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Original Contribution

## Acupuncture vs intravenous morphine in the management of acute pain in the ED ☆☆☆★☆☆

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## ABSTRACT

**Background:** Acupuncture is one of the oldest techniques to treat pain and is commonly used for a large number of indications. However, there is no sufficient evidence to support its application in acute medical settings.

**Methods:** This was a prospective, randomized trial of acupuncture vs morphine to treat ED patients with acute onset moderate to severe pain.

Primary outcome consists of the degree of pain relief with significant pain reduction defined as a pain score reduction  $\geq 50\%$  of its initial value. We also analyzed the pain reduction time and the occurrence of short-term adverse effects. We included in the protocol 300 patients with acute pain: 150 in each group.

**Results:** Success rate was significantly different between the 2 groups (92% in the acupuncture group vs 78% in the morphine group  $P < .001$ ). Resolution time was  $16 \pm 8$  minutes in the acupuncture group vs  $28 \pm 14$  minutes in the morphine group ( $P < .005$ ). Overall, 89 patients (29.6%) experienced minor adverse effects: 85 (56.6%) in morphine group and 4 (2.6%) in acupuncture group ( $P < .001$ ). No major adverse effects were recorded during the study protocol. In patients with acute pain presenting to the ED, acupuncture was associated with more effective and faster analgesia with better tolerance.

**Conclusion:** This article provides an update on one of the oldest pain relief techniques (acupuncture) that could find a central place in the management of acute care settings. This should be considered especially in today's increasingly complicated and polymedicated patients to avoid adverse drug reactions.

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## 1. Introduction

Pain is a common cause of ED visits and its control remains a challenge and health priority worldwide. Many techniques were developed to control pain and to ensure patients comfort but their application is

still difficult especially in ED settings, due to the variety of treated conditions, the nonavailability of qualified practitioners, and the patients' specifications [1]. Pharmacologic methods, in particular intravenous (IV) opioids, are the most used analgesic agents with regard to their rapid action and high efficacy, but the use of these drugs can be limited by their adverse effects [2]. Nonpharmacologic pain relief techniques such as acupuncture have been proposed. During the second half of the twentieth century, acupuncture was established in Europe and in the last 2 decades, and it has spread around the world [3]. In Tunisia, acupuncture was introduced into the health system in the 90s, particularly to treat pain.

The World Health Organization has recognized acupuncture as a safe and effective therapy for a myriad of conditions causing pain and discomfort [4]. However, the introduction of acupuncture in the treatment of pain in the ED is rare. Acupuncture was shown to be as effective as morphine and it has a better safety profile which makes it a suitable method of pain control in certain circumstances such as headaches, migraines, back pain, cervical pain, and osteoarthritis [5].

In a recent systematic review, it has been concluded that there is insufficient evidence for the use of acupuncture in the ED settings because

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★★ Author contributions: HB and SN conceived the study, and designed the trial. SN, HB, WB, RB, MHG, HB, and KB supervised the conduct of the trial and data collection. HB was the acupuncturist of the study. HB, NB, NF, and MAM undertook recruitment of patients and managed the data, including quality control. SN, HB, NB, and MHG performed statistical analysis and analyzed the data. SN drafted the manuscript. HB and NB revised the manuscript. SN takes the responsibility for the paper as a whole. This study was supported in part by the Tunisian Ministry of Scientific Research.

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of the paucity of randomized controlled trials and the suboptimal methodological qualities of related studies [6].

The aim of our study was to evaluate the efficacy and safety of acupuncture compared with morphine for the management of acute pain in adult ED patients.

## 2. Patients and methods

This is a prospective, randomized, nonblinded interventional trial of acupuncture vs IV morphine in adult patients presenting to the ED with acute pain syndromes. The study was performed over 1-year period between April 2012 and March 2013 at the Fattouma Bourguiba University Hospital in Tunisia which is a tertiary care facility with approximately 110 000 ED patient visits per year.

