

L'ANESTHESIE DE DEMAIN

Une science ou une fiction



2017

Dr F. BART
F. RABECHAULT



LE DÉCORS

Préambule



Original Article

One year of anaesthesia in France: A comprehensive survey based on the national medical information (PMSI) database. Part 1: In-hospital patients

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Enquête réalisée du 01/01/2010 au 31/12/2010

Résultats :

11 323 630 procédures anesthésiques
Concernant 8 568 630 séjours

42,7% d'augmentation par rapport à 1996 (7 937 000 procédures anesthésiques)

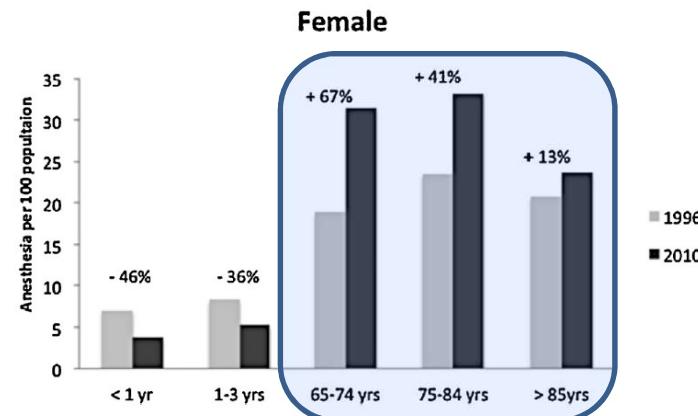
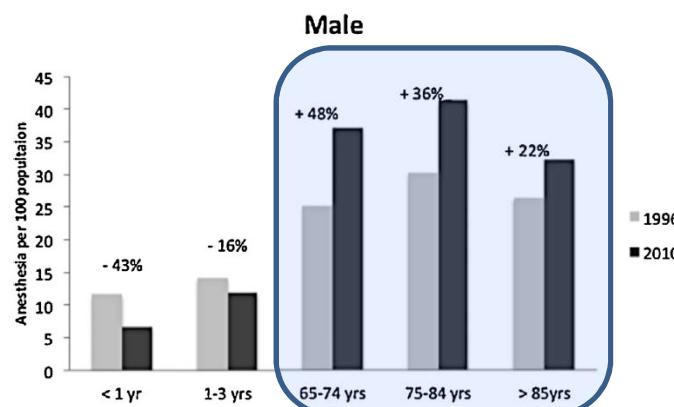


Fig. 5. Comparison of the annual rate of anaesthesia in the extremes of age groups (per 100 population).

The demographics of French Anaesthesiologists have increased by 17.8% in the same period (8347 anaesthesiologists in 1996 vs. 9831 in 2010) [11]. The number of anaesthetic procedures increased by 42.7%. The number of anaesthetic procedures per anaesthesiologist for one year has grown from 951 acts/anaesthetist/year, in 1996, to 1152 acts/anaesthetist/year in 2010. On the other hand, the mean age of French anaesthetists increased and 63.1% of anaesthetists were over 50 years old.

