*Bahrain Medical Bulletin, Vol. 36, No. 4, December 2014*

# The Effectiveness of Using Modified Transcutaneous Spinal Electroanalgesia on Patients with Acute Sickle Cell Painful Episode

Ibrahim A. AL-Dabbous, MBBS, DCH, ABCP* Amin A. AL-Gafly, MCs, SS**
Ali H. AL-Jam'a, MBBS, ABCIM*** Ghada A. Alqudaihi, MBBS, MSc****

**Objective: To evaluate the effectiveness of modified Transcutaneous Spinal Electroanalgesia (mTSE) on acute painful episode in sickle cell disease (SCD).**

**Design: Prospective Non-Randomized Experimental Study.**

**Setting: Pediatric and Medical Ward, Qatif Central Hospital, Eastern Province of Saudi Arabia.**

**Method: A prospective study conducted between April to July 2004. It included all SCD patients admitted in pediatric and medical wards with moderate/severe acute pain involving lower back and/or lower limbs, not responding to the initial management over the first four hours of presentation. Modified Transcutaneous Spinal Electroanalgesia (mTSE) was used for 90 minutes. Data entry and analysis were done by Epi-Info software (Version 3.2.2).**

**Result: One hundred seven patients were included in the study. Age ranged between 5 and 50 years. Males were 57 (53.27%); 50 (51.10%) of the females were adults and 32 (56.14%) of the males were pediatrics. The mTSE had lowered the pain level to mild in 20 (38.46%) adults, compared to 32 (58.18%) children. Twenty-eight (49.12%) males showed improvement, compared to 28 (56%) females. Post-mTSE pain score was 3.6±2.5, compared to 7.5±2.1 pre-mTSE, (p-value<0.01). The response to mTSE was more apparent in pediatrics (3.1±2.7) compared to adults (4.1±2.2), P-value=0.01. Pediatric male patients responded better to mTSE (2.8±2.6) compared to adult male patients (4.1±1.8), P-value=0.005.**

**Conclusion: Our preliminary study reveals the efficacy of mTSE in controlling bony pain of acute painful episodes in SCD patients.**

---

* Consultant
Pediatric Department
** Senior Physical Therapist
Physiotherapy Department
*** Consultant
Internal Medicine Department
**** Epidemiologist
Epidemiology Department
Qatif Central Hospital
Qatif, Kingdom of Saudi Arabia

Email: idabbous@gmail.com

Painful episode is the most common acute complication in sickle cell disease (SCD) patients; it is responsible for more than 50% of hospital admissions and most of emergency room visits[1-3]. The management of SCD patients during an acute painful episode remains frustratingly symptomatic and supportive[4-5].

Vaso-occlusion in sickle cell disease and its underlying pathophysiology have neither been understood nor the management of painful episodes has improvement tremendously. Various treatment methods of vaso-occlusive episodes have been tried but failed to replace the traditional present method of management[4-9].

The pain resulting from bony vaso-occlusive episodes is usually very severe and sometimes excruciating[10]. In the majority of cases, strong analgesics including narcotics are usually required. These medications have many side effects[5-8]. Although not frequent, narcotic tolerance and dependence are real concerns and once established are difficult to manage. Therefore, the attempt to find non-pharmacologic approach is continuous. Transcutaneous Electric Nerve Stimulation (TENS) has been tried in the management of sickle cell pain, but the efficacy was not optimal[9]. A special form of Transcutaneous Electrotherapy called Transcutaneous Spinal Electroanalgesia (TSE) known with its supposed wider spread analgesia, compared to the peripheral nerve stimulation was thought to be more effective in controlling pain[11-16].

To the best of our knowledge, no previous study has addressed the use of TSE in acute painful episode in SCD. The null hypothesis of this study would be that there is no difference in the pain level in SCD patients with acute painful episodes regardless of whether they used mTSE or not to alleviate the pain.

The aim of this study is to evaluate the effectiveness of modified Transcutaneous Spinal Electroanalgesia (mTSE) in the management of acute painful episode in sickle cell disease (SCD).

## METHOD

A prospective non-randomized non-controlled experimental clinical study was conducted from April to July 2004. Patients with sickle cell anemia and sickle cell β-thalassemia, admitted to both pediatric (< 12 years) and medical wards (≥ 12 years) with simple acute bone pain only involving the lower back and lower limbs were eligible for enrolment in the study. Exclusion criteria included evidence of SCD and non-SCD complications, history of seizures, implanted stimulating device (such as a cardiac pacemaker), skin problems, and upper limb pain.