### 2.1. Study design and settings

Patients were screened for inclusion in the triage unit during the day between the hours of 8:00 AM and 7:00 PM, Monday through Friday. Eligible patients were those who presented for moderate to severe acute onset pain with stable clinical conditions that did not require any resuscitation measures or specific procedures except for treatment of painful condition. These patients were at first informed about the protocol design and asked to participate. After obtaining written informed consent, the triage doctor started the randomization using a computerized random number generation system with sealed envelopes. Patients were first examined by the ED physician to ensure their eligibility for the study and demographic data and clinical characteristics were recorded. Then the designed treatment was started based on the scheduled protocol.

A standard form was used to collect data including demographic and clinical characteristics. Demographic data included age, sex, and comorbidities. Clinical data included the injury severity score for trauma patients, the cause of trauma, the time between the start of pain and randomization, the intensity of pain estimated by visual analogic scale (VAS), systolic and diastolic blood pressure (SBP/DBP), heart rate (HR), respiratory rate (RR), pulse oximetry, and diagnosis at ED discharge. When the patients had difficulties in understanding how to use the VAS, they were allowed to use a numerical rating scale (NRS) (from 0 to 100). All treatments sessions were limited to 1 hour. During it, patients were continuously monitored for pain intensity (VAS and NRS), vital signs (SBP, DBP, HR, pulse oximetry, RR and consciousness), and the occurrence of adverse effects.

### 2.2. Patients

#### 2.2.1. Inclusion criteria

Patients were included in the protocol if they were  $\geq 18$  years of age and met the following criteria: acute onset pain  $< 72$  hours of the ED presentation; pain intensity  $\geq 40$  of the VAS or NRS (ranging from 0 for no pain to 100 for maximum imaginable pain); acute musculoskeletal pain with no evidence of fracture or dislocation, including ankle and knee sprains without signs of severity (ligament rupture, laxity); shoulder and elbow tendonitis; upper and lower limb mechanical pains and lower back pain with no evidence of neurological deficit; acute abdominal pain with no urgent surgical intervention including renal colic and dysmenorrhea; and acute headache that meets the criteria of primary headache as described by the International Headache Society [7].

#### 2.2.2. Exclusion criteria

Patients were excluded from the study protocol if any of the following were applicable: temperature  $> 37.5^\circ\text{C}$ , patients under anticoagulant drugs or with coagulation abnormalities, skin affections (infections, hematomata, dermatosis) that would impair the use of certain acupuncture points, patients that were judged unable to participate in the study at the discretion of the treating physician, refusal, inability to consent,

inability to assess the degree of pain using the VAS or NRS, patients who had received analgesics in the 6 hours before the enrollment, an initial pain score  $\leq 40$  on the VAS or NRS, patients who had presented to the ED in the last 24 hours with the same complaint, and pregnancy.

### 2.3. Interventions

#### 2.3.1. Acupuncture group

After allocation to this group, patients were redirected to the ED acupuncture unit. The acupuncturist was an ED doctor with medical acupuncture qualification accredited by the National Tunisian Council of Doctors with 10-years experience in the field. Treatment protocols were determined through review of major clinical manuals and textbooks, literature review, and a panel of specialist acupuncturists from Chinese medicine backgrounds [8]. The protocols, which allow acupuncture points to be selected from a pool of predetermined points for each condition, provide sufficient standardization to assist replication, yet are flexible enough to allow individualized treatments. These protocols also allow for additional points, such as “ashi points”, to be used at the discretion of the acupuncturist. The location of the points, angle of insertion, and depth of insertion were sourced from a popular text “A Manual of Acupuncture” [9] and described in the annexe table (Annexe 1). The average time to place needles is 5 minutes.

#### 2.3.2. Morphine group

Patients in this group received IV titrated morphine. Morphine was prepared onsite and diluted in a manner to obtain a dose of 1 mg in each mL of normal saline. The initial dose was 0.1 mg/Kg and repeated regularly at the dose of 0.05 mg/Kg every 5 minutes until reaching objective. The maximum allowed dose was 15 mg.

