: Mann-Whitney Test * Statistically significant change (P < 0.05)

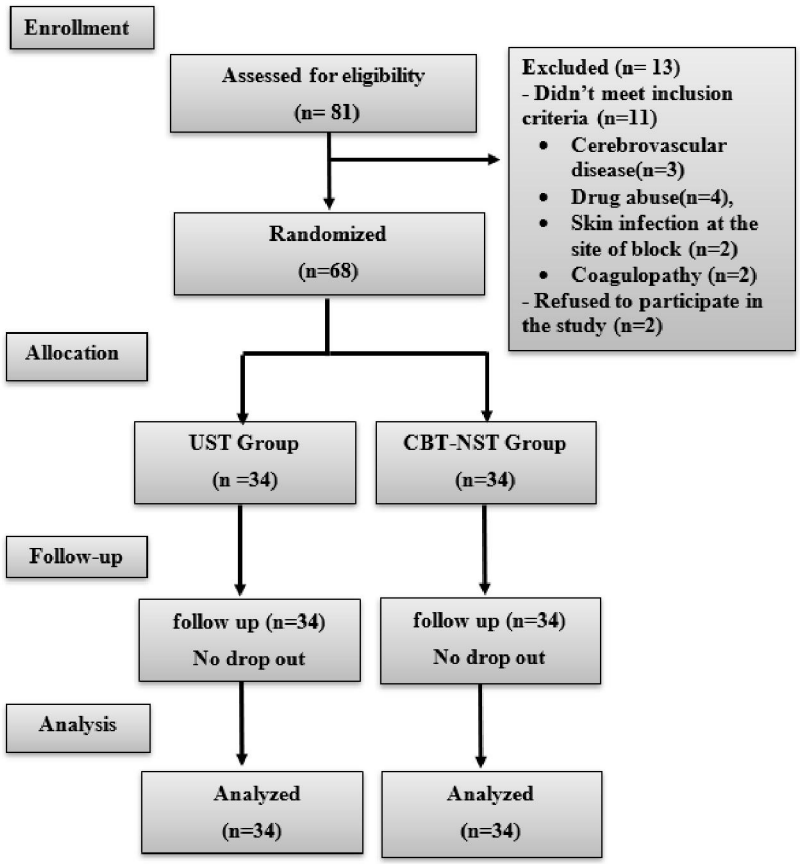
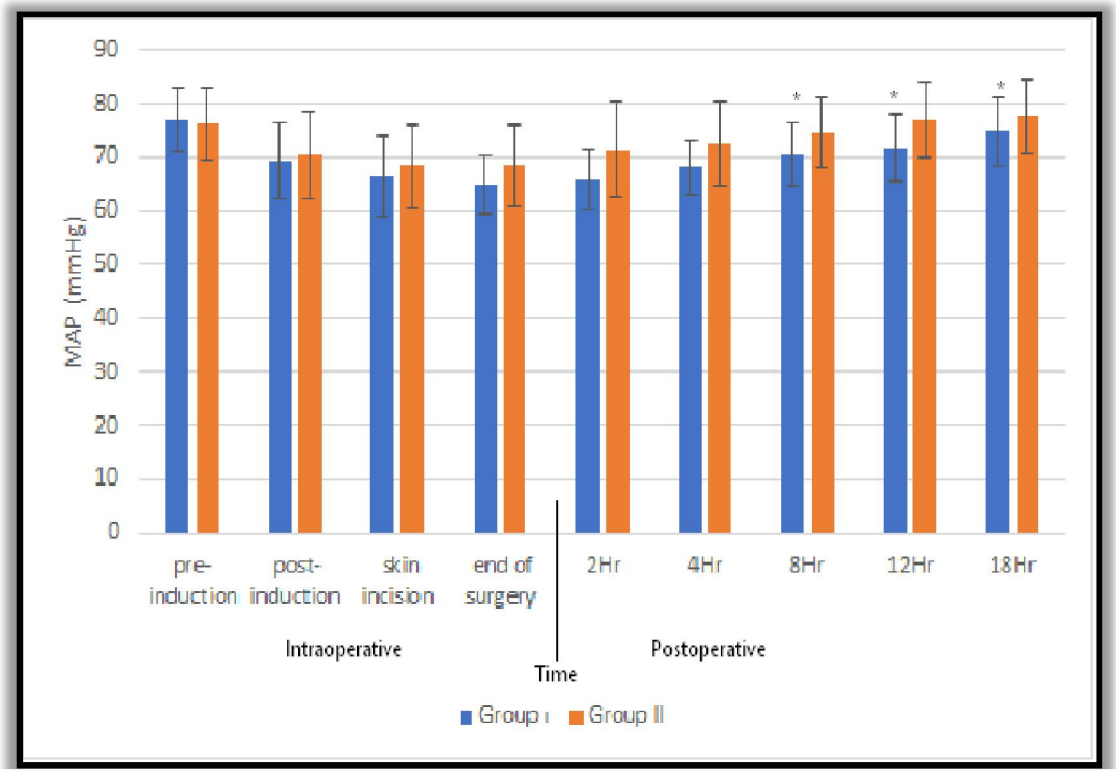


