Efficacy of transcutaneous electrical nerve stimulation (Active TENS versus Sham TENS) on hemodynamic stability and renal tissue perfusion guided by NGAL test for patients with hypovolemic shock - A prospective randomized clinical study

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Research

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Abstract

Background: Hypovolemic shock occurs due to many causes and it has complex patho-physiology which finally leads to decreased all organs perfusion. Transcutaneous electrical nerve stimulation (TENS) consists of a generic application of low-frequency, pulsed electrical currents transmitted by electrodes through the skin surface to stimulate the primary afferent pathways (peripheral nerves) to produce various physiological effects.

Objective: Was to evaluate the effect of transcutaneous electrical nerve stimulation application on the renal tissue perfusion and hemodynamic stability for patients with hypovolemic shock.

Design: A prospective, single-blind, randomized, sham-controlled trial. Patients were randomized into two groups (active TENS versus sham TENS). Active TENS group received resuscitation protocol and transcutaneous electrical nerve stimulation while sham TENS group received resuscitation protocol only.

Setting: Data was collected from general and obstetric ICU.

Main Outcome Measures: Improvement of renal tissue perfusion was considered the primary outcome and secondary outcomes was improvement of hemodynamic parameters.

Results: TENS application had caused a highly statistical significant change in serum Creatinine and NGAL test (74.43 ± 7.16 in active TENS versus 114.48 ± 13.6 2 in sham TENS) and (7.35 ± 0.7716 in active TENS versus 20.76 ± 2.11 in sham TENS) (P = 0.007 & P= 0.000) respectively. There was highly statistical significant difference before treatment and after treatment regarding urea, creatinine and NGAL test in the control group (P= 0.002 & P= 0.006& P= 0.000) respectively and there was highly statistical significant difference before treatment and after treatment in TENS group regarding to serum Creatinine (P= 0.003).

Conclusion:

We concluded the following; Application of TENS is extremely effective on improvement of renal tissue perfusion and and hemodynamic parameters. Also TENS should be used as a nursing intervention to maintain hemodynamic stability in patients with hypovolemic shock in the intensive care unit and we found patients with hypovolemic shock who received active TENS had better outcomes than patients who received sham TENS.

Introduction

Hypovolemic shock occurs due to many causes and it has complex patho-physiology which finally leads to decreased all organs perfusion and multi-system organ failure. These organs depend on preservation of both macro- and micro-circulation. There was great progress in last two decades in the development of less and non-invasive monitoring of macro hemodynamics. [12]

Transcutaneous electrical nerve stimulation (TENS) consists of a generic application of low-frequency, pulsed electrical currents transmitted by electrodes through the skin surface to stimulate the primary afferent pathways (peripheral nerves) to produce various physiological effects. TENS is mainly known for its analgesic action [3-4].

It is a non-pharmacological, non-invasive, inexpensive, easy to use and widely applied therapeutic modality used in clinical practice. The common electrical pulses emitted by TENS devices are described as monophasic rectangular, balanced asymmetrical biphasic rectangular, or symmetrical biphasic rectangular; the biphasic pulses are the most commonly used. [5-6]

It has been suggested that transcutaneous electrical nerve stimulation (TENS) could reduce the sympathetic activity by reducing pain [7]. On the other hand, some studies have reported that TENS may affect the autonomic nervous system by reducing over-activity of the sympathetic nervous system, even in the absence of pain) [9]. Among the therapeutic applications of TENS are pain relief, temperature alteration, and blood flow increase. Transcutaneous electrical nerve stimulation (TENS) is widely practiced method to increase blood flow in clinical practice. [9]

It is clear that stimulation applied to an organism impacts its endocrine and autonomic nervous systems. This impact may change cardiovascular function and result in blood flow alterations [10]. According to the best available knowledge, however, the best location of stimulation to achieve optimal blood flow has not yet been determined.

The NGAL Test is a particle-enhanced turbid metric immunoassay for the quantitative determination of Neutrophil Gelatinase-Associated Lipocalin (NGAL) in human EDTA plasma for testing on automated clinical chemistry analyzer [11]. The main Indication for Use: An NGAL test as an aid in the risk assessment for the development of stage II or III acute kidney injury (AKI) within 1 day of patient assessment in patients in the intensive care unit (ICU) who are hypotensive (MAP <70 mmHg) and/or receiving vasopressor support providing physicians the opportunity to intervene early in order to limit the extent of renal injury. [11]

We therefore aimed to study the effect of TENS application (active TENS versus sham TENS) on the renal tissue perfusion (using The NGAL Test and renal chemistry) and hemodynamic stability using vital signs and different perfusion parameters in patients with hypovolemic shock.

