RANDOMISED CONTROLLED TRIAL STUDY OF THE EFFECT OF TENS AND NSAID (OPOID) DRUG IN THE MANAGEMENT OF POST OPERATIVE GYNAECOLOGICAL PAIN.

[1]AAG Jimoh, [1]LO Omokanye, [2]GA Salaudeen, [4]Suleiman ZA [2]K Durowade, [3]EO Adewara,

[1]Department of Obstetrics and Gynaecology, University of Ilorin Teaching Hospital, Nigeria.
[2]Department of epidemiology and community Health, University of Ilorin Teaching Hospital, Nigeria.
[3]Department of Obstetrics and Gynaecology, Federal Medical centre, Ido-Ekiti, Ekiti, Nigeria.
[4]Department of Anaesthesia College of Health Sciences University of Ilorin Nigeria.

ABSTRACT

Background: TENS is a non-invasive, safe nerve stimulation intended to reduce pain, both acute and chronic. However there is controversy regarding its effectiveness in relieving this pain.

Objective: This study was designed to establish the effectiveness of TENS compared with NSAID drugs in the management of patient with post operation pain due to gynaecological conditions (Hysterectomy/myomectomy) and caesarean section.

Methods: Thirty (30) patients with diagnosis of fibroid for hysterectomy/myomectomy, caesarian section and surgical procedures were assigned into three groups of 10 patients each.

Group 1: treated with NSAID drugs

Group 2: treated with NSAID drugs with TENS

Group 3: treated with TENS

Pain intensity was assessed using the Visual Analogue Scale (VAS) at the beginning pre-treatment and at the end of every week for three uninterrupted weeks in each group and compared.

Results: The groups were comparable with VAS scores over three weeks post operative period. A statistically significant difference was found in all the three groups between the mean pre-treatment and post-treatment pain intensities for the three weeks ($p=0.00$). The mean VAS score decreased with each groups; however the mean VAS scores of TENS with drug decreased significantly compared with drug and TENS alone groups ($p<0.05$). Although NSAID alone controlled the pains better than TENS alone this superiority was not appreciated until the third week ($p= 0.01$).

Conclusion: We conclude that TENS with NSAID was more effective than either NSAID or TENS alone in the management of post operation pain

Keywords: Transcutaneous electrical nerve stimulation, Non steroidal anti inflammatory drugs, Gynaecological conditions

INTRODUCTION

The Taxonomy Committee of the International Association for the study of Pain (ISAP) defines

Corresponding Author: Lukman Omotayo Omokanye, Department of Obstetrics and Gynaecology, University of Ilorin Teaching Hospital, PMB 1549, Ilorin, Nigeria.
Phone no: +2348033630497
E-mail address: omostuff1111@yahoo.com

pain as "As unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage1. Postoperative pain is both distressing and detrimental for the patients. The management of postoperative pain involves assessment of the pain in terms of intensity at rest and activity associated pain, treatment by pharmacological and non-pharmacological means as well as monitoring induced side-effects2.

Transcutaneous electric nerve stimulation (TENS) has been established to be effective in the management of many painful conditions like dysmenrrhoea, labour pain, dental pain and general acute muscular skeletal pain3 but there is controversy on the effectiveness of TENS on chronic painful conditions, specifically joint pain.

The clinical application of TENS today evolved from Shealy's developmental work on neuro-modulation techniques in the 1960s4which is underpinned by the 'gate control theory'5. It is thought that pain may be alleviated by using peripheral stimulation, such as rubbing, vibration, heat or cold, or, as in the case of TENS, electrical stimulation directly over the area of pain. This peripheral stimulation induces electrical activity which inhibits the brain's perception of pain.

The 'gate control theory' is based on the principle that there is a gateway in the dorsal horn of the spinal cord, which somehow controls or regulates the flow of pain messages that are then sent to (ascending) and from (descending) higher levels of the brain for central processing, thus reducing the perception of pain. Other postulated mechanisms of the pain relief mediated by TENS include the promotion of endorphin release in the brain6 and local dilatation of blood vessels in injured tissue7.