Figure (1): Patient flowchart



Figu ...ups

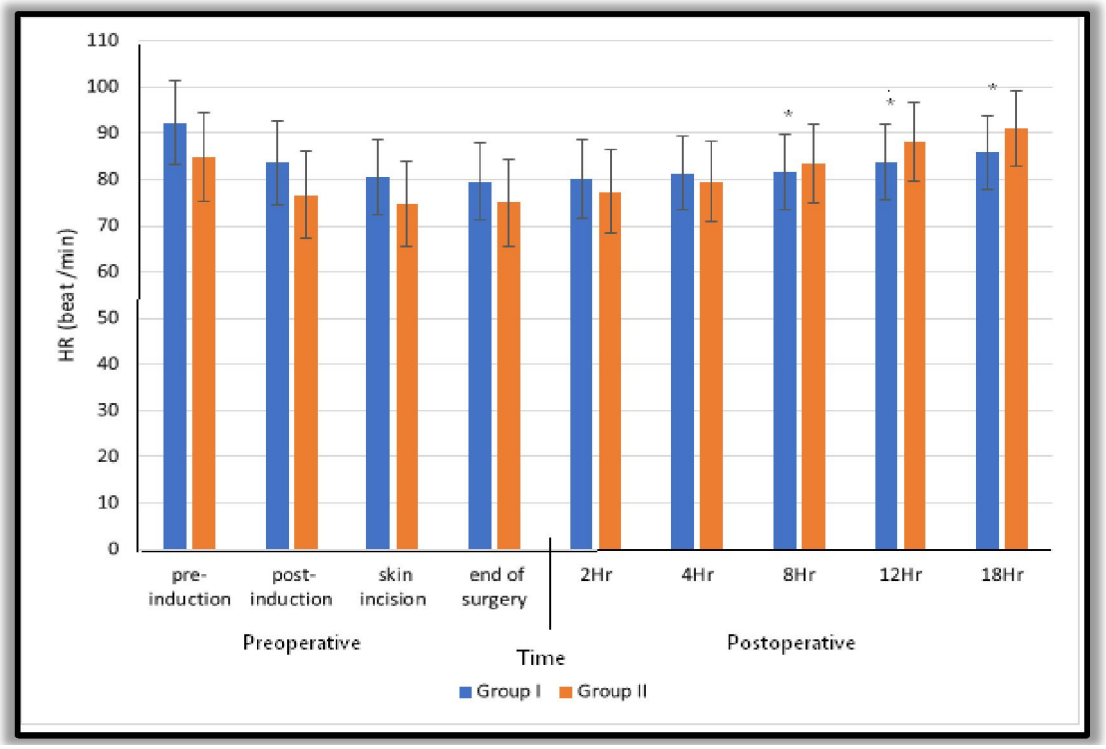


Figure (3): Comparison of heart rate (HR) changes (beats/min) between the two studied groups

4. Discussion

Postoperative pain control is a challenging concern of almost all anesthesiologist. Pain after home discharge is correlated with degree of pain immediately after operation; therefore, the key is to abort pain throughout the recovery period. Greater opioid requirement, prolonged hospitalization, increased rates of hospital readmission, and higher rates of postoperative nausea and vomiting has been associated with insufficient postoperative pain control.[9]

Despite this wide range of PNB applications, it was not a popular technique in daily practice in general, obstetric or urologic surgeries, perhaps because of lack of knowledge of the block or because of the frequency of blind blocks with variable or incomplete results.[10]

