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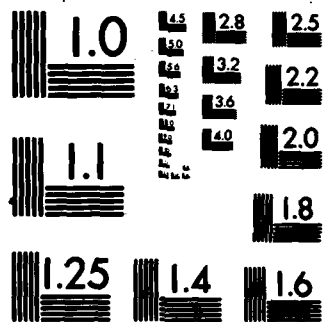
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REPORT VI

POINT ELECTROANESTHESIA (GENERAL ELECTROPHARMACEUTICAL ANESTHESIA)

FINAL REPORT

by

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A. Atinault
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July 1980

Supported by
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Fort Detrick, Frederick, Md. 21701

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Our ultimate objective remains the total elimination of drugs and the production of pure electroanesthesia. At the present stage of our research, a mixed method called electropharmaceutical anesthesia has been developed. Drugs are still used for induction, but in most cases anesthesia is maintained throughout surgery with the analgesic effect of electrical current. There is far less pharmaceutical		

Block 20 continued :

intoxication than with classical anesthesia since the maintenance of anesthesia is made by means of electric current according to the routine protocols thus avoiding injections of drugs which are known to be toxic.

Two double-blind studies were made upon request of the site-visit team. The efficiency of current was then evaluated during a first study on 50, then a second one on 37 volunteer patients. The induction was the same for all patients, but maintenance was different in the two studies.

In the first study anesthesia was to be maintained with electrical current and fentanyl if necessary, but actually current was stopped in 26 cases (unknown to the surgeon and anesthesiologist) in order to really check the action of current. The results showed a significant decrease in the use of fentanyl when current was on.

In the second study, anesthesia was supposed to be maintained with current plus N_2O , and fentanyl if necessary, but actually, in order to remain as objective as possible, in some cases current and N_2O were suppressed, in other cases, only current was, in others, only N_2O was (always unknown to surgeons and anesthesiologists). But this study did not give satisfying results as regards the analgesic efficaciousness of current. Therefore, another comparative study (not double-blind) was initiated, which gave very satisfactory results.

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F O R E W O R D

This is the continuation of work previously done under contract n° DAMD 17 75 C 5039 "Point Electroanesthesia" (principal investigator Aimé Limoge).

All studies have been conducted under the scientific control of Professor Maurice Cara, Chairman of the Department of Anesthesiology at Necker University Medical Center, and with the cooperation of surgeons of the urological clinic headed by Professor J. Cuckier.

In conducting the research described in this report, the investigators adhered to the International Guide to DHEW policy on the protection of human subjects as promulgated by the U.S. Department of Health, Education and Welfare (publication number NIH 72 102), December 1, 1971.

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x x x

x x

x

ROUTINE ELECTROANESTHESIA METHOD

I N T R O D U C T I O N

Thanks to the funds provided by the U.S. Army Medical Research and Development Command since 1973, we have been able to perform deep investigation in our research on the application of transcranial currents on man and we have thus developed a method of electropharmaceutical anesthesia.

During these past six years of experimental studies and clinical human essays, not only have we been able to find efficacious currents provoking neither initial shock, pain or unpleasant sensation, nor burns or other cutaneous damage, or muscular contractures, respiratory depression or cerebral lesion, but we have been able to locate ideal site for the electrodes, and to select the most efficient drug associations at a minimum dose.

x x x

x x

x

MATERIAL AND METHOD

Many goals have been attained since 1973 :

A. NATURE OF CURRENT.

The output current is biphasic. It is composed of modulated high-frequency pulse trains (peak-to-peak intensity 300 mA, average intensity = 0). The on-time of the wave-trains is 3 or 4 mS, followed by a 10, 8 or 6 mS off-time (Table I). These wave trains are composed of successive impulsional waves of a particular shape : one positive impulse of high intensity and short duration, followed by a negative impulse of weak intensity and long duration adjusted in such a way that the positive surface be equal to the negative surface. The use of such a negative phase makes it possible to eliminate all risks of burn (fig. 1, 2)^(19,21).

Position L.F.	on-time t (ms)	repetition per. T (ms)
A	3	13 $\pm$ 4%
or B	4	12 $\pm$ 4%
or C	3	10 $\pm$ 4%
H.F.	+ μ S	- μ S
F1	1.2	4.8
or F2	2	4

TABLE I - PRESELECTION OF ELECTRIC PARAMETERS. A, B, C positions are three different L.F. cyclic ratios. Positions F1 and F2 are two different H.F. cyclic ratios.

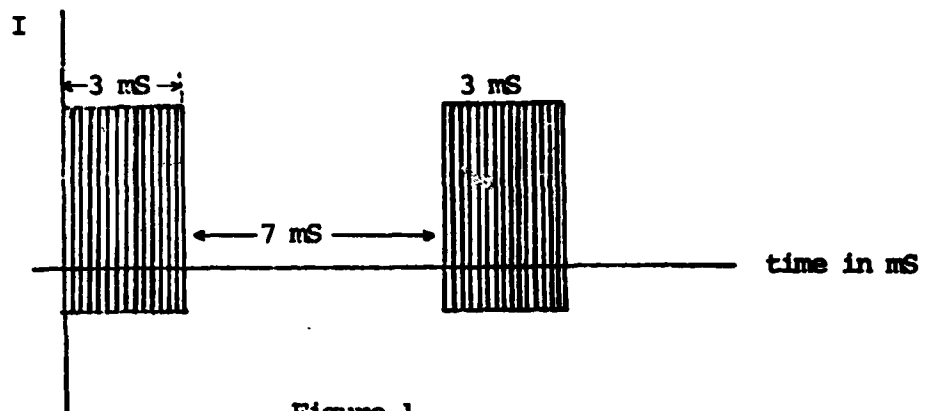


Figure 1

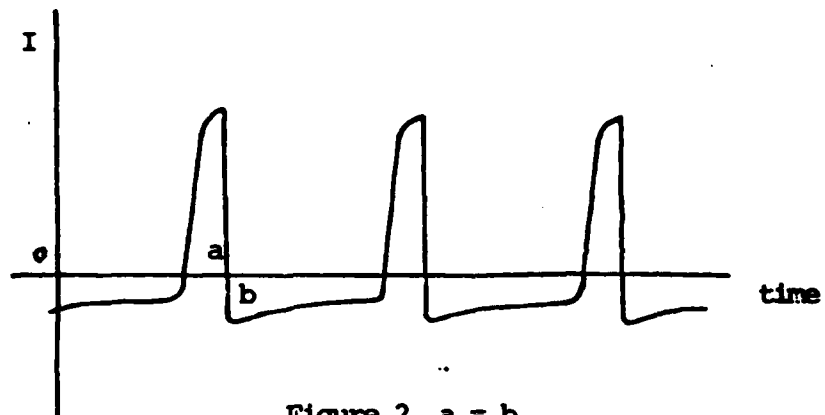


Figure 2. $a = b$

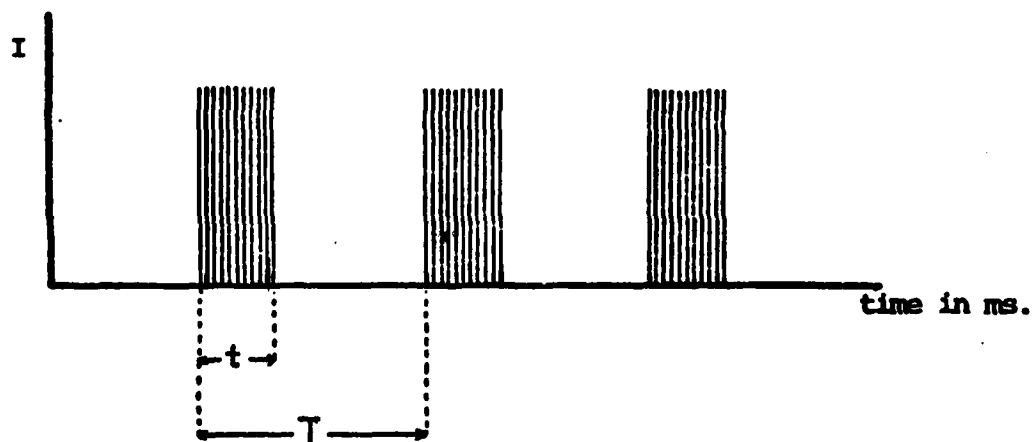


Figure 3

shape of the impulsional trains of waves

This type of current found its shape very progressively as the human clinical essays proceeded. The current initially used was composed of unidirectional high frequency trains consisting of 3 mS rectangular pulses modulated at 130 kHz with a frequency of repetition of 77 Hz and an average intensity of 8 mA (fig. 3, 4)^(1,2,3,7).

At the beginning we studied the on-time and the cyclic rate of repetition of the wave trains, i.e. t/T (t = on-time of the wave trains and T = cyclic rate of repetition). The best results obtained were with the three pairs : $\frac{3\text{ms}}{13\text{ms}}$, $\frac{4\text{ms}}{12\text{ms}}$ and $\frac{4\text{ms}}{10\text{ms}}$. These pairs have been selected because they permit to change the low-frequency cyclic ratio during long-duration surgery in order to avoid accustoming^(5,6).

The various electric parameters (cyclic ratio, shape of waves, peak-to-peak voltage) have been checked with an oscilloscope. The peak-to-peak intensity was measured with a P 6021 AC Tektronix current probe placed on one of the output threads of the electroanesthesia generator and connected to the oscilloscope (see our first annual report under contract n° DADA 17 73 C 3056, year 1974)⁽¹⁸⁾.

Then we came to study the value of high frequency, the shape of the HF waves and the HF cyclic ratio. No significant difference has ever been reported during our clinical observations between 100 and 700 kHz and this is why we have empirically chosen the intermediary 167 kHz (6 μS) which we now use. But, on the other side, the shape and the cyclic ratio of the HF waves are of utmost importance to provoke analgesia. Various shapes of waves have been tested (triangular, rectangular, exponential), and the best result was given by the signal with an exponential ascent and acute fall. As regards the cyclic ratio of the HF waves, 1/5 was the best one, i.e. $t' = 1.2 \mu\text{S}$ and $T' = 6 \mu\text{S}$ (fig. 5).

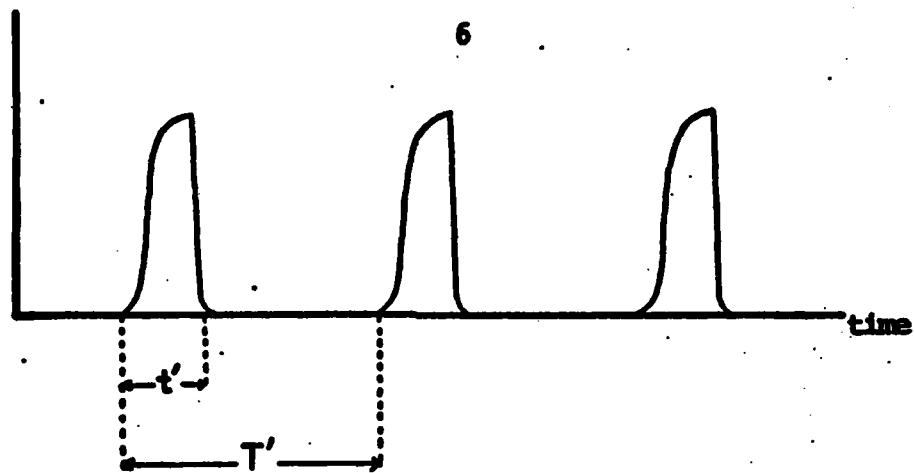


Figure 4. shape of the high-frequency waves

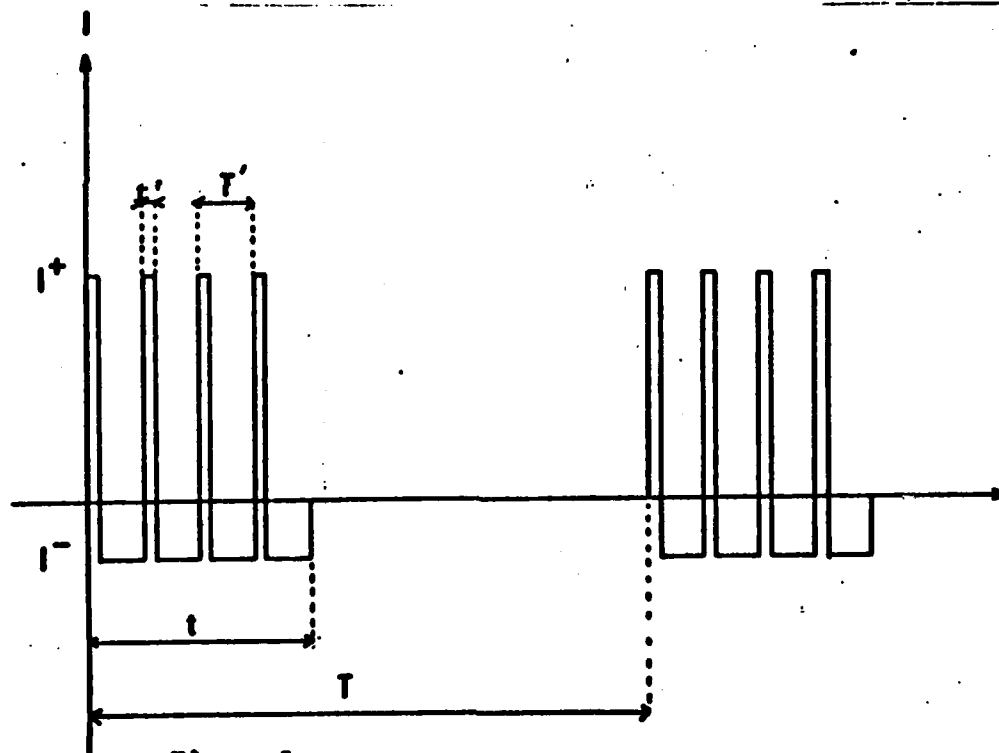


Figure 5.