Methods

Design: A prospective, single-blind, randomized, sham-controlled trial.

Setting: Data was collected from general and obstetric intensive care units of Assuit University hospitals.

The project was reviewed and approved by the Ethics Committees in faculty of medicine at X (reports number X) and has therefore been performed in accordance with the ethical standards of the Declaration of Helsinki. It was also registered in the records of protocols system ClinicalTrials.gov (X identifier) and

written informed consent was obtained from all patients prior to their inclusion in the study and after they had been informed of the benefits and risks of the investigation.

Patients who were eligible to the study (adult 18 years or older, GCS 15 and who were free of acute or chronic pulmonary disease) were identified and recruited by the investigator after being informed about the study and asked for their participation. If they agree, they were invited to sign the informed consent.

We excluded from the study any patient with one or more of the following conditions: Renal insufficiency requiring dialysis, received a previous renal transplantation, moderate to severe AKI, pregnant women, progressive cancer, skin disorder making it impossible to use TENS and presence of a pacemaker/defibrillator.

After baseline assessment, they were randomized into two groups (Active TENS versus Sham TENS).

Randomization occurred through data generated by random.org online software Haahr M& Haahr S 1998. The sequence of numbers was generated by researchers “blind” to the study after the selection of patients for eligibility criteria and disclosed prior to the start of the intervention program.

Patient’s assessment tool was used to assess the patient conditions to form base line data to be compared with. This tool contained the assessment of the socio-demographic patient's profile that included Patient’s name, sex and age and assessment of the patient's clinical data which included medical diagnosis, length of ICU stay, length of hospital stay and assessment of the patient's conscious level by GCS. Outcomes assessment tool included primary and secondary outcomes.

Both active TENS and sham TENS group received routine ICU care:-

- Insertion of wide bore cannula, mostly CVP catheter.
- Administration of oxygen therapy using different tools (simple mask up to CPAP mask) if patient is conscious and mechanical ventilation if patient was indicated.
- Take of blood sample for complete lab. Investigations and evaluation of ABG.
- Resuscitations firstly by fluids (crystalloid) and by backed RBCs transfusion in case of bleeding like hemorrhagic shock.
- Correction of metabolic acidosis by NaHco3 when indicated.
- Administration of positive inotropes like noradrenaline, adrenaline and dopamine when indicated (it is given in infusion form).

Two nurses involved in the study and trained to perform the procedures in this study. Nurse 1 was responsible for the evaluation of primary and secondary outcomes in all patients in the study and was blinded know if the patient received the active or sham TENS. Nurse 2 was responsible for administering TENS in all patients in the study. Only Nurse 2 knew if the patient received the active or sham TENS. Nurse 2 instructed patients not to report their perceptions during the TENS administration to the nurse conducting the assessments.

Interventions:-

1. Application of Active TENS

The use of active TENS was conducted with a Neurodyn Portable TENS unit (IBRAMED) with two channels. The generator emits asymmetric, balanced, biphasic pulses. Two self-adhesive electrodes (VALUTRODE - 9 × 5 cm) were placed in parallel on retroperitoneal site in both sides with a 6-cm distance between them and on vastus lateralis, vastus medialis, and peroneus longus of both lower extremities. The TENS application was three sessions during the first 24 hour of resuscitation (one session each shift, each session take 55 minutes) at a frequency of 100 Hz and a pulse duration of 100 microseconds. The intensity (amplitude) was increased until the patient is able to feel a strong but comfortable tingling sensation. Patients were asked about the intensity of the TENS every 10 minutes. In the case of sensory habituation, the amplitude was increased until the individual again feels a strong but comfortable tingling sensation.

2. Application of Sham TENS

The use of the sham TENS were performed with an apparatus identical in appearance to the active TENS (Neurodyn Portable TENS, IBRAMED) that is specially designed for this study. The device remains active only during the first 30 seconds of application. After the initial 30 seconds, the current amplitude was gradually decreased over 15 seconds until it reaches the zero value, thereby interrupting the emission of electric current. The unit remained inactive for the rest of the application. The sham TENS device displays a light during the entire application, indicating to the patient that the device is active. Patients were informed that TENS may cause a slight tingling sensation or no sensation during the procedure.