Effective blockade of the nerve depends on accurate identification of anatomic landmarks around the nerve. Fluoroscopy had been the most popular guidance for blockade of the nerve adjacent to the ischial spine. However, this technique involves inserting the needle to the tip of the ischial spine, which may not reliably place the needle in the interligamentous plane (between the sacrospinous and sacrotuberous ligaments) where the pudendal nerve lies. Furthermore, the sciatic nerve may be accidently anesthetized because its proximity is not well delineated under fluoroscopy and the risk of radiation exposure is added.[11]

At present, with the popularity of US-guided blocks, PNB has become simple to perform with improved accuracy and without need for radiation exposure. Patients undergoing the US-based procedure are reported to develop reliable perineal sensory blocks owing to direct visualization of important structures, such as the pudendal artery, sciatic nerve, sacrotuberous and sacrospinous ligaments, needle tip and the spread of local anesthetics.[11]

Despite the interest in the use of US imaging to guide performance of peripheral nerve blocks is growing, controversy still exists as to whether US is superior to the previously approved nerve localization techniques such as the use of a peripheral nerve stimulator (PNS).[12]

As regard the **ease of sonographic identification** of anatomical structures as an indicator of the feasibility of US guided PNB; we judged and rated the quality of the US images as **Good** when proper visualization of anatomic structures (rectum, ischial spine, pudendal artery, deep and superficial perineal muscles, sacrotuberous ligaments) occurred in 73.5% of our patients. When these anatomic structures were detected after few attempts, the image was rated as **Fair** which occurred in 17.6 % of our patients and considered **Poor** images when these structures were undetectable which were in 8.8% of patients and despite poor identification of anatomic structures, the colored Doppler helped us to detect the pudendal artery and the local anesthetic was injected medial to it. In details, the US visualization of ischium and rectum was always possible even in poor images. This was a valuable point in improving safety to avoid a puncture of the rectum, which is a septic site. We found some difficulty in US visualization especially in patients who had local obesity at buttocks specially in females and the local anesthetic spread was poorly seen in these patients. This difficulty can possibly be explained by the fact that fat density is almost as anechoic as that of the local anesthetic. Low visibility of the pudendal nerve was reported, and it might be due to its very small diameter.[13, 14] The average diameter of the pudendal nerve is approximately 4 to 6 mm and nerves of this size are generally difficult to be visualized at increasing depths using US imaging.[11, 15] The pudendal nerve is also surrounded by dense connective or fatty tissue, making it more difficult to identify from its surrounding tissue.[16]

In agreement with our results, ***Rofaeel et. al.*** [8] examined the feasibility of performing PNB at interligamentous plane under real-time US guidance; while patients in prone position; and compared it with the conventional fluoroscopic-guided one in 17 patients with pudendal neuralgia. They found that both the ischial spine and the internal pudendal artery were easily identifiable bony and vascular signals on US images and concluded that US technology can be used to provide high-quality images of the anatomical landmarks, guide needle placement to target the pudendal nerve, and reliably monitor the distribution of the injected local anesthetic.

Also**, *Bellingham et. al.***[11] compared the US technique used by ***Rofaeel et. al.***[8] with fluoroscopy aiming to demonstrate the feasibility of determining the sonoanatomy of the area adjacent to pudendal nerve and observed that the pudendal nerve was sonographically visible in 57% of patients, while other structures (ischial spine, pudendal artery, sciatic nerve, sacrotuberous and sacrospinous ligaments) were easily seen in 96% of patients. They attributed the low visibility of pudendal nerve to small nerve diameter and at the level of the ischial spine.[11] They postulated that both techniques were equally accurate, but fluoroscopy was unable to detect the pudendal nerve at the interligamentus plane.

Moreover, ***Bendtsen et. al.***[17] described a new US-guided technique to block the pudendal nerve inside the Alcock canal by following the margin of the hip bone sonographically along the greater sciatic

notch, the ischial spine, and the lesser sciatic notch through an anterior urogenital (transperineal) approach in three patients with chronic pelvic pain with the patient lying in lateral decubitus. They concluded that, the sonoanatomical patterns were easily recognizable.

Also, ***Gaudet - Ferrand I. et al.***[18] studied the feasibility and ease of bilateral US guided PNB in 60 children aged 1-15 years and they accomplished that, the quality of ultrasonographic image was good in 81% of blocks, with easy visualization of ischium and rectum in more than 95% of cases, intermediate in 18.49% and never considered bad. The possible cause of absence of bad images was due to exclusion of obesity factor because children with mean weight of 20.8 ±12.4 were participated in their study.

