

SICUREZZA & OTTIMIZZAZIONE DELLE PROCEDURE D'ABLAZIONE DELLA FA

Gestione Anestesiologica nell'ablazione a campo pulsato (PFA) : pratiche attuali e criticità

Prof. Gerardo Nigro

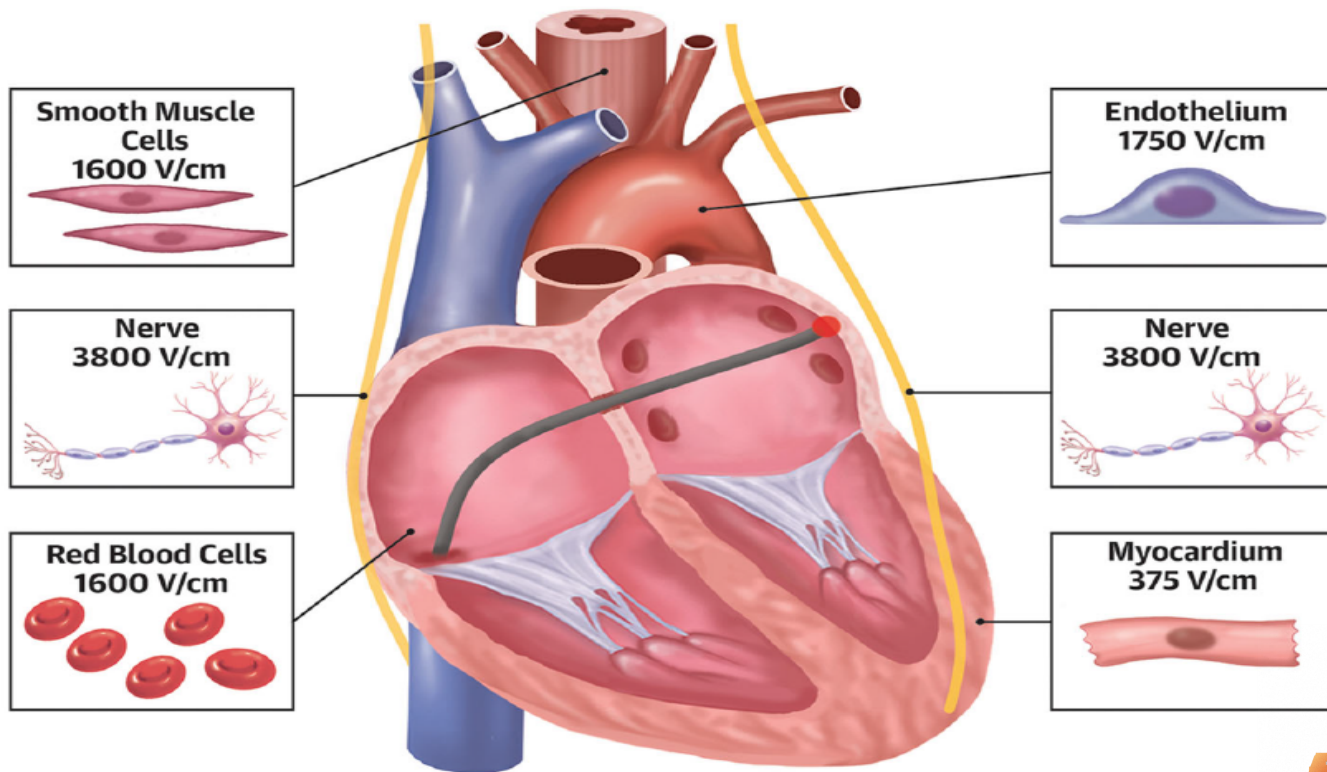
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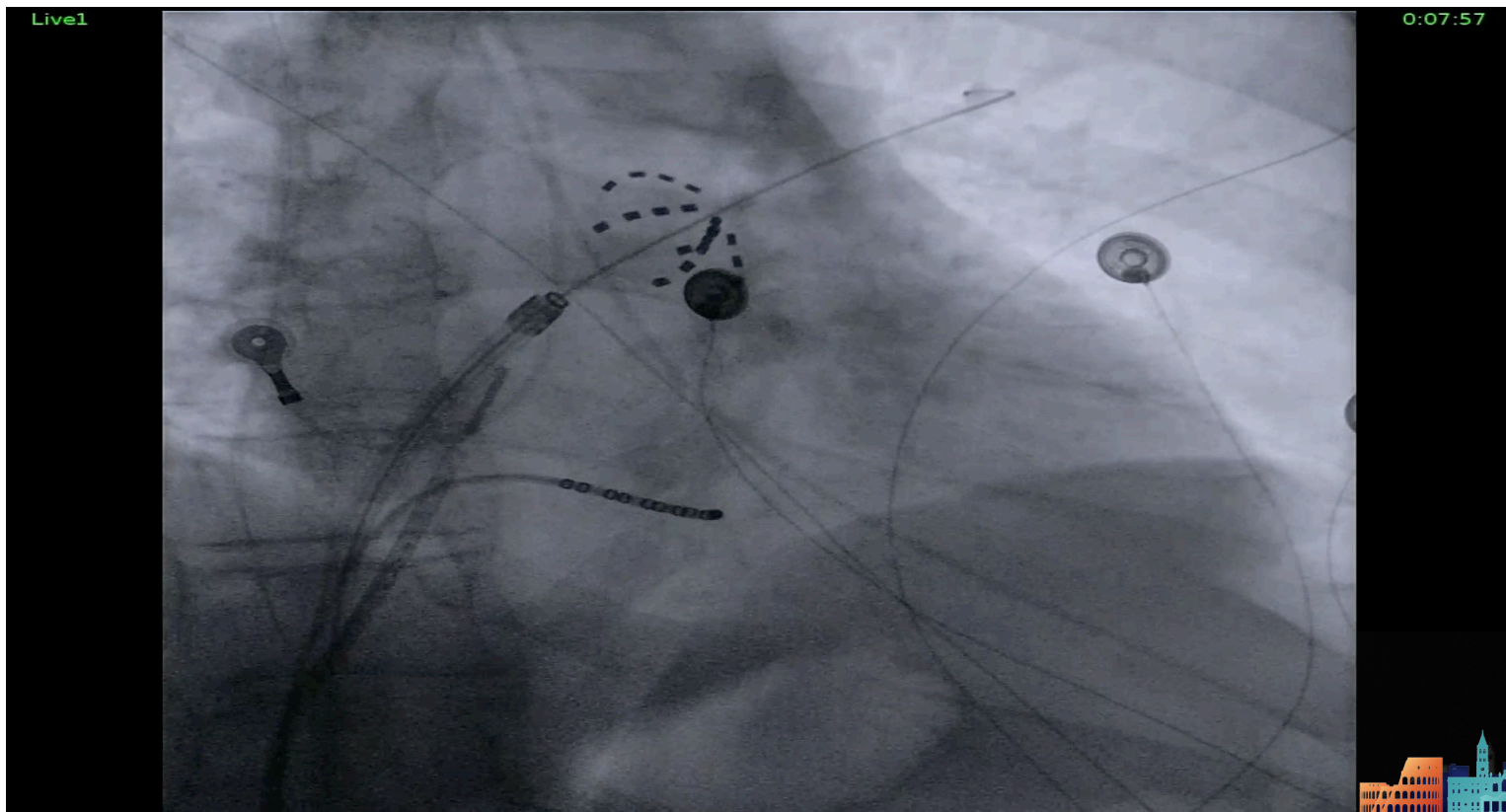
V: Università
degli Studi
della Campania
Luigi Vanvitelli