Treatment with TENS has the advantages of being controlled by the patient and does not involve the use of medication. TENS is inexpensive and virtually without risk, and there are few contraindications. However, NSAID's are heterogeneous groups of agents that mediate anti-inflamatory, analgesic, antipyretic and platelet inhibitory effects. NSAID's are effective in the postoperative setting and their usefulness may be limited due to their tendency to cause gastro-intestinal and surgical site haemorrhage and renal failure especially in high risk patients2.This study was intended to establish the effectiveness of TENS compared with NSAID drugs in the management of patient with post operation pain due to gynaecological conditions (Hysterectomy/myomectomy) and caesarean section.

MATERIALS AND METHODS

Thirty (30) patients with diagnosis of fibroids and obstructed labour. They were aged between 34-55 years. They were patients referred for physiotherapy at UITH. Prior to experimentation, subjects were informed of the experimental procedures and each volunteered, to be included into the study by signing an informed consent. The subjects were assigned into three groups of ten each.

Inclusion: subjects with post operation conditions like (Hysterectomy, myomectomy ceaserian section e.t.c) were included, whereas, subjects with other post operation conditions were excluded.

Instrumentation:

TENS machine (model promedics)

Visual Analogue Scale (VAS)

NSAID/OPOIDS Drug

Hospital Bed

General Description

The stimulate N604SD Timer TENS is a battery operated pulse generator that sends electrical impulses electrodes to the body and reach the nerves causing pain. The device is provided with two controllable output channel, each independent of each other. An electrodes pair can be connected to each output channel.

The electronics of the stimate N603SD TENS creates electrical impulses whose intensity, duration, number per second and modulation may be altered with the control switches. Dial controls are very easy to use and the slide cover prevents accidental changes in the setting.

The TENS unit sends comfortable impulses through the skin that stimulate the nerve(s) in the treatment area. In many cases, this stimulation will greatly reduce or eliminate the pain sensation the patient feels. Pain relief varies by individual patient, mode selected therapy and the type of pain.

In many patients, the reduction or elimination of pain last longer than the actual period of stimulation (sometimes as much as three-four times longer) in others, pain is only modified while stimulation actually occurs.

Research Design: We compared pain intensity in all the three groups at the beginning of the study (Pre-treatment) at the end of every treatment week for the duration of the study, which was three uninterrupted weeks. All subjects were treated daily for three weeks.

Experimental Procedures

A brief history of the origin and duration of the pain and any associated problems were conducted.

Assessment and examination of the patients was conducted to establish the painful areas. Palpation and localization of the painful area was by mild pressure via the thumb on the surgical site.

Intensity of pain was rated using the Visual Analogue Scale (VAS), numerically [8] and verbally using the modified verbal rating scale [9]

Drug therapy was administered for the selected twenty patients

TENS machine with a set of 4- self Adhesive electrodes were used. The unit delivered a rectangular monophase DC wave form of IMSEE duration at a rate of 100HZ. Electrodes were applied to 4 points on the painful area and the TENS was applied for 10 minutes.

All subjects in this study followed the experimental procedure and were instructed to report any medical problem immediately.

RESULTS

A total of thirty subjects in three groups of ten were used for the study. The subjects were randomized into three experimental groups- TENS with drug, Drug alone and TENS alone. The mean ages of the subjects were 44.50±8.11, 47.30±6.86, 44.80±5.09 for subjects in TENS with drug, Drug alone and TENS alone respectively. The mean Body Mass Index (BMI) for the TENS with Drug group was 32.6±7.86 kg/m2, while it was found to be 36.4±8.34kg/m2 and 34.3±6.38 kg/m2 for the Drug alone and TENS alone group respectively.(table 1).

The mean pre-treatment pain intensity was found to be 8.60±0.69, 9.30±0.48, and 9.20±0.63 for the TENS with Drug, Drug alone and TENS alone respectively. Also, the mean post-treatment intensity for the TENS with Drug group was found to be 6.90±0.99, 4.10±1.19 and 2.10±0.74 for the first to the third weeks respectively. It was also found to be 8.00±0.67, 5.40±0.52 and 3.10±0.74 for the Drug alone group for the three weeks respectively. For the

TENS alone group, the mean post-treatment intensity was 7.60±0.52, 5.90±0.88 and 4.40±1.01 for the three weeks respectively.