**Au 01/01/2014 :
57,3% des MAR >
50 ans**

ATLAS DE LA DÉMOGRAPHIE
MÉDICALE EN FRANCE

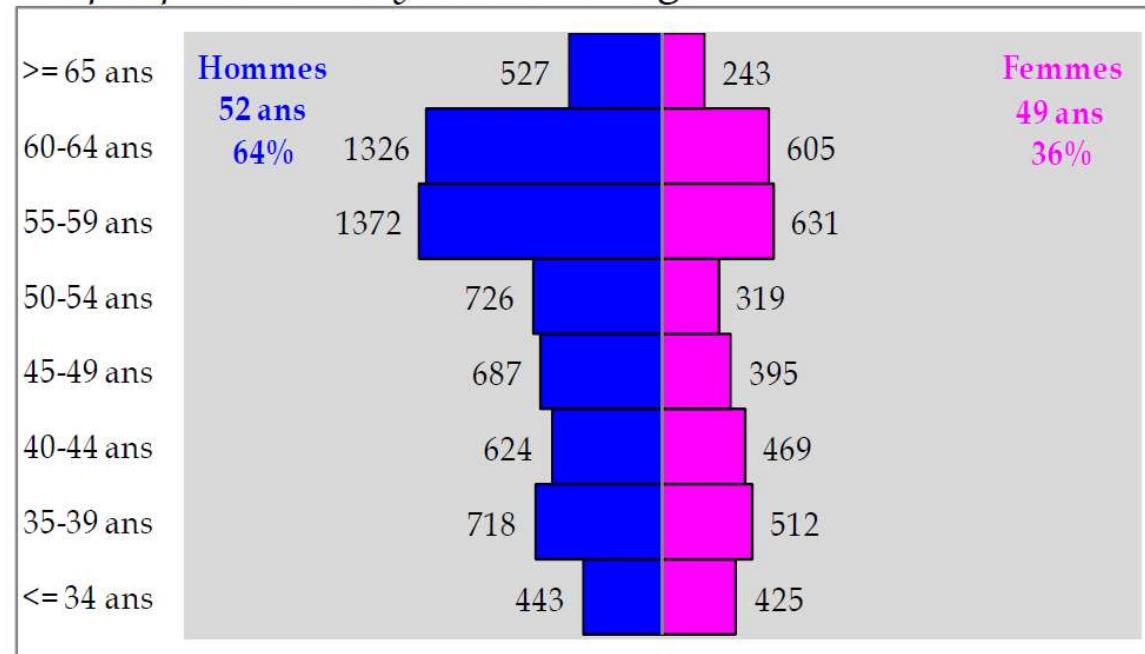
SITUATION AU 1^{ER} JANVIER 2014

CONSEIL NATIONAL DE L'ORDRE DES MÉDECINS
Dr Patrick BOUET, Président

Sous la direction du Dr Jean-François RAULT,
Président de la Section Santé Publique et Démographie Médicale.
Réalisé par Géraldine LE BRETON-LEROUVILLIOIS,
Géographe de la santé.



Graphique n°46 : Pyramide des âges



Comparatif sur l'évolution des anesthésistes :

+17,8% qui doivent être pondéré à l'augmentation des anesthésies (+42,7%)

Donc :

Passage de 951 anesthésie/an (1996)

À 1152 anesthésie/an (2010)

Soit 21% d'augmentation du nombre d'anesthésie par anesthésistes

Augmentation entre 1996 et 2010 de **58,64%** du nombre des IADEs.

theses/year, compared to 1152 anaesthesias/year in 2010. This represents an increase of 21% in the number of anaesthetics per year for every anaesthetist. The question is: how did we deal with that increase in the number of anaesthesia procedures? One hypothesis to explain the absorption of a greater number of cases is probably the more systematic presence of nurse anaesthetists during the anaesthetic care and as such the possibility for the anaesthetist to work concomitantly in two operating theatres. The number of nurse anaesthetists grew from 5000 in 1996 to 8526 in 2010, with an average annual growth rate of 4.6% [20]. On the other

Augmentation du nombre d'anesthésies	42,7%
Augmentation du nombre d'anesthésistes	17,8%
Augmentation du nombre d'IADEs	58,64%

Informations Rapides

■ Dette trimestrielle de Maastricht des administrations publiques - 1^{er} trimestre 2017

À la fin du premier trimestre 2017,
la dette publique s'établit à 98,9 % du PIB

La dette de Maastricht des APU en fin de trimestre et sa répartition par sous-secteur et par instrument

(en milliards d'euros)

	2016T1	2016T2	2016T3	2016T4	2017T1
Ensemble des adm. publiques	2139,5	2171,2	2161,0	2147,2	2209,6
en point de PIB (*)	97,1%	98,1%	97,4%	96,3%	98,9%
dont, par sous-secteur, consolidée (*) :					
Etat	1694,7	1724,5	1722,2	1709,9	1759,4
Organismes divers d'adm. centrale	19,5	18,7	17,2	12,7	11,7
Administrations publiques locales	194,3	194,7	193,1	199,6	198,4
Administrations de sécurité sociale	231,0	233,3	228,5	225,0	240,1

1995 1997 1999 2001 2003 2005 2007 2009 2011 2013 2015 2017

The Perioperative Surgical Home as a Future Perioperative Practice Model

Zeev N. Kain, MD, MBA,* Shermeen Vakharia, MD, MBA,* Leslie Garson, MD,* Scott Engwall, MD, MBA,* Ran Schwarzkopf, MD,† Ranjan Gupta, MD,† and Maxime Cannesson, MD, PhD*

From the Departments of *Anesthesiology & Perioperative Care, and
†Orthopedic Surgery, University of California Irvine, Irvine, California.

