

Auriculotherapy in the prevention of postoperative urinary retention in patients with thoracotomy and thoracic epidural analgesia

A randomized, double-blinded trial

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Abstract

Background: Thoracic epidural analgesia is associated with a high rate of postoperative urine retention (POUR). Auriculotherapy can reduce visceral dysfunction and can be helpful in anesthesiology and pain control. The aim of this study was to test the efficacy of preoperative auriculotherapy to decrease the occurrence of POUR.

Methods: This single-center, double-blinded, 2-arm randomized study was performed between January 2015 and May 2016 in a tertiary care university hospital. Male patients scheduled for an elective lung surgical procedure under combined general anesthesia and thoracic epidural analgesia were included. Auriculotherapy (A group) was performed once the patient was under general anesthesia with 5 semi-permanent needles inserted in both ears at the “Shen Men” “bladder”, “pelvic parasympathetic”, “anterior hypothalamus”, and “frontal lobe” points. Five small round patches of adhesive pads were positioned bilaterally at the same points in the control group (C group). The main outcome measure was the requirement for bladder catheterization during the day and the first night following surgery.

Results: Fifty-three patients were randomized and 25 analyzed in each group. Requirement for bladder catheterization was different between groups: 24 C group patients (96%) and 18 A group patients (72%) ($P = .049$, Fisher exact test; Odds Ratio = 0.11 [0.01–0.95]). The number of patients needed to treat with auriculotherapy to avoid 1 case of bladder catheterization was 4. No adverse effect was observed due to auriculotherapy.

Conclusion: This study demonstrates that auriculotherapy is a safe and useful technique reducing POUR in thoracotomy patients benefiting from thoracic epidural analgesia.

Trial registration: Clinicaltrials.gov identifier: NCT 02290054 (November 13, 2014).

Abbreviation: POUR = postoperative urine retention.

Keywords: auriculotherapy, thoracic epidural analgesia, urinary retention

1. Introduction

Despite the development of minimally invasive thoracic surgery procedures (video-assisted thoracoscopic surgery or robotic

surgery), many cases still require the use of a posterolateral thoracotomy, which generates often intense post-operative pain. Although thoracic epidural analgesia has recently been challenged as the gold standard for preventing or treating post-thoracotomy pain,^[1] many anesthesiology teams continue to use it, especially when surgeons use a large approach like a posterolateral thoracotomy, perhaps in part because of its non-analgesic favorable effects.^[2] Among its drawbacks, epidural analgesia is associated with a high rate of postoperative urine retention (POUR) which can reach 79% when patients receive epidural morphine after anorectal surgery.^[3] Other factors involved in this multifactorial side-effect being in particular excessive infusion of intravenous perioperative fluids and administration of opioids.^[4] POUR is more frequently observed in male patients and leads often to bladder catheterization, with the potential to cause complications, including catheter-related infections, urethral trauma, prostatitis, and patient discomfort.

Auriculotherapy is a diagnostic and treatment method based on normalizing body dysfunction by treating points on the external ear. Although various ear treatments by healers or Doctors have been reported punctually over a long time in the Mediterranean area, auriculotherapy was developed by the French Doctor Paul Nogier. In 1956, he identified auricular points empirically and described a somatotopic organization of the body represented on

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the human pavilion of the ear. The publication of the first map of the ear in 1957 marked the emergence of a new modern era for auriculotherapy application.^[5] The stimulation of specific points, according to their representations, has been shown to improve the function of an impaired organ. Randomized controlled trials have demonstrated that auriculotherapy has a helpful place in anesthesiology and pain control in decreasing preoperative anxiety,^[6] reducing anesthetic requirement in healthy individuals,^[7] reducing vomiting following transabdominal cholecystectomy in female patients,^[8] relieving postoperative pain^[9] and chronic pain in cancer patients.^[10]

To our knowledge, there has been no study having assessed auriculotherapy effectiveness in preventing POUR although stimulation of auricular points has been shown to reduce visceral dysfunction, essentially via the activation of vagal tonus.^[11,12] We, therefore, tested the hypothesis that auriculotherapy administered preoperatively and maintained throughout the first postoperative hours could decrease the occurrence of POUR leading to bladder catheterization in male patients undergoing thoracic surgery under combined general anesthesia and thoracic epidural analgesia.