Concerning the **duration of the technique**, which began in the present study when the US probe was applied to the perineum till the injection was finished for US technique and from palpation of ischial tuberosity till the injection was finished for the nerve stimulator technique. Long technique performance time was recorded with US guided technique than nerve stimulator guided one with mean time of (19.44 ± 4.9) min and (8.67 ±2.57) min respectively. This long duration of US technique was recorded in correlation with fair and poor US images as multiple trials were done to achieve proper visualization of anatomic structures.

Although, there was a lack of literature concerning comparison of the duration of US technique with nerve stimulator guided one, some literatures discussed each technique separately.

Regarding the US technique**,** ***Bellingham et. al.***[11] recorded significant differences between US and fluoroscopic-guided procedures in the duration of technique. They started to record time from when the probe was applied till the injection was finished. The mean time in seconds taken to complete the US-guided technique was 428 seconds. The duration of US technique in their study was short when compared with our result. This can be explained by the small sample size of their study.

Also, ***Gaudet - Ferrand et. al.***[18] recorded mean duration of the US technique from ultrasonographic identification of anatomical structures to withdrawal of the needle (2.32 min). It was shorter than our result (19.44± 4.9) as we calculated time from application of US probe till the injection was finished.

In agreement with our results regarding the nerve stimulator technique, ***Kim et. al.***[5] a trans perineal nerve stimulator guided PNB depending on palpation of the ischial spine through the rectum. They observed that, PNB took just minutes to perform and was well tolerated by the patients. The duration to perform the technique ranged from (7.5 to 8.5 min) which was nearly equal to our result (8.67 ±2.57 min).

On the contrary of our result, ***Naja et. al.***[19] compared caudal block with nerve stimulator guided PNB hypospadias repair. They reported three to five-minute duration range for completion of the technique. The short duration of the technique may be related to the different patient group as they included only children in their study.

Entropy is an innovative monitoring based on the acquisition and processing of raw EEG and facial electromyogram (FEMG) signals by using entropy algorithm. Two entropy parameters exist: fast reacting RE and steadier SE. RE is sensitive to the activation of facial muscles. Activation of RE to painful stimulus may be interpreted as sign of inadequate analgesia.[20]

As regard **Entropy monitoring**, depending upon the hypothesis that the difference between RE and SE reflects nociception so, motor response to noxious stimulation has been used as one of the indicators of inadequate analgesia.[21] We recorded both RE and SE at post induction, skin incision and at end of surgery. We found that at these times, both RE and SE were within the required limits of adequate hypnosis and analgesia (40-60) with absent statistically significant difference between RE and SE at any of these times. These results can refer to the success of the PNB either guided by US or nerve stimulator to achieve adequate analgesia and balanced anesthesia.

Our results were supported by ***Wheeler et. al.***[22] who observed rapid increases in RE and elevation of the RE - SE difference to a level of > 10 during painful stimulation. Their result supported the relation between FEMG and patient analgesia.

Also, ***Puttappa et. al.***[23] noted during their observational study a sudden large increase in response RE and SE to awake values despite absence of autonomic signs of inadequate depth of anesthesia or analgesia (HR and MAP remaining stable). This finding can support our hypothesis that both entropy components can detect early hypnotic and analgesic changes before autonomic signs.

Moreover, ***Tewari et. al.***[24] found that patients monitored by entropy demonstrated lesser consumption of propofol and more consumption of fentanyl. They postulated that, Entropy monitor is a useful tool allowing distinction between analgesic and hypnotic components of GA.

However, ***Weil et. al.***[25] aimed in their study to assess the correlation between entropy parameters, analgesic drug concentration and clinical response to a noxious stimulation, as well as to examine the influence of NMB on this relationship. They observed that, no difference was found in RE, SE, or (RE - SE) between patients with or without hemodynamic response to stimulations.

Also, ***Aho et. al.***[21] concluded from their study that Entropy RE−SE difference cannot reliably be used as an indicator of nociception in patients anesthetized with propofol, nitrous oxide, and remifentanil without neuromuscular blocking agent (NMBAs) because EMG activity can contaminate the interpretation and give false reading.