OSPEDALI DEI COLLI
MONALDI - COTUGNO - C.T.O.

I vantaggi dell'elettroporazione



Esempio di isolamento di una vena polmonare



Come “eliminare l’anestesista”





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Original Article

Investigating Deep Sedation With Intravenous Ketamine in Spontaneous Respiration During Pulsed-Field Ablation

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Objectives: The authors report their experience of a protocol for deep sedation with ketamine in spontaneous respiration during the pulsed-field ablation (PFA) of atrial fibrillation (AF).

Design: Observational, prospective, nonrandomized fashion.

Setting: Single-center hospitalized patients.

Participants: All consecutive patients undergoing PFA of AF.

Interventions: Patients undergoing deep sedation with intravenous ketamine.

Measurements and Main Results: The authors' sedation protocol involves the intravenous administration of fentanyl (1.5 µg/kg) and midazolam (2 mg) at low doses before local anesthesia with lidocaine. A ketamine adjunct (1 mg/kg) in 5-minute boluses was injected about 5 minutes before the first PFA delivery. The authors enrolled 117 patients (age = 59 ± 10 y, 74.4% males, body mass index = 27.6 ± 5 kg/m², fluoroscopy time = 24 ± 14 minutes, skin-to-skin time = 80 ± 40 minutes and PFA LA dwell time = 24 ± 7 minutes). By the end of the procedure, pulmonary vein isolation had been achieved in all patients using PFA alone. The mean time under sedation was 54.9 ± 6 minutes, with 92 patients (79%) being sedated for <1 hour. A satisfactory Ramsay Sedation Scale level before ketamine administration was achieved in all patients, except one (80.3% of the patients with rank 3; 18.4% with rank 2). In all procedures, the satisfaction level was found acceptable by both the patient and the primary operator (satisfactory in 98.2% of cases). All patients achieved a Numeric Rating Scale for Pain ≤3 (none or mild). No major procedure or anesthesia-related complications were reported.