2. Methods

This study is a randomized, double-blind, controlled single-center trial performed in a tertiary care university hospital (Hôpital Foch, Suresnes, France), in accordance with the Declaration of Helsinki. Ethical approval for this study was provided by the Ethical Committee Ile de France VI (N° 121-13; November 22, 2013; Chairperson Dr L. Capelle), Paris, France. The study was designed in accordance with the Consolidated Standards of Reporting Trials (CONSORT 2010) and published on the Clinical.trials.gov website (NCT 02290054; November 13, 2014).

2.1. Study population

We studied male patients 18 to 85-years-old, scheduled for an elective surgical lung procedure under combined general anesthesia and thoracic epidural analgesia, who gave their written informed consent. The surgeries were either lung resection for cancer or pleural abrasion for recurrent pneumothorax. Subjects were not included if they

- (1) had ear infection or abnormality;
- (2) had neurological bladder disease;
- (3) had had previous major surgery of the urinary tract;
- (4) had end-stage renal failure or were under renal dialysis;
- (5) had a contraindication to epidural analgesia (i.e., coagulopathy, skin infection).

We also excluded patients who had a contraindication to total intravenous anesthesia with propofol and remifentanyl or were incapable of performing a self-assessment of comfort and anxiety. Patients with benign prostate enlargement could be included in the study. Patients who were taking medication with potential side effects of urine retention such as drugs with anticholinergic activity, opioids, detrusor relaxants, and calcium channel antagonists were not excluded from the study. Patients were enrolled after verbal explanation of the protocol plus delivery of a written information notice. They signed an informed consent after a suitable interval.

Enrolled subjects were excluded from the study, before the randomization if the anesthesiologist failed to insert the thoracic epidural catheter, and after the randomization

- (1) if the epidural catheter was removed within the first 18 hours following insertion because of analgesic inefficacy or
- (2) if the patient required bladder catheterization for hemodynamic monitoring.

2.2. Investigators

Auriculotherapy, effective and control treatments, was performed by 2 experienced anesthesiologists. These 2 anesthesiologists underwent the same 2-year auriculotherapy course at the University Paris XIII, they had 7 years of auriculotherapy practice at the time of the study and to avoid any discrepancy, they verified regularly that they had the same method. They were not in charge of the anesthesiology of the patients treated in the study.

2.3. Randomization

The allocation procedure to the auriculotherapy group (A) or to the control group (C) was managed by the sponsor (Direction of the Research Unit, Hôpital Foch). The random allocation sequence, with a 1:1 ratio and blocks of 10, was generated through the site "Randomization.org", of which the generator can be considered to be validated by experience. Scratch cards were generated and printed on a special printer; they were then kept in a secure location until used. For a given patient, the card was sent directly to the anesthesiologist in charge and the group of randomization was revealed after successful insertion of the epidural catheter. The time at which decoding occurred was recorded on the card itself.

2.4. Auriculotherapy

The process of Auriculotherapy was conducted according to STRICTA guidelines (see the supplemental file, <http://links.lww.com/MD/D26>).

Since Nogier published his somatotopic organization of the body represented on the human auricle, there have been many maps describing the position of the auriculotherapy points. Table 1 recapitulates the points used in this study with their

Table 1
Points used in this study.

Puncture points according to the French nomenclature	Localization of these points according to the WHO nomenclature	Attended effect	Number in Fig. 1
Shen men	TF2	Relaxation	1
Bladder	IH3	Regulation of bladder muscular function	2
Pelvic parasympathetic	ST5	Enhancement of the parasympathetic nervous system action on the bladder: excitement of the detrusor and inhibition of the urethral smooth muscles	3
Anterior hypothalamus	CW1	Enhancement of the parasympathetic nervous system action on the bladder: excitement of the detrusor and inhibition of the urethral smooth muscles	4
Frontal lobe	L02	Control of micturition	5

WHO = World Health Organization.



Acupoints used in the study (French nomenclature)

1. “Shen Men”
2. “Bladder”
3. “Pelvic parasympathetic”
4. “Anterior hypothalamus”
5. “Frontal lobe”

- Visible points
- Hidden points

Figure 1. Points chosen for the study. All points are located on the front side (or anterior side) of the external ear. Points 1 and 5 are visible and presented as circles. Point 2, 3, and 4 are hidden, underside the auricle or perpendicular to the surface; they are presented as squares.