Initial management was started by hydration and analgesia. Those patients with moderate to severe painful episodes who did not respond to the initial management for the first 4 hours were offered mTSE treatment.

Informed consent was obtained from the patient or the parents as appropriate. A pretest structured questionnaire was filled by the team itself. The questionnaire contained four variables:

age, gender, pain score before applying mTSE and pain score after applying mTSE. Patients who met the inclusion criteria were asked to sign a consent form. Numerical rating (0-10) and visual analogue scales were used for pain intensity assessment in both adult and pediatric age groups respectively; 0 signifies "no pain" and 10 being "worst imaginable pain", the patients were asked to indicate their pain intensity before and after using mTSE[17-19].

The primary TSE device used was Endomed 982. The TENS mode of this device can give minimum wave length of 20 microseconds, and maximum frequency of 200Htz. Due to the hospital limited device availability, those parameters were modified as follows: maintain a wave length of 20 microseconds, frequency of 100Htz and an amplitude of maximum tolerated; that gives just a tingling sensation, which could reach up to 50M Amp to obtain the required device parameters for TSE, wave length of less than 10 microseconds, and a frequency of 600Htz.

The application time was 90 minutes unified for all patients. The electrodes were placed, as recommended for TSE, on the skin overlying the spinal cord. The anode was placed over spinous process of T1 and the cathode over spinous process of T12, regardless of the pain sites.

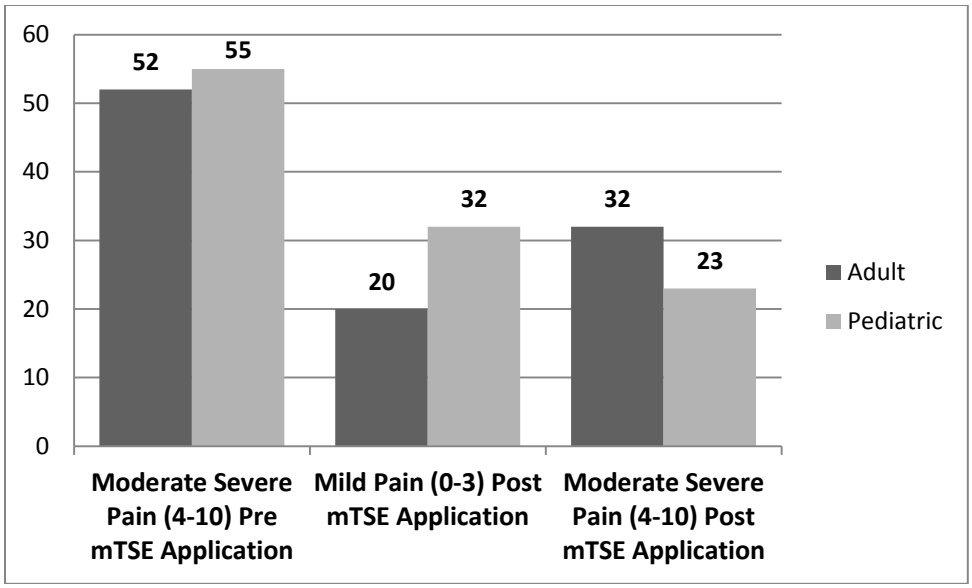
Data entry and analysis were done by Epi-Info software (Version 3.2.2). The frequencies of all the studied variables were calculated. In comparison, Chi-square ($x^2$) and P-value were used for categorical variables.

## RESULT

The study included a total of 107 Saudi patients with moderate to severe pain level (4-10). Age ranged between 5-50 years. Their mean age and SD were (18.0 ± 12.6 years). Sickle cell disease male patients were 57 (53.27%).

Twenty-seven (54%) female patients were in the adult age group (>12 years), while the males were the majority of the pediatric age group 32 (56.14%).