May 2014 • Volume 118 • Number 5

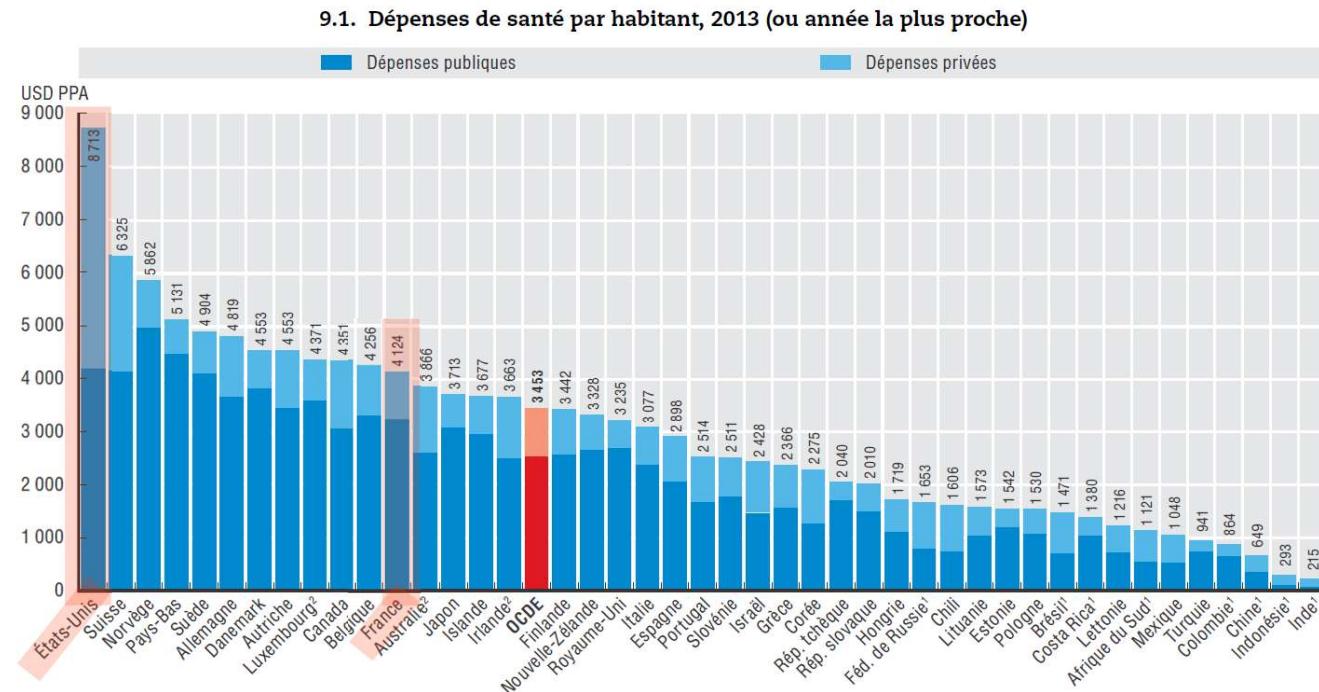
Pourquoi les dépenses de santé sont aussi élevées aux USA avec les indicateurs qualités à la traîne?

Future

A Call to

Zeev N. Kain
Berend Meijer

Des équipes
de soins
à domicile
et au travail
Mardi 10 mai
lieu : Paris

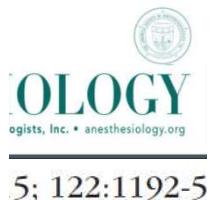


Note : Les dépenses excluent les investissements, sauf indication contraire.