They were asked every 10 minutes about the intensity of TENS, reinforcing the idea that lack of sensation occurs in most cases due to habituation to the electric current. Patients were observed throughout the administration of TENS. The mode of application of the electrodes and the duration of the sham TENS was the same as described in the active TENS.

Outcomes measurement: Improvement of renal tissue perfusion was considered the primary outcome and Secondary outcomes was improvement of hemodynamic parameters.

To evaluate renal tissue perfusion, NGAL test was used which is one of the most promising and best-studied acute kidney injury (AKI) biomarkers.

Two peripheral blood samples were withdrawn (4 ml each) after good sterilization for all study participants for NGAL measurements (the first sample was taken within the first 2 hour of resuscitation and the second sample was taken after 24 hours of resuscitation). The sera were separated and stored at -20 c. Human NGALELISA kit (Bioassay Technology Laboratory Co.,Ltd) (Catalog No : E1719Hu) was used for quantitative measurement of serum human NGAL levels. The assay was performed according to the manufacturer’s instructions.

The assessment of hemodynamic parameters, were done all over 24 hours especially cardiac monitoring. The monitor was attached to the patient immediately after ICU admission to measure blood pressure, heart rate, oxygen saturation and body temperature (using a thermistor probes placed under axilla for five minutes) over the 24 hours at regular intervals according to ICU protocol. All data were recorded on a digital recorder, with subsequent analysis being carried out by trained professionals.

Statistics

All analyses were performed using SPSS Statistical Software (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY, USA). Continuous variables were presented as mean±SD, and categorical variables, as frequencies. Differences between the groups at baseline were evaluated by an unpaired *t*test or the Mann–Whitney test for comparison of continuous variables. The Chi-square test or Fisher's exact test was employed to compare categorical variables. Analyses were performed by comparing baseline and post intervention variables in the subgroups (active TENS versus sham TENS)

Results

Personal and clinical data of the patients in the two groups were evaluated. Results showed that there were no a significant statistical difference between the two groups in relation to socio-demographic data and clinical characteristics (P value > 0.05) **(Table 1).**

The application of TENS didn't show any significant change on heart rate (107.83 ± 3.90 in active TENS Versus 104.17 ± 4.29 in sham TENS) (P value > 0.05), whereas the resuscitation protocol resulted in a significant reduction in HR within the two groups (P value < 0.05). In addition, TENS didn't result any significant change on MAP (73.93 ± 2.62 in active TENS versus 73.80 ± 3.28 in sham TENS), whereas the resuscitation protocol resulted in a significant increase in MAP within the two groups (P value < 0.05).Moreover, TENS didn't cause any significant effect on SPO2 (98.97 ± 0.21in active TENS versus 98.53 ± 0.34 in sham TENS), whereas the resuscitation protocol resulted in a significant increase in SPO2 within the two groups (P value < 0.05).Also, there was not a significant effect of TENS on CVP (11.10 ± 0.64in active TENS versus 10.97 ± 0.62 in sham TENS), whereas the resuscitation protocol resulted in a significant increase in CVP within the two groups (P value < 0.05) **(Table 2).**

The application of TENS didn't show any significant change on tissue perfusion parameters (P-value > 0.05) except CO2 gap (7.40 ± 0.58 in active TENS versus 4.30 ± 0.43 in sham TENS) but within the groups there was a significant difference in CO2 gap and tissue perfusion index (P value < 0.05).**Table (3)**

The application of TENS didn't show any significant change on skin turgor and peripheral pulse (P-value > 0.05), whereas the resuscitation protocol resulted in a significant change in skin turgor and peripheral pulse within the two groups (P value < 0.05) **Table (4).**

TENS application had caused a highly statistical significant changein serum creatinine and NGAL test (74.43 ± 7.16in active TENS versus114.48 ± 13.6 2 in sham TENS) and (7.35 ± 0.7716in active TENS versus20.76 ± 2.11 in sham TENS)(P = 0.007 & P= 0.000) respectively. There was highly statistical significant difference before treatment and after treatment regarding urea, creatinine and NGAL test in the control group (P= 0.002 & P= 0.006& P= 0.000) respectively and there was highly statistical significant difference before treatment and after treatment in TENS group regarding to serum Creatinine (P= 0.003) **Table (5).**