- t' : high frequency on-time
- T' : high frequency pulse duration
- t : low frequency on-time
- T : low frequency period

The following calculations come to support the clinical observation. The product of pulse magnitude and pulse duration (positive) equals the product of pulse magnitude and duration (negative).

$$t' I^+ = (T' - t') I^- \quad (1)$$

$$n = \text{HF cyclic ratio} = \frac{t'}{T'}$$

$$n I^+ = (1 - n) I^- \quad (2)$$

The peak-to-peak intensity I is :

$$I = I^+ + I^- \quad (3)$$

The corresponding power delivered over a period T' to resistance R is proportional to the square of the current :

$$P^+ = n R (I^+)^2 = R n (1 - n)^2 I^2 \quad (4)$$

and

$$P^- = (1 - n) R (I^-)^2 = R (1 - n) n^2 I^2 \quad (5)$$

The *total power* delivered during one high frequency period is (4) + (5) :

$$P_T = P^+ + P^- = R n (1 - n) I^2 \quad (6)$$

The ratios of P^+/P_T and P^-/P_T are :

$$\frac{P^+}{P_T} = 1 - n \quad (7)$$

$$\frac{P^-}{P_T} = n \quad (8)$$

This illustrates that for n small (0.2), most of the power is the narrow I^+ pulse.

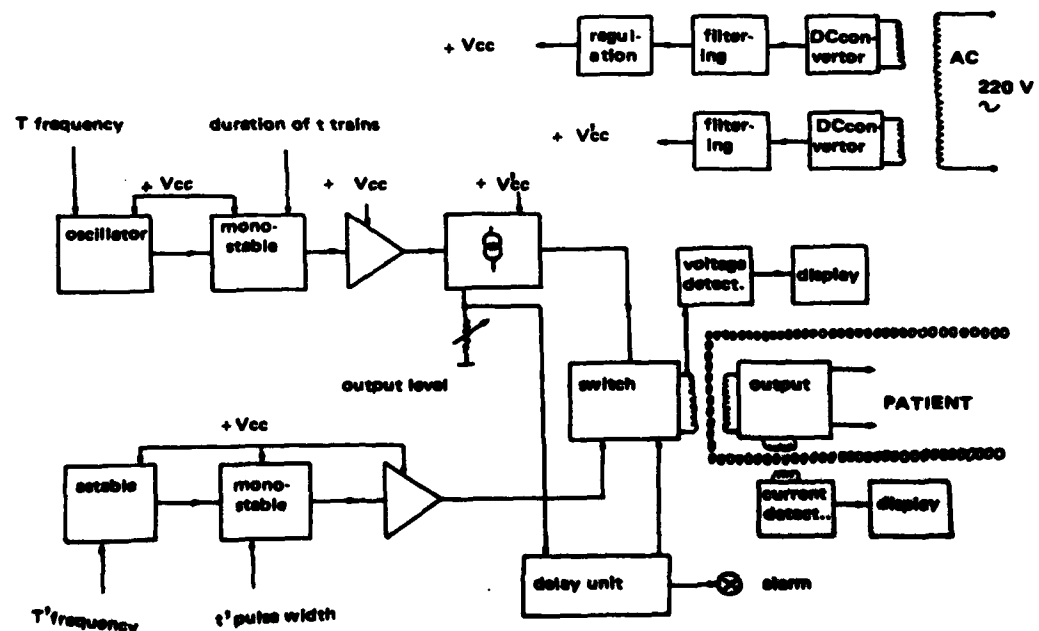
This spike of short duration seems to be necessary to obtain analgesic stimulation. Each time we tried a bi-phasic "symmetric" wave the result turned out to be unsatisfactory (fentanyl > 0.1mg/h).

B. GENERATOR FOR ELECTROANESTHESIA.

1. Operating principle.

The generator is composed of (diagram I) :

- . 1 H.F. oscillator (T' frequency) and a one-shot circuit with two possible widths of impulse ($F1'$, $F2$).
- . 1 oscillator with L.F. relaxation and one-shot circuit for sampling of the impulses. Three frequencies are possible (T_A , T_B , T_C), and three "On" widths are pre-determined (T_A , T_B , T_C).
- . 1 source of power and amplifier with potentiometer at the output.
- . 1 delay circuit in order to stop output when its level is too high.
- . 1 transformer for floating connection between generator and patient.
- . 1 peak-to-peak voltage detector with a two-digit display unit.
- . 1 peak-to-peak current detector with a three-digit display unit.



2. Display of intensity and voltage.

The peak-to-peak detector measures the amplitudes of current and tension applied to the patient and these two values can be read permanently on the frontside of the device, thus permitting to check not only the level of current but whether the contacts between skin and electrodes are correct too.

The efficacious intensities and voltages corresponding to the display (Tables II and III) have been calculated according to the following mathematical formulae :

$$\begin{aligned}
 I_{err}^2 &= \frac{1}{T} \int_0^T i^2 dt - \frac{1}{T} \int_0^t I^2 dt \\
 &= \frac{1}{T} \frac{t}{T'} \left[\int_0^{t'} I_+^2 dt + \int_{t'}^T I_-^2 dt \right] \\
 &= \frac{t}{T T'} \left[t' I_+^2 + (T' - t') I_-^2 \right] \quad (1)
 \end{aligned}$$

$$I_+ = \left[\frac{T' - t'}{T'} \right] I_{pp} \quad (2)$$

$$I_- = \frac{t'}{T'} I_{pp} \quad (3)$$

(1), (2), (3) $\rightarrow$

$$I_{err}^2 = \frac{t}{T T'} \left[t' \frac{(T' - t')^2}{T'^2} I_{pp}^2 + (T' - t') \frac{t'^2}{T'^2} I_{pp}^2 \right]$$

$$I_{err}^2 = \frac{t}{T} \frac{t'}{T'} \left[\frac{T' - t'}{T'} \right] I_{pp}^2$$

$$I_{err} = I_{pp} \sqrt{\frac{t}{T} \frac{t'}{T'} \left[1 - \frac{t'}{T'} \right]}$$

with the same means of calculation:

$$V_{err} = V_{pp} \sqrt{\frac{t}{T} \frac{t'}{T'} \left[1 - \frac{t'}{T'} \right]}$$

I p.p	I eff. (mA)			HF.
	A	B	C	
100mA	19	23	25	F ₁
	23	27	30	F ₂
150mA	29	35	38	F ₁
	34	41	45	F ₂
200mA	38	46	51	F ₁
	45	54	60	F ₂

TABLE II

V p.p	V eff (volts)			HF
	A	B	C	
10 V	1.9	2.3	2.5	F ₁
	2.3	2.7	3.0	F ₂
15 V	2.9	3.5	3.8	F ₁
	3.4	4.1	4.5	F ₂
20 V	3.8	4.6	5.1	F ₁
	4.5	5.4	6.0	F ₂
25 V	4.8	5.8	6.3	F ₁
	5.7	6.8	7.5	F ₂

TABLE III

3. Patient's safety system.

The use of electrosurgery units during electroanesthesia requires an excellent electric isolation of the Anesthelec in order to avoid any risk of return of the current or skin burns under the electrodes in the case of a fault in electrosurgery units. An isolation transformer is used to supply power from 220 V. lines, with less than 10 μ A leakage current (diagram II).

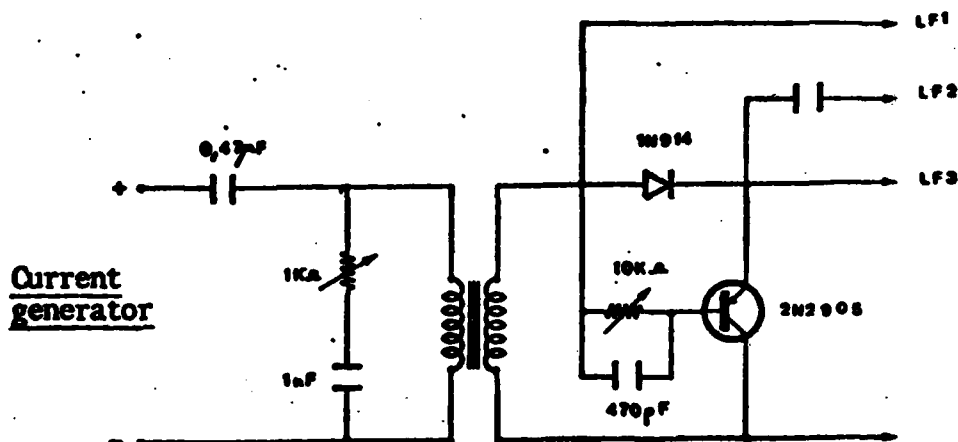


Diagram II - Output stage isolation

Four isolated outputs (LF_1 , LF_2 , LF_3 , and frontal) are available for use from the device, although only one combination (LF_1 : frontal) has been utilized. This output is biphasic, having zero average current (eliminating chemically induced irritation at the electrode sites). Isolation of the electroanesthesia leads eliminates the device as a potential pathway for electrical current in the case of a fault in an electrosurgery unit. Isolated outputs on the electrosurgery units provide additional protection.

The patient cable is an interlocking type, preventing accidental disconnection. A visual alarm indicates loss of E.C.G. lead continuity. In the event that potentially unsafe combination of control settings is chosen (i.e. turning on/off switch with the intensity control set at high level), a protection circuit prevents circuit operation and visually indicates the occurrence.

The device has been duly controlled according to international safety standards (The Hague) by the Governmental Central Laboratory for Electric Industries, and duly agreed for use on the human, under number 5-AN-76 (Journal Officiel de la République Française, Nov. 26 and Dec. 11, 1976).

4. Description of the front part.

The Anesthelec TAX 01 has been simplified in order to facilitate its use (figure 6).

C. ELECTRODES.

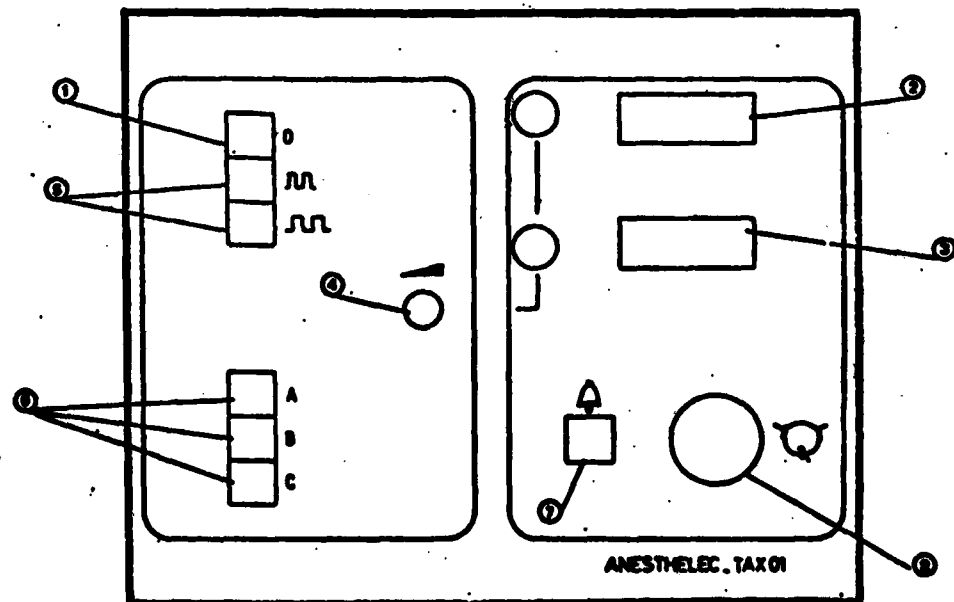
No particular study has been made as regards the site of electrodes because we thought we could work on what had been determined in previous research, i.e. the places of lesser electric resistance (hence the phrase *Point Electroanesthesia*).