Furthermore, ***Kommula et. al.***[26] compared ANI (analgesia nociception index) (based on the high frequency component of HR variability) with RE during administration of bolus doses of fentanyl and observed that RE did not change significantly in response to bolus doses of fentanyl administered during the course of surgery and so, RE was less sensitive to respond to noxious stimuli.

Concerning, **Isoflurane consumption** was used in our study as an indicator of block efficacy. Although the exact mechanism by which neural blockade results in a reduced requirement for anesthesia is not clear but an acute decrease in afferent input from the surgical site to the brain will be expected to decrease the level of consciousness and thereby increase susceptibility to anesthetic agents.

In the present study, the consumption of isoflurane was significantly lower with US technique (20.9 ± 3.6 ml) than the nerve stimulator one (24.62 ± 4.1). This can be explained by the fact that the reduced anesthetic consumption was directly related to the accuracy of the block by US technique which was superior to nerve stimulator due to direct visualization of the sonographic anatomical structures. In accordance to our result, the following studies confirmed that peripheral nerve block can reduce the inhalational anesthetic requirement.

Higashizawa et. al.[27] reported reduced isoflurane consumption and postoperative pain in patients undergoing endoscopic endonasal maxillary sinus surgery with infraorbital nerve block. The consumption of isoflurane was lower in the block group than the control group.

Moreover, ***Shih et. al.***[28] and ***Kannan et al***[29] examined bilateral superficial cervical plexus block (BSCPB) in patients scheduled for elective thyroid surgery through assessment of intraoperative inhalational agent consumption. There was significant decrease of inhalational agent consumption with (BSCPB) compared to the control group.

As regard the intra and post-operative efficacy of the PNB concerning **Hemodynamics**; In our study, MAP and HR in US group showed significant decrease in its values at time of skin incision till end of surgery and extending up to 18 hours post-operatively in comparison with baseline values (pre-induction), while in nerve stimulator group MAP and HR were significantly reduced at skin incision till end of surgery and extending only to 8 hours post-operatively in comparison with baseline values (pre-induction). These autonomic changes can be considered as a mirror of pain and patient discomfort which was proved by changes in RE intraoperatively and VAS post operatively.

In agreement with our results, ***Naja et. al.***[30] compared the analgesic and anesthetic efficacy of nerve stimulator guided PNB with that of dorsal penile nerve block in elective circumcision. They considered an increase in HR of more than 25% from baseline as inadequate analgesia and they found stable hemodynamic response to surgery in both groups.

Also, ***Naja et. al.***[19], studied PNB in children scheduled for hypospadias repair comparing it with caudal block. They considered an increase in HR and MAP>20% from baseline as inadequate analgesia. They revealed that mean values of HR and MAP were nearly equal during surgery and after recovery with no statistically significant difference and postulated that peripheral nerve block was as efficient as neuraxial block as regard hemodynamic stability.

Khalil et. al.[31] studied nerve stimulator guided PNB versus GA for postoperative pain management after anterior and post vaginal wall repair. They found that MAP was significantly lower in PNB group compared to GA group during and at the end of the operation.

In our study, **VAS** was a crucial point for post-operative assessment of the block efficacy. Patients were questioned postoperatively by an anesthesiologist who was blind to the study groups. We found that, at 2,4,8 hours post-operatively VAS score in the two studied groups ranged from no pain (0) to mild pain (1-3) with no statistically significant difference between the two groups, while at 12 and 18 hours post operatively VAS in nerve stimulator guided group ranged from mild (1-3) to moderate (4-6) pain which was higher than the US guided group with statistically significant difference. This present study showed longer duration of analgesia in favor of the US technique.

Naja et. al.[6] studied 90 patients undergoing hemorrhoidectomy. They determined that patients who received PNB had significantly superior pain relief, faster return to daily activities, reduced need for analgesics, and higher satisfaction than patients who received GA alone or GA and placebo nerve block.

Similarly, ***Imbelloni et. al.***[9] studied bilateral PNB guided by nerve stimulator versus placebo in 100 patients scheduled for hemorridectmy under spinal anesthesia. The PNB group was found to have better postoperative pain relief, reduced need for analgesics, and patient satisfaction. Mean analgesic duration was 23.8 ± 4.8 hours. This analgesic duration was longer than our results, and it can be attributed to injection of

large volume of local anesthetics and PNB was done after the end of surgery.