A nondecrease of VAS by at least 50% within the first 30 minutes was considered as failure and the treatment was suspended. Patients were allowed to receive other treatments adapted to their conditions if judged necessary. Nonpharmacological measures, such as ice application, compression, elevation, and rest were allowed.

### 2.4. Outcomes

#### 2.4.1. Primary outcome

**2.4.1.1. Pain severity.** The pain score was measured at the start of the protocol (T0) and at 5, 10, 20, 30, 45, and 60 minutes. Success of treatment was defined by a drop in the pain intensity of at least 50% of its baseline value (T0).

#### 2.4.2. Secondary outcome

**2.4.2.1. Resolution time.** This interval was defined by the time (in minutes) elapsed between the start of the protocol (T0) and the decrease of the pain score of at least 50% of its initial value.

**2.4.2.2. Adverse events.** Possible adverse events related to the delivered care were investigated via a checklist, during the 1-hour protocol treatment and after, until the patient was discharged from the ED.

Reported adverse effects included bleeding, itching, needling pain, needle breakage, some sympathetic reactions including drowsiness and fainting, and other more serious complications like pneumothorax [10].

The adverse events related to morphine [11] may include allergic reactions, headaches, nausea, vomiting, and major adverse effects like hypotension and drowsiness. If major adverse effects occurred, the protocol was immediately terminated. Major adverse effects were defined as allergic manifestations such as rash and generalized edema, severe hypotension defined by a drop of the SBP under 90 mm Hg or a loss of more than 20 mm Hg of the initial SBP, recurrent vomiting, altered mental status, uncontrolled bleeding from the site of needle insertion,

**Table 1**

Baseline characteristics in the two treatment groups.

	Morphine n = 150	Acupuncture n = 150	Difference (95% CI)	P
Age, mean (SD), y	42 (16.0)	42 (15.0)	0.04 (−3.5 to 3.6)	.983
Sex male, n (%)	86 (57.3)	70 (46.7)	10.7 (−7 to 22)	.064
Comorbidity, n (%)				.485
Hypertension	24 (16.0)	19 (12.7)	3.3 (−4.6 to 11.3)	
Diabetes mellitus	17 (11.3)	17 (11.3)	0 (−7.2 to 7.2)	
Ulcer	5 (3.3)	3 (2.0)	1.3 (−2.3 to 5)	
Traumatic origin, n (%)	41 (27.3)	33 (22.0)	5.3 (−4.5 to 15.1)	.284
Pain localization, n (%)				
Abdominal pain	79 (52.7)	60 (40.0)	12 (7 to 23.3)	.037
Upper and/or lower limbs	29 (19.3)	36 (24.0)	−4.6 (−4.7 to 14)	.328
Low back pain	27 (18.0)	44 (29.3)	−12 (−21.5 to −2.5)	.014
Headaches	7 (4.7)	7 (4.7)	0 (−4.8 to 4.8)	1.000
Others	8 (5.3)	3 (2.0)	3.2 (−1 to 7.6)	.134
Vital signs at ED admission, mean (SD)				
HR, beats/min	80 (15)	79 (12)	1.2 (−2.2 to 4.7)	.490
SBP, mm Hg	132 (21)	129 (23)	3.3 (−2.3 to 9)	.256
DBP, mm Hg	79 (12)	75 (16)	3.5 (−0.01 to 7.1)	.057
Pain scale*, mean (SD)	78.8 (14.7)	80.4 (13.9)	−1.6 (−4.9 to 1.5)	.316

\* Visual analogic scale or numeric rating scale (range 0–100).

**Table 2**

Patient's main outcomes.