There are three electrodes : the frontal one is placed between the eyebrows and the two posterior ones are placed behind the mastoid process, on each side of the occiput. The intracerebral electric field thus obtained spreads on each side of the median line, but a great part of the electric current spreads over the scalp thus provoking peripheral electrostimulation (fig. 7 and 8).

Owing to the use of biphasic current we are able to employ "Patch ECG" self sticking electrodes made of silver (active diam. 30mm)

figure 6

- a) A luminous push button (1) is used to switch on or off.
- b) Two peak-to-peak detectors measure the amplitudes of current and voltage applied to the patient. These two numbers can be read permanently on the front face of the apparatus (2) and (3). These visual checks permit to make sure that the contacts between skin and electrodes are correct, and permits constant evaluation of the level of current injected.
- c) The potentiometer (4) permits to check the quantity of current injected.
- d) Five luminous push buttons (5) and (6) permit to select six different electric combinations. The duty cycle of the H.F. pulse train is adjustable by two-position switches (5). F1 position gives 1/4 H.F. cyclic ratio and F2 gives 1/3 H.F. cyclic ratio. The modulating pulse train is adjustable in frequency and duty cycle (6). The modulating waveform is a L.F. pulse train which gates the H.F. signal (100% modulation).
- e) The generator is connected to the patient by means of three cables (8). At the end of each is a "Patch ECG" self sticking electrode made of silver (active diam. 30mm).



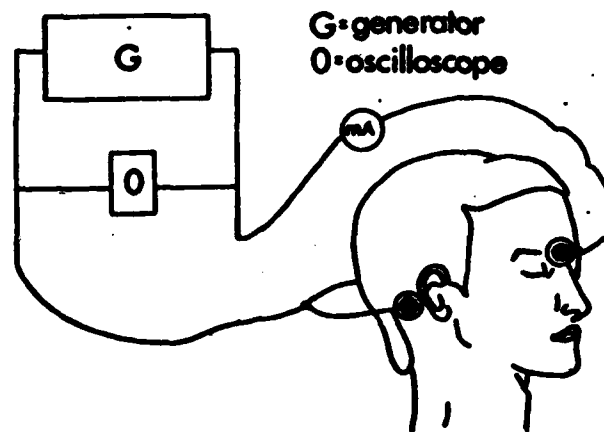


figure 7 - Location of electrodes

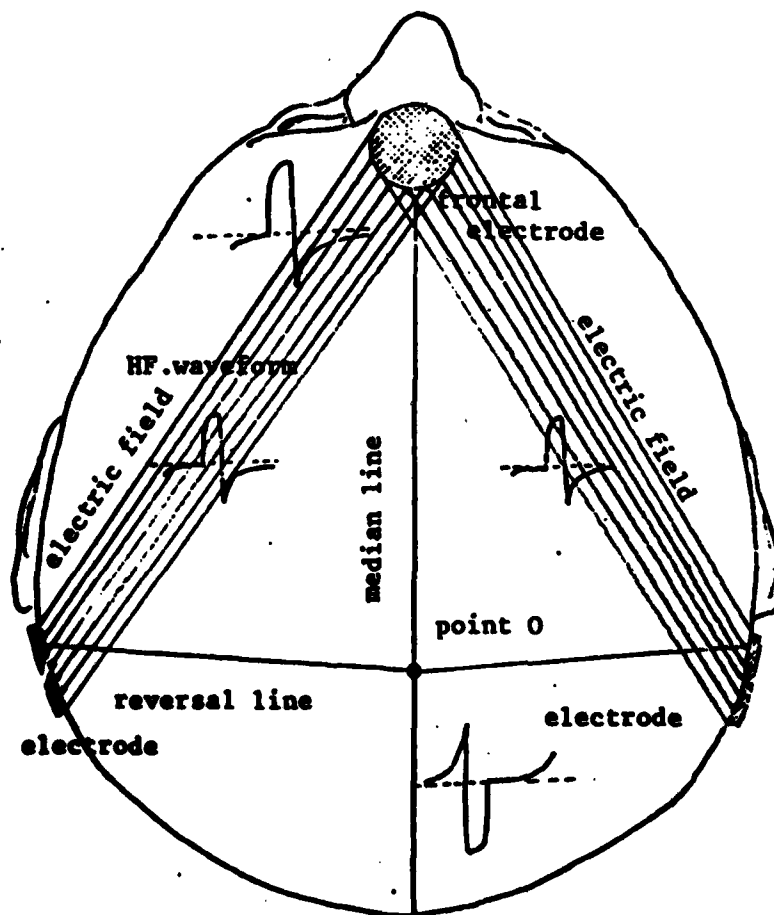


figure 8 - Shape of wave on the scalp

D. CHOICE OF INDUCTION DRUGS. (5,8,22)

The drug association used for induction is composed of a neuroleptic, a narcotic, and sometimes an analgesic, for the following reasons :

- . Security : a classic anesthetic drug must be possible at once in case of need ;
- . Each parameter must be changeable at any time (for neurovegetative protection, narcosis, analgesia) ;
- . Suppressing one drug or the other should permit to determine the real action of current.

During our clinical essays we have been able to determine which drugs promote the action of electric current in such a way that further injections are not necessary, whatever the duration of surgery : the current maintains anesthesia. Good results have been obtained only with the following combinations :

. droperidol, diazepam or flunitrazepam	}	<i>with or without fentanyl</i>
. perimetazine, diazepam or " "		
. diethazine, " " "		
. cyamepromazine, " " "		

It looks as though butyrophenone or phenothiazine derivatives were indispensable to obtain good anesthesia.

As a conclusion to all our clinical essays and all our biological and neurological tests, we have been in a position to establish a routine protocole for electroanesthesia and to demonstrate the advantages of this new technique.

E. GENERAL PROTOCOLE. (22)

A. PREMEDICATION.

45 minutes before the beginning of anesthesia, intramuscular injections of :

- . vagolytic drug (atropine, scopolamine...)
- . anxiolytic drug (benzodiazepine, butyrophenone, etc.)

B. SETTING OF ELECTRODES AND CURRENT.

a) Cleansing of skin,
preparation of electrodes with the gel,
location of electrodes and setting.

b) Application of current :

Increase of intensity up to 300 mA (30 V. voltage). It is quite possible to apply current on patients who are fully conscious since the current we use does not provoke the slightest sensation or contracture. As the maximum effect of the current occurs within 15 to 20 minutes, it is applied preferably before induction drugs.

C. DRUG INDUCTION.

a) It is still necessary to use chemical induction on man in order to obtain optimal results from electroanesthesia. The most frequently used combination in France is the following :

- . neuroleptic (droperidol 10 mg)
- . hypnotic (diazepam 15 mg, or flunitrazepam 1 mg)
- . analgesic (fentanyl 0.1 mg)

b) Other combinations are studied such as Gamma OH or steroids (alfatesine), propanidine, ethomidate, thiopental (physiological sleep doses).

D. INTUBATION.

It is performed with or without myorelaxant, but always with anesthesia of the larynx (the endotracheal probe should be covered with an anesthetic gel).

E. VENTILATION.

A 50% mixture of N_2O-O_2 . It has been reported that the electric current is potentialized by N_2O .

F. MAINTENANCE OF ANESTHESIA.

50% mixture of N_2O-O_2 plus electric current (the parameters are changed every twenty minute in order to avoid habituation. No further injection of induction drugs should be made, apart from myorelaxants. Still, if analgesia turns out to be insufficient in spite of - the modification of the LF cyclic ratio (from A to B),

- the increase of intensity,
- the modification of the HF cyclic ratio (from F_1 to F_2),

0.1 mg of fentanyl (analgesic) is reinjected.

In case the patient recovers consciousness without any sign of pain, 5 mg of diazepam (hypnotic) are injected.

In case the patient does not receive any more current, whatever the reason may be, the analgesic effect will decrease within a few minutes and surgery will not be possible any longer, but it will be easy to carry it on with a classical technique.

G. CLINICAL MONITORING.

It is the same as for any general anesthesia, i.e. :
 . clinical signs of waking up (eye or hand movements...),

- . clinical signs of pain (grin, eyebrow movements, cutaneous vaso-constriction, increase in arterial pressure or pulse, sweating, tear, etc.),
- . control of consciousness (reaction to speech, noise..),
- . abnormal manifestations (hic-ups, swallowing, cough..),
- . duration of possible apnea, and spontaneous ventilation spirometry during and at the end of anesthesia if no curarization was made,
- . checking of : central and peripheral temperatures,
 pulse rate,
 arterial and central venous pressure,
- . permanent ECG monitoring.

RESULTS

Of course, we would not go as far as saying that we have been doing miracles, but still, over 10 000 operations have been performed with our method in France, and not a single accident has ever been reported, although this method was applied for various types of surgery (urological, abdominal, general, thoracic, cardiac, orthopedic, traumatologic, ophtalmologic, or gynecologic), and often on patients presenting a pathological background such as renal insufficiency, cardio-vascular syndromes (myocardial infarction, total right branch block, arterial hypertension), lower limb arteritis, moderate chronic respiratory insufficiency, asthma, diabetes, alcoholism, epilepsy... Some of them even suffered from several associated syndromes.

A. PER-OPERATIVE PHASE. (17, 20, 22)

++ All patients have been operated on as scheduled, in satisfactory conditions, without any secondary effect such as muscle contractures of trunk, limbs or face, or abnormal bleeding.

++ The use of electrocoagulation did not provoke any change in wave trains or any waking up of the patient (fig. 9). But the use of electrosurgery unit in a prolonged way instead of by short successive phases tended to provoke interferences as well as a decrease of intensity, interfering with the stability of anesthesia.

∴ Central temperature would progressively decrease during electroanesthesia when no heating device was used. It could go down as low as 34° C if the duration of surgery exceeded 8 hours. Generally speaking, the temperature could decrease by 1 to 2° C as compared with the initial temperature for a 3 h. anesthesia.

∴ Operative spirometry on non curarized patients was normal, with an average flow of 7 liters/min and a frequency of 15/min (total flow 500 ml).

∴ Cardio-vascular action :

. Arterial pressure fell slightly after induction drugs (10 to 30 mmg Hg). But after the use of current and during electroanesthesia, an increase of arterial pressure (systolitic and diastolitic) of 28 mmg Hg (average) was observed on 60% patients. In the other cases, no change of arterial pressure was reported. It remained remarkably stable.

. Venous pressure underwent no noticeable change.

∴ Heart rate : an increase of pulse rate (12 beats/min, av.) was observed on 40% patients during E.A., but there was no arhythmia.

∴ Abnormal movements : some were very typical of E.A., such as swallowing movements, chewing of the probe, slight limb movements, but there was no sign of pain, i.e. no modification of blood pressure, no tears, etc. Pupil myosis was noted.

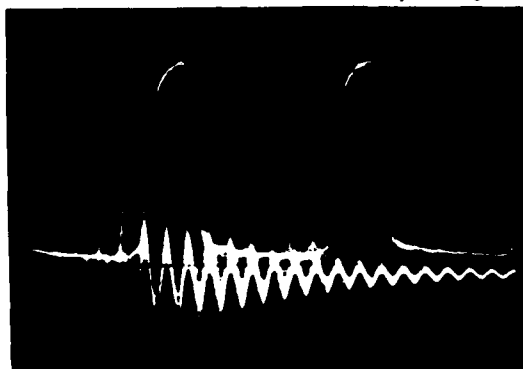


figure 9 - the electrocoagulation wave

++ The analgesic effect of current was studied by comparing the quantities of analgesic drugs used on 30 patients receiving electric current or not (group I, EA, group II, CA). Both groups had the same induction drugs and were submitted to the same type of surgery with the same anesthesiologist (table IV).

Population studied	Type of surgery	Induction
GROUP I EA n = 15 M = 10 F = 5 av. age 51 av. weight 69 kg	prostatic adenoma 5 pyelolithotomy 4 anti-reflux uretero- vesical implantation 2 partial cystectomy 1 coraliform calculus 1 silicone ureteroplasty 1 nephro-ureterectomy 1	drop. 20 mg diaz. 20 mg phenop. 2 mg
GROUP II CA n = 15 M = 9 F = 6 av. age 53 av. weight 70.5 kg	prostatic adenoma 6 pyelolithotomy 3 anti-reflux uretero- vesical implantation 4 nephro-ureterectomy 1 epididymo-deferential anastomosis 1	drop. 20 mg diaz. 20 mg phenop. 2 mg

TABLE IV - GROUPS STUDIED

Studying the quantities of drugs injected during the course of surgery in the two groups (table V) shows that :

Group I received no further injection of droperidol or diazepam and that further injections of phenoperidine were very light ($3.62 \cdot 10^{-5}$ mg/kg/mn) ;

whereas :

Group II required further injections of droperidol ($2.17 \cdot 10^{-3}$ mg/kg/mn), of diazepam ($2.36 \cdot 10^{-4}$ mg/kg/mn), and particularly of phenoperidine ($30.73 \cdot 10^{-5}$ mg/kg/mn).

The statistical comparison of phenoperidine doses injected after induction is very significant ($p < 0.001$). Which tends to ascertain the analgesic effect of electric current.