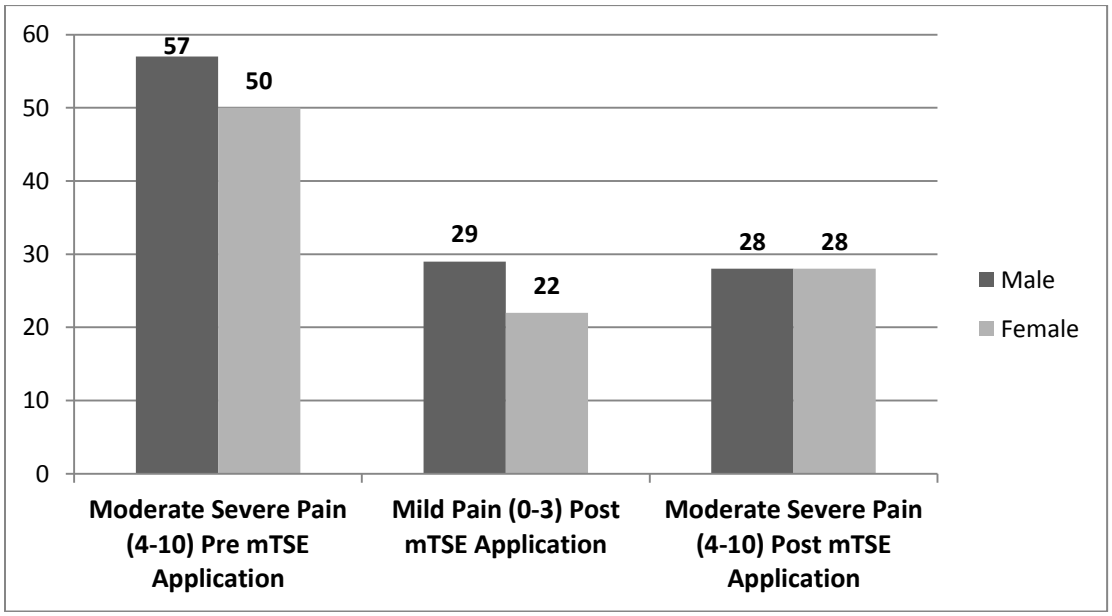
Twenty (38.46%) adult patients had their pain level lowered to mild (0-3) after the use of modified TSE. Thirty-two (58.18%) pediatric patients have reported mild pain (0-3) after applying the mTSE, see figure 1.




*Pain scale; numerical and visual pain scale, where 0-3 represents mild pain, and 4-10 represents moderate-severe pain[17-19]. **mTSE; modified Transcutaneous Spinal Electroanalgesia

**Figure 1: Modified Transcutaneous Spinal Electroanalgesia (mTSE) use according to Age**

Twenty-eight (56%) patients had reported decrease in their pain level to mild, compared to 28 (49.12%) male patients who had their pain improved after applying mTSE, see figure 2.




*Pain scale; numerical and visual pain scale, where 0-3 represents mild pain, and 4-10 represents moderate-severe pain[17-19]. **mTSE; modified Transcutaneous Spinal Electroanalgesia

**Figure 2: Modified Transcutaneous Spinal Electroanalgesia (mTSE) use according to Gender**

There was no observed statistically significant difference in the mean pain score level before applying mTSE between pediatric (M 7.3 ± 2.3) and adult age group (M 7.7 ± 1.8) (Kruskal-Wallis test for two groups=1.3), (P-value 0.11), see table 1.

**Table 1: Modified Transcutaneous Spinal Electroanalgesia (mTSE) use according to Gender and Age**

| | | Mean±§SD | Mean± SD | Total | Mann-Whitney/Wilcoxon Test (Kruskal-Wallis test) | *P value |
|---|---|---|---|---|---|---|
| **Age** | Male | 29.8±13.7 | 8.5±2.2 | 57 | **NA | NA |
| | Female | 27. 3±8.0 | 8. 9 ± 1.8 | 50 | | |
| **Pre † mTSE Pain Score** | | 7.7±1.8 | 7.3±2.3 | - | 1.3 | 0.2 |
| **Pre mTSE Pain Score** | Male | 6. 6±1. 0 | 7.4±2.1 | 57 | 1.7 | 0.19 |
| | Female | 8. 8±1.8 | 7.1±2.7 | 50 | 5.4 | 0.02 |
| **Post mTSE Pain Score** | | 4.1± 2.2 | 3.1± 2.7 | - | 6.5 | 0.01 |
| **Post mTSE Pain Score** | Male | 4.1±1.8 | 2.8±2.6 | 57 | 8.0 | 0.005 |
| | Female | 4.0±2.6 | 3.6±2.9 | 50 | 0.4 | 0.5 |

*P-value ≤ 0.05 indicates statistical significance, § SD; Standard Deviation.
**NA, not applicable, †mTSE; modified Transcutaneous Spinal Electro analgesia

The response to mTSE was statistically pronounced in pediatric age group (M 3.1 ± 2.7) compared to adult age group (M 4.1 ± 2.2), (Kruskal-Wallis test for two groups: 6.5), P value 0.01, see table 1.