French classification taught by Nogier and Alimi,^[13,14] and their localization according to the international nomenclature of the World Health Organization.^[15]

In the experimental group (auriculotherapy treatment, A group) 5 semi-permanent needles of 0.2 mm diameter and 0.9 mm length (New Pyonex-Seirin, www.acushop.fr) were inserted in both ears at the points chosen for the study (“Shen Men”, “bladder”, “pelvic parasympathetic”, “anterior hypothalamus”, and “frontal lobe”; Table 1) after careful disinfection of the skin using 70° modified alcohol and after a 1-minute pause. Each needle was covered by a small round patch of adhesive tape. In the control group (control, C group) 5 small round patches of adhesive pads were positioned bilaterally at the same points (Fig. 1).

2.5. Blinding

Insertion of needles or positioning of adhesive pads were performed once the patient was anesthetized and before surgical positioning and incision. The investigators asked the anesthesiologist in charge and the operating room staff not to look at the patient’s head during the minute it took to perform the treatment; so, they were blinded to the treatment group. The anesthesiologist and the nurses in care of the PACU were aware of the patient’s inclusion in the study but as all the patients presented with small round patches of adhesive tape on their ear so they could not tell which of the patients had the real treatment. As the semi-permanent needles we use do not induce any pain or discomfort when already positioned, the patients were also blinded to the treatment.

2.6. Thoracic epidural analgesia, general anesthesia, and postoperative management

Patients received hydroxyzine 100 mg 60 minutes before arrival in the operating room. Before induction of general anesthesia, an epidural catheter was inserted into the T5–T6 or T6–T7 intervertebral space via a median or paramedian approach and the loss-of-resistance method. A 20-gauge catheter was advanced

5 to 7 cm; subarachnoid placement was excluded by injection of 3 ml of lidocaine 2% with epinephrine 5 µg/ml. A first dose of 6 ml of levobupivacaine (2.5 mg/ml) and 20 µg of sufentanil was administered and followed by a continuous infusion of 5 ml/h of levobupivacaine (1.25 mg/ml) and sufentanil (0.25 µg/ml).

Total intravenous general anesthesia was then induced and maintained with remifentanyl and propofol to keep the bispectral index between 40 and 60. Tracheal intubation with a double-lumen tube was facilitated by atracurium.

The anesthesiologist in charge of the patient was asked to limit Ringer Lactate solution administration to 5 to 7 ml/Kg/h, to compensate blood loss volume for volume first by a modified gelatin fluid (Plasmion; Fresenius Kabi, Sèvres, France), and to start blood transfusion if hemoglobin decreased below 9 g/dL. If mean arterial pressure was below 70% of the value recorded before induction of general anesthesia, the anesthesiologist was asked to first use ephedrine boluses up to a total dose of 30 mg, then to administer boluses of phenylephrine and a continuous infusion of norepinephrine in case of persistent hypotension. Nefopam 20 mg was administered 30 minutes before extubation.

After tracheal extubation, the patient was transferred to the PACU where he stayed until the morning after surgery. Ringer Lactate solution administration was limited to 0.9 à 1.2 ml/kg/h and the same rules of blood loss compensation were followed. Epidural efficacy was evaluated hourly and co-analgesics were limited to paracetamol 1000 mg every 6 hours and nefopam 20 mg every 6 hours.

A bladder ultrasound was performed at arrival in the post-anesthesia care unit, then 6 hours later and every 3 hours until spontaneous voiding or bladder catheterization. Bladder catheterization was performed if the volume evaluated using ultrasonography was superior to 500 ml and/or if the patient was uncomfortable due to the bladder distension. In case of spontaneous voiding, an ultrasonography was systematically performed to rule out a residual post-micturition urine volume superior to 200 ml. In case of residual urine volume greater than 200 ml, surveillance was pursued every 3 hours during the stay in the post-anesthesia care unit, as if the patient had not voided. At

any time, the anesthesiologist in charge could decide on a bladder catheterization for hemodynamic monitoring.

The patient was asked to assess his degree of anxiety and comfort by the anesthesiologist in charge of the PACU 6 hours after his arrival there and the morning after surgery. Two auto-evaluation numerical scales were used, from 0 “no anxiety” to 10 “maximum anxiety” and from 0 “maximum discomfort” to 10 “maximum comfort”.

After one night in the PACU, the patient was discharged to the ward and the study was ended; the auricular needles and the patches of adhesive tape were removed at the end of the study to prevent a hypothetical injury of the patient or in the ward.