•Studio prospettico monocentrico(n=117)

Sedazione profonda in **respiro spontaneo**

Protocollo: Midazolam 2 mg + Fentanyl 1.5 mg/kg

•Ketamina boli (≈1–3 mg/kg)

•Procedura PFA: PVI **100% successo**

•Tempo medio: Sedazione: ~55 min

•Procedura: ~80 min



Table 4

Sedation Parameters Before and After Ketamine Administration

Parameter	Before Ketamine Infusion (Step 1-2)	After Ketamine Infusion (Step 3)	p Value
SpO ₂ , % O ₂	99.6 ± 0.9	99.9 ± 0.4	0.0001
HR, beats/min	78.1 ± 8	99.7 ± 11	< 0.0001
Systolic SP, mmHg	132.3 ± 13	151.3 ± 15	< 0.0001
Diastolic SP, mmHg	77.7 ± 9	81.9 ± 6	0.0001
Arterial pCO ₂ , pH	/	39.9 ± 3	/
Arterial PH, mmHg	/	7.4 ± 0.03	/
Arterial pO ₂ , mmHg	/	177.3 ± 24	/

Abbreviations: HR, heart rate; SP, systemic pressure.

Table 5

Adverse Events During/After Sedation

Event	n (%)
Termination or change of sedation protocol	1 (0.9)
Aborted procedure due to sedation issues	0 (0)
Prolonged hypotension (systolic blood pressure <90 mmHg for >5 min)	0 (0)
Oxygen desaturation (SpO ₂ < 90%) despite airway management	0 (0)
Psychomimetic effects	1 (0.9)
Administration of hemodynamic support medications	0 (0)
Sustained hemodynamically relevant bradycardia necessitating pacing	0 (0)
Vomiting	1 (0.9)

- Nessuna complicanza maggiore anestesilogica
- Nessuna desaturazione significativa (<90%)
- Dolore minimo (NRS ≤3 in tutti)
- Soddisfazione elevata (~98%)
- Recupero rapido (<15 min nella maggioranza)





Randomized single-blinded study comparing sedation effectiveness and hemodynamic stability of remifentanyl vs dexmedetomidine infusion for electrophysiology procedures in patients of National Heart Institute cathlab

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Abstract

Background While studies comparing the effectiveness of remifentanyl and dexmedetomidine are prevalent in other nations, using remifentanyl alone is uncommon in Malaysia. This research aims to evaluate the effectiveness of sedation with remifentanyl or dexmedetomidine infusion in monitored anesthesia care for electrophysiology procedures.

Methods This study is a single-center, single-blinded, prospective randomized clinical study. One hundred twenty patients were randomized into two groups (remifentanyl vs dexmedetomidine). Demographic characteristics and clinical outcomes, including level of sedation, vital signs, and patient satisfaction were monitored and recorded.

Results Group R showed a higher mean observer's assessment of alertness/sedation score (3.9 ± 0.7 vs 3.6 ± 0.8 ; $p = 0.008$), mean arterial pressure (92.0 ± 12.0 vs 83.0 ± 13.0 mmHg; $p < 0.001$), heart rate (82.0 ± 20.0 vs 73.0 ± 18.0 beats/min; $p = 0.006$), systolic blood pressure (139.0 ± 16.0 vs 123.0 ± 17.0 mmHg; $p < 0.001$) and diastolic blood pressure (75.0 ± 13.0 vs 69.0 ± 14.0 mmHg; $p = 0.009$) than Group D. Oxygen saturation ($99.0 \pm 1.0\%$; $p = 0.220$) and respiration rate (16.0 ± 3.0 breaths/min; $p = 0.361$) for both groups were the same. Adverse events, including hypotension, bradycardia, and respiratory depression were observed in both groups. Both groups gave positive responses ranging from fair to good for patient satisfaction.

Conclusion Dexmedetomidine is a better choice of anesthesia as it was associated with a higher level of sedation, more stable hemodynamics, lower incidence of adverse events, and better patient satisfaction.

Design

- Studio randomizzato, prospettico, single-blind
- 120 pazienti sottoposti a procedure EP
- 2 gruppi:
 - Remifentanyl (0.025–0.2 mcg/kg/min)
 - Dexmedetomidina (0.2–0.7 mcg/kg/h) [\[JICE ago 2...mifentanyl | PDF\]](#)

Target di sedazione

- OAAS 3–4 (sedazione moderata)
- Respirazione spontanea mantenuta
- Monitoraggio continuo (BP, HR, SpO₂, RR) [\[JICE ago 2...mifentanyl | PDF\]](#)

Endpoints

- Profondità della sedazione
- Stabilità emodinamica
- Eventi avversi
- Soddisfazione del paziente [\[JICE ago 2...mifentanyl | PDF\]](#)



Risultati principali

- Sedazione più profonda con dexmedetomidina (OAAS ↓)
- Migliore stabilità emodinamica: ↓ MAP, HR, BP
- Minor depressione respiratoria vs remifentanyl
- Maggiore soddisfazione paziente

Sicurezza

- Remifentanyl: ↑ depressione respiratoria (27% vs 3%)
- Dexmedetomidina: ↑ ipotensione (trend)
- Limiti
- Single-center
- Esclusi pazienti ad alto rischio
- Nessun follow-up a lungo termine

Conclusione → Dexmedetomidina: miglior equilibrio sedazione/stabilità/emergenza respiratoria

