TENS COMPARED TO OPIOIDS IN POSTOPERATIVE ANALGESIC THERAPY AFTER MAJOR SPINAL SURGERY WITH REGARD TO COGNITIVE FUNCTION

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Abstract

Background: Long term use of opioids causes cognitive decline. Transcutaneous nerve stimulation (TENS) applied preincisionally and postoperatively reduces postoperative opioid requirement and provides sufficient analgesia after major spinal surgery. Aim of this study was to find out the impact of TENS compared to opioids, prescribed for postoperative analgesia on early postoperative cognitive function.

Methods: This study was prospective and randomised-controlled. Patients and observers were blinded to the study design.

Forty-one patients of both sexes planned for lumbar interbody fusion were admitted and divided randomly into 2 groups. 35 Patients finished the study. Group A received TENS preincisionally and postoperatively, group B received piritramide intravenously (IV) by patient-controlled analgesia pump. The adjuvant analgesic therapy diclofenac 75 mg IV and the rescue medication paracetamol 1g IV was the same for all patients. Pain intensity was assessed by visual analogue scale (VAS). A battery of objective, standardized psychological tests was administered in the same order the day before surgery and 24 to 30 hours postoperatively.

Results: The two groups were compared by pairs. Pre- and postoperative attention and memory differed significantly in both groups ($p < 0,05$). The postoperative fatigue was lower in group A ($p < 0,05$). Neither age, sex, body mass index, duration of operation, the need of rescue medication nor the incidents of hypotensive phases showed any significant association with postoperative cognitive decline.

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Conclusions: Augmentation of fatigue in early postoperative phase was less in patients treated with TENS than with opioids for analgesic therapy after major spinal surgery. Further investigations on the duration of opioid therapy when cognitive functions decline are necessary.

Key words: transcutaneous electrical nerve stimulation; major spinal surgery, postoperative neurobehavioral manifestation, opioid, fatigue.

Introduction

The impact of anesthetics and oxygen desaturation on postoperative cognitive dysfunction was investigated recently[1-3].

The advantage concerning postoperative cognitive function of epidural analgesia versus patient-controlled opioid based analgesia after abdominal operation has been shown[4]. Long term treatment with opioids causes cognitive dysfunction[5]. Transcutaneous electrical nerve stimulation (TENS) was proved efficient and opioid sparing in postoperative analgesia after major spinal surgery[6].

The intention of this study was to clarify a possible difference in early postoperative cognitive function between patients treated for postoperative analgesia with TENS and patients treated with piritramide given by a patient controlled analgesia (PCA)-pump after major spinal surgery. A visual analogue scale (VAS) score of pain of 3 or less was considered to be sufficient.

Material and Methods

Ethical approval of this study (Ethical Committee N° 1236) was provided by the appropriate Ethical Committee on 28 July 2010.

Forty-one opioid naïve patients of both sexes American Society of Anesthesiologists Grade I to III planned for elective posterior interbody fusion of 2 or 3 lumbar vertebrae were included into the study on the preoperative day. Written informed consent was obtained from all patients

No participant had been treated by TENS before. A prospective randomized patient and observer blinded study was designed to test the hypothesis that the patient controlled intravenous administration of PCA pump filled with piritramide (PCA-IV) impacts the cognitive function differently compared to TENS for postoperative analgesia within 24 hours.

Patients were divided randomly in 2 groups by rolling the die. According to a former study on TENS patients of the two groups were treated in the following manner[6]. Group A received TENS therapy for 30 minutes prior to skin incision, for 24 hours after the end of operation and PCA pump filled with saline; group B-sham TENS therapy for 30 minutes prior to skin incision, for 24 hours after the end of operation and PCA pump filled with piritramide. Due to necessity of postoperative analgesic treatment a control group without either TENS or PCA-IV was not created. In both groups TENS or sham TENS was started immediately after skin closure still under anesthesia.

In both groups 4 cutaneous self-adhesive electrode pads, sized 16 cm² (tens/ems, Promed GmbH, D-82490, Farchant, Germany) were attached on either side in a distance of 4 cm to the planned skin incision at dermatomal levels.