2.7. Outcomes

The primary endpoint of the study was the requirement for bladder catheterization during the day and the first night following surgery. The secondary endpoints of the study were the determination of predictive factors for bladder catheterization and the anxiety and the comfort of the patient 6 hours after arrival in the PACU and the morning after surgery.

2.8. Sample size

Before the study, 20 patients undergoing thoracic surgery with epidural analgesia and treated by auriculotherapy were compared to a group of 20 patients without auriculotherapy in the same conditions. POUR occurred in 67% of the cases without auriculotherapy and in 28% with. Consequently, assuming the same frequency, a sample size of 50 is necessary to achieve a significance level of $\alpha=0.05$ with a power $(1-\beta)$ of 80%. The number of subjects increases to 64 to consider possible dropouts.

2.9. Statistical methods

All statistical analyses were done on a per-protocol basis.

Qualitative data are presented as numbers (proportion) and comparisons used a Chi-square test, if the numbers in each group were greater than 5, and Fisher exact test otherwise. Quantitative data are presented as means \pm standard deviation when the distribution followed a normal distribution and as medians [interquartile range] otherwise. For univariate analyses, estimates of dependency measures between variables (Estimates [CI95]) will be provided with their confidence interval in the form of the Odds Ratio between 2 quantitative variables, the d of Cohen between a qualitative variable and a quantitative variable with a Gaussian distribution, and the Hodges–Lehman estimator between a qualitative variable and a quantitative variable when the latter does not have a Gaussian distribution. In the case of a Gaussian distribution of the data, the quantitative variables were compared using a Student t test, otherwise with a Mann–Whitney test.

A survival analysis (log rank test) was performed to compare the timing of bladder catheterization between groups

Intraoperative and postoperative variables were compared between patients randomly assigned either to the auriculotherapy group or to the control treatment group. Comparison of percentage of patients with bladder catheterization according to the use of auriculotherapy was done with Fisher exact test. The number needed to treat, that is, the number of patients who will receive auriculotherapy to prevent 1 additional patient requiring bladder catheterization, was calculated according to Chatellier et al.^[16]

Finally, postoperative anxiety and comfort of patients were compared among auriculotherapy and control groups using the Mann–Whitney test.

All analyses were done with software R version 3.1.3 (“The R Foundation for Statistical Computing”, Vienna, Austria).

The data sets generated and analyzed during the current study are available in the Dryad repository.

3. Results

Between January 7, 2015 and May 5, 2016, 101 patients were screened for the study, 35 declined or were judged ineligible, 66 patients were eligible in the preoperative visit and 53 patients were randomized: 27 in the C group and 26 in the A group. In 3 patients (2 in the C group and 1 in the A group) the epidural analgesia was judged inefficient 3 hours after arriving in the PACU and was removed. Twenty-five patients were analyzed in each group (Fig. 2).

Demographic and morphometric characteristics are summarized in Table 2 with comorbidities and treatment characteristics.

3.1. Intraoperative and postoperative management

Anesthesia duration, intraoperative and postoperative management (fluids and vasoactive drugs), and total amounts of antalgics were similar in the control and in the auriculotherapy groups except for intraoperative norepinephrine administration (Table 3).

3.2. Requirement for bladder catheterization between groups

There was no difference for ultrasound bladder measurement on arrival in the PACU: 271 [211–405] ml and 254 [175.5–386.5] ml in the C and A groups, respectively ($P=.523$). But requirement for bladder catheterization during the stay in the PACU was different between groups: 24 out of the 25 C group patients (96%) required a bladder catheterization and 18 out of the 25 A group patients (72%) ($P=.049$, Fisher exact test; Odds Ratio = 0.11 [0.01–0.95]) (Table 3). The number of patients needed to treat with auriculotherapy to avoid 1 case of bladder catheterization was 4. There was no difference for urinary volume at the time of the bladder catheterization in the 2 groups: 600 [475–700] and 600 [482.5–662.5] ml in the C group and the A group, respectively ($P=.694$). Time until bladder catheterization is represented as a survival time analysis. The median “survival time”, that is, the time at which half the patients have no bladder catheter, is 9 hours in the C group and 12 hours in the A group ($P=.018$ with Hazard Ratio = 0.44 [0.23–0.84] (Fig. 3). No post-void residual urine volume over 200 ml was measured in the eight patients who did not need bladder catheterization.