Variables	Group R (n = 59)	Group D (n = 60)	p-value
<i>Observer's assessment of alertness/sedation (OAAS) score</i>			
Mean ± SD	3.9 ± 0.7	3.6 ± 0.8	0.008*
Median (Q1, Q3)	4 (4, 4)	4 (3, 4)	
Range score 1–2	1 (1.8%)	2 (3.6%)	0.558
Range score 3–5	55 (98.2%)	54 (96.4%)	
<i>Pain score</i>			
Mean ± SD	0.8 ± 1.0	0.5 ± 0.9	0.061
Median (Q1, Q3)	0.0 (0.0, 1.5)	0.0 (0.0, 1.0)	
Range score < 3	56 (98.2%)	55 (100.0%)	0.324
Range score > 4	1 (1.8%)	0 (0.0%)	
<i>Vital signs</i>			
Mean arterial pressure (MAP) (mmHg)	92.0 ± 12.0	83.0 ± 13.0	< 0.001*
Heart rate (HR) (beats/min)	82.0 ± 20.0	73.0 ± 18.0	0.006*
Systolic blood pressure (SBP) (mmHg)	139.0 ± 16.0	123.0 ± 17.0	< 0.001*
Diastolic blood pressure (DBP) (mmHg)	75.0 ± 13.0	69.0 ± 14.0	0.009*
Oxygen saturation (SPO ₂) (%)	99.0 ± 1.0	99.0 ± 1.0	0.220
Respiration rate (RR) (breaths/min)	16.0 ± 3.0	16.0 ± 3.0	0.361
<i>Adverse events</i>			
Hypotension	5 (8.5%)	10 (16.7%)	0.263
Bradycardia	6 (10.2%)	1 (1.7%)	0.126
Respiratory depression (SPO ₂ < 94%)	16 (27.1%)	2 (3.3%)	< 0.001*
<i>Patient satisfaction</i>			
Fair	7 (11.9%)	2 (3.3%)	0.205
Good	38 (64.4%)	41 (68.3%)	



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ORIGINAL RESEARCH



Feasibility of pulsed field ablation for atrial fibrillation under mild conscious sedation

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Abstract

Background Pulsed field ablation (PFA) is a new modality for pulmonary vein isolation (PVI) for atrial fibrillation (AF). PFA is performed under general anaesthetic (GA) or deep sedation with propofol, but this requires anaesthetic support in many countries, restricting use. No study has tested the feasibility of PFA under mild conscious sedation (MCS).

Methods We prospectively recruited patients undergoing PFA PVI, offered the option of MCS delivered by electrophysiologists, and compared these with patients who opted for GA. MCS comprised intravenous midazolam and fentanyl. All procedures were performed under anaesthetic supervision in case of requirement to convert to GA, which formed the primary outcome.

Results Twenty-three patients were recruited (8 MCS, 15 GA). One patient (1/8 [12.5%]) required conversion from MCS to GA. Total procedural times were similar between groups (MCS 92 ± 12.4 min vs. GA 101 ± 17.3 min; $p=0.199$). High mean sedative doses were required in the MCS group (5.12 ± 0.83 mg midazolam and 209 ± 40 mcg fentanyl). Median intraprocedural pain perception by the patient, rated from 0 to 100 was 45 (IQR 22.5–72.5) in the MCS group. Post-procedural groin pain (0 [0–0] vs. 5 [0–35]; $p=0.027$) and throat pain (0 [0–0] vs. 10 [5–40]; $p=0.001$) were lower in the MCS group.

Conclusion PFA under MCS is feasible in selected patients but pain and tolerance may be suboptimal, and high sedative doses are required.

Keywords Atrial fibrillation · Catheter ablation · Pulsed field ablation · Sedation

- Studio prospettico (n=23; MCS vs GA)
- Sedazione: midazolam + fentanyl
- Conversione a GA: 12.5%
- Procedural time: simile a GAN
- necessarie dosi elevate di sedativi



	MCS (<i>n</i> = 8)	GA (<i>n</i> = 15)	<i>p</i> -value
Total procedure time (mins)	92 ± 12.4	101 ± 17.3	0.199
Skin-to-skin time (mins)	64 ± 12.0	63 ± 15.2	0.868
Left atrial dwell time (mins)	43 ± 7.8	43 ± 12.9	0.948
Ablation time (mins)	22.5 [17.8–29.0]	21.0 [18.0–30.5]	0.974
Setup time (mins)	16.5 [14.5–18.5]	25 [20–32.5]	0.002
Turnaround time (mins)	11.4 ± 5.3	11.3 ± 4.4	0.984
Fluoroscopy time (mins)	10.4 ± 3.1	16.9 ± 5.1	0.004
Contrast dose (ml)	76 ± 42	95 ± 34	0.240
Non-PVI ablation performed, <i>n</i> (%)	1 (12.5)	5 (33.3)	0.369
Number of PFA applications	32 [32–36]	38 [33–46]	0.062
Acute procedural success (%)	100	100	> 0.999
Complications (%)	-	-	-