1. Inclut les investissements.
2. Les données se rapportent à 2012.

Source : Statistiques de l'OCDE sur la santé 2015, <http://dx.doi.org/10.1787/health-data-fr>; Base de données de l'OMS sur les dépenses de santé mondiales.

StatLink <http://dx.doi.org/10.1787/88893282187>



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5; 122:1192-5

santé
du
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ORGANISATION OU REORGANISATION

Acte I

Récupération améliorée après chirurgie : points clés

AVANT

PHASE PRÉ OPÉRATOIRE

Les jours précédents l'intervention pour amener le patient à la meilleure condition possible

- Information et éducation du patient (consultation dédiée).
- Évaluation des comorbidités et optimisation de la condition physique (adaptation des traitements, anémie, nutrition, sevrages, kinésithérapie ou rééducation préopératoire, etc.).
- Préparation de la sortie.

Le jour de l'intervention

- Apport préopératoire de glucose ou hydrates de carbone.
- Pas de jeûne préopératoire prolongé (durée le plus souvent raccourcie).
- Prévention des infections.
- Prévention des complications thromboemboliques.
- Pas de prémédication anxiolytique systématique.

PENDANT

PHASE PEROPÉRATOIRE

Facteurs anesthésiques

- Prise en charge individualisée des apports hydriques.
- Prévention de l'hypothermie peropératoire.
- Analgésie multimodale et épargne des analgésiques morphiniques.
- Prévention des nausées et vomissements post opératoires.

Facteurs chirurgicaux (selon spécialités)

- Techniques d'abord chirurgical mini-invasives.
- Prise en compte des complications potentielles de la chirurgie.
- Réduction de l'usage des drains, des sondes naso-gastriques (chirurgie abdominale).

APRÈS

PHASE POST OPÉRATOIRE

Mobilisation

- Analgésie multimodale.
- Stimulation du transit intestinal en chirurgie abdominale (motilité).
- Réalimentation précoce.
- Lever et mobilisation précoce.
- Prévention des complications thromboemboliques.
- Préparation de la sortie.

Suivi

- Assurer le suivi à la sortie de l'hôpital.
- Reprise des activités du patient.
- Évaluation et retour sur l'expérience du patient.



HAUTE AUTORITÉ DE SANTÉ

Synthèse du rapport d'orientation

Programmes de récupération améliorée après chirurgie (RAAC)

Juin 2016

Juin 2016

RAPPORT D'ORIENTATION

Programmes de récupération améliorée après chirurgie (RAAC) : état des lieux et perspectives

Tableau 10. Exemple des intervenants lors des phases d'un programme RAAC (d'après P. Alfonsi, données personnelles)

Actions	Intervenants
Phase préopératoire	
Informations et conseils au patient	Patient ; IAO* ; Chirurgien ; MAR
Consultations spécialisées	Patient ; IAO ; Chirurgien ; MAR ± stomathérapeute ± nutritionniste ± gériatre ± cardiologue ± diabétologue ± pneumologue ± kinésithérapeutes...
Immunonutrition (si cancer)	Patient ; IAO ; Chirurgien
Préparation chirurgicale spécifique	Patient ; IAO ; Chirurgien ; IDE
Préparation médicale spécifique	Patient ; IAO ; MAR ; IDE
Kinésithérapie respiratoire	Patient ; IAO ; kinésithérapeute ; MAR
Jeun préopératoire	Patient ; MAR ; IDE
Apport en carbohydrates	Patient ; MAR ; IDE
Phase peropératoire	
Chirurgie mini-invasive par laparoscopie	Chirurgien ; MAR
Administration de corticostéroïdes	MAR ; IADE
Prévention de l'hypothermie	MAR ; IADE ; IBODE
Antibioprophylaxie	MAR ; IADE
Optimisation des apports liquidiens	MAR ; IADE
Prévention NVPO	MAR ; IADE
Ablation de la sonde nasogastrique	Chirurgien ; MAR ; IADE
Phase postopératoire	
Analgésie postopératoire: Principes généraux	MAR ; IADE ; IDE SSPI ; IAO ; IDE secteur d'hospitalisation
Analgésie postopératoire: Laparoscopie	MAR ; IADE ; IDE SSPI ; IAO ; IDE secteur d'hospitalisation
Analgésie postopératoire: Laparotomie	MAR ; IADE ; IDE SSPI ; IAO ; IDE secteur d'hospitalisation
Alimentation orale	Patient ; IAO ; Chirurgien ; IDE secteur d'hospitalisation ; MAR
Drainages chirurgicaux	Patient ; IAO ; Chirurgien ; IDE secteur d'hospitalisation
Drainage urinaire	Patient ; IAO ; Chirurgien ; IDE secteur d'hospitalisation
Thromboprophylaxie	Patient ; IAO ; Chirurgien ; IDE secteur d'hospitalisation ; MAR
Mobilisation	Patient ; IAO ; Chirurgien ; IDE secteur d'hospitalisation ; kinésithérapeute
Mastication de gommes (chewing-gum) : 3/ jour	Patient ; IAO ; Chirurgien ; IDE secteur d'hospitalisation
Education par Stomathérapeute (si stomie)	Patient ; IAO ; Stomathérapeute ; IDE secteur d'hospitalisation
Apports nutritionnels supplémentaires (si besoin)	Patient ; IAO ; Nutritionniste ; IDE secteur d'hospitalisation
Kinésithérapie respiratoire	Patient ; IAO ; kinésithérapeute ; IDE secteur d'hospitalisation