3.3. Postoperative anxiety and comfort

Anxiety and comfort 6 hours after the arrival in PACU and at the discharge of the PACU the morning after were not different in the control and auriculotherapy groups (Table 4).

3.4. Adverse events

An adverse event occurred in 4 cases (16%) and 10 cases (40%) in the C and A groups, respectively ($P=.066$, Fisher exact test).

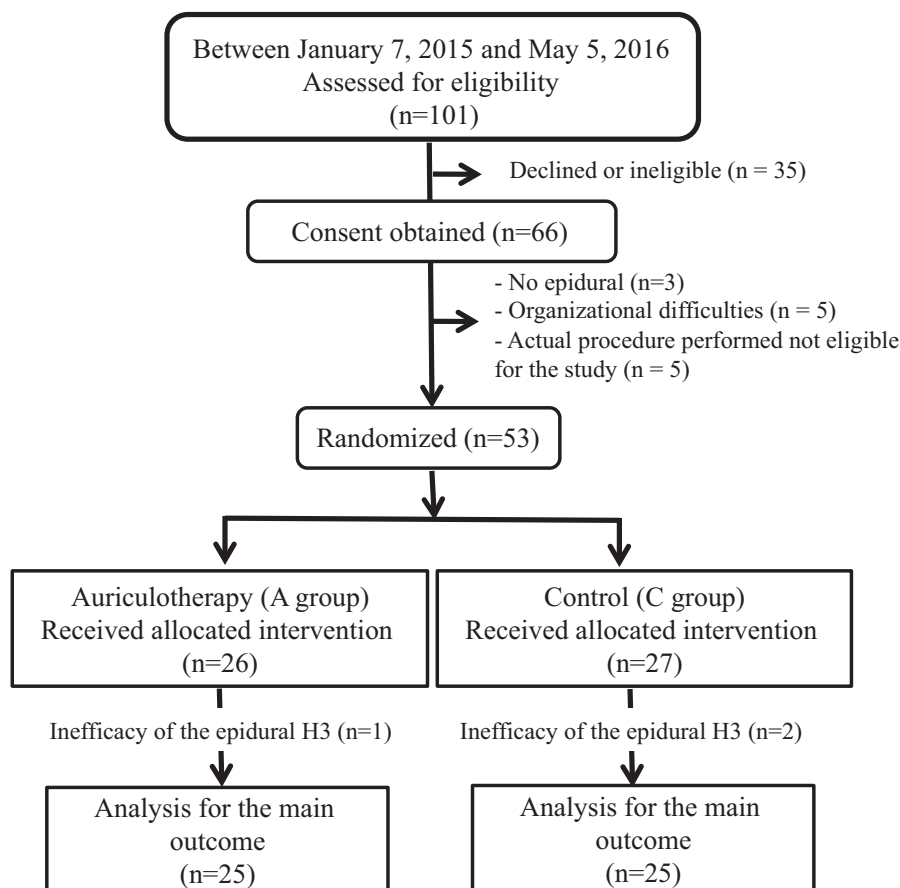


Figure 2. Flow chart.

They were always related to the surgical procedure and not attributed to the study (no complaint of pain, pruritus or local discomfort at the site of the implantation of the needles and no bleeding or irritation noticed locally during the study and at the removal of the needles).

Table 2
Demographic and morphometric characteristics of the patients.

	C group n=25	A group n=25	P value
Age, years	58 [55 - 62]	66 [58-72]	.016
Height, cm	176.0±7.8	175.6±8.4	.849
Weight, kg	83.3±11.9	73.7±13.1	.009
BMI	27.0±4.3	24.0±4.6	.020
Underlying pathology			1
Cancer	22 (88%)	22 (88%)	
Other	3 (12%)	3 (12%)	
Comorbidities and preoperative treatment			
Benign Prostatic enlargement	5 (20%)	4 (16%)	1
Sequelae of stroke	1 (4%)	0 (0%)	1
Diabetes	5 (20%)	2 (8.3%)	.417
Alcoholism	0 (0%)	3 (12.5%)	.110
Beta-blockers	5 (20%)	4 (16%)	1

C group = control treatment group, A group = auriculotherapy group, BMI = body mass index. Continuous variables are expressed as means±SD (normal distribution) or medians [25–75%, interquartile ranges] (non-normal distribution). Categorical variables are expressed as numbers (percentages).