	GROUP I (EA)	GROUP II (CA)	
Droperidol 10^{-3} mg/kg/mn	0	2.17	
Diazepam 10^{-4} mg/kg/mn	0	2.36	
Phenoperidine 10^{-5} mg/kg/mn	3.62	30.73	$p < 0.001$
Pancuronium 10^{-4} mg/kg/mn	4.83	4.16	N.S.

TABLE V - Quantities of drugs injected during surgery

B. POST-OPERATIVE PHASE.

. Recovery of consciousness : As soon as the current was stopped, ventilation came spontaneously back to normal in a satisfactory manner, thus allowing extubation. Within five minutes the patients could understand and execute orders (such as "give me your hand" or "pull out your tongue") and they recovered consciousness very quickly, but they remained in a state of indifference for a period of 6 to 12 hours after their return to bed, with periods of sleep if not stimulated. Most of them had a good night's sleep without any hypnotic drug, which is rather exceptional.

. Post-operative antalgia : Complaints of patients after EA were less frequent in our recovery room as compared with patients submitted to narconeuroleptanalgesia. Two groups of 100 patients each have been compared :

. Identical drug induction in both groups : droperidol (20 mg), diazepam (20 mg), phenoperidine (2 mg).

. Maintenance in group I (CA) with medicamentous injections, and with electric current in group II (EA).

. The study was made during the first sixteen hours after surgery (Table VI).

. The patient was to receive 15 mg of pentazocin in case of complaint.

. Group I (CA) received an average of 29.7 mg of pentazocin per head, whereas group II (EA) received 8.1 mg per head (average), i.e. 3.6 times less. The analysis of detailed results in Table VI shows that in group I (CA) only 20% patients did not require any analgesic injection whereas they were 65% in group II (EA).

. The difference between the two groups is statistically significant ($p < 0.001$).

. *This remaining and prolonged antalgia is perhaps the most important advantage of the method.*

PENTAZOCIN injections	GROUP I (CA) n = 100	GROUP II (EA) n = 100
none	20	65
One (15 mg)	14	20
Two (30 mg)	28	11
Three (45 mg)	24	4
Four (60 mg)	14	0
Average per head (mg)	29.7 ±19.88	8.1 ±12.69

TABLE VI - Comparison of two groups receiving pentazocin during the first 16 hours after surgery

Post-operative sepsis. Two comparative groups composed of patients submitted to urological surgery have been studied.

In group I (one hundred patients under narconeurolept-analgesia) two endotoxic shocks (2%) and 27 skin abscesses (27%) were reported in the 48 hours following surgery, whereas in group II (one hundred and eighty patients under electroanesthesia) only seven skin abscesses (3.8%) were reported during the same 48 hours after surgery. Local infection seems to be less frequent after EA. In order to explain this difference (statistically significant : $p < 0.001$) one should study chemiotaxis and phagocytosis by polynuclear cells after EA.

. Central temperature. As mentioned above, the central temperature was generally low during the per-operative phase at the end of surgery. It came back to normal within an hour while the patient was shivering intensely. In 77% cases it continued to rise until 39°C, and the average peak temperature was 1.5° above 37 (38.5°C), whereas in a comparative lot of a hundred patients submitted to narconeuroleptanalgesia it was 0.8° (37.8°C). This lead us to conclude that the intensity of shivers provokes a more intense thermic rise, which is usually inhibited by drugs in other types of anesthesia. The use of a heating mattress should be systematic during electroanesthesia in order to avoid cooling of the patient, causing the shivers and thus causing an exaggerated consumption of oxygen and glucose during the post-operative period.

. Intestinal transit. It came back to normal fairly quickly, and diuresis turned out to be more satisfactory than with CA. Hourly diuresis was measured during the first sixteen post-operative hours on sixty patients presenting no renal insufficiency and not submitted to induced polyuria for bleeding of the urinary tract. The average total quantity of urine flow was 2063 ml (129 ml/h) for average perfused quantities of 3100 ml (194ml/h).

. The post-operative EEG was always normal and comparable to the pre-operative one. No abnormal sign appeared. When an EEG was made shortly after surgery, one could sometimes note an alternate rhythm of wake and sleep.

CONCLUSION

Anesthesiology tries to establish a fair balance between the different drugs used in order to provide the patient with sufficient anesthesia and less intoxication. Still, the duration of surgery is more and more important (micro-surgery, cardiac surgery, peripheral neuro-surgery, etc.) and requires more and more important doses of drugs. The balance between physical and chemical methods, permitting a decrease in the use of drugs and an equally good quality of anesthesia and protection of the patient is therefore a rather attractive prospect.

THE ADVANTAGES of electropharmaceutical anesthesia were found progressively^(9,10,11,12,13,14,15,16) :

- . The method is safe, as demonstrated by the absence of incident, not in the research performed by our teams, but by other teams too.

- . It is quite easy to carry on an operation with neuroleptanalgesia in case of failure of current or generator.

- . There is no per-operative respiratory depression in the absence of myorelaxant. This permits to keep adequate spontaneous ventilation throughout surgery and to avoid any respiratory depression upon recovery of consciousness (Study conducted by Professor Torri, Milano, 1979).

- . The quick recovery of consciousness gives the full cooperation of the patient for moving, coughing, etc. This is the best way to avoid thrombo-embolism.

- . Post operative antalgia is such a comfort to the patient that those who have been submitted to electroanesthesia in the past will not want any other anesthetic method. This happened on orthopedic patients operated on both legs, one after the other, and in a case of second cesarectomy.

. The decrease of post-operative infections is significant and seems to us to be the most important advantage.

. The technique being easy to apply on all patients, even on weak ones, makes it become more and more popular (382 operations under electroanesthesia in 1975, over 10 000 cases in 1979).

. The fact that weaker doses of drugs are required makes it especially recommended on patients suffering from renal, hepatic or respiratory insufficiency, and on old people.

. Last but not least, this method is money saving. According to the French School, it allows to save 46% neuroleptics, 70% narcotics and 84% morphinomimetics.

THE DISADVANTAGES consist in :

- a) A slight hypertension which must be taken into account. If ever it becomes dangerous on certain patients it is necessary to go back to conventional narconeuroleptanalgesia ;
- b) It is difficult to use this technique in neurosurgery because of the location of the electrodes.

To sum it up, one can say that electroanesthesia is now part of the various possibilities at the disposal of anesthesiologists. It is especially recommended in major surgery of long duration (over three hours), and with patients suffering from renal, hepatic or respiratory insufficiency, or in a state of shock, or myasthenia, or suffering from septicemia or acute infection. It is not to be recommended for short duration surgery or on patients suffering from serious arterial hypertension with decrease of vascular elasticity.

The method is still to be perfected because the mode of action of the current is not yet totally elucidated. We hope to grasp the full understanding of its mechanism by studying biological and neurological tests and by performing more double-blind studies.

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DOUBLE-BLIND STUDIES

In spite of all the theoretical advantages of electroanesthesia, the technique is liable to be criticized and it is not easily adopted because it is not yet "pure" electroanesthesia.

This method requires the utilization of a number of supplements, especially induction, which is performed with butyrophenone (droperidol) and benzodiazepine (diazepam) compounds, or maintenance of anesthesia which is made with a 50% mixture of nitrous oxide-oxygen.

Accordingly, the use of supplements along with electrical currents clouds the issue, and the anesthesiologists rightly want to know if really the current is necessary and what part electricity is playing in this technique.

From a scientific standpoint, all prior evaluation of electroanesthesia, as used on the human, could be considered as anecdotal and as a metaphysical curiosity based on the subjective interpretation of results by surgeon- and anesthesiologist-searchers.

In order to avoid these criticisms and in order to evaluate the real action of current, it has been decided together with the military site-visit team to initiate double-blind studies.

• • •

I - GENERAL PRINCIPLES.

All patients involved in the studies had given their informed consent for electrical anesthesia (EA), being fully aware of all possible problems and knowing that they might or might not receive EA. All regulations and procedural guidance as required for the use of humans in research were strictly followed.

Neither the patient, nor the anesthesiologist or the surgeon knew, at any time, whether or not the intervention was conducted under classical or electric anesthesia. For this reason the generator used in the double-blind studies were equipped with an additional switch positioned internally, permitting delivery or not of the current. All dials and indicators (internal circuit) provided voltage and current information in the same

manner for procedures under classical or electric anesthesia. The switch was in a key-position prior to each intervention according to the code of random drawing for each participant so that no one knew whether or not current was delivered to the patient.

II - ANESTHETIC PROTOCOLE.

1. FIXED ELEMENTS

- . One hour prior to induction, each patient received :
 - . atropine 0.5 mg
 - . diazepam 10 mg
- . At induction, each patient received :
 - . droperidol 10 mg
 - . diazepam 15 mg
 - . pancuronium 0.08 mg/kg
- . Intubation was accomplished with the maximum allowed dosage of 5 ml xylocaine spray.
- . Artificial ventilation was maintained with air and oxygene only.

The generator was connected to the patient by means of three cables, each one ended with a self-sticking electrode (30mm diameter), one being placed between the eyebrows and the other two behind the mastoid process.

The electric current output was 150 mA peak-to-peak and the total duration of each high-frequency (HF) wave train was 6 μ S (a positive 1.2 μ S impulse was followed by a negative 4.8 μ S impulse).

2. VARIABLE ELEMENTS

The digital dial always indicated the same current in every surgical intervention. However, in the case of EA the patient received current whereas during classical anesthesia (CA) the patient received nothing through the electrodes.

During surgery (whether under EA or under CA) if there was any sign of possible pain (tears, increase of blood pressure, movements, etc.), the anesthesiologist was meant to :

- . First change the low-frequency (LF) cyclic ratio, i.e. change A (3/13 ms) for B (4/12 ms), or change B for C (3/10ms).
- . Then, if the above mentioned procedure could not counteract the problem within two to four minutes, he was to inject 0.1 mg of fentanyl.

If, on the other hand, the patient happened to become conscious (responding to orders such as opening or closing his eyes, etc.) without any evidence of suffering, he was injected another 5 mg of diazepam. Should the surgeon have asked for considerable muscular relaxation, a maximum of 0.00125 mg/kg would have been injected.

3. CLINICAL COURSE

Were constantly observed throughout the course of surgery : pulse, arterial and venous pressure, eye and skin signs, etc. In addition to visual control, all the usual electronic devices continually monitored heart beat as well as central and peripheral temperatures.

III - FIRST STUDY.

No N₂O was used in this study.

1. Population studied (Tables VII and VIII).

The study involved fifty patients submitted to the same surgical procedure : suprapubic or retropubic prostatectomy.

Twenty four patients were operated under EA (group A) : average age 67.71 ± 6.50 ; average weight $74.63 \text{ kg} \pm 12.60 \text{ kg}$; average procedure time $151.88 \text{ mn} \pm 44.06 \text{ mn}$.

Twenty six patients were operated under CA (group B) : average age 70.08 ± 8.99 ; average weight $70.62 \pm 12.36 \text{ kg}$; average procedure time $166.31 \text{ mn} \pm 46.43 \text{ mn}$.

Examination of table IX shows that the two groups A and B are statistically matched from the standpoint of age, weight, current duration and pain duration, from incision to skin closure ($p > 0.05$ **).

	GROUP A EA n=24	GROUP B CA n=26	p for D = 48
AGE	67.71 ± 6.50	70.08 ± 8.99	> 0.05
WEIGHT (kg)	74.63 ± 12.60	70.62 ± 12.36	> 0.05
CURRENT DURATION (mn)	151.88 ± 44.06	166.31 ± 46.43	> 0.05
PAIN DURATION	118.75 ± 32.55	127.50 ± 37.58	> 0.05

TABLE IX - STATISTICAL COMPARISON OF THE 2 GROUPS

* The significance of the difference between average data of both groups of patients was analyzed using a pooled variance modification of Student's t test and it was expressed as "p".