*Avec : IAO : Infirmière d'Accueil et d'Organisation ; MAR : Médecin Anesthésiste Réanimateur ; IDE : Infirmier Diplômé d'Etat ; IADE : Infirmier Anesthésiste Diplômé d'Etat ; IBODE : Infirmier de Bloc Opératoire Diplômé d'Etat ; SSPI : Salle de Surveillance PostInterventionnelle, AL : Anesthésiques Locaux, NVPO Nausées et Vomissements PostOpératoires



La préhabilitation. Préparer les patients à la chirurgie pour améliorer la récupération fonctionnelle et réduire la morbidité postopératoire

Prehabilitation. Preparing patients for surgery to improve functional recovery and reduce postoperative morbidity

C. Debes, M. Aissou, M. Beaussier*

Département d'anesthésie-réanimation chirurgicale, hôpital St-Antoine, université Pierre et Marie-Curie Paris 6, hôpitaux universitaires Est-Parisiens, AP-HP, 184, rue du Faubourg-St-Antoine, 75571 Paris cedex 12, France

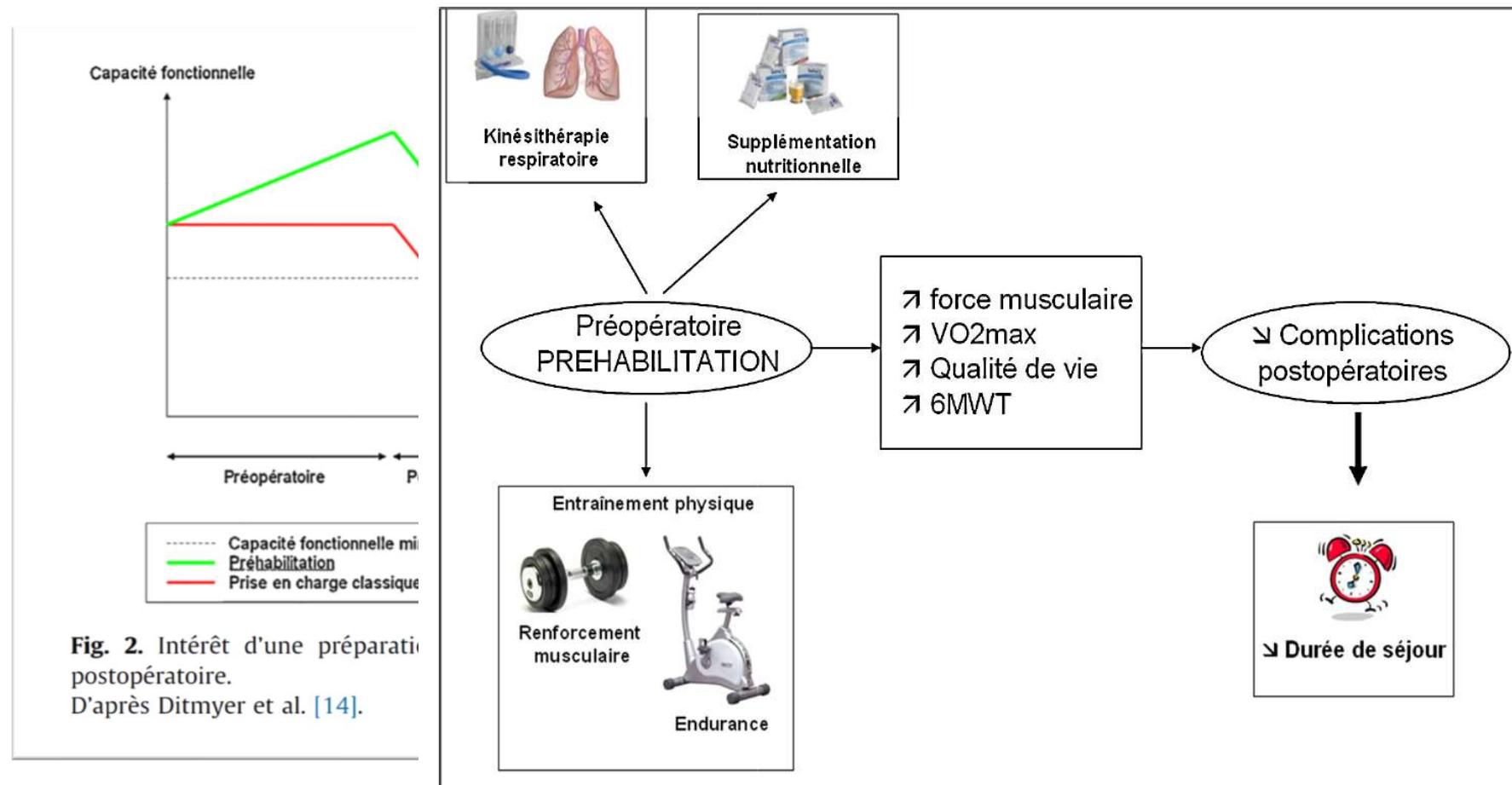


Fig. 2. Intérêt d'une préparation postopératoire.
D'après Ditmyer et al. [14].

Fig. 3. Schéma global du principe de préhabilitation et de ses bénéfices attendus.

La préhabilitation. Préparer les patients à la chirurgie pour améliorer la récupération fonctionnelle et réduire la morbidité postopératoire



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4. Conclusion