P values for continuous variables were obtained with Student or Mann–Whitney test as appropriate. P values for categorical variables were obtained with Fisher Exact test.

4. Discussion

This double-blinded, randomized controlled clinical trial showed that auriculotherapy decreases the frequency of POUR leading to bladder catheterization in patients having a lung procedure and benefiting from thoracic epidural analgesia. However, we must underline that the P value corresponding to the comparison of the percentage of patients having required a bladder catheterization is borderline significant (P=.049). To our knowledge, it is the first such study on this subject while auriculotherapy has been tried in several indications related to anesthesiology.

Thoracic epidural analgesia is still widely used for efficient pain relief after major surgery, particularly after thoracic surgical procedures. POUR is one of the most frequent side effects of thoracic epidural analgesia, with an average incidence of 26%.^[4] Beyond patient discomfort and risk of urine infection, urinary retention makes the following of the early recovery after surgery (ERAS) guidelines more difficult. The practice of each anesthesia team varies: bladder catheterization only when the patient has urinary retention, which is our attitude, prophylactic bladder catheterization (insertion during anesthesia) and early or late removal of the catheter. Since age and benign prostate hypertrophy are risk factors for POUR,^[4] its incidence could be higher in thoracic surgical patients, who are frequently elderly male patients. Hence, we report here a very high prevalence of bladder catheterization in our male patients, up to 96% in the control group.

We decided, in this clinical trial, to choose an association of standardized auricular points and use them for every subject. The

Table 3
Intraoperative and postoperative management.

	C group (n=25)	A group (n=25)	Estimate [CI95]	P value
Intraoperative management				
Anaesthesia duration (min)	192 ± 63.1	181 ± 49.9	-0.2 [-0.8; 0.4]	.501 [†]
Ringer Lactate (volume infused, ml)	1360.1 ± 547.5	1351.2 ± 678.3	-0.01 [-0.6; 0.6]	.959 [†]
Modified fluid gelatin (ml)	0 [0-500]	0 [0-125]	1.7.10 ⁻⁵ [-5.1.10 ⁻⁵ ; 1.2.10 ⁻⁵]	.513 [‡]
Ephedrine (total dose, mg)	27 [18-30]	24 [9-27]	3.0 [-6.1.10 ⁻⁵ ; 9.0]	.171 [‡]
Phenylephrine (total dose, µg)	200 [0-400]	350 [0-575]	-50.0 [-350.0; 5.5.10 ⁻⁵]	.212 [‡]
Norepinephrine (maximum dosage, mg/h)	0 [0-0]	0 [0-0.4]	-8.3.10 ⁻⁶ [-0.2; 2.6.10 ⁻⁵]	.037 [‡]
Blood loss (ml)	0 [0-150]	50 [0-175]	-1.2*10 ⁻⁵ [-50.0; 50.0]	.865 [‡]
Nefopam (total dose, mg)	20 [20-20]	20 [20-20]	4.0*10 ⁻⁵ [-2.4*10 ⁻⁵ ; 7.7*10 ⁻⁵]	.312 [‡]
Sufentanil (total dose, µg)*	20.9 [20.6 - 21.0]	20.8 [20.7-21.0]	0.03 [-0.11-0.18]	.600 [‡]
Postoperative management				
Bladder catheterization	24 (96%)	18 (72%)	0.11 [0.01 - 0.95]	.049 [§]
Ringer Lactate (volume infused, ml)	1150 [782-1450]	942 [710-1419]	83 [-235; 399]	.551 [‡]
Chest tube drainage (ml)	450 [212.5-595]	362 [290-572]	16.8 [-190; 180]	.865 [‡]
Nefopam (total dose, mg)	60 [60-60]	60 [60-60]	3.3.10 ⁻⁵ [-1.4.10 ⁻⁵ ; 1.9.10 ⁻⁵]	.542 [‡]
Sufentanil (total dose, µg)*	26.5 [25.0-28.8]	29.5 [27.0-32.3]	-2.3 [-4.8-0.5]	.148 [‡]
Length of stay in post-anaesthesia care unit (h)	19 [15-21]	18 [14-20]	1.0 [-1.0; 3.0]	.402 [‡]