	Morphine n = 150	Acupuncture n = 150	Before adjustment		After adjustment			
			Mean difference	95% CI		Mean difference	95% CI	
				Lower	Upper		Lower	Upper
Success rate at 60 min, n (%)	118 (78)	138 (92)	14	8.2	19.8	13.2	5.2	21.3
Resolution time in min, mean (SD)	28 (14)	16 (8)	12.0	9.2	14.9	12.8	9.9	15.8
Pain score* difference 0–60 min, mean (SD)	56 (21)	64 (22)	7.7	2.6	12.7	9.6	4.5	14.6

\* Visual analogic scale or numeric rating scale (range 0–100).

and respiratory distress with capillary saturation under 95% or signs of pneumothorax.

The protocol was approved by the ethics committee of our institution. The protocol was registered at [clinicaltrials.gov](http://clinicaltrials.gov) under: NCT02460913.

### 2.5. Data analysis

A sample size of 150 per treatment group was calculated to detect an absolute difference of at least 13% in the VAS with 90% power and  $\alpha$  level of .05. Variables are expressed as mean (SD), median with 25% to 75% interquartile range or values (95% confidence interval [CI]) as appropriate. Comparisons were made among continuous variables using analysis of variance for independent samples.  $\chi^2$  test was used for discrete variables. Comparison between the 2 groups was examined using Wilcoxon rank-sum test and adjustment for baseline variables was made. All tests were 2-tailed and a *P* value less than 0.05 was considered statistically significant. Calculations were performed with a software package for windows (SPSS Inc, version 18).

## 3. Results

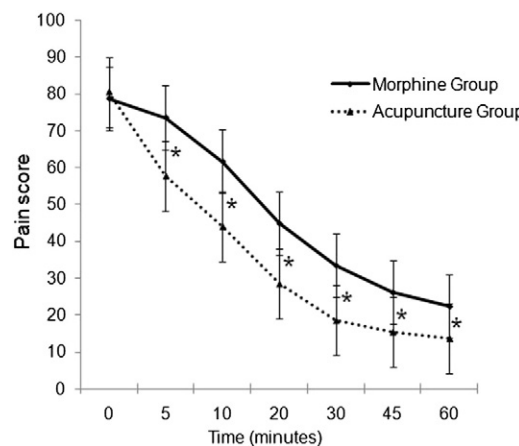
During the study period, 300 patients with acute pain were included: 150 in morphine group and 150 in acupuncture group. At baseline, the 2 study groups were comparable in terms of age, sex, and comorbidities. There were significantly more abdominal pain patients in the morphine group and more low back pain cases in the acupuncture group (Table 1).

Success rate was significantly different between the 2 groups (92% in the acupuncture group vs 78% in the morphine group *P* < .01). Resolution time was  $16 \pm 8$  minutes in the acupuncture group vs  $28 \pm 14$  minutes in the morphine group. The difference was statistically significant (*P* < .01). The mean absolute difference in pain score between the 2

groups was 7.7. This difference is not clinically significant because the minimal clinically significant absolute difference reported by Todd et al is 13. In morphine group, the mean total dose of morphine administered was  $0.17 \pm 0.08$  mg/Kg (Table 2).

The pain scale change from baseline at each time point in the 2 groups is shown in Figure. From the 5-minute time point, the acupuncture group reported significantly larger pain decrease compared with the morphine group. This difference persisted during the entire study period. Change of blood pressure, HR, RR, and oxygen saturation was not significant in both groups.

Overall, 89 patients (29.3%) experienced minor adverse effects: 85 (56.6%) in morphine group and 4 (2.6%) in acupuncture group; the difference was significant between the 2 groups (Table 3). The most



**Figure.** The pain score (VAS or NRS ranging from 0 to 100) changes from baseline at each time point in the 2 groups. (\*: significant change in pain scores between the 2 study groups with *P* < .05).