Le problème de la prise en charge de patients âgés et polypathologiques en périopératoire de chirurgie lourde va se poser de plus en plus dans les années à venir compte tenu de l'allongement de l'espérance de vie et de la meilleure accessibilité à ce type de chirurgie.

La préhabilitation consiste à préparer physiquement les patients à une intervention lourde, par un programme d'entraînement physique complet, progressif et adapté aux capacités de chaque individu. Son efficacité a été démontrée en chirurgie cardiovasculaire et probablement en chirurgie abdominale lourde. Elle doit s'intégrer dans une prise en charge complète du patient, et doit s'associer à une renutrition préopératoire et à des protocoles de réhabilitation postopératoire. C'est en optimisant toutes les étapes de la prise en charge chirurgicale, du diagnostic à la guérison, que nous pourrons améliorer le pronostic de ces patients fragiles.

La meilleure balance entre l'efficacité d'un programme de préparation et sa faisabilité reste encore mal connue. Les protocoles actuels sont mal codifiés et de nombreux paramètres restent à investiguer. La mise en place de tels protocoles peut être délicate en termes de disponibilité du personnel et de l'infrastructure à mettre en place. La réussite de cette prise en charge ambitieuse passera forcément par la mise en place de réseaux multidisciplinaires ville-hôpital impliquant l'ensemble du personnel médical et paramédical (chirurgien, anesthésiste, cancérologue, kinésithérapeute, nutritionniste).