- Dolore intra-procedurale elevato
- median pain score ≈45/100
- Peggior tolleranza rispetto a GA
- Maggior richiesta sedativi
- Migliore comfort post-procedurale (no intubazione)

Table 3 Differences in patient experience

	MCS (<i>n</i> = 8)	GA (<i>n</i> = 15)	<i>p</i> -value
Intraprocedural pain	45 [23–73]	0 [0–0]	0.005
Intraprocedural discomfort	0 [0–0]	0 [0–0]	0.195
Intraprocedural anxiety	10 [0–10]	0 [0–0]	0.014
Post-procedural groin pain	0 [0–0]	5 [0–35]	0.004
Post-procedural throat pain	0 [0–0]	10 [5–40]	0.001
Post-procedural chest pain	0 [0–0]	0 [0–0]	0.558
Pain Likert (1–5) score	2.5 [2.0–3.5]	4.0 [4.0–5.0]	0.027
Discomfort Likert (1–5) score	4.0 [3.0–5.0]	3.0 [3.0–4.0]	0.466
Anxiety Likert (1–5) score	5.0 [4.0–5.0]	4.0 [3.0–4.0]	0.006
Friends and family test (Likert 1–5)	5.0 [5.0–5.0]	5.0 [5.0–5.0]	0.869

Scores are rated 0–100 (higher=worse). Likert scales are rated 1–5 (1=much worse than expected, 2=worse than expected, 3=as expected, 4=better than expected, and 5=much better than expected), aside from the ‘friends & family test’ which is rated 1–5 (1=definitely would not recommend, 2=would not recommend, 3=neutral, 4=would recommend, and 5=would definitely recommend). All values are reported as median (interquartile range)



Farmaci utilizzati negli studi :

- Propofol
- Ketamina



richiede anestesista
(normativa italiana)

- REMIMAZOLAM (Benzodiazepina a breve emivita)



Non richiede anestesista
(normativa italiana)

VANTAGGI REMIMAZOLAM:

↓ **Depressione respiratoria**

↑ **Stabilità emodinamica**



La vera domanda oggi non è quale farmaco è migliore....

..... macome eliminare l'anestesista



INCLUSION CRITERIA :

- Atrial Fibrillation paroxysmal and persistent

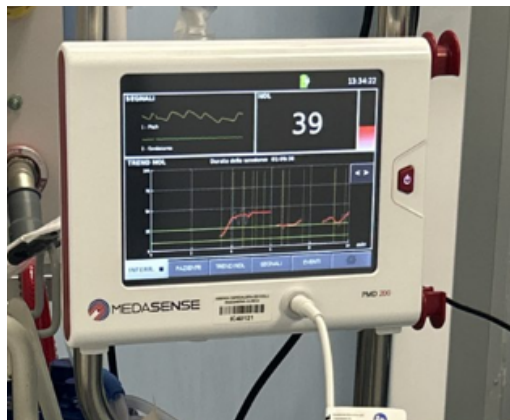
EXCLUSION CRITERIA

- ASA III-IV
- Sleep Apnea Obstruction
- Difficult patient airways
- Patient choice





VR MASK FOR PATIENT



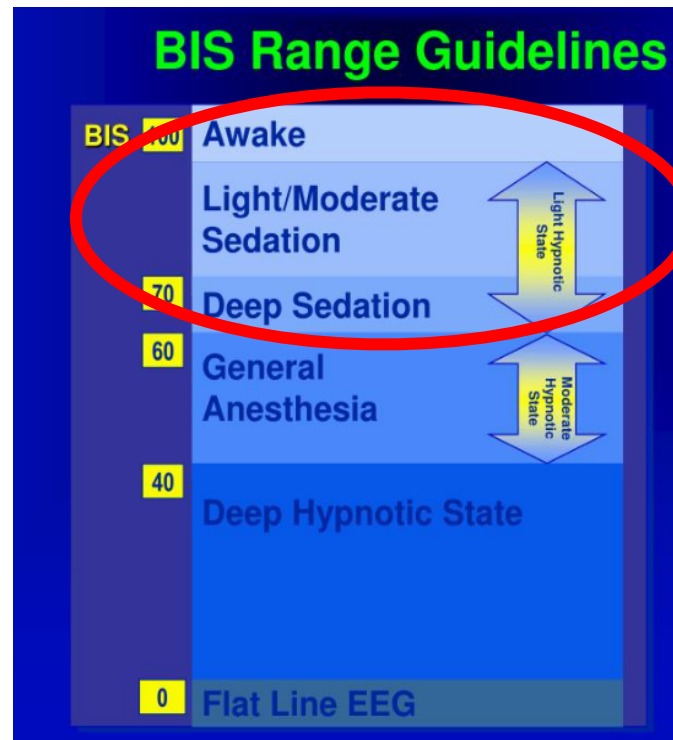
NOL



BIS



The Bispectral Index (BIS) Module provides numerics and high-resolution trends to help monitor consciousness and sedation in the OR, ICU, and in other clinical settings such as outpatient surgery and conscious sedation.