Also, ***Naja et. al.***[30] tested nerve stimulator PNB for pediatric circumcision, lower pain scores were detected with PNB compared to dorsal penile nerve block during the first 12 hours postoperatively. The duration of postoperative analgesia with nerve stimulator in our study was up to 8 hours only.

Moreover, ***Akkaya. et. al.***[32] randomized 40 patients scheduled for TURP into two groups in lithotomy position, pudendal group under US guidance and control group aiming to investigate the effects of this approach on postoperative analgesia and catheter-related discomfort. VAS was higher in the control group than in the pudendal block group and concluded that the administration of a PNB to patients undergoing TURP provides effective postoperative analgesia and reduces catheter-related discomfort reaching to 24 hours.

Similarly, ***Bellingham et. al.***[11] studied US and fluoroscopic guided PNB and demonstrated successful block with no significant difference between US- and fluoroscopic-guided techniques.

Also, ***Kendigelen et. al.***[33] assessed postoperative pain intensity and found that, 3 patients in PNB and all of caudal block patients needed additional analgesia within 24 hours post operatively and concluded that PNB provided more effective postoperative analgesia during the first 24 hours and improved parent satisfaction.

Moreover, ***Kalava et. al.***[34] examined US guided PNB combined with a nerve stimulator to optimize accuracy and adequacy of nerve block in three men (a case series) undergoing urethroplasty and they concluded that PNB had been shown to provide up to 12-18 hours of postoperative analgesia with good pain control which is consistent with our result.

Regarding postoperative **total morphine consumption** (rescue analgesia), it was higher in nerve stimulator guided group compared with US group. Postoperatively, no patient needed rescue analgesia till four hours in nerve stimulator group and till eight hours in the US group. In our study, there was a relation between the efficacy of the US guided PNB, the long duration of analgesia and the low consumption of postoperative morphine.

In consistent with our study, ***Naja et. al.*** [6] found that, the vast majority of GA and PL patients needed supplemental IV or oral analgesics during the first six postoperative days and pethidine consumption in the GA and PL groups was significantly higher compared to the PNB group.

Imbelloni et. al.[9] found that there was no need for oral codeine in the first 24 hours in the pudendal group; however, in the control group all patients needed from 1 to 7 doses of oral codeine in the first 24 hours. The opioid consumption in the control group was significantly higher compared with the pudendal group. The extended period of postoperative analgesia that significantly outlasted the expected duration of the local anesthetic solution used for the block might be due to injection of large volume which promoted mean duration of 23.8 hours analgesia. Also, the block was done at the end of the surgery.

Naja. et al.[19] compared caudal block (CB) with nerve stimulator-guided PNB. The key finding of their study is that PNB demonstrated prolonged postoperative analgesia and less analgesic consumption compared with CB for pediatric hypospadias repair. The number of patients who did not need analgesics was significantly higher in the PNB group compared with the CB group.[19]

Also, ***Khalil et. al.*** [31] compared the effectiveness of nerve stimulator–guided PNB versus GA and concluded that, nerve stimulator-guided PNB could be used as an alternative to GA for AP vaginal wall repair. Total analgesic consumption was significantly lower in the PNB within the first and second postoperative days. The longer duration of analgesia may be related to the large volume of local anesthetic and the use of additive (adrenaline and clonidine).

In contrary to our results, ***Abramov et. al.***[35] studied the effect of preemptive transvaginal PNB (blind technique) on pain relief a consumption of hydromorphone after transvaginal pelvic reconstructive surgery versus placebo. They found that PNB did not affect postoperative pain intensity or opioid consumption. The negative result of their study can be explained by the fact that PNB without nerve stimulation frequently fails and the patient sample was not homogenous (surgical procedures included transvaginal hysterectomy, colporrhaphy, enterocele repair among others).

During our study, complication due to the technique as hematoma, local anesthetic toxicity or nerve palsy specially inadvertent sciatic nerve block (foot drop) did not occur. Also, complication due to rescue analgesia as postoperative nausea and vomiting, sedation or respiratory depression did not occur. This was in accordance with the result ***of Imbelloni et. al.***[9]***, Naja et. al.***[30]***, Kim et. al.***[5] and ***Khalil et. al.*** [31].

Conclusion:

PNB either by US or nerve stimulator guidance presented an excellent adjuvant to GA for patient undergoing wide range of perineal surgeries, however the US guidance technique was superior to nerve stimulator one as regard nerve visualization and localization, intra and postoperative analgesic efficacy and reduced postoperative opioid requirements.