Discussion

Since 1965, TENS has become known worldwide and is also considered to be one of the most common therapeutic resources used in clinical practice for the relief of chronic and acute pain. However, in recent decades, some authors have observed that, in addition to its analgesic effects, TENS can alter skin temperature and increase blood flow. [12]

Validating the efficacy of TENS as an adjuvant technique for physical exercise is an important opportunity to improve the outcomes of critically ill patients. To the best of our knowledge, this is the first study to examine the effect of TENS application on patients with Hypovolemic shock. Hypovolemic shock is very critical complication that may increase the length of ICU and hospital stay or may be death. [13]

Previous studies have found that TENS applied to ganglion region has a vasodilatation effect and leads to a reduction in peripheral systolic blood pressure, whereas application of TENS in this study didn't show any significant change on hemodynamic parameters as heart rate, MAP, SPO2 and CVP (P value > 0.05). [14]

These finding were in contrast with Silva M, 2015 who reported that TENS resulted in a significant reduction in SBP in the group of younger adults (TENS – pre: 111 _ 2 mm Hg; post: 105 _ 2_2 mm Hg; placebo – pre: 113 _ 1_8 mm Hg; post: 114 _ 2_5 mm Hg; GEE, P < 0.01) [15]. Moreover, these results were opposite with Nilgun Kavrut Ozturket al., 2016 who found no significant differences were observed in oxygen saturation and MAP during the postoperative period. [16]

In previous study, systolic blood pressure, which is non-invasive marker of peripheral blood pressure, was reduced by the application of TENS in the group of younger adults [17]. Hollman and Morgan [18] found that the application of TENS to the forearm resulted in a reduced sympathetically mediated pressure response, which is not compatible with the present findings.

The resuscitation protocol in this study resulted in a significant increase in all hemodynamic parameters within the two groups before and after treatment (P value < 0.05). This could be attributed by that hypovolemic shock causes significant organ hypo-perfusion which stimuli sympathetic response by increasing heart rate, hypotension and decrease in CVP ,which rapidly response to rapid resuscitation by decreasing heart rate, and increasing in MAP and CVP. [19]

All of the reports relating to blood flow and TENS are based on measurements of skin temperature. Although skin temperature measurements provide indirect estimates of skin blood flow, they do not provide information about blood flow to underlying muscle as renal tissues. Regarding to skin temperature in this study, there was a considerable difference between groups; this wasn't in line with Walsh et al., who showed decreases in blood flow can possibly be attributed to cutaneous vasoconstriction produced by exposure to a non-thermo-neutral environment. [20]

The application of TENS in this study didn't show any significant change on tissue perfusion parameters as peripheral perfusion index, capillary refill, skin molting, skin turgor and peripheral pulse (P-value > 0.05). These results were not in agreement with Wong and Jette1984 who reported that, in healthy people, blood flow was decreased by the application of three forms of TENS (high-frequency, low-frequency, and burst-mode) [21].

In addition, Kaada 1990 found that low-frequency and burst mode TENS may increase blood flow in patients with diabetic polyneuropathy and Raynaud phenomenon. Both of these studies attributed circulatory changes to sympathetic activity. [22]

In one analysis of >2,000 critically ill patients, 20% were NGAL-positive without an increase in serum creatinine which can be interpreted as subclinical AKI or false positive results. However, these patients are at great risk of subsequent renal replacement therapy (RRT), longer ICU and hospital stay, and death, similar findings were observed in emergency department patients. [23]

Results of this study show that there was highly statistical significant difference between the two groups in relation to serum creatinine, NGAL test after treatment (P = 0.007 & P= 0.000) respectively. This can be explained by that electrical therapy could increase the renal perfusion rate and its excretory function. [24]

One possible explanation for the increase in blood flow is the activation of sensory neurons mediated through large myelinated afferent nerve fibers which, in turn, activate local inhibitory circuits within the dorsal horn of the spinal cord. Such circuits may inhibit sympathetic transmission in the spinal cord [25]. The arrangement of inhibitions mediated by Fibers is probably segmental. Polysegmental inhibitory circuits also exist, but they tend to require higher intensity stimuli to activate them since these inhibitory mechanisms are largely mediated by A delta and C afferents. [26]

The tubular damage marker "Neutrophil gelatinase associated lipocalin" (NGAL) is one of the most investigated renal biomarker. NGAL is typically upregulated in kidney tissue when exposed to nephrotoxic or inflammatory stress, but also released by activated neutrophils with specific forms of the molecule released from the kidney (monomeric) and neutrophils (dimeric). [27-28]

These findings were in line with Janda J et al., 1996. Who investigated the effect of electrotherapy on established ischemic renal failure in rats? In this study, electrotherapy with Rebox apparatus was performed directly on the ischemic kidney at a frequency of 1 – 10 kHz. The results showed a significant enhanced diuresis and sodium excretion [29].