The PMD-200™ system with the NOL® index

The PMD-200 is a physiological monitor that personalizes analgesic dosing by providing a numeric, non-linear scale of nociceptive response levels, called NOL – the nociception level index. During surgical stimulation under general anesthesia, a NOL value of zero indicates no nociception, and NOL of 100 indicates extreme nociception.

System components

The PMD-200 system consists of a display and computing unit, a reusable non-invasive finger probe and a single-use sensor.

The proprietary signal acquisition sensor platform (the combination of the finger probe and the single-use sensor) acquires physiological signals. Using advanced algorithms, the system processes and analyses multiple nociception-related physiological parameters and their various derivatives, which correspond with the sympathetic nervous system's response to noxious stimuli.

The finger probe and single-use sensor continuously acquire four physiological signals through the following four sensors (See Figure 6):

1. Photoplethysmograph (PPG)
2. Galvanic Skin Response (GSR)
3. Peripheral Temperature (Temp)
4. Accelerometer (ACC)







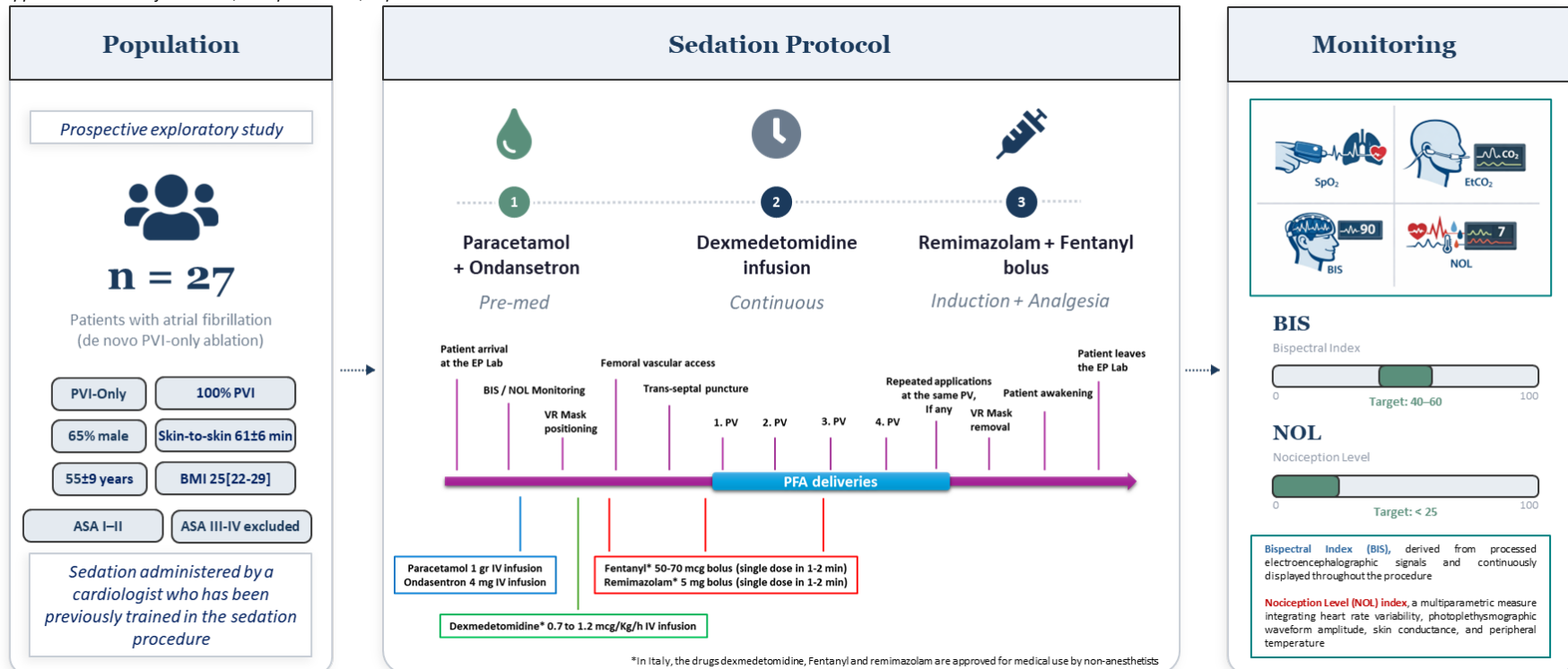
Baseline characteristics	N=51
AGE, years	60 ± 18
MALE, n (%)	31 (61)
Parox AF, n (%)	28 (55)
Redo-AF (parox), n (%)	9 (18)
Pers-AF, n (%)	7 (14)
ASA I, n (%)	40 (78)
ASA II, n (%)	11 (22)
Ischemic, n (%)	6 (12)
LVEF, %	55 %

Procedural characteristics	N=51
Lab-occupancy time, min	90 min
Skin-to-skin time, min	60 min
Time to full recovery of consciousness, min	15 min
Additional lesion set, n (%)	2 (4%)
PVI-only, n (%)	49 (96%)
# PFA deliveries, n	32 (PVI Only) 40 (PVI+PWI)