The TENS electrodes were connected to the TENS device (tens 1000 s, D-82490, Farchant, Germany). Stimulation was set in a synchronized mode. With a bidirectional electrical current wave a pulse width of 0.25 ms without bursts. The frequency was regulated on 100 Hz. Depending on the individual tolerance patients of group A received an intensity of 10 to 20 mA. The intensity of the electrical stimulation was set on 0mA for group B. Patients in group B were told that they cannot feel the electrical stimulation. The flashing "in use" light on TENS device was shown to them with intent to prove its correct mode of operation. The treatment by TENS or sham TENS lasted for 24 to 30 hours postoperative, shortly interrupted by changing the bandage on the postoperative day.

In both groups propofol was used for induction and sevoflurane for maintenance of anesthesia; analgesia was provided by fentanyl during the intra operative period. Rocuronium was used to facilitate intubation and for intra operative muscle relaxation. A forced air patient warming system was used to keep body temperature over 36°C during the whole operation.

Depending on the cause either fluids or phenylephrine were administered to improve hypotension.

Blood haemoglobin levels were kept over 8g dl^{-1} by autotransfusion of salvaged erythrocytes. Patients of both groups received piritramide 0.08mg kg^{-1} intravenously (IV) and diclofenac 75 mg IV 20 minutes before the expected end of skin closure. All patients received diclofenac 75 mg IV 12 hours after operation.

Patients' level of pain (from 0 no pain to 10 worst pain imaginable) was assessed by a standard 10 cm visual analogue scale (VAS) (DoloMeter, Mundipharma Ges.m.b.H., A-1072 Wien, Austria) during analgesic therapy.

The pain score was evaluated when the patients were awake and able to obey simple commands before leaving the recovery room, before psychological testing, and if necessary before administration of rescue medication. With intention to achieve a VAS of 3 or less single injections of piritramide were administered by the medical staff until the discharge from the recovery room.

The PCA pump, in group A filled with saline and in group B filled with piritramide, was connected and explained before the patients were dismissed on ordinary ward. The bolus dose in group B was piritramide 2mg, the lockout time was 20 minutes, and the maximum dose within 4 hours was piritramide 15mg. Concerning the injected volumes the PCA pump was adjusted equally in group A.

Paracetamol 1g IV was administered as an additional rescue medication if either TENS or PCA therapy failed to achieve a VAS of 3 or less.

A battery of psychological tests was administered to the patients on the day before operation and was repeated 24 hours to 30 hours after surgery. The order of administration of the tests was the same in both sessions.

The Mini Mental State Examination (MMSE) is a short neuropsychological test for the assessment of cognitive deficit[7]. The MMSE is divided into two sections: The first requires vocal responses only and covers orientation, memory and attention. The second tests ability to name, follow verbal and written commands, write a sentence spontaneously and copy a complex figure. The test is not timed, requires 5-10 minutes and has several parallel forms. The maximum total score is 30.

The Short Cognitive Performance Test (SCT) is

Table 1
Range, Mean and SD of Age, BMI, Sex distribution and OP duration by groups

		Treatment Groups		P
	All Patients (n = 35)	A (n = 17)	B (n = 18)	(Student t-test)
Age				
Range	41-75	41-74	43-75	
Mean (± SD)	60.49 (± 9.96)	56.65 (± 11.07)	64.33 (± 8.86)	0.031
Age > 65 y	15/35	4/17 (24%)	11/18 (61%)	P = 0.041
BMI				
Range	20.42-35.02	21.25-31.99	20.42-35.02	
Mean (± SD)	27.30 (± 3.45)	26.46 (± 3.17)	28.13 (± 3.73)	NS (0.16)
Sex				
Male	N = 18 (51.4%)	N = 8	N = 10	P = 1.0
Female	N = 17 (48.6%)	N = 9	N = 8	
Length of operation (min)				
Range	88-237	90-237	88-228	
Mean (± SD)	161.86 (± 37.84)	160.82 (± 39.07)	162.89 (36.61)	NS (0.87)

BMI: Body-Mass-Index

Table 2

Rescue medication and hypotensive phases by groups

	All Patients (n = 35)		Treatment Groups		P
	N	%	A (n = 17)	B (n = 18)	
Rescue medication					
0 gramme	23	65.7	12	11	P = 0.58
1 gramme	11	31.4	5	6	
2 gramme	1	2.8	0	1	
Hypotensive phases					
no	30	85.7	15	15	P = 1.0
Blood pressure systolic between 71 and 80 mmHg					
yes	5	14.3	2	3	
Exact Pearson Chi-Square based on Monte Carlo method.					

a brief neuropsychological test battery that consists of nine subtests to measure neuropsychological functions as memory, attention and related cognitive functions, taking into account the speed of information processing[8]. The SCT has been used in the assessment of treatment responses in numerous clinical trials for treatment of dementia in our institution. It requires 10-15 minutes to administer and has five parallel forms (A-E). The maximum total score is 24.