Also our results were in line with Di Iorio etal., 2012 who studied High-frequency external muscle stimulation in acute kidney injury. There was a significant difference in serum creatinine in electrotherapy group. [30]

Another study by J. Kjartansson and T. Lundeberg 1990 showed that treatment with ENS (high intensity, high/frequency) increases blood flow in an ischemic surgical flap compared with placebo-ENS. The increased blood flow level correlates well with the long-term survival of the flap. The increase in blood flow generally started 10-15 min after the commencement of treatment. Repeated ENS treatments on consecutive days resulted in gradual improvement of the blood flow. [31]

Conclusion

We concluded the following; Application of TENS is extremely effective on improvement of renal tissue perfusion and TENS should be used as a nursing intervention to maintain hemodynamic stability in patients with hypovolemic shock in the intensive care unit and we found patients with hypovolemic shock who received active TENS had better outcomes than patients who received sham TENS.

Declarations

- **Ethical Approval and Consent to participate;**

The project was reviewed and approved by the Ethics Committees in faculty of medicine and has therefore been performed in accordance with the ethical standards of the Declaration of Helsinki. It was also registered in the records of protocols system ClinicalTrials.gov and written informed consent was obtained from all patients prior to their inclusion in the study and after they had been informed of the benefits and risks of the investigation.

- **Consent for publication;**

We (all authors of the manuscript: Efficacy of transcutaneous electrical nerve stimulation -Active TENS versus Sham TENS- on hemodynamic stability and renal tissue perfusion guided by NGAL test for patients with hypovolemic shock - A prospective randomized clinical study) agree to publish it Critical care journal.

- **Availability of supporting data;**

We certify that, to the best of our knowledge and after reasonable inquiry, the information contained in this manuscript, and any supporting documents provided with this manuscript, are available upon request, correct and complete, and that this research has not been conducted or published before.

- **Competing interests;**

The authors report no conflict of interest during the performance of this study.

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- **Authors' contributions;**

All authors of this manuscript share in data collection, observation, methodology and writing of this study.

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Table

Table (1): Distribution of personal and clinical data of the active TENS (a TENS) and sham TENS (s TENS) groups, (total patients' number = 60)

Personal and clinical data	a TENS (n= 30)	s TENS(n= 30)	P-value
	No.%	No.%	
Height ,cm, mean	170.52	171.34	0.40
Weight ,kg, mean	81.6	80.1	0.52
BMI	26.55	26.33	0.60
APACHI Score(Mean ± SE)	8.53±3.51	7.60±3.81	0.33
ICU stay: (days) Mean ± SE	2.77 ± 0.30	2.73 ± 0.28	0.879

-Independent samples t-test for comparing two groups.

-Chi-square test for qualitative variables.

-Data is represented as number (percentage) or mean ± standard deviation where appropriate. There was no significant difference (P-value >0.05) between studied groups.

*significant difference at P-value <0.05

Table (2): Distribution of the active TENS (ATENS) and sham TENS (STENS) groups in relation to hemodynamics and oxygen saturation.

Hemodynamics & oxygen saturation	a TENS (n= 30)	s TENS (n= 30)	P-value 1
Heart rate:			
Before treatment:			
Mean ± SD	128.50 ± 3.74	127.27 ± 3.92	0.708
After treatment:			
Mean ± SE	107.83 ± 3.90	104.17 ± 4.29	0.496
P-value[2]	0.000*	0.000*	
Temperature:			
Before treatment:			
Mean ± SE	37.01 ± 0.23	36.85 ± 0.19	0.805
After treatment:			
Mean ± SD	37.39 ± 0.15	37.27 ± 0.12	0.617
P-value[2]	0.023*	0.014*	
MAP:			
Before treatment:			
Mean ± SE	44.33 ± 2.77	50.17 ± 2.77	0.167
After treatment:			
Mean ± SD	73.93 ± 2.62	73.80 ± 3.28	0.976
P-value[2]	0.000*	0.000*	
Respiratory rate:			
Before treatment:			
Mean ± SD	20.37 ± 1.83	16.70 ± 0.80	0.373
After treatment:			
Mean ± SE	17.73 ± 1.48	16.23 ± 0.76	0.964
P-value[2]	0.002*	0.482	
SPO_2:			
Before treatment:			
Mean ± SD	97.60 ± 0.35	97.87 ± 0.49	0.244
After treatment:			
Mean ± SD	98.97 ± 0.21	98.53 ± 0.34	0.653
P-value[2]	0.000*	0.219	
CVP:			
Before treatment:			
Mean ± SD	5.37 ± 0.74	4.93 ± 0.76	0.976
After treatment:			
Mean ± SD	11.10 ± 0.64	10.97 ± 0.62	0.806
P-value2	0.000*	0.000*	