There was a statistically significant difference between the mean pre-treatment pain intensities of the TENS with drug and drug alone, TENS with drug and TENS groups with p values of 0.02 and 0.05 respectively. However, the difference was not statistically significant between the mean pre-treatment intensities of the Drug alone and TENS alone groups with a p value of 0.20. (table 2)

The mean of the difference between the pre-treatment pain intensity and the post treatment pain intensities for the TENS with drug group was 1.70±0.678, 4.50±0.85 and 6.50±0.97 for the first three weeks respectively. However, while the mean of the difference between the pre-treatment pain intensity and the post treatment pain intensities was found to be 1.30±0.48, 3.90±0.57, and 6.20±1.03 for the Drug alone group for the three weeks respectively, it was 1.60±0.52, 3.30±0.82 and 4.80±1.03 for the TENS alone group for the three weeks respectively. Also, a statistically significant difference was found in all the three groups between the mean pre-treatment pain intensities and the mean post-treatment pain intensities for the three weeks with p values of 0.000 each. (table 3).

The mean post treatment pain intensities were also compared in all the three groups. For the TENS with Drug and Drug alone, a statistically significant difference was found between their mean post treatment pain intensities for all the three weeks with p values of 0.01, 0.01 and 0.01 respectively. Also, similar finding was replicated between the mean post treatment pain intensities for the TENS with Drug and TENS group with p values of 0.05, 0.00 and 0.01 for the three weeks respectively.

However, this was not so when the mean post treatment pain intensities of Drug alone and TENS alone were compared. For the first two weeks post treatment, there was no statistically significant difference between their mean post treatment pain intensities with p values of 0.22 and 0.20 respectively. However, a significant difference was found between their mean post treatment pain intensities at the third week post treatment with p value of 0.01. (table 4).

DISCUSSION

Postoperative pain involve and worries the multidisplinary team as far as choosing the best way of decreasing it, especially because its presence can mask postoperative surgical complications and hinder patient recovery10. In this study TENS was found to be effective in relieving post operative pain as evidence by a statistically significant difference between the mean pre-treatment pain intensities and the mean post-treatment pain intensities for the three weeks. This is similar to finding obtained from previous studies11-13. Also, the acute pain management guideline panel of the Agency for Health Care Policy and Research (AHCPR) in the United State of America concluded that TENS was effective in reducing post operative pain and improving function14.

On the contrary, Reeve et al15, Carroll et al16 and Bandolier et al17 concluded that TENS did not produce significant post operative pain relief in their series. This finding was corroborated by the report of the Australian and New Zealand College of Anaesthetists (ANZCA) and Faculty of Pain's Medicine Acute Pain Management which states that 'there is limited evidence that physical therapies [such as TENS] help acute pain18

NSAID was also found to relief post operative pain significantly and has shown to be superior to TENS most especially at the third week. However, the possibility of development of undesirable side effects following its prolonged use will limit its wider application in relieving of post operative pain2.

It was also clearly demonstrated in this study that combination of TENS and NSAID's was more effective than either TENS and NSAID's alone. This agrees with the findings of Bjordal et al19. This is also inconsonance with the report of the Royal College of England and the Faculty of Anaesthetists Working Party on Pain after surgery with the conclusion that TENS was not effective as a stand-alone treatment for moderate to severe post operative pain20.

In conclusion, there is credible evidence that TENS reduce postoperative pain though less than NSAID. The use of TENS with NSAID was more effective than either TENS or NSAID alone. Further research is required to elucidate this finding since the sample size of the study is limited.

Table 1: *Mean of the Parameters of subjects in the three experimental groups*

TENS with Drug	**Mean**	**Standard deviation n=10**
Age	44.50	8.11
Height	1.485	0.13
Weight	66.60	7.07
Pre treatment pain intensity	8.60	0.69
Post treatment pain intensity		
1st week	6.90	0.99
2nd week	4.10	1.19
3rd week	2.10	0.74
BMI	32.60	7.86
Drug		
Age	47.30	6.86
Height	1.45	0.14
Weight	75.10	14.52
Pre treatment pain intensity	9.30	0.48
Post treatment pain intensity		
1st week	8.00	0.67
2nd week	5.40	0.52
3rd week	3.10	0.74
BMI	36.40	8.34
TENS		
Age	44.80	5.09
Height	1.53	0.95
Weight	79.20	9.38
Pre treatment pain intensity	9.20	0.63
Post treatment pain intensity		
1st week	7.60	0.52
2nd week	5.90	0.88
3rd week	4.40	1.01
BMI	34.30	6.38
TENS		
Age	44.80	5.09
Height	1.53	0.95
Weight	79.20	9.38
Pre treatment pain intensity	9.20	0.63
Post treatment pain intensity		
1st week	7.60	0.52
2nd week	5.90	