C group = control group, A group = auriculotherapy group.
 For continuous variables estimates [CI95] are Cohen d effect size with 95% confidence intervals (normal distributions) or Hodges-Lehmann estimator with 95% confidence intervals (non-normal distributions). For categorical variables estimates [CI95] are Odds Ratio with 95% Confidence Intervals.
 Continuous variables are expressed as means ± SD (normal distribution) or medians [25-75%, interquartile ranges] (non-normal distribution).
 *Epidurally administered sufentanil.
[†]P value obtained with a Student t test.
[‡]P value obtained with a Mann-Whitney test.
[§]P value obtained with a Fisher exact test; NA: non-applicable.

choice of these points was based on the French cartography and the treatment protocol taught by Alimi and Chelly.^[14] The selection of the points responded to a basic physiopathological vision of the POUR: insufficiency of parasympathetic tone, role of bladder distension, role of stress and anxiety, role of social control in micturition (frontal control).

Some of these points have frequently been used in studies. For example, the points located in the concha are frequently used to reduce visceral dysfunction. Stimulation of the conchae inferior, a region that is known to be innervated by vagal afferents, is responsible for an increase of the vagal tone. This increase in vagal tone has been shown to reduce hypertension, arrhythmia or

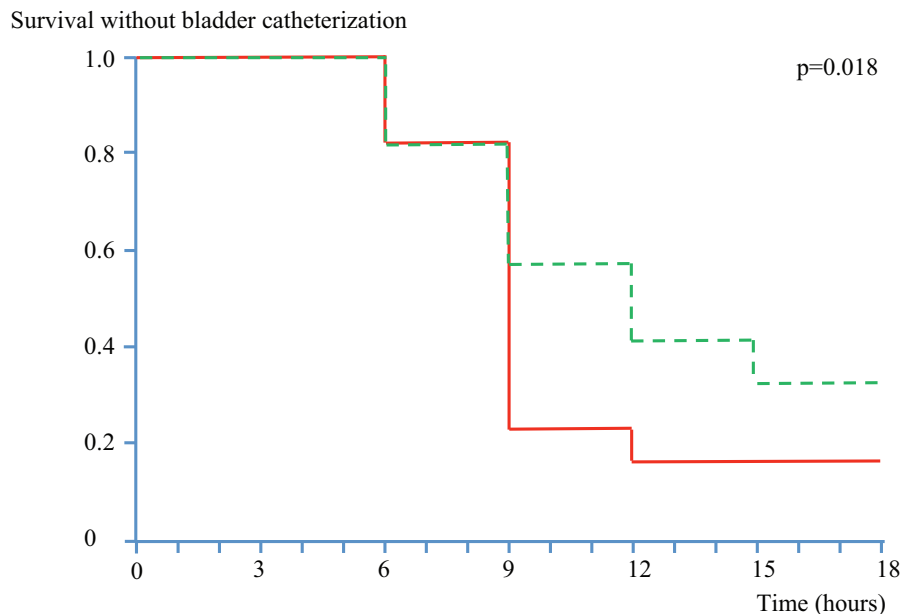


Figure 3. Time (hours) between arrival in the post-anesthesia care unit and bladder catheterization in the 2 groups. Green dotted line: auriculotherapy group. Red line: control group.

Table 4
Postoperative anxiety and comfort.

	C group n=25	A group n=25	Estimate [CI95]	P value
Anxiety				
Sixth postoperative hour	0 [0–1]	2 [0–3]	–0.9 [–2.9; 3.6×10^{-5}]	.104
Missing data	6	11		
The following morning surgery	0.5 [0–3.8]	1 [0–2.8]	3.9×10^{-5} [–1.0; 1.9]	.942
Missing data	11	11		
Comfort				
Sixth postoperative hour	10 [7.5–10]	8 [6.2–9]	0.9 [– 5.7×10^{-6} ; 2.0]	.131
Missing data	5	11		
The following morning surgery	9 [8–10]	7.5 [5.2–8]	1.9 [– 1.1×10^{-5} ; 2.9]	.074
Missing data	11	11		

C group = control group, A group = auriculotherapy group.

For continuous variables estimates [CI95] are Hodges–Lehmann estimator with 95% confidence intervals (non-normal distribution).

Continuous variables are expressed as medians [25–75%, interquartile ranges] (non-normal distribution).