CASES N-24	AGE	WEIGHT (kg)	FENTANYL tot. dose (mg)	(a)		(b)		DIAZEPAM	
				CURRENT DURAT.	FENTA- NYL (1)	PAIN (2) DURAT.	FENTA- NYL (1)	TOTAL (3)	R (4)
3	65	69	0.40	140min.	4.14	110min.	5.27	2.07	5mg
5	60	79	0.70	170	5.21	120	7.38	1.49	5
7	63	75	0.75	185	5.40	130	7.18	1.08	0
9	72	76	0.80	175	6.01	135	7.80	1.13	0
10	79	68	0.50	115	6.39	85	8.65	2.56	5
13	76	60	0.40	160	4.16	110	6.06	1.56	0
16	63	74	0.70	110	8.60	90	10.51	1.84	0
17	67	92	1.05	250	4.56	170	6.71	0.65	0
21	68	63	0.70	120	9.25	100	11.11	3.63	12.5
22	64	73	0.60	130	6.32	120	6.85	1.58	0
24	70	92	0.60	215	3.03	170	3.84	1.26	5
26	72	63	0.50	140	5.49	105	7.56	1.64	0
28	75	52	1.10	255	8.29	210	10.07	1.51	5
31	57	74	0.50	105	6.43	75	9.01	1.93	0
32	74	115	1	185	4.70	150	5.80	1.17	0
34	68	74	0.90	155	7.85	140	8.69	1.31	0
37	63	73	0.60	120	6.84	110	7.47	2.28	0
38	56	72	0.60	140	5.94	105	7.93	1.49	0
39	60	74	0.80	110	9.83	90	12.01	3.07	0
40	79	68	0.75	190	5.81	145	7.61	1.74	7.5
42	68	72	0.40	110	5.05	90	6.17	1.89	0
46	70	73	0.30	100	4.11	85	4.83	2.05	0
48	73	90	1	150	7.40	110	10.10	1.85	10
50	63	70	0.40	115	4.96	95	6.01	1.86	0
AVERAGE		67.71	74.63	0.67	151.88	6.07	118.75	7.69	2.29
STAND. deviat.		6.50	12.60	0.23	44.06	1.74	32.55	2.04	3.68

(1) - Dose = 10^{-5} mg/kg/min.

(2) - From the time of incision to closure of the skin.

(3) - Dose = 10^{-3} mg/kg/min.

(4) - Re-injections

TABLE VII - WITH ELECTRIC CURRENT (E.A.)

CASES N-26	AGE	WEIGHT (kg)	FENTANYL tot. dose (mg)	(a)		(b)		DIAZEPAM	
				CURRENT DURAT.	FENTANYL (1)	PAIN (2) DURAT.	FENTANYL (1)	TOTAL (3)	R (4)
1	63	65	0.50	110min	6.99	75min.	10.26	2.10	0mg
2	60	68	0.85	200	6.25	155	8.06	2.57	20
4	75	70	1.10	220	7.14	165	9.32	1.30	5
6	73	53	1.45	180	15.20	155	17.65	1.57	0
8	65	70	1	130	10.99	100	14.29	1.65	0
11	74	60	0.40	170	3.92	110	6.06	1.47	0
12	50	108	1.50	280	4.96	140	9.92	0.61	10
14	78	85	0.40	100	4.71	75	6.27	1.76	0
15	78	70	0.60	135	6.34	95	9.02	2.11	5
18	54	86	1	110	10.57	75	15.5	1.58	0
19	70	67	0.80	155	7.70	150	7.96	1.44	0
20	71	60	1	170	9.80	140	11.90	1.71	2.5
23	81	60	0.95	180	8.79	150	10.56	1.85	0
25	77	70	0.80	200	5.71	150	7.62	1.78	10
27	56	84	0.75	102	8.75	75	11.90	1.75	0
29	74	72	1.05	220	6.63	210	6.94	0.95	0
30	74	63	1.10	180	9.70	145	12.04	1.76	5
33	88	68	0.45	95	6.97	85	7.78	3.10	0
35	82	82	0.40	155	5.50	120	7.11	1.18	5
36	68	56	0.70	160	7.81	100	12.50	5.58	20
41	62	63	0.80	170	7.48	140	9.07	2.34	10
43	69	64	1.55	245	9.88	210	11.53	1.27	5
44	70	83	1	130	9.27	105	11.47	1.85	0
45	75	70	0.90	142	9.05	120	10.71	1.50	0
47	72	64	0.80	205	6.09	130	9.61	1.52	10
49	63	63	1	180	8.81	140	11.34	1.32	0
AVER.	70.08	70.62	0.88	166.31	7.89	127.50	10.25	1.83	4.13
Stand dev.	8.99	12.36	0.32	46.43	2.40	37.58	2.82	0.91	5.96

TABLE VIII - WITHOUT ELECTRIC CURRENT (C.A.)

2. Results.

A. COMPARATIVE STUDY OF THE QUANTITY OF FENTANYL USED IN EACH GROUP.

((A)) - From start to finish of EC (current duration) :

The comparison of the average doses of fentanyl injected in Group A (6.07 ± 1.74) and in Group B (7.89 ± 2.40) shows a significant difference ($p < 0.005$), thus proving that electric current increases the effect of analgesia. This effect of electric current permits to save 23.07% fentanyl as compared with the reference dose of Group B (CA) (Table X ((A))).

((B)) - From incision to skin closure :

During this double-blind study, the amount of droperidol as well as that of diazepam were "fixed elements" regardless of the weight of the patient. However, in 18 cases (7 EA and 11 CA), the induction drugs were insufficient to obtain the stage of surgical anesthesia and fentanyl injections were necessary prior to incision because these patients were moving even during the preparation of the skin and the intubation, in spite of pancuronium injections (0.08 mg/kg).

Therefore, it seemed worth comparing the doses of analgesics serving as reference criterion in the study in order to evaluate the influence of electric current from the time of incision to that of closure of the skin, i.e. during the period of surgical pain.

The comparison of the doses of fentanyl injected in Group A during this period ((B)) (7.69 ± 2.04) and in Group B (10.25 ± 2.82) shows an even more significant difference than during period ((A)) ($p = 0.003$). Here again, analgesia is increased by electric current, permitting to save 24.98% fentanyl as compared with the reference dose in Group B (CA) (Table x ((B))).

GROUP A EA n=24	GROUP B CA n=26	t	p	EA/CA
((A)) 6.07±1.74	7.89±2.40	3.08	< 0.005	76.93%
((B)) 7.69±2.04	10.25±2.82	3.71	≈ 0.003	75.02%

TABLE X - average doses of fentanyl and comparison of the two groups

B. ABNORMAL SIGNS.

In spite of the difficulty of this study, all operatory procedures were conducted satisfactorily. No deterioration effects were ever reported, but abnormal signs sometimes occurred (Table XI).

	EA	CA
Tears	6 cases (25%)	10 cases (38%)
Increase of arterial pressure	7 cases (29%)	18 cases (69%)
Inc. of peripheral pulse	3 cases (12%)	8 cases (31%)
Inc. of cardiac frequency	6 cases (25%)	17 cases (65%)
Abnormal impulses	16 cases (67%)	21 cases (81%)

TABLE XI

Except in case n° 6 of Group B (CA) where the patient had received a heavy dose of fentanyl (15.20×10^{-5} mg/kg/mn), the awakening was quite rapid in both groups, but some were slow in answering simple commands : One (4%) in Group A (EA) and three (11%) in Group B (CA). And some of them were not completely coherent in expressing themselves : four (16%) in Group A and sixteen (61%) in Group B.

3. Discussion.

a) Anesthetic protocole.

The anesthetic protocole imposed by the site-visit team included a certain number of parameters invariable, especially the very precise quantities of drugs for induction and maintenance of anesthesia. From the scientific viewpoint, this is excellent in order to evaluate one single parameter, but it caused numerous difficulties to the anesthesiologist. For indeed since the anesthesiologist never knew whether or not there was electric current, he had to change the LF cyclic ratio when it appeared that the patient might be suffering, and he had to wait for a minimum of one minute (maximum 3 mn) before injecting 0.1 mg fentanyl. One must realize that when current was not actually employed the patient had to remain one to three minutes without any medication when fentanyl was necessary. Consequently, this most possibly explains the fact that the analysis of the patients' anesthetia sheets showed more abnormal signs with patients of Group B (CA) (Table XI). Furthermore, it is an evidence of the efficaciousness of the current.

An alteration to the above-mentioned protocole was deemed absolutely necessary : if a patient appeared to be conscious without any sign of pain we decided to allow a 5mg dose of diazepam in order to prevent any recollection of the operation. (The site visit team had of course allowed variations in the protocole in case of absolute necessity). So, 8 patients in the EA group (24 patients) required additional diazepam, and 12 did in the CA group composed of 26 patients (tables VII and VIII).

Owing to these reinjections, the question was : were the two groups still comparable as regard the initial dose of diazepam (according to the patient's weight and duration of surgery), as well as to the doses injected during surgery. And the statistical comparison of both groups concerning injections and reinjections of diazepam turned out to be not significant ($p > 0.05$) (table XII).

	GROUP A EA n=24	GROUP B CA n=26	t	P for D = 48
INJECT. 10^{-3} mg/kg/mn	1.78 ± 0.64	1.83 ± 0.91	0.28	> 0.05
REINJECT. mg	2.29 ± 3.68	4.13 ± 5.96	1.30	> 0.05

TABLE XII - Diazepam injections and further injections, comparison of the two groups

Diazepam reinjections can be considered as a "fixed element" which does not modify the imposed anesthetic protocole. The decrease of fentanyl injections remains therefore an excellent criterion permitting to evaluate the analgesic efficaciousness of both current and nitrous oxide.

b) The anesthesiologists.

The analysis of average fentanyl doses used by our two anesthesiologists (Table XIII) showed that one of them tended to give more fentanyl in both groups of patients : In group A (EA), R. Coeytaux gives $0.81 (10^{-5})$ mg/kg/mn more than A. Atinault, and he gives $1.05 (10^{-5})$ mg/kg/mn more in group B (CA). If there

is a significant difference between the two anesthesiologists' behaviour, our study should be considered as wrong because the results could not be statistically compared. Still, the difference of doses used by each of them is not significant ($p > 0.05$), (Table XIV).

FENTANYL 10^{-5} mg/kg/min.							
E.A. GROUP A				C.A. GROUP B			
CASES	A.A.*	CASES	R.C.**	CASES	A.A.	CASES	R.C.
7	5.40	3	4.14	2	6.25	1	6.99
9	6.01	5	5.21	8	10.99	4	7.14
13	4.16	10	6.39	11	3.92	6	15.20
16	8.60	21	9.25	12	4.96	18	10.57
17	4.56	31	6.43	14	4.71	19	7.70
24	3.03	32	4.70	15	6.34	20	9.80
26	5.49	34	7.85	27	8.75	23	8.79
28	8.29	37	6.84	29	6.63	25	5.71
46	4.11	38	5.94	43	9.88	30	9.70
48	7.40	39	9.83	44	9.27	33	6.97
50	4.96	40	5.81	45	9.05	35	5.50
		42	5.05	47	6.09	36	7.81
				49	8.81	41	7.48
11***	5.64	12	6.45	13	7.36	13	8.41
	± 1.79		± 1.76		± 2.22		± 2.54

* A.A. = Dr. Alain ATINAULT, M.D.

R.C. = Dr. Raymond COEYTAUX, M.D.

*** The sum of patients equals 49 because one case (n°22) was conducted by another anesthesiologist due to illness.

TABLE XIII - Injections of fentanyl in each group by the two anesthesiologists

	GROUP A EA n=24	GROUP B CA n=26	t'	p'	%EA/CA
A.A.	5.64 ± 1.79 n = 11	7.36 ± 2.22 n = 13	2.02	≈ 0.05 D = 22	77%
R.C.	6.45 ± 1.76 n = 12	8.41 ± 2.54 n = 13	2.22	< 0.05 D = 23	77%
t	1.09	1.12			
p	> 0.05 D = 21	> 0.05 D = 24			

TABLE XIV - Average doses of fentanyl (10^{-5} mg/kg/min) used in both groups according to the anesthesiologist

Yet, the results obtained in both groups A and B by each anesthesiologist show a significant difference between EA and CA ($p' \approx 0.05$ for A. Atinault and $p' < 0.05$ for R. Coeytaux), and an identical decrease of fentanyl (23%) when current is used.

CONCLUSION CONCERNING THIS FIRST DOUBLE-BLIND STUDY : The results are considered to be most encouraging. Of course, we still have to decrease the quantities of diazepam and of fentanyl, but a first step has been made and it is now possible to make an objective evaluation of electrical analgesia by never using any N_2O and by comparing the quantities of fentanyl injected in the EA group and in the CA group.

IV - SECOND STUDY. (N₂O and/or electric current).

In order to obtain more significant results we divided the patients into four different groups :

- GROUP I - No electric current and no N₂O (O.O.)
- GROUP II - Use of electric current but no N₂O (E.O.)
- GROUP III - No electric current but use of N₂O (O.N.)
- GROUP IV - Use of electric current and of N₂O (E.N.)

1. Population studied

The study involved 37 patients submitted to the same surgical procedure : lithiasis.

GROUP I (O.O.) : Nine patients - average age 38.89 ± 9.53 ;
average weight 64.44 ± 11.33 kg ; average
procedure time 217.78 ± 105.57 minutes.

GROUP II (E.O.) Six patients - average age 41 ± 11.98 ;
average weight 67.17 ± 12.17 kg ; average
procedure time 218.33 ± 89.14 minutes.

GROUP III (O.N.) Ten patients - average age 36.6 ± 13.53 ;
average weight 57.20 ± 6.86 kg ; average
procedure time 213.5 ± 71.69 minutes.

GROUP IV (E.N.) Eight patients - average age 42.5 ± 8.78 ;
average weight 66.13 ± 12.92 kg ; average
procedure time 196.87 ± 52.64 minutes.