-Chi-square test used and data were represented as mean ± standard deviation.

-There were significant differences in all hemodynamic parameters after TENS compared to before TENS.

- *significant difference at P-value <0.05

-**MAP:** mean arterial pressure -**CVP**: central venous pressure

Table (3): Distribution of the active TENS (a TENS) and sham TENS (s TENS) groups in relation to perfusion parameters.

Perfusion parameters	a TENS (n= 30)	s TENS (n= 30)	P-value
GCS			
Before treatment:			
Mean ± SE	13.77 ± 0.58	13.57 ± 0.64	0.976
After treatment:			
Mean ± SE	13.97 ± 0.56	13.27 ± 0.72	0.677
P-value[2]	0.059	0.892	
CO2 gap			
Before treatment:			
Mean ± SE	3.39 ± 0.53	2.87 ± 0.56	0.414
After treatment:			
Mean ± SE	7.40 ± 0.58	4.30 ± 0.43	0.000*
P-value[2]	0.000*	0.004*	
Peripheral perfusion index			
Before treatment:			
Positive	11	36.7	9
Negative	19	63.3	21
After treatment:			
Positive	3	10.0	2
Negative	27	90.0	28

-Data is represented as number (percentage) or mean ± standard deviation where appropriate.

-Independent samples t-test for comparing two groups

-Chi-square test for qualitative variables.

-*significant difference at P-value <0.05

Table (4): Distribution of the active TENS (ATENS) and sham TENS (STENS) groups in relation to perfusion parameters.

	a TENS (n= 30)		s TENS (n= 30)		P-value
	No.	%	No.	%	
Capillary refill					
Before treatment:					0.671
Positive	28	93.3	26	86.7	
Negative	2	6.7	4	13.3	
After treatment:					1.000
Positive	28	93.3	29	96.7	
Negative	2	6.7	1	3.3	
P-value[2]	1.000		0.353		
Skin mottling					
Before treatment:					0.424
Positive	2	6.7	5	16.7	
Negative	28	93.3	25	83.3	
After treatment:					1.000
Positive	2	6.7	3	10.0	
Negative	28	93.3	27	90.0	
P-value[2]	1.000		0.706		
Skin turgor					
Before treatment:					0.584
Cold	19	63.3	21	70.0	
Warm	11	36.7	9	30.0	
After treatment:					1.000
Cold	4	13.3	3	10.0	
Warm	26	86.7	27	90.0	
P-value[2]	0.000*		0.000*		
Peripheral pulse					
Before treatment:					0.605
Positive	15	50.0	17	56.7	
Negative	15	50.0	13	43.3	
After treatment:					0.671
Positive	26	86.7	28	93.3	
Negative	4	13.3	2	6.7	
P-value[2]	0.002*		0.001*		

-Data is represented as number (percentage) or mean ± standard deviation where appropriate.

-Independent samples t-test for comparing two groups

-Chi-square test for qualitative variables.

-*significant difference at P-value <0.05

Table (5): Distribution of the active TENS (ATENS) and sham TENS (STENS) groups in relation to renal function and NGAL.

Renal function and NGAL	a TENS (n= 30)	s TENS (n= 30)	P-value
Urea:			
Before treatment:			0.663
Mean ± SE	5.94 ± 0.76	7.66 ± 1.38	
After treatment:			0.124
Mean ± SE	5.82 ± 0.74	8.73 ± 1.42	
P-value[2]	0.280	0.002*	
Creatinine:			
Before treatment:			0.425
Mean ± SE	91.74 ± 10.31	95.09 ± 17.26	
After treatment:			0.007*
Mean ± SE	74.43 ± 7.16	114.48 ± 13.62	
P-value[2]	0.003*	0.006*	
NGAL:			
Before treatment:			0.070
Mean ± SE	7.78 ± 0.91	10.91 ± 1.30	
After treatment:			0.000*
Mean ± SE	7.35 ± 0.77	20.76 ± 2.11	
P-value2	0.484	0.000*	

-Data is represented as number (percentage) or mean ± standard deviation where appropriate.