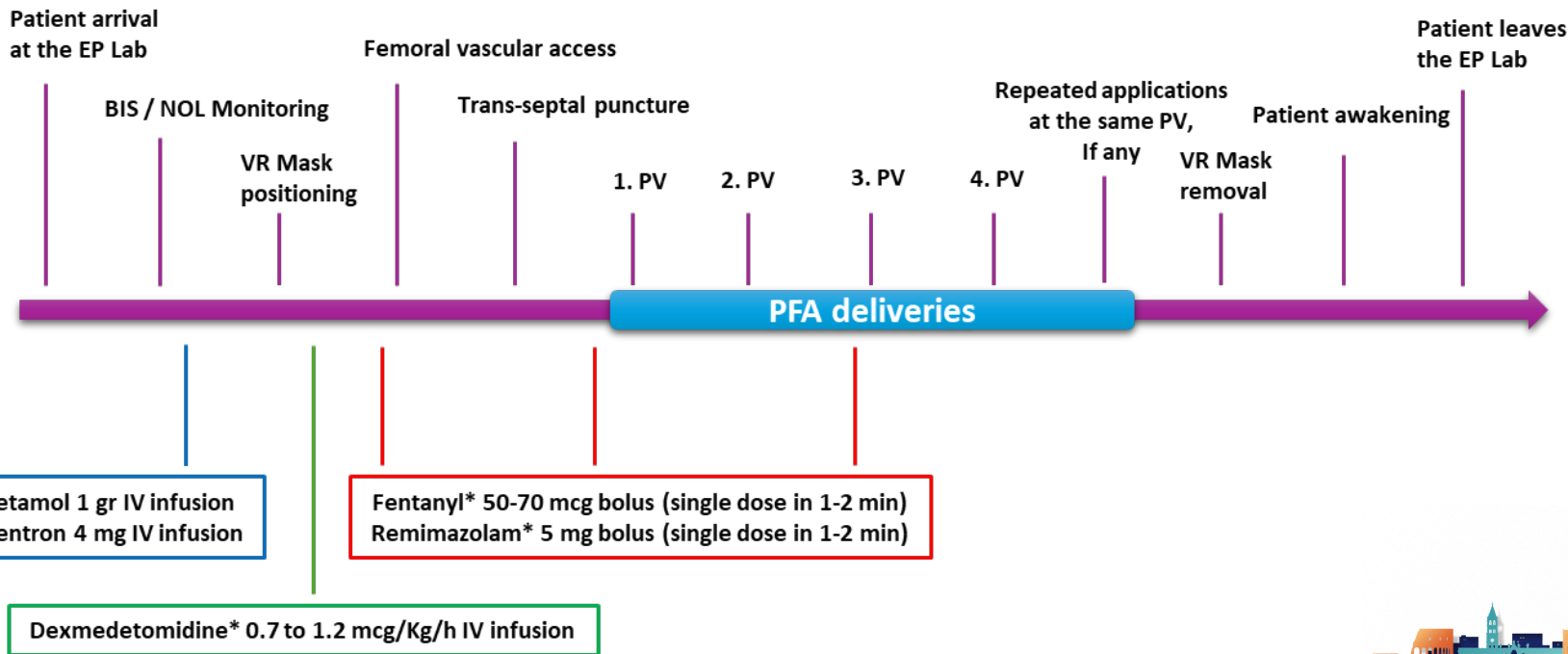
Ospedale Monaldi Prof. Nigro / Dr.ssa Della Cioppa-Guarino

Della Cioppa et al. Heart Rhythm 2026, accepted article, in press

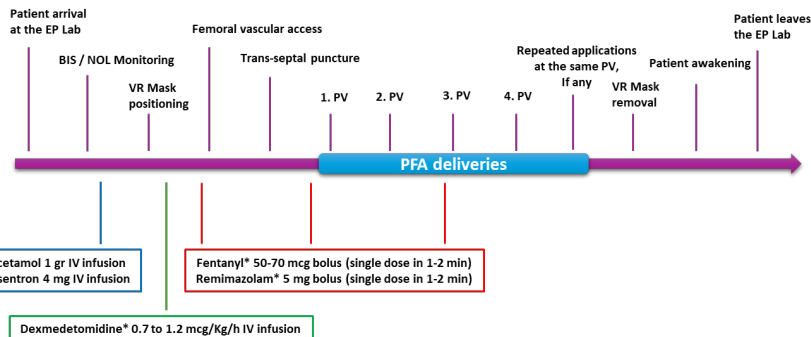


*In Italy, the drugs dexmedetomidine, Fentanyl and remimazolam are approved for medical use by non-anesthetists