Four patients could not be included in the study owing to an inadequate protocole used by the anesthesiologist.

Table XV shows that the four groups of patients are statistically matched from the standpoint of age, weight, procedure time.

	GROUP I O.O. n = 9	GROUP II E.O. n = 6	GROUP III O.N. n=10	GROUP IV E.N. n = 8
AGE	38.89 $\pm$ 9.53	41 $\pm$ 11.98	36.6 $\pm$ 13.53	42.5 $\pm$ 8.78
WEIGHT(kg)	64.44 $\pm$ 11.33	67.17 $\pm$ 12.17	57.20 $\pm$ 6.86	66.13 $\pm$ 12.92
Durat. (mn.)	217.78 $\pm$ 105.57	218.33 $\pm$ 89.14	213.5 $\pm$ 71.69	196.87 $\pm$ 52.64

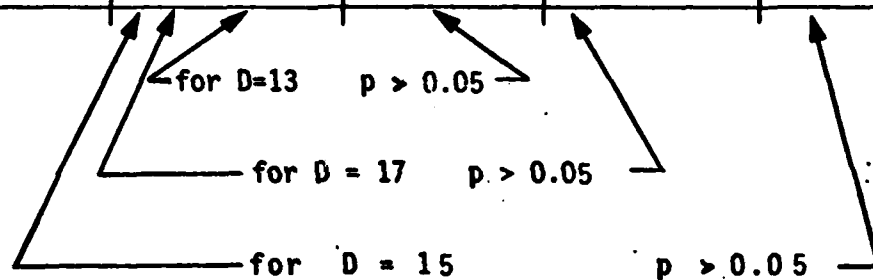


TABLE XV - STATISTICAL COMPARISON OF THE FOUR GROUPS

Groups II, III and IV are not significantly different from group I, therefore, the four groups can be considered as comparable and results are worth studying.

*A.A. = Alain ATINAULT ; **JB.C. = Jean-Bernard CAZALAA ; ***R.C. = Raymond COEYTAUX -

Cases n=9	Age	Height kg	Duration mn	PANCUR. (10 ⁻⁴)		DROPER. (10 ⁻⁴)		DIAB. (10 ⁻³)		FENT. (10 ⁻⁵)	
				mg	mg/kg/mm	mg	mg/kg/mm	mg	mg/kg/mm	mg	mg/kg/mm
1	50	70	165	8.4	7.27	14	12.12	22.5	1.94	0.635	5.49
5	25	53	450	12.6	5.28	10	4.19	77	3.22	1.25	5.24
11bis	44	44	200	5.6	6.36	10	11.36	47	5.34	0.475	5.39
38	30	76	315	11.8	4.92	20	8.35	65	2.71	1.4	5.84
39	50	63	135	6.2	7.28	12.5	14.69	15	1.76	0.3	3.52
44	46	72	240	8.6	4.97	15	8.68	22.5	1.30	0.525	3.03
75	34	74	130	8.4	8.73	15	15.59	23.5	2.44	0.225	2.33
78	42	73	190	10.8	7.78	14	10.09	40	2.88	0.79	5.69
83	29	55	135	7.1	9.56	11	14.81	30	4.04	0.355	4.78
Aver.	38.89	64.44	217.78	8.83	6.91	13.5	11.10	38.05	2.85	0.66	4.59
St.dev.	± 9.53	11.33	105.57		1.66		3.71		1.24		1.29

TABLE XVI - Group I (O.O.), no electric current and no H₂O

Cases n=6	Age	Weight kg	Duration mn	Pancur. (10 ⁻⁴) mg mg/kg/mm	Droper. (10 ⁻⁴) mg mg/kg/mm	Diaz. (10 ⁻³) mg mg/kg/mm	Fent. (10 ⁻⁵) mg mg/kg/mm				
6	58	71	150	7.2	6.76	20	18.77	25	2.34	0.45	4.22
12	50	80	150	8	6.66	16	13.33	30	2.50	0.64	5.33
37	32	52	170	5	5.65	10	11.31	18	2.03	0.35	3.95
46	46	52	340	12	6.78	10	5.65	17.5	0.98	0.45	2.54
73	30	72	325	15	6.41	20	8.54	60	2.56	0.825	3.52
81	30	76	175	15.2	11.42	15	11.27	45	3.38	0.525	3.94
Aver.	41	67.17	218.33	10.4	7.28	15.23	11.48	32.58	2.30	0.54	3.92
St.dev.	11.98	12.17	89.14		2.07		4.46		0.79		0.91

A.A.

A.A.

JB.C.

JB.C.

R.C.

R.C.

TABLE XVII - Group II (E.O.), use of electric current
but no N₂O

Cases n=10	Age	Height kg	Duration mn	Pancur. (10^{-4}) mg mg/kg/mn	Droper. (10^{-4}) mg mg/kg/mn	Diaz. (10^{-3}) mg mg/kg/mn	Fent. (10^{-5}) mg mg/kg/mn
4	31	46	230	9	8.50	31.25	0.5
8	19	55	135	5.5	7.40	13	0.205
9	25	63	155	5.75	5.88	16	0.325
10	46	51	270	6.4	4.64	15	0.35
41	24	59	210	8	6.45	20	0.45
42	48	53	345	7.6	4.15	20	0.4
43	26	70	140	7	7.14	22.5	0.35
74	60	62	160	6.6	5.91	20	0.185
79	39	54	300	8.7	5.37	13.5	0.44
82	48	59	170	8	7.97	15	0.345
Aver.	36.6	57.20	213.5	7.25	6.34	18.62	0.35
St.dev.	13.53	6.86	71.69	1.42	3.35	0.62	0.87

A.A.

A.A.

A.A.

A.A.

JB.C.

JB.C.

JB.C.

R.C.

R.C.

R.C.

TABLE XVIII - Group III (O.N.), no electric current
but use of H_2O

Cases n=8	Age	Weight kg	Duration min	PANCUR. (10 ⁻⁴) mg mg/kg/min		DROPER. (10 ⁻⁴) mg mg/kg/min		DIAZ. (10 ⁻³) mg mg/kg/min		FENT. (10 ⁻⁵) mg mg/kg/min	
2	33	51	155	5.6	7.08	10	12.65	12.5	1.58	0.2	2.53
3	47	67	140	7	7.46	14	14.92	17	1.81	0.26	2.77
40	41	60	210	6.8	5.39	12	9.52	20	1.58	0.42	3.33
47	55	68	310	9.4	4.45	15	7.11	17.5	0.83	0.15	0.71
48	46	61	170	6.8	6.55	12	11.57	15	1.44	0.3	2.89
76	46	95	210	11	5.51	20	10.02	30	1.50	0.3	1.50
77	45	67	175	6.2	5.28	12.5	10.66	15	1.27	0.33	2.81
80	27	60	205	8	6.50	12	9.75	20	1.62	0.55	4.47
Aver.	42.5	66.13	196.87	7.6	6.03	13.43	10.78	18.37	1.45	0.313	2.63
St. dev.	8.78	12.92	52.64		1.03		2.33		0.30		1.13

A.A.

:

A.A.

J.B.C.

J.B.C.

J.B.C.

R.C.

R.C.

R.C.

TABLE XIX - Group IV (E.N.), use of electric current
and H_2O

2. Results (tables XVI, XVII, XVIII, XIX).

COMPARATIVE STUDY OF THE QUANTITIES OF DRUGS INJECTED :

A. IN GROUPS I AND II

The comparison of the average doses of the four drugs injected does not show any significant difference (N.S.) for $D = 13$ ($p > 0.05$). (table XX)

	GROUP I O.O. n = 9	GROUP II E.O. n = 6	t
Pancuronium	6.91 ± 1.66	7.28 ± 2.07	0.39
Droperidol	11.10 ± 3.71	11.48 ± 4.46	0.18
Diazepam	2.85 ± 1.24	2.30 ± 0.79	0.96
Fentanyl	4.59 ± 1.29	3.92 ± 0.91	1.10

TABLE XX - Average doses of the four drugs injected in groups I and II

One can therefore consider that the analgesic effect of electric current does not show.

B. IN GROUPS I AND III (table XXI)

The difference is not significant between these groups as far as pancuronium and droperidol are concerned ($p > 0.05$), whereas it is for diazepam ($p < 0.02$) and fentanyl ($p < 0.01$).

	GROUP I O.O. n=9	GROUP III O.N. n=10	t	p for D=17	O.N./O.O.
Panc.	6.91 $\pm$ 1.66	6.34 $\pm$ 1.42	0.80	> 0.05	N.S.
Drop.	11.10 $\pm$ 3.71	10.36 $\pm$ 3.35	0.45	> 0.05	N.S.
Diaz.	2.85 $\pm$ 1.24	1.65 $\pm$ 0.62	2.70	< 0.02	57.89 %
Fent.	4.59 $\pm$ 1.29	3.05 $\pm$ 0.87	3.08	< 0.01	66.44 %

TABLE XXI - average doses of the four drugs
injected in groups I and III

The influence of N₂O shows in group III : there is a decrease of 42.11 % for diazepam and 33.56 % for fentanyl as compared with group I (reference group). One can say that N₂O has a narcotic and analgesic effect.

C. IN GROUPS I AND IV

As above, the comparison of the average doses of drugs in each group does not show any significant difference as regards pancuronium and droperidol ($p > 0.05$), whereas the difference is significant for diazepam and fentanyl ($p < 0.01$). (Table XXII).

	GROUP I O.O. n=9	GROUP IV E.N. n=8	t	for p D=15	E.N./O.O.
Panc.	6.91 $\pm$ 1.66	6.03 $\pm$ 1.03	1.29	> 0.05	N.S.
Drop.	11.10 $\pm$ 3.71	10.78 $\pm$ 2.33	0.21	> 0.05	N.S.
Diaz.	2.85 $\pm$ 1.24	1.45 $\pm$ 0.30	3.09	< 0.01	50.87 %
Fent.	4.59 $\pm$ 1.29	2.63 $\pm$ 1.13	3.31	< 0.01	57.29 %

TABLE XXII - average doses of the four drugs injected in groups I and IV

Here again, the influence of N₂O shows : there is a decrease of 49.13 % of diazepam and 42.71 % of fentanyl as compared with group I (reference group).

D. IN GROUPS II AND III

There is no significant difference between the average doses of the four drugs injected in each group ($p > 0.05$ for $D = 14$) (table XXIII).

E. IN GROUPS III AND IV

As above, no significant difference shows between the average doses of the four drugs injected in each group ($p > 0.05$ for $D=16$) (see table XXIV).

	GROUP II E.O. n = 6	GROUP III O.N. n = 10	t
Pancuronium	7.28 $\pm$ 2.07	6.34 $\pm$ 1.42	1.08
Droperidol	11.48 $\pm$ 4.46	10.36 $\pm$ 3.35	0.57
Diazepam	2.30 $\pm$ 0.79	1.65 $\pm$ 0.62	1.83
Fentanyl	3.92 $\pm$ 0.91	3.05 $\pm$ 0.87	1.90

*TABLE XXIII - Average doses of the four drugs
injected in groups II and III*

	GROUP III O.N. n = 10	GROUP IV E.N. n = 8	t
Pancuronium	6.34 $\pm$ 1.42	6.03 $\pm$ 1.03	0.52
Droperidol	10.36 $\pm$ 3.35	10.78 $\pm$ 2.33	0.29
Diazepam	1.65 $\pm$ 0.62	1.45 $\pm$ 0.30	0.82
Fentanyl	3.05 $\pm$ 0.87	2.63 $\pm$ 1.13	0.90

*TABLE XXIV - Average doses of the four drugs
injected in groups III and IV*

F. IN GROUPS II AND IV

The comparison of average doses of the four drugs injected in each group does not show any significant difference for pancuronium and droperidol ($p > 0.05$). But the difference is significant as far as diazepam ($p < 0.02$) and fentanyl ($p < 0.05$) are concerned.

	GROUP II E.O. n=6	GROUP IV E.N. n=8	t	p for D=12	E.N./E.O.
Panc.	7.28±2.07	6.03±1.03	1.50	> 0.05	
Drop.	11.48±4.46	10.78±2.33	0.39	> 0.05	
Diaz.	2.30±0.79	1.45±0.30	2.82	< 0.02	63.04 %
Fent.	3.92±0.91	2.63±1.13	2.29	< 0.05	67.91 %

TABLE XXV - Average doses of the four drugs injected in groups II and IV

Here again, one can see the influence of N₂O in group IV : there is a 36.96% decrease in diazepam and a 32.09% decrease in fentanyl as compared with group II.

DISCUSSION.

These various results are gathered together in the comparative diagram next page. (diagram III).