The Profile of Mood States (POMS) is a self-report instrument to assess current mood states with 35 adjectives[9-11].

The 4 POMS subscales are measuring: "depressive state" (maximum score 98), "fatigue" (maximum score 49), "vigour" (maximum score 49)

Table 3

MMSE, SCT & POMS for all patients and different groups

	All Patients (n=35)		Treatment Groups						A vs. B
			A (n=17)			B (n=18)			
	pre	post	pre	post	*P*	pre	post	P	P
MMSE									
Mean (± SD)	28.29 (±2.07)	28.49 (±1.82)	29 (±1.41)	28.65 (±1.97)	NS (0.42)	27.61 (±2.38)	28.33 (±1.71)	NS (0.09)	NS (0.14)
SCT									
Mean (± SD)	2.71 (±2.86)	4.71 (±3.63)	2.59 (±2.94)	5.06 (±3.90)	0.0003	2.83 (±2.85)	4.39 (±3.43)	0.014	NS (0.84)
POMS_d									
Mean (± SD)	31.37 (±16.16)	30.86 (±19.11)	32.12 (±18.16)	27.82 (±15.29)	NS (0.251)	30.67 (±14.58)	33.72 (±22.20)	NS (0.4)	NS (0.69)
POMS_f									
Mean (± SD)	21.69 (±7.18)	25.2 (±8.60)	21.12 (±5.87)	23.35 (±8.12)	NS (0.25)	22.22 (±8.36)	26.94 (±8.91)	0.016	NS (0.32)
POMS_v									
Mean (± SD)	25.57 (±6.80)	23.17 (±6.61)	25.06 (±6.79)	22.88 (±6.05)	NS (0.26)	26.06 (±6.97)	23.44 (±7.27)	NS (0.17)	NS (0.69)
POMS_a									
Mean (± SD)	13.91 (±8.55)	13.46 (±9.00)	14.47 (±10.09)	13.29 (±9.45)	NS (0.53)	13.39 (±7.04)	13.61 (±8.84)	NS (0.9)	NS (0.89)
MMSE: Mini Mental State Examination, SCT: Short Cognitive Performance Test, POMS: Profile of Mood States									
(d: depressive state, f: fatigue, v: vigour, a: anger).									

and "anger" (maximum score 49). The POMS requires about 5 minutes.

Repeated measures analysis of variance (ANOVA) with one fixed factor (group A vs group B) were applied to analyze data. For post-hoc comparisons, paired and unpaired Student t-tests were used. Exact Pearson Chi square tests were used to analyze distributions of sex, rescue medication and hypotensive phases. Whiskerplots with 95% confidence intervals were used to illustrate data. A p-value less than 0.05 indicates a statistically significant result. All computations were done with STATISTICA 6.1 (StatSoft, Inc. (2004). STATISTICA (data analysis software system), version 6).

Results

Thirty-five patients finished the study. Five patients were cancelled for surgical reasons after the preoperative testing. One patient dropped out because another than the planned operation was performed.

Concerning age (P = 0.03) and age over 65 years (P = 0.041) the groups differed significantly (Table 1). Regarding height (P = 0.37), weight (P = 0.47), sex (P = 1.0), body mass index (BMI) (P = 0.16), length of operation (P = 0.87)(Table 1) and necessity of rescue medication no significant difference was found between the groups (Table 2).

No significant difference was found between the two groups with respect to the frequency of hypotensive phases (P = 1.0) (Table 3).

MMSE was analyzed with a repeated measure ANOVA to compare the means with the fixed factor "group". No significant differences between the two groups were found (P = 0.14).

Furthermore, no effect was found concerning the mood states within the groups A and B, before and after the operation for the scales "depressive state" (P_A = 0.25, P_B = 0.40) "vigour" (P_A = 0.26, P_B = 0.17) and "anger" (P_A = 0.53, P_B = 0.90) of the POMS.