Conflicts of interest: Nil.

References:

1. De Pinto M, Dagal A, O'Donnell B, Stogicza A, Chiu S, Edwards WT. Regional anesthesia for management of acute pain in the intensive care unit. International journal of critical illness and injury science. 2015;5:138.
2. Winacoo JN, Maykel JA. Operative anesthesia and pain control. Clinics in colon and rectal surgery. 2009;22:41.
3. Imbelloni LE, Vieira EM, Carneiro AF. Postoperative analgesia for hemorrhoidectomy with bilateral pudendal blockade on an ambulatory patient: a controlled clinical study. Journal of Coloproctology. 2012;32:291-6.
4. Tepetes K, Symeonidis D, Christodoulidis G, Spyridakis M, Hatzitheofilou K. Pudendal nerve block versus local anesthesia for harmonic scalpel hemorrhoidectomy: a prospective randomized study. Techniques in coloproctology. 2010;14:1-3.
5. Kim SH, Song S, Paek O, Lee H, Park D, Lee J. Nerve‐stimulator‐guided pudendal nerve block by pararectal approach. Colorectal Disease. 2012;14:611-5.
6. Naja Z, Ziade MF, Lönnqvist P-A. Nerve stimulator guided pudendal nerve block decreases posthemorrhoidectomy pain. Canadian Journal of Anesthesia. 2005;52:62.
7. Koscielniak‐Nielsen Z. Ultrasound‐guided peripheral nerve blocks: what are the benefits? Acta anaesthesiologica scandinavica. 2008;52:727-37.
8. Rofaeel A, Peng P, Louis I, Chan V. Feasibility of real-time ultrasound for pudendal nerve block in patients with chronic perineal pain. Regional anesthesia and pain medicine. 2008;33:139-45.
9. Imbelloni LE, Vieira EM, Gouveia MA, Netinho JG, Spirandelli LD, Cordeiro JA. Pudendal block with bupivacaine for postoperative pain relief. Diseases of the colon & rectum. 2007;50:1656-61.
10. Rojas-Gómez MF, Blanco-Dávila R, Tobar-Roa V, Gómez-González AM, Ortiz-Zableh AM, Ortiz-Azuero A. Regional anesthesia guided by ultrasound in the pudendal nerve territory. Revista Colombiana de Anestesiología. 2017;45:200-9.
11. Bellingham GA, Bhatia A, Chan C-w, Peng PW. Randomized controlled trial comparing pudendal nerve block under ultrasound and fluoroscopic guidance. Regional anesthesia and pain medicine. 2012;37:262-6.
12. Abrahams M, Aziz M, Fu R, Horn J-L. Ultrasound guidance compared with electrical neurostimulation for peripheral nerve block: a systematic review and meta-analysis of randomized controlled trials. British Journal of Anaesthesia. 2009;102:408-17.
13. O'bichere A, Green C, Phillips RK. New, simple approach for maximal pudendal nerve exposure. Diseases of the colon & rectum. 2000;43:956-60.
14. Mahakkanukrauh P, Surin P, Vaidhayakarn P. Anatomical study of the pudendal nerve adjacent to the sacrospinous ligament. Clinical Anatomy. 2005;18:200-5.
15. Peng PWH, Narouze S. Ultrasound-Guided Interventional Procedures in Pain Medicine: A Review of Anatomy, Sonoanatomy, and Procedures: Part I: Nonaxial Structures. Regional anesthesia and pain medicine. 2009;34:458-74.
16. Kovacs P, Gruber H, Piegger J, Bodner G. New, simple, ultrasound-guided infiltration of the pudendal nerve. Diseases of the colon & rectum. 2001;44:1381-5.
17. Bendtsen TF, Parras T, Moriggl B, Chan V, Lundby L, Buntzen S, et al. Ultrasound-guided pudendal nerve block at the entrance of the pudendal (Alcock) canal: description of anatomy and clinical technique. Regional anesthesia and pain medicine. 2016;41:140-5.
18. Gaudet‐Ferrand I, De La Arena P, Bringuier S, Raux O, Hertz L, Kalfa N, et al. Ultrasound‐guided pudendal nerve block in children: A new technique of ultrasound‐guided transperineal approach. Pediatric Anesthesia. 2018;28:53-8.
19. Naja ZM, Ziade FM, Kamel R, El-Kayali S, Daoud N, El-Rajab MA. The Effectiveness of Pudendal Nerve Block Versus Caudal Block Anesthesia for Hypospadias in Children. Anesthesia & Analgesia. 2013;117:1401-7.
20. Ghodki PS, Thombre SK, Sardesai SP, Harnagle KD. Dexmedetomidine as an anesthetic adjuvant in laparoscopic surgery: An observational study using entropy monitoring. Journal of anaesthesiology, clinical pharmacology. 2012;28:334.
21. Aho AJ, Yli-Hankala A, Lyytikäinen LP, Jäntti V. Facial muscle activity, Response Entropy, and State Entropy indices during noxious stimuli in propofol–nitrous oxide or propofol–nitrous oxide–remifentanil anaesthesia without neuromuscular block. British Journal of Anaesthesia. 2009;102:227-33.
22. Wheeler P, Hoffman WE, Baughman VL, Koenig H. Response entropy increases during painful stimulation. Journal of neurosurgical anesthesiology. 2005;17:86-90.
23. Puttappa A, Sheshadri K, Boylan J, Conlon N. Large increases in both response and state