**Table 3**  
Treatment adverse effects.

	Morphine n = 150	Acupuncture n = 150	P
Minor, n			
Drowsiness	2	0	.156
Dizziness	64	0	<.001
Nausea and vomiting	36	0	<.001
Rush	2	0	.156
Palpitation	3	0	.082
Needle breakage	0	3	.082
Fainting	4	1	.176
Major, n	0	0	1
Total, n	85	4	<.001

frequent adverse effect was dizziness in the morphine group (42%) and needle breakage in the acupuncture group (2%). No major adverse effect was recorded during the study protocol. (See Table 4.)

#### 4. Discussion

Oligoanalgesia in EDs is known to be common [12]. Large studies conducted in ED patients with moderate-to-severe pain demonstrated that only the half of patients with acute pain received analgesics, and the same proportion reported that their pain had not been relieved at discharge from the ED [13]. It is now well proven that inadequate treatment of acute pain increases the risk of acute physiologic alterations and decrease patient satisfaction [14]. Furthermore, quality of pain treatment is one of the main factors influencing patient satisfaction in the ED [13]. Systemic administration of opioid analgesics such as IV morphine is commonly prescribed in the ED to relieve severe pain. However, adverse effects can impede their use and their effectiveness [11]. A variety of acupuncture techniques was applied to control pain in acute conditions. Auricular acupuncture, traditional Chinese medicine style body acupuncture, electro acupuncture, active acupuncture, and mixture of these techniques were used in previous studies [8]. When reviewing the evidence for the use of acupuncture in acute settings, only few studies were available to support its effectiveness. In a recent review by Kim et al [6], only 2 randomized controlled trials and 2 controlled observational studies were identified. In the randomized controlled trials, acupuncture was compared with standard ED management, concomitantly and separately. Standard ED management included a variety of treatment protocols but no specific drug was used. The authors of this review concluded that current evidence is insufficient to make any recommendation concerning the use of acupuncture in the ED.

**Table 4**  
Absolute pain score difference between the 2 study groups calculated at each time point.

Time interval (min)	Morphine n = 150	Acupuncture n = 150	Difference (95% CI)
Pain score, mean (SD)			
Baseline	78.8 (14.7)	80.4 (13.9)	−1.6 (−4.9 to 1.5)
5	73.6 (16.8)	57.6 (19.0)	15.9 (11.8 to 20)
10	61.6 (21.4)	44 (19.2)	17.6 (13 to 22.2)
20	45 (25.6)	28.7 (19.4)	16.2 (11.1 to 21.4)
30	33.6 (25.1)	20.2 (19.2)	13.3 (8.2 to 18.4)
45	26 (25.4)	17.6 (22)	8.3 (2.9 to 13.7)
60	22 (26)	15.9 (22.4)	6 (0.5 to 15.5)
Pain reduction ≥50% from time point (min), n (%)			
5	2 (1.3)	20 (13.3)	−12 (−17.8 to −6.2)
10	12 (8)	47 (31.3)	−23.3 (−32 to −14.7)
20	57 (38)	56 (37.3)	0.7 (−10.4 to 11.7)
30	30 (20)	18 (12)	8 (−0.3 to 16.3)
45	12 (8)	3 (2)	6 (1.1 to 10.9)
60	15 (10)	0	10 (5.2 to 14.8)

As far as we know, our study was the first to compare acupuncture with IV morphine using a simple, fast, and reproducible protocol conducted by a well trained acupuncturist assigned for this special purpose in an ED setting.

Although, the efficacy of acupuncture in acute conditions is still controversial. Our data support that it is at least as efficacious as IV morphine in relieving acute pain in the ED. In our study, the safety profile of acupuncture was good and we did not record any major complications. This finding supports the further use of this nonpharmacologic pain relief technique in ED settings.