The pair wise comparisons (Student t-tests) showed statistically significant differences in the Short Cognitive Performance Test within both groups (P_A = 0.0003, P_B = 0.014) (Fig. 1). Score augments in both groups, which means the cognitive function of the patients declined postoperatively.

Fig. 1

SCT score for group A vs. B, before and after the operation. Higher scores mean lower cognitive function

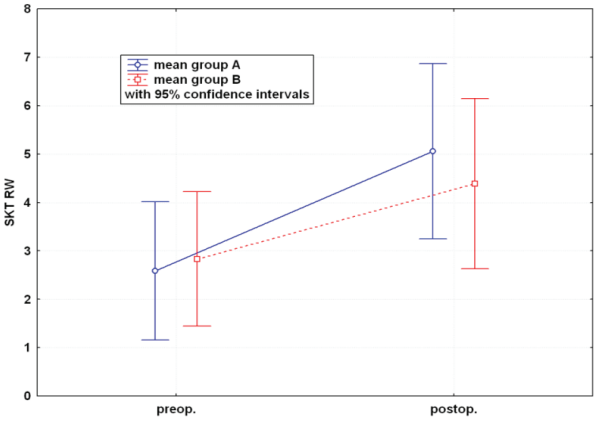
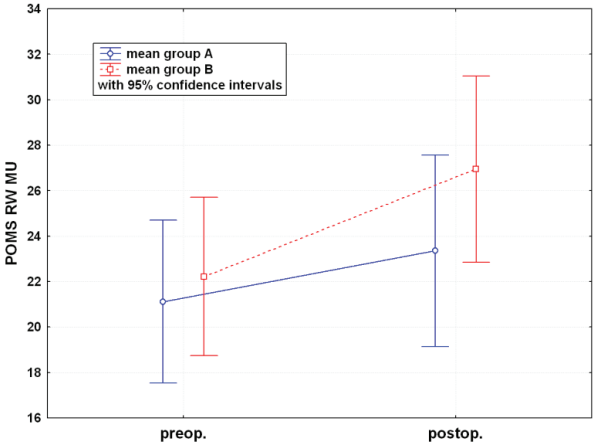


Fig. 2

Scores for the POMS scale "fatigue" group A vs. B, before and after the operation. Higher scores mean higher fatigue



Concerning the fatigue of the patients evaluated with POMS it was found a significant augmentation within group B (sham TENS plus piritramide, P_B = 0.016), but not in group A (TENS, P_A = 0.25). Consequently patients treated with TENS showed an equal fatigue before and after the operation.

Discussion

Because participants could not be encouraged to be tested for longer than 20 minutes, the simple, just for screening reasons used SCT was performed. Intending to deepen findings concerning attention, memory, and especially cognitive processing speed, more specific tests for verbal memory, visual memory, and attention should be done[12]. Connect-the-number-test would gain

more findings on cognitive processing speed[13].

Because it is not possible to design a true ‘‘control’’ for the electrical tapping sensation, patients were told that the perception of the electric pulse depends on one´s individual threshold of sensibility[14]. Although a double-blind study design would have been preferable, the study was not biased by interviewers. They were blinded in regard to randomization.

In order to increase patients' comfort and to reduce oxygen consumption by avoiding shivering after anesthesia participants were warmed throughout the whole operation[15]. This probably contributed to the postoperative decline in cognitive function within both groups[16].

Our findings concerning the necessity of rescue medication interfere with Unterrainer's and Dawood's studies which showed a non opioid analgesic sparing effect of TENS[6,17].

Particularly with regard on Hudetz's findings cognitive function was not influenced by metabolic syndrome[18]. BMI did not differ significantly within the groups.

The investigated cognitive functions were equal in both groups. We assume that both analgesic methods are of the same value in treating postoperative cognitive deficits caused by pain.

This study proves that postoperative cognitive ability declines within 24 hours to 30 hours postoperatively in both groups independently from analgesic treatment. On the one hand this might be caused by an overhang of sevoflurane, on the other hand by post operative sleep disturbances, inflammatory stress response and environmental factors[19-21].

Orientation concerning time and place, retentiveness, ability of memorization, speech, the understanding of speech, reading, writing, drawing, and calculating were not influenced differently by postoperative analgesic treatment.

Further studies will be necessary to find out the duration of opioid therapy when cognitive functions decline.

This study shows that the augmentation of postoperative fatigue was less in analgesic treatment by TENS than by opioids. Free of doubt this contributes to patients' comfort.

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