Table 2: *Comparing Mean of Pre-treatment pain intensity in the three experimental groups*

Variable	TENS with drug	Drug	t	df	p
Value					
Pre treatment pain intensity					
Mean	8.60	9.30			
Standard deviation	0.69	0.48	0.987	18	0.0235
	TENS with drug	TENS			
Pre treatment pain intensity					
Mean	8.60	9.20			
Standard deviation	0.69	0.63	2.03	18	0.048
	Drug	TENS			
Pre treatment pain intensity					
Mean	9.30	9.20			
Standard deviation	0.48	0.63	0.399	18	
0.1995					

Table 3: *Comparing Mean of Pre and Post treatment pain intensity in all the groups*

Variable	TENS with drug	d	t	df	p value
Pre treatment pain intensity					
Mean	8.60				
Standard deviation	0.69				
Post treatment pain intensity(1st week)					
Mean	6.90		1.70		
Standard deviation	0.99		0.678	7.965	90.000
Post treatment pain intensity(2nd week)					
Mean	4.10		4.50		
Standard dev iation	1.19		0.85	16.745	
90.000					
Post treatment pain intensity(3rd week)					
Mean	2.10		6.50		
Standard deviation	0.74		0.97	21.151	
90.000					
Drug					
Pre treatment pain intensity					
Mean	9.30				
Standard deviation	0.48				
Post treatment pain in tensity(1st week)					
Mean	8.00		1.30		
Standard devi ation	0.67		0.48	8.510	90.000
Post treatment pain intensity(2nd week)					
Mean	5.40		3.90		
Standard deviation	0.52		0.57	21.726	90.000
Standard deviation	0.69				
Post treatment pain intensity(1st week)					
Mean	6.90		1.70		
Standard deviation	0.99		0.678	7.965	90.000
Post treatment pain intensity(2nd week)					
Mean	4.10		4.50		
Standard dev iation	1.19		0.85	16.745	
90.000					
Post treatment pain intensity(3rd week)					
Mean	2.10		6.50		
Standard deviation	0.74		0.97	21.151	
90.000					
Drug					
Pre treatment pain intensity					
Mean	9.30				
Standard deviation	0.48				
Post treatment pain in tensity(1st week)					
Mean	8.00		1.30		
Standard devi ation	0.67		0.48	8.510	90.000
Post treatment pain intensity(2nd week)					
Mean	5.40		3.90		
Standard deviation	0.52		0.57	21.726	90.000
Post treatment pain intensity(3rd week)					
Mean	3.10		6.20		
Standard deviation	0.74		1.03	18.984	90.000
TENS					

Table 4: *Comparison of Mean of Post treatment pain intensity in all the groups*

Variable	TENS with Drug	Drug	t	df	p value
Post treatment pain intensity(1st wk)					
Mean	6.90	8.00			
Standard deviation	0.99	0.67	-2.909	18	0.014
Post treatment pain intensity(2nd wk)					
Mean	4.10	5.40			
Standard deviation	1.19	0.52	-3.166	18	0.01
Post treatment pain intensity(3rd wk)					
Mean	2.10	3.10			
Standard deviation	0.74	0.74	-3.022	18	0.01
	TENS with Drug	TENS			
Post treatment pain intensity(1st wk)					
Mean	6.90	7.60			
Standard deviation	0.99	0.52	-1.979	18	0.045
Post treatment pain intensity(2nd wk)					
Mean	4.10	5.90			
Standard deviation	1.19	0.88	-3.846	18	0.001
Post treatment pain intensity(3rd wk)					
Mean	2.10	4.40			
Standard deviation	0.74	1.01	-5.809	18	0.01
	Drug	TENS			
Post treatment pain intensity(1st wk)					
Mean	8.00	7.60			
Standard deviation	0.67	0.52	1.491	18	0.223
Post treatment pain intensity(2nd wk)					
Mean	5.40	5.90			
Standard deviation	0.52	0.88	-1.547	18	0.202

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