-Independent samples t-test for comparing two groups

-Chi-square test for qualitative variables.

-*significant difference at P-value <0.05

Figures

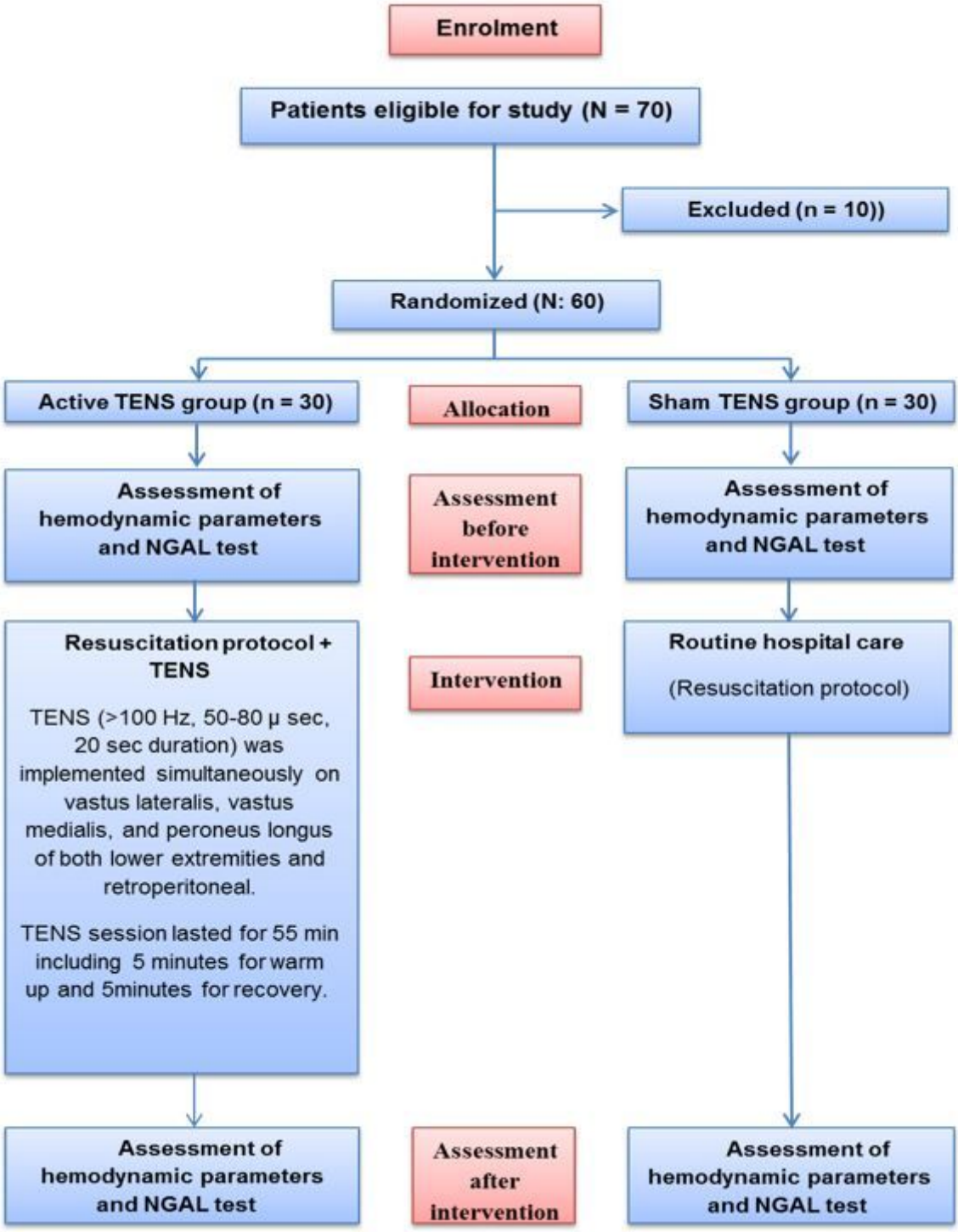

Figure 1

CONSORT flow diagram of randomized controlled trial.