Female pediatric patients had statistically significant less mean pain score before application of mTSE (M 7.1 ± 2.7) compared to female adult patients (M 8. 8± 1.8) P value 0.02, see table 1.

Male pediatric age group have responded better to mTSE (M 2.8± 2.6) compared to male adult age group (M 4.1±1.8), P value 0.005), see table 1.

## DISCUSSION

TSE was mainly used in the management of patients with chronic pain. In addition, it was used in some acute painful conditions such as post-operative pain[11]. Although it was not significantly effective in patients with acute postoperative pain, there was a trend toward possible efficacy over control group[14]. Unlike our group of patients who clearly demonstrated that mTSE is effective in reducing acute pain of sickle cell disease.

Significant inflammation and or excessive movement were among the factors that prohibit TSE efficacy in patients with painful conditions[11]. Release of inflammatory mediators is an indicator of inflammatory reaction in acute painful crises[20,21]. Although this study did not address the inflammatory process involved in acute pain, the high statistical significance of the findings, despite the modification of TSE parameters, supports its efficacy in such setting.

Regardless of pain site, electrode placement on T1 and T12 is associated with wide spread analgesia due to the proposed centrally provided stimulation[11]. Despite the inclusion of only patients with pain in the trunk and lower extremities, it is theoretically expected that SCD patients with upper limb pain may respond to TSE. Further studies are needed to explore such an issue.

The effect was more apparent in pediatric SCD patients. This is not unusual because adults had long-term exposure to the disease and usually complicated with anxiety, depression and possible tolerance to narcotics[22,23]. Adult females have responded better than adult males, while the opposite has occurred in pediatric SCD age group. There is no clear explanation other than a possible placebo effect in adult females, and or females in pediatric age group could not appreciate the difference as they had less pain pre application of mTSE.

TSE mechanism of action to relieve pain is not well understood. It includes the gait theory, and possible release of endorphins. Tolerance to exogenous narcotics may cause blunted response to released endorphins.

The effect of the psychosocial factors on both perception of severity of pain, and the amount of pain relief by various management modalities cannot be ignored.

The use of mTSE parameters needs to be confirmed by further studies. If the efficacy can be replicated, this will make it possible for places with limited facilities to try this modality for acute pain management. Furthermore, the mechanism of action of such modification in pain management needs to be explored.

The present study has a number of caveats, which need to be acknowledged. First, the clinical trial was limited to patients only and no control group for comparison. Second, the main outcome of the study was subjective with no supportive objective measures to evaluate the efficient use of mTSE in acute pain management. Third, the pain relieving effect was measured immediately with no known period for its long lasting effect.

The fact that TSE can be used repeatedly without apparent side effects, and post application long duration of pain relief may last up to few days in chronic painful conditions makes it feasible to explore the repeated application in the future studies. Small portable devices with TSE capabilities are available for self-application to treat pain in its early stages than when it is well-established

## CONCLUSION

**This preliminary study reveals the efficacy of mTSE in controlling pain of acute sickle cell episodes which might be helpful to reduce the need for pharmacological pain relieving agents. Multicenter randomized controlled trials to explore the use of mTSE in generalized pain are advised.**

---

**Author Contribution:** All authors share equal effort contribution towards (1) substantial contribution to conception and design, acquisition, analysis and interpretation of data; (2) drafting the article and revising it critically for important intellectual content; and (3) final approval of manuscript version to be published. Yes.