1		2	3
A	I (O.O.)	D	S.
	II (E.O.)		
B	I (O.O.)	E	S.
	III (O.N.)		
C	I (O.O.)	F	S.
	IV (E.N.)		
		economy Diaz. -36.96% Fent. -32.09%	

* Not significant
 ** Significant
 *** Very significant

DIAGRAM III

The analysis of this diagram shows that :

- + When comparing the results of groups I and IV (box n° 1) one can see that N_2O allows a significant decrease of diazepam and fentanyl, and there seems to be a slight influence of the current since the C series shows a decrease, as compared with the B series, of 7.02% diazepam and 9.16% fentanyl.
- + But when comparing the results of groups III and IV (box 2) one can see that the current does not seem to improve the analgesic results and does not potentialize the effects of N_2O since the differences in the injected doses are not significant (N.S.). On the other hand, the results of groups II and IV (box 3) shows that N_2O plays an important part since, here again, there is a decrease of 36.96% of diazepam and 32.09% of fentanyl as compared with group II (use of current with no N_2O).

Such disappointing results call for a thorough investigation. For indeed the results obtained in this second study (groups I and II) are in contradiction with those obtained during the first study where a decrease of 23% fentanyl was obtained.

The first remark is that the number of patients in the second study is too low (6 cases in group II) to allow conclusions.

The second remark is that although the type of surgery in the second study (lithiasis) is of longer duration, it is less painful than that of the first study (prostatic adenoma), therefore it requires less analgesics.

ANESTHESIOLOGISTS	Gr. I	Gr. II	Gr. III	Gr. IV	Aver.	St. dev.	(10 ⁻³ mg/kg/mn)	
							DIAZEPAM	FENTANYL
A. Atinault	4.79	4.78	3.34	2.65	3.89	1.07		
JB. Cazalaa	4.68	3.25	3.13	2.31	3.34	0.98		
R. Coeytaux	4.27	3.73	2.60	2.93	3.38	0.76		
A. Atinault	2.95	2.42	1.85	1.70	2.23	0.57		
JB. Cazalaa	2.24	1.51	1.66	1.28	1.67	0.41		
R. Coeytaux	3.12	2.97	1.37	1.46	2.23	0.94		

TABLE XVI - Quantities of drugs used in each group by each anesthesiologist

If the use of low quantities of diazepam (2.85 ± 1.24) and fentanyl (4.59 ± 1.29) in group I of the second study as compared with group B of the first study (Diaz. 4.13 ± 5.96 , fent. 7.89 ± 2.40) is sufficient to obtain good anesthesia, it is nevertheless difficult to evaluate the analgesic results when the operations are of long duration but not very painful.

Anyway, only what is comparable can be compared, and it so happens that the patients of the first study are quite different from those of the second study. Still, we must keep in mind that the use of N_2O in groups III and IV gave positive results.

We then compared the "behaviour" of our three anesthesiologists during this second study. The analysis of average fentanyl and diazepam doses they used turned out to be not significant ($p > 0.05$) (tables XXVI and XXVII).

FENTANYL	A. ATINAULT J.B. CAZALAA	3.89 ± 1.07 3.34 ± 0.98	$t = 0.75$
	A. ATINAULT R. COEYTAUX	3.89 ± 1.07 3.38 ± 0.76	$t = 0.77$
	J.B. CAZALAA R. COEYTAUX	3.34 ± 0.98 3.38 ± 0.76	$t = 0.06$
DIAZEPAM	A. ATINAULT J.B. CAZALAA	2.23 ± 0.57 1.67 ± 0.41	$t = 1.59$
	A. ATINAULT R. COEYTAUX	2.23 ± 0.57 2.23 ± 0.94	$t = 0$
	J.B. CAZALAA R. COEYTAUX	1.67 ± 0.41 2.23 ± 0.94	$t = 1.08$

TABLE XXVII - Quantities of fentanyl and diazepam used by each anesthesiologist

As a conclusion we were forced to admit that the results obtained with electric current were bad. Until we found the reason of this failure :

When the study was over, the generator was checked on a cathodic oscilloscope with the P 6021 Tektronix probe, and it was found that the current used throughout this double-blind study was not the one described and used in our previous work. The generator was delivering H.F. current of triangular shape instead of exponential (fig 10,11). We have always stressed the fact that the shape of waves and the cyclic ratios are of utmost importance to analgesia. Since the study was double-blind, we had no means to check if the L.F. cyclic ratios were in conformity with the selection (fig.12).

Still, this study was useful in the way that it permitted to demonstrate the importance of the part played by electric current in anesthesia.

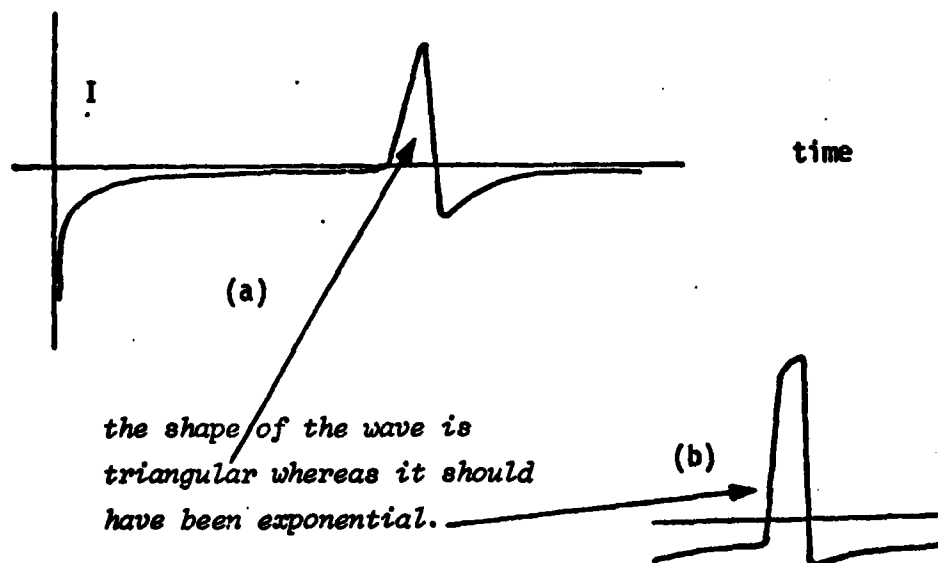


figure 10

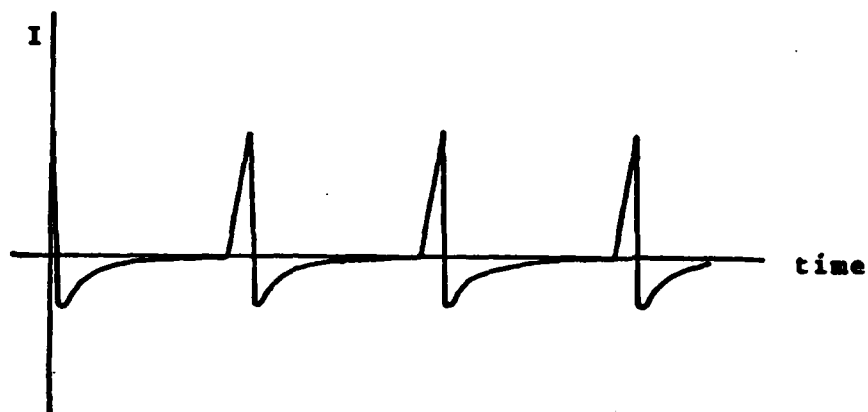


figure 11 - the H.F. waveforms are bad

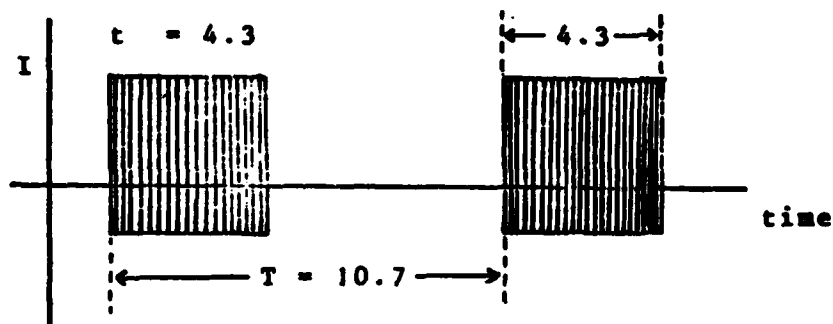


figure 12

The programmed LF cyclic ratio was:

$$t = 4 \text{ mS} ; T = 10 \text{ mS}$$

but the generator delivered:

$$t = 4.3 \text{ and } T = 10.7$$

CONCLUSION CONCERNING THE SECOND DOUBLE-BLIND STUDY : We would not want to draw hasty conclusions, but two remarks can be made. One is that it is indeed difficult, if not impossible, to perform a real double-blind study with so many variable elements and subjective criteria of evaluation. The other one is that the patients are very reluctant to give their consent for a study during which they might feel pain when they are supposed to be "submitted to surgery in the best conditions".

We might add that although they pretend to be objective these studies are actually rather subjective because surgeons as well as anesthesiologists fear something might go wrong and they tend to inject drugs in quantities which are not always necessary.