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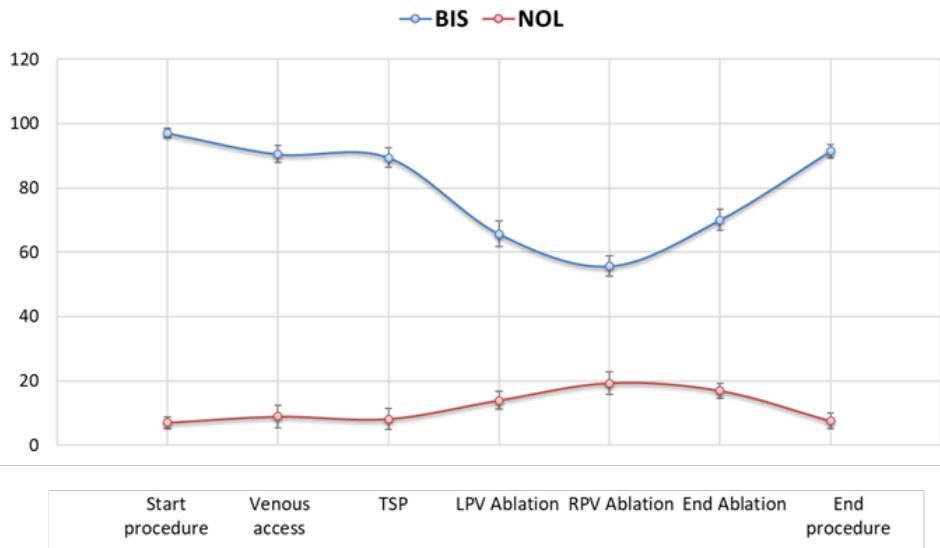


- No patients requiring conversion to GA
- Time to full recovery of consciousness = 15 ± 4 min.
- Flumazenil was not required in any procedure.
- No major sedation related complications occurred.
- In one patient, an additional bolus of remimazolam (5mg) and fentanyl (50–70 μ g) was required after the first PFA delivery due to patient-reported pain.

- 1) Intravenous paracetamol (1 g) and ondansetron (4 mg) were administered for preemptive analgesia and antiemetic prophylaxis, respectively.
- 2) 10-15 minutes before the beginning of the EP procedure, an intravenous infusion of dexmedetomidine was initiated at 0.7-1.2 μ g/kg/h and maintained throughout the procedure.
- 3) 2-5 minutes before femoral vein puncture, a single intravenous bolus of remimazolam (5 mg) and fentanyl (50–70 μ g) was administered.
- 4) Local anaesthesia for femoral access was achieved using subcutaneous lidocaine.
- 5) 3-5 minutes before delivery of electroporation energy for each pair of PVs, an intravenous bolus of remimazolam (5 mg) and fentanyl (50–70 μ g) was repeated and administered over 1–2 minutes.
- 6) Specific reversal agent (flumazenil) was available at the bedside during all procedures.



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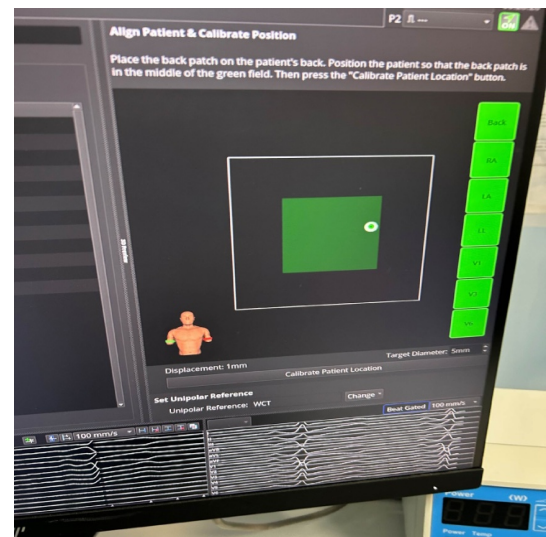


- The median NRS score was 1[1–2], indicating minimal discomfort.
- No patients reported severe pain (NRS $\geq$ 7).
- 98% patients rated their procedural pain as mild (NRS $\leq$ 2).
- No patients exhibited episodes of abnormal respiratory rate (<8 or >30 breaths/min) or significant movements.



No Patch displacement
at the end of procedure

First PFA delivery - LSPV



0 %

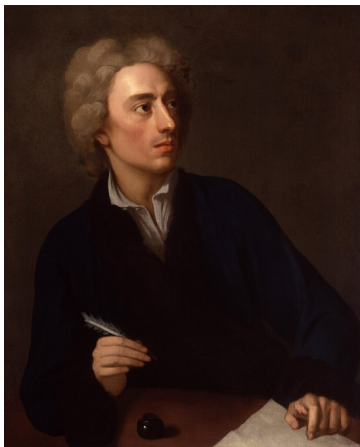
No Pain
No Memories

100

Comfortable for Cardiologist
Comfortable for Patients

%





GRAZIE DELL'ATTENZIONE

*Bisogna insegnare agli uomini avendo l'aria di non insegnare affatto,
proponendo loro cose che non sanno come se le avessero soltanto
dimenticate.....*

Alexander Pope, Saggio sulla critica, 1711



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degli Studi
della Campania
Luigi Vanvitelli