P value obtained with a Mann–Whitney test.

favor gastrointestinal regulation among other effects. It has been shown in animal studies that electric stimulation of the concha induces, via the auricular branch of the vagal nerve, the stimulation of the nucleus of the solitary tract which has links to visceral organs and other brain structures.^[12] A 3-arm (control, placebo, acupuncture treatment) human experimental study has shown that electrical stimulation in the concha induces the stimulation of the vagal nerve.^[17] One can hypothesize that they could physiologically favor micturition.^[12] The Shen men point is a very common point, it is frequently used in combination with other auricular points for the treatment of pain, stress, and anxiety.^[18] Otherwise, the use of the Shen men point and vagal points on the conchae could perhaps explain the higher use (although not statistically significant) of phenylephrine in the A group.

As no studies have been published regarding prevention of POUR, we decided to compare the treatment of these points, hypothesizing that they should be effective, to the absence of treatment (patches of adhesive pads). In a second study, it would be interesting to compare these points, which proved to be “specific”, to other points.

Although we obtained a positive result, a better result could possibly have been obtained with modifications of the methodology. In order to keep our patients blind to the treatment we decided to treat them during the anesthesia phase, so they did not feel the light puncture of the semi-permanent needle. One can wonder if an inhibitory effect of anesthesia on auriculotherapy could attenuate the efficacy of the treatment. To our knowledge attenuated responses to auriculotherapy during anesthesia have not been described. For example, electrical stimulation of the auricle in anesthetized healthy volunteers decreased anesthetic requirement, demonstrating an effect even if the treatment was done during the anesthetic period.^[19] Moreover, auriculotherapy treatment is active, at least, as long as the needles are implanted in the auricula, during and after anesthesia.

The types of treatment are also an issue. Although many types of treatment have been described, some of them seem more efficient than others. We favored treatments that could be reproducible, allow the blinding of the surrounding teams, and that were powerful enough but not painful for the patient while staying in the post-anesthesia care unit. Our modest result encourages us to envisage another type of treatment for a subsequent study. In order to decrease the sensation for the

patient, we used short needles (0.9 mm), whereas others use longer needles (1.5 mm)^[9] or larger ones.^[10] The manual stimulation of the needles is probably also a way of increasing the effect, we did not propose this to our patients.

4.1. Limitations of the study

Despite some strengths (well-balanced groups regarding potential confounders such as age, diabetes mellitus; no patient with other known polyneuropathy which could have influenced the efficacy of the auriculotherapy; quadruple (patient–anesthesiologist–evaluator–analyst) blinded study design minimizing the potential biases), our study suffers from some limits.

We have chosen to perform our study only on men since POUR is more frequent among them due at least in part to a greater urethral resistance.^[4] Another reason is that bladder catheterization is more difficult and more often complicating for men than for women.

High incidence of POUR in this study could also be due to the systematic administration of nefopam which is known to frequently cause urinary retention but nefopam doses did not differ significantly between groups.

Some methodological points can be discussed as limits of the study:

- (1) we could have used electro-acupuncture, or stimulation of the needle by acupressure, or larger and/or longer needles to increase therapeutic efficacy;
- (2) according to Nogier or Alimi, the sensitive points are chosen when possible. However, since our patients were anesthetized, we could not test the sensitivity of the points, thus this could have diminished the efficacy of auriculotherapy;
- (3) we asserted that the 5 points that we decided to use were specific but other points could also have been tested;
- (4) we compared an auricular points group and a control group but it could have been interesting to complete the study with a “non-specific points control group” – there is no sham control group to consider the placebo effect on auriculotherapy.

Even if the semi-permanent needles are very fine and not felt by the patient, one could imagine that if the patients pressed very hard on the patch he could feel some pain and perhaps know that

he is in the auriculotherapy group. This hypothetical pain sensation could affect the subjects' blinding and this is a limit of our study.

Moreover, no conclusion can be drawn for anxiety and comfort since we deplore a large number of missing data.

4.2. Generalizability

Generalization of results is limited because of the small number of participants enrolled in this feasibility study and because of the limited value of the significant difference between groups ($P=.049$) but this result, slightly inside the statistical significance level, must be associated with the longer time to bladder catheterization in the treated group ($P=.018$) and with the low number (4) of patients needed to be treated with auriculotherapy to avoid 1 case of bladder catheterization.

5. Conclusion

In conclusion, findings from our study demonstrate that auriculotherapy is a safe and useful technique which may reduce POUR in thoracotomy patients with thoracic epidural analgesia.

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