entropy to awake values antagonized with administration of incremental rocuronium. British Journal of Anaesthesia. 2015;115:934-5.
24. Tewari S, Bhadoria P, Wadhawan S, Prasad S, Kohli A. Entropy vs standard clinical monitoring using total intravenous anesthesia during transvaginal oocyte retrieval in patients for in vitro fertilization. Journal of clinical anesthesia. 2016;34:105-12.
25. Weil G, Passot S, Servin F, Billard V. Does spectral entropy reflect the response to intubation or incision during propofol-remifentanil anesthesia? Anesthesia & Analgesia. 2008;106:152-9.
26. Kommula LK, Bansal S, Umamaheswara GR. Analgesia Nociception Index Monitoring During Supratentorial Craniotomy. Journal of neurosurgical anesthesiology. 2017.
27. Higashizawa T, Koga Y. Effect of infraorbital nerve block under general anesthesia on consumption of isoflurane and postoperative pain in endoscopic endonasal maxillary sinus surgery. Journal of anesthesia. 2001;15:136-8.
28. Shih M-L, Duh Q-Y, Hsieh C-B, Liu Y-C, Lu C-H, Wong C-S, et al. Bilateral Superficial Cervical Plexus Block Combined with General Anesthesia Administered in Thyroid Operations. World Journal of Surgery. 2010;34:2338-43.
29. Kannan S, Surhonne NS, Kumar C. Effects of bilateral superficial cervical plexus block on sevoflurane consumption during thyroid surgery under entropy-guided general anesthesia: a prospective randomized study. Korean journal of anesthesiology. 2018;71:141.
30. Naja Z, Al‐Tannir M, Faysal W, Daoud N, Ziade F, El‐Rajab M. A comparison of pudendal block vs dorsal penile nerve block for circumcision in children: a randomised controlled trial. Anaesthesia. 2011;66:802-7.
31. Khalil I, Itani SE, Naja Z, Naja AS, Ziade FM, Ayoubi J-M, et al. Nerve stimulator guided pudendal nerve block vs general anesthesia for postoperative pain management after anterior and posterior vaginal wall repair: a prospective randomized trial. Journal of clinical anesthesia. 2016;34:668-75.
32. Akkaya T, Ozkan D, Karakoyunlu N, Ergil J, Gumus H, Ersoy H, et al. Pudendal block in transurethral prostatectomy: A randomised trial. European Journal of Anaesthesiology. 2015;32:656-7.
33. Kendigelen P, Tutuncu AC, Emre S, Altindas F, Kaya G. Pudendal Versus Caudal Block in Children Undergoing Hypospadias Surgery: A Randomized Controlled Trial. Regional anesthesia and pain medicine. 2016;41:610-5.
34. Kalava A, Pribish AM, Wiegand LR. Pudendal nerve blocks in men undergoing urethroplasty: a case series. Rom J Anaesth Intensive Care. 2017;24:159-62.
35. Abramov Y, Sand PK, Gandhi S, Botros SM, Miller J-JR, Koh E-K, et al. The effect of preemptive pudendal nerve blockade on pain after transvaginal pelvic reconstructive surgery. Obstetrics & Gynecology. 2005;106:782-8.

7/7/2019