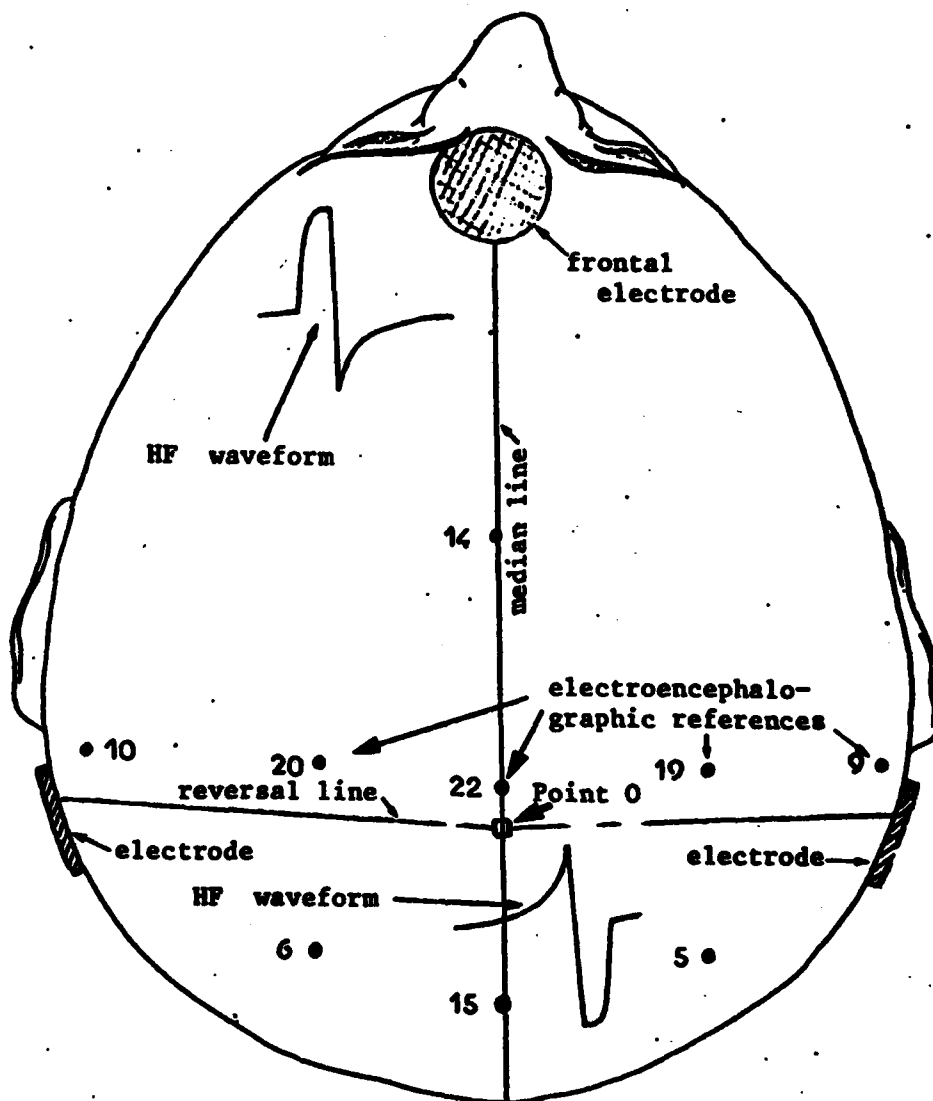
OTHER STUDIES

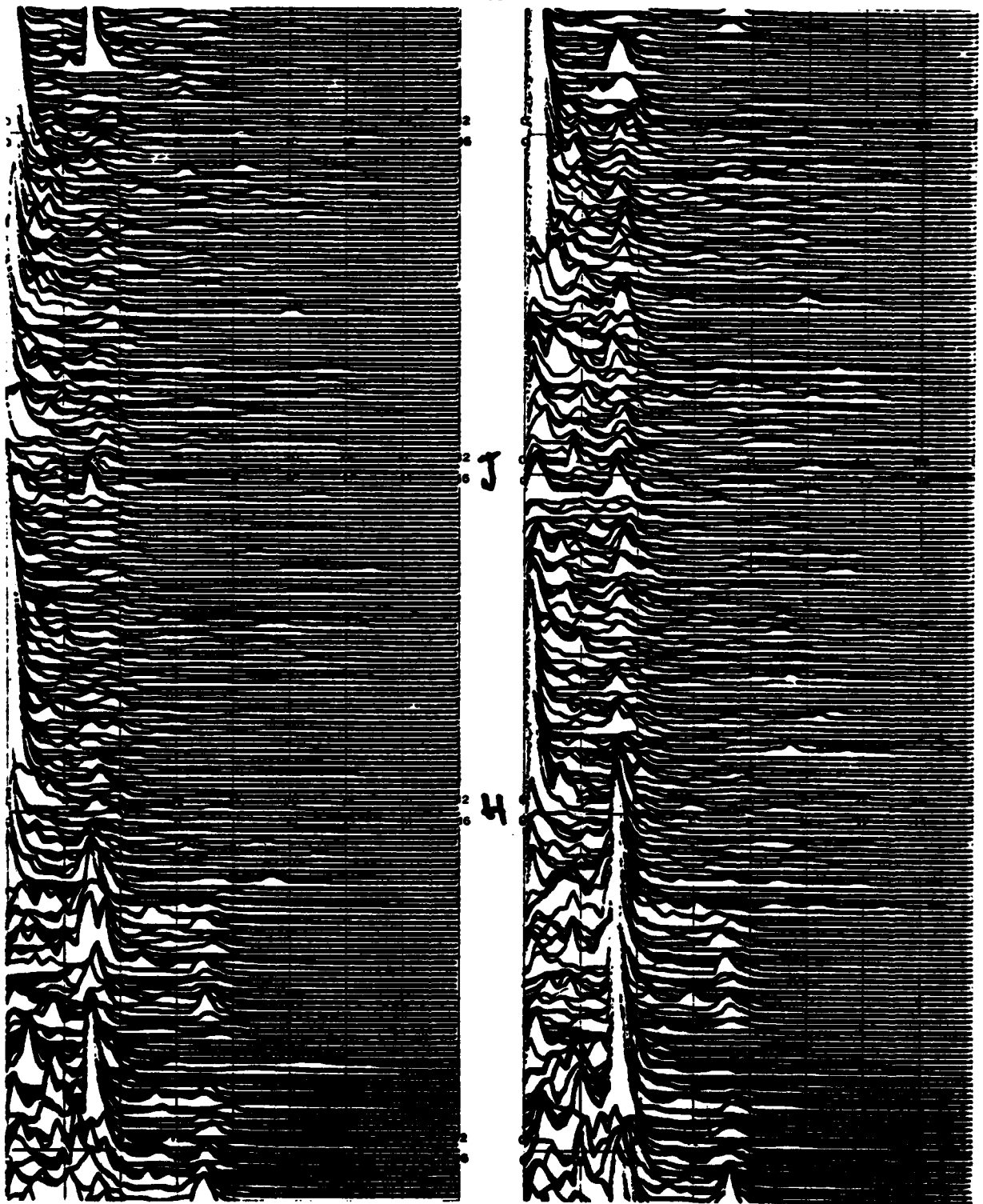
I - DISTRIBUTION OF CURRENT ON THE SCALP.

It must be borne in mind that the patients do not always give their consent to the principle of double-blind study and we cannot work on as many cases as we would like to. Still, most patients accept electroanesthesia and biological tests and this is why, when we are not allowed to do the double-blind study we study other fields connected with our research, especially the distribution of current on the scalp with the Tecktronix P 6006 probe.

We have been able to locate a point Zero and a line where the current is reversed. In order to have accurate references, we used those used for E.E.G. electrodes (fig.13). Point 0 is next to point 22 and the reversal line goes from the left retro-mastoidian to the right retro-mastoidian electrode. The amplitude of the waveform decreases progressively on the median line between the frontal electrode and point 0.

Now that this point 0 is known, we should be able to eliminate interferences provoked by the current on the E.E.G. recordings. We want to obtain continuous information about the cerebral electrical activity in the course of electroanesthesia, and for this reason, we have been trying these last six months to record E.E.G. with an apparatus which includes a small fast computer capable of calculating the Fourier transform. The great advantage of this Berg-Fourier Analyzer is its capacity of synthesizing E.E.G. signals. With this device many hours of E.E.G. activity are compressed into a pictorial and synoptic representation showing in real time the distribution of frequencies as well as the intensity of total electrical activity (fig.14).

*figure 13*



Recording of about two hours of carbonemic coma.
figure 14

II - THE EFFECT OF CURRENT : A COMPARATIVE STUDY.

Eighteen patients were divided into two groups before being submitted to urological surgery. They were anesthetized by the same anesthesiologist according to the following protocole :

Anesthetic protocole

- . 45 minutes prior to induction, each patient received :
 - atropine 0.5 mg
 - diazepam 10 mg
 - dipotassic chlorazepate 100 mg
- . The induction was composed of :
 - diethazine ⁽¹⁾ 250 mg I.V.
 - diazepam 10 to 40 mg I.V.
- . Intubation was accomplished with :
 - xylocaïne spray
- . Artificial ventilation was maintained with :
 - 50% mixture of N₂O-O₂
- . Anesthesia was maintained with :
 - 50% mixture of N₂O-O₂
 - plus : either electric current and diazepam if the patient gave signs of consciousness (opening of the eyes, mastication, etc...) GROUP I ;
 - or diazepam without electric current. GROUP II.

(1) drug used to cure Parkinsonian disease.

N°	Sex	Age	Height kg	Duration min.	Type of surgery	D I A Z E P A M INDUCT.		P A N C U R O N I U M REINJ.	
						mg	mg/kg	mg	xxx
1	M	26	70	150	Epididymo-deferential anastomosis	20	0.29	10	0.95
2	M	67	61	160	Urethral stricture	20	0.33	0	0.00
3	M	72	60	150	Prostatic adenoma	40	0.67	10	1.11
4	M	74	72	120	Prostatic adenoma	40	0.57	0	0.00
5	M	83	60	240	Gastrect.+sygmoidect. + prostatic adenoma	30	0.50	15	1.04
6	F	45	87	120	External urethrotomy	30	0.34	5	0.48
7	M	40	63	210	Right pyelolithotomy	10	0.16	15	1.13
8	F	26	52	210	Bilateral antireflux	30	0.58	20	1.83
9	M	68	90	150	Prostatic adenoma	30	0.33	0	0.00
Average		55.67	68.33	167.78		--	0.42	--	0.73
St. dev.		21.65	12.85	42.36		--	0.17	--	0.64

* in 10^{-3} mg/kg/min

xxx in 10^{-4} mg/kg/min

TABLE XVIII - Maintenance of anesthesia with electric current, diazepam and N_2O/O_2

N°	Sex	Age	Weight kg	Duration min.	Type of surgery	D I A Z E P A M			PANCURONIUM		
						INDUCT. mg	mg/kg	REINJ. mg	*	mg	xxx
10	F	35	78	150	Suspension of bladder neck	30	0.38	130	11.11	7	5.98
11	F	62	76	150	Vesical prolapse	20	0.26	65	3.89	9	7.89
12	M	61	72	150	Prostatic adenoma	20	0.28	50	4.63	6	5.56
13	M	24	68	120	Partial cystectomy	30	0.44	50	4.90	7	8.58
14	F	35	78	120	Pyelolithotomy	30	0.38	120	12.86	7	7.48
15	M	71	65	120	Prostatic adenoma	30	0.46	60	7.69	6	7.69
16	F	42	75	220	Suspension of bladder neck	10	0.24	60	5.33	6	3.64
17	M	24	76	120	Epididymo-defer. anast.	25	0.33	25	2.74	6	6.58
18	F	57	78	150	Repair of incisional hernia	20	0.26	50	5.34	7	5.98
Average		45.67	74	144.44		--	0.34	--	6.49	-	6.60
St. dev.		17.51	4.72	32.06		--	0.08	--	3.40	-	1.51

* in 10^{-3} mg/kg/mnxxx in 10^{-4} mg/kg/mnTABLE XIX - Maintenance of anesthesia with diazepam and N_2O/O_2

Neither diethazine nor fentanyl were to be injected in the course of surgery in either group. Only diazepam injections were allowed.

The electrical parameters used in Group I were those already described.

Population studied (tables XXVIII and XXIX).

Nine patients were operated with electric current and diazepam (Group I) : average age 55.67 ± 21.65 ; average weight 68.33 ± 12.85 kg ; average procedure time 167.78 ± 42.36 mn.

Nine patients were operated with diazepam only (Group II) : average age 45.67 ± 17.51 ; average weight 74 ± 4.72 kg ; average procedure time 144.44 ± 32.06 mn.

Examination of table XXX shows that the two groups I and II are statistically matched from the standpoint of age, weight, procedure time ($p > 0.05$).

	GROUP I n = 9	GROUP II n = 9	t 2.12	p for D = 16
Age	55.67 ± 21.65	45.67 ± 17.51	1.08	> 0.05 N.S.
Weight (kg)	68.33 ± 12.85	74 ± 4.72	1.24	> 0.05 N.S.
Durat. (mn)	167.78 ± 42.36	144 ± 32.06	1.32	> 0.05 N.S.

TABLE XXX - Statistical comparison of both groups

R E S U L T S (tables XXVIII and XXIX).

Although we were not allowed to use fentanyl, especially in group II (without electric current), the surgeons' cooperation as well as the injections of diazepam permitted surgery without too many problems (such as increase in blood pressure, sweating, etc.), but this protocole is definitely not recommended when one wants to obtain excellent anesthesia.

The average doses of diazepam injected in group I (0.73 ± 0.64 mg/kg/mn) and in group II (6.49 ± 3.40 mg/kg/mn) are significantly different, which demonstrates the efficaciousness of electric current to produce anesthesia.

This effect of electric current permits to save 88.75% of diazepam as compared with the reference dose of group II (table XXXI).

GROUP I n = 9	GROUP II n = 9	t 2.12	p for D=16	I/II
0.73 + 0.64	6.49 + 3.40	5.00	< 0.001	11.25%

TABLE XXXI - Average doses of diazepam (10^{-3} mg/kg/mn)

D I S C U S S I O N

The results obtained with electric current are very promising and rather good as compared with those obtained in the second double-blind study. Such good results suggest that the type of surgery of group I might be less painful than that of group II. But the comparative analysis of the two types of surgery does not reveal any great difference. Furthermore, case 5 of group I (E.C.) submitted to gastrectomy + sigmoidectomy + prostatic adenomectomy underwent a particularly painful and long operation.

It is reminded that the anesthetic protocole included two variable parameters : the quantities of diazepam before surgery and the quantities of pancuronium during surgery. Still, the analysis of table XXXII show; no significant difference as regards the mg/kg quantities of diazepam and the 10^{-4} mg/kg/min quantities of pancuronium. Therefore, the comparative study of diazepam quantities during surgery is correct and the results are very significant, all the more so since no analgesic is used in this study.

	Group I n=9	Group II n=9	t 2.12	p for D = 16
Diazepam mg/kg	0.42 $\pm$ 0.17	0.34 $\pm$ 0.08	1.31	> 0.05 N.S.
Pancuro. 10^{-4} mg/kg/min	5.94 $\pm$ 1.49	6.60 $\pm$ 1.51	0.93	> 0.05 N.S.

**TABLE XXXII - Quantities of diazepam before surgery
and of pancuronium during surgery**

C O N C L U S I O N of the comparative study.

This study confirms the real action of a type of current with very specific characteristics, especially the particular form of its H.F. waves.

The effects of this current permit a decrease in the quantities of drugs injected, which is of utmost importance in case of major surgery of long duration on patients suffering from antecedent syndromes (renal, chronic, respiratory insufficiencies, etc.)

GENERAL CONCLUSION

These last five years devoted to the study of electroanesthesia turned out to be most fruitful, although we are not yet in a position to clearly define the mode of action of electric current. We are deeply convinced that even more efficacious waveforms can be found so that one day drugs can be totally eliminated in the anesthetic process.

It is our wish that cooperation with the United States continues until the goal is reached because there is no doubt that such a cooperation between our two specific countries is a very important asset in the venture.

We have good reasons to believe that this view of things is shared by at least a few American scientists. Let us report, for instance, some of the lines written by Prof. Stanley last September upon his return to the U.S. after a nine months stay in Paris to study our work : "...It has been an unqualified success and I believe our work may have a very important effect on the practice of anesthesiology throughout the world in the next few years. (...) Our data combined with those obtained by Prof. Limoge in the past few years strongly suggest that a means of administering electrical anesthesia without any other anesthetics (intravenous or inhalation) or more simplistically put "pure electric anesthesia" should be possible. It is my opinion that much effort and support should be put behind these projects" (signed T.H. Stanley, M.D., Professor of Anesthesiology and Surgical Research, Director of the Anesthesiology Laboratories - The University of Utah College of Medicine, Salt Lake City).

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