**Potential Conflicts of Interest:** None.

**Competing Interest:** None. **Sponsorship:** None.

**Submission Date**: 1 September 2014. **Acceptance Date:** 1 November 2014.

**Ethical Approval:** Research Committee, Qatif Central Hospital, Kingdom of Saudi Arabia.

## REFERENCES

1. Murtaza LN, Stroud CE, Davis LR, et al. Admissions to Hospital of Children with Sickle-Cell Anaemia: A Study in South London. Br Med Journal 1981; 282(6269): 1048-1051.
2. Al-Dabbous IA, Abu-Srair H, Al-Faris S. Pattern of Admissions of Children with Sickle Cell Disease in Qateef Central Hospital. Bahrain Medical Bulletin 1994; 16(1):3-6.
3. Hunt S, Alisky J. Inpatient Management of Sickle Cell Disease. Hosp Med Clin 2013; 2(2):e247-e62.
4. Platt OS, Thorington BD, Brambilla DJ, et al. Pain in Sickle Cell Disease: Rates and Risk Factors. N Engl J Med 1991; 325(1):11-16.
5. AL-Jam'a AH, AL-Dabbous IA. Management of Painful Crisis. In: AL-Jam'a AH, AL-Dabbous IA, eds. Management Manual of Sickle Cell Disease. Dammam; AL-Shati Modern P Press, 1992:36-51.
6. Quinlan J and Carter K. Acute Pain Management in Patients with Persistent Pain. Curr Opin Support Palliat Care 2012; 6(2):188-193.
7. Kaya B. Managing the Acute Painful Episode in Sickle Cell Disease, Thalassemia Reports 2011; 1(s2): e26.
8. Ballas SK, Gupta K, and Adams-Graves P. Sickle Cell Pain: A Critical Reappraisal. Blood 2012; 120(18): 3647-56.
9. Wang WC, George SL, Wilimas JA. Transcutaneous Electrical Nerve Stimulation Treatment of Sickle Cell Pain Crises. Acta Haematol 1988; 80(2):99-102.
10. Jacob E: The Pain Experience of Patients with Sickle Cell Anemia. Pain Manag Nurs 2001; 2(3):74-83.
11. Macdonald AJR, Coates TW. Discovery of Transcutaneous Spinal Electroanalgesia and its Relief of Chronic Pain. Physiotherapy 1995; 81(11): 653-661.
12. Thompson JW, Bower S, Tyrer SP. A Double Blind Randomised Controlled Clinical Trial on the Effect of Transcutaneous Spinal Electroanalgesia (TSE) on Low Back Pain. Eur J Pain 2008; 12(3):371-7.
13. Jung JH, Ignatius MI, Schuls CF, et al. Advances in Spinal Cord Stimulation for Treatment of Chronic Pain. Current Physical Medicine and Rehabilitation Reports 2013; 1(2).
14. Hamm-Faber TE, Aukes HA, de Loos F, et al. Subcutaneous Stimulation as an additional Therapy to Spinal Cord Stimulation for the Treatment of Lower Limb Pain and/or Back Pain: A Feasibility Study. Neuromodulation 2012; 15(2):108-16; discussion 116-7.
15. Epstein LJ, Palmieri M. Managing Chronic Pain with Spinal Cord Stimulation. Mt Sinai J Med 2012; 79(1):123-32.
16. Heffernan AM, Gregg A, Naik R, et al. Efficacy of Transcutaneous Spinal Electroanalgesia in Acute Postoperative Pain Management. American Society of Anesthesiologists 2001. Available at: http://www.asaabstracts.com/strands/asaabstracts/abstract.htm;jsessionid=11613C697B6

77E44F723711D45A112E6?absnum=1660&index=11&year=2001. Accessed in December 2013.
17. Ferreira-Valente MA, Pais-Ribeiro JL. Jensen MP. Validity of Four Pain Intensity Rating Scales. Pain 2011; 152(10): 2399-404.
18. Hiermstad MJ, Favers PM, Haugen DF, et al. Studies Comparing Numerical Scales, Verbal Rating Scales, and Visual Analogue Scales for Assessment of Pain Intensity in Adults: A Systematic Literature Review. J Pain Symptom Manage 2011; 41(6): 1073-93.
19. Williamson A, Hoggart B. Pain: A Review of Three Commonly Used Pain Rating Scales. J Clin Nurs 2005; 14(7): 798-804.
20. Yale SH, Nagib N, Guthrie T. Approach to the Vaso-occlusive Crisis in Adults with Sickle Cell Disease. Am Fam Physician 2000; 61(5):1349-56, 1363-4.
21. Serjeant G. Sickle-cell Disease. Lancet 1997; 350(9079):725-30.
22. Levenson JL. Psychiatric Issues in Adults with Sickle Cell Disease, Primary Psychiatry 2008; 15(5):45-49.
23. Elander J, Lusher J, Bevan D, et al. Understanding the Causes of Problematic Pain Management in Sickle Cell Disease: Evidence that Pseudoaddiction Plays a More Important Role than Genuine Analgesic Dependence. J Pain Symptom Manage 2004; 27(2):156-69.