#### 4.1. Limitations

Our study had some limitations that should be discussed. First, the main flow of this trial is the lack of blinding. In fact, in these settings, sham acupuncture has been proposed to provide a comparable experience to the study participants and to minimize the effects of nonblinding. However, in our study sham, acupuncture use would be impossible given the workload of a single acupuncturist. Second, our population represents rather a homogenous cultural and ethnical group including predominantly young and healthy participants for whom acupuncture is a culturally accepted practice, which would augment any placebo effect. This implicates that future external validation studies are required. Third, the intensity of pain was assessed mainly by the visual analogue scale and the numeric rating scale, which reflects only 1 side of pain evaluation. As it is known, the perception of pain is multifactorial [15] and includes various components (emotional, cultural, and psychological) that were not investigated in this study. Moreover, the duration of the protocol was limited to 60 minutes, whereas the beneficial effects of treatments and some adverse events may show later. Duration of acupuncture could also be subject of concern. In our study, it was 20 to 30 minutes. In a study by Cheing et al [16], acupuncture session for 40 minutes was associated with the highest therapeutic effect and longer lasting results. This means that our results may have underestimated the effect of acupuncture. Finally, other aspects of our evaluation were not studied in our trial such as the generalization of acupuncture in EDs and its economic impact on both patients and health cost [4]. In this context, acupuncture should be done by trained personnel.

#### 5. Conclusion

Our study demonstrated that in patients with acute pain syndromes presenting to the ED, acupuncture is at least as efficacious and has a better safety profile than IV morphine. The results of this study suggest that acupuncture has a potential role in controlling acute pain conditions presenting to EDs and appears to be safe and effective. Future studies should be performed in international populations.



## Appendix Annexe 1. Acupuncture point selection protocol

	Local points	Distal points
Lower back pain	DU3, DU4, Huatuajiaji, BL23, BL25, Yaoyan EP21, Ashi points	BL40, BL54, KI3
Sciatalgia	BL23, BL25, BL52, BL54, Ashi points	GB30, GB31, BL36, BL37, BL40, BL54, BL57, GB34, BL60
Ankle sprain	ST41, GB40, BL60, BL62, KI2, KI3, KI6, SP5, Ashi points	GB34, ST36
Renal colic	BL23, BL52, Ashi points	SP6, SP9, KI3, ST36
Gonalgia	ST34, ST35, GB33, GB34, SP10, SP9, EP36, Ashi points	
Headache	ST8, GB2, GB4, GB6, GB7, GB8, GB9, GB14, EP2, BL2, DU20, DU23, Ashi points	LV2 or LV3, KI3, GB43, BL60, ST44, SJ5 or SJ3, LI4
Shoulder pain	LI15, LI14, SJ14, Jian Hou, Jian Qian, Ashi points	IG10, IG11, GI11, GI4, SJ5
Neck pain	DU14, BL10, SI14, GB20, GB21	IG3, IG7, TR3, V60, EP26
Dysmenorrhea	CV3, CV4, KI12, ST30	BL23, BL32, DU4, SP6, SP8
Dorsalgia	DU9, Shu points, Huatuajiaji, Ashi points	DU26, BL40
Abdominal pain	CV4, CV6, CV12, ST25, LV13, GB24,	BL19, BL20, BL21, GB34, ST36, ST37, ST39, SP4, SJ6
Epigastralgia	CV12, ST21, LV13	BL20, BL21, SP6, LV2, ST36, PC6
Chest pain	CV17, Ashi points	PC4, PC6, BL14, BL15
Elbow pain	LI11, SI8, SJ10, LU5, Ashi points, LI10	LI4, SJ5
Hip pain	GB30, BL32, BL36, BL54, Ashi points	GB34, GB39
Calf pain	BL40, BL56, BL57, Ashi points	BL60
Wrist pain	SJ4, SJ5, LI4, LI5, SI5, Ashi points	LI11

BL: bladder; CV: Ren Mai; DU: Du Mai; EP: extra point; GB: gallbladder; HT: heart; KI: kidney; LI: large intestine; LU: lung; LV: liver; PC: pericardium; SI: small intestine; SJ: triple energizer; SP: spleen; ST: stomach

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