Personalised Prehabilitation in High-risk Patients Undergoing
Elective Major Abdominal Surgery

A Randomized Blinded Controlled Trial

Anael Barberan-Garcia, MSc,* Marta Ubrié, MD,† Josep Roca, Prof. PhD,* Antonio M. Lacy, Prof. PhD,‡
Felip Burgos, PhD,* Raquel Risco, MD,† Dulce Momblán, PhD,§ Jaume Balust, MD,† Isabel Blanco, PhD,*
and Graciela Martínez-Pallí, PhD¶

TABLE 4. Postoperative Outcomes of the Intention-to-treat Population

	Control (n = 63)	Intervention (n = 62)	P
Hospital days of stay	13 (20)	8 (8)	0.078
ICU days of stay	4 (13)	1 (2)	0.078
Surgical reintervention	6 (10%)	2 (3%)	0.273
In-hospital mortality	1 (2)	1 (2)	1.000
Patients suffering postoperative complications	39 (62%)	19 (31%)	0.001
Number of complications per patient	1.4 (1.6)	0.5 (1.0)	0.001
Medical complications	0.9 (1.2)	0.2 (0.6)	<0.001
Surgical complications	0.5 (0.6)	0.3 (0.7)	0.119
Type of complication			
Medical			
Cardiovascular	8 (13%)	1 (2%)	0.033
Respiratory	10 (16%)	4 (7%)	0.155
Neurological	5 (8%)	2 (3%)	0.440
Acute kidney injury	4 (6%)	0 (0%)	0.119
Nausea/vomiting	6 (10%)	3 (5%)	0.491
Deep venous thrombosis	1 (2%)	0 (0%)	1.000
Urinary tract infection	4 (6%)	3 (5%)	1.000
Bloodstream infection (lab confirmed)	4 (6%)	1 (2%)	0.365
Infection of uncertain source	7 (11%)	0 (0%)	0.013
Others*	13 (21%)	6 (10%)	0.134
Surgical			
Postoperative hemorrhage	6 (10%)	4 (7%)	0.744
Anastomotic breakdown	3 (5%)	3 (5%)	1.000
Paralytic ileus	10 (16%)	0 (0%)	0.001
Surgical site infection (superficial and deep)	1 (2%)	1 (2%)	1.000
Surgical site infection (organ and space)	1 (2%)	1 (2%)	1.000
Mechanical ileus	0 (0%)	1 (2%)	0.496

Data are n (%) or mean (standard deviation).

*Liver insufficiency, diabetic decompensation, acute urinary retention. ICU, Intensive Care Unit.

A systematic review of prehabilitation programs in abdominal cancer surgery

Yasser Hijazi ^a, Umair Gondal ^b, Omer Aziz ^{a, b, *}

^a Colorectal and Peritoneal Oncology Centre, The Christie NHS Foundation Trust, UK

^b Faculty, Institute of Cancer Sciences, University of Manchester, UK



**Préhabilitation dans la chirurgie carcinologique abdominale reste hétérogène :
Dans leur composition, leur mode d'administration, les données mesurées
...il faut standardiser avant de pouvoir évaluer sur large échelle**

PRE-SURGERY EXERCISE AND POST-OPERATIVE PHYSICAL FUNCTION OF PEOPLE UNDERGOING KNEE REPLACEMENT SURGERY: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

REVIEW ARTICLE

Maria A. PEER, PT, MSc¹, Robert RUSH, MSc¹, Peter D. GALLACHER, FRCS, T&O² and Nigel GLEESON, PhD, FBases¹
From the ¹School of Health Sciences, Queen Margaret University, Edinburgh and ²The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, Oswestry, UK

Journal of Rehabilitation Medicine **JRM**

J Rehabil Med 2017; 49: 304–315

Manque de preuves solides pour guider des recommandations de pré habilitation préopératoire d'arthroplastie totale du genou efficacement

British Journal of Anaesthesia 114 (1): 8–9 (2015)
Advance Access publication 21 August 2014 · doi:10.1093/bja/aeu265

Anaesthesiology and perioperative medicine around the world: different names, same goals

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² Department of Anaesthesiology and Critical Care, University College of London, London, UK

Problématique : Comment faire mieux avec moins?

Diminution des recettes fiscales, et avoir pour objectifs d'améliorer la satisfaction et les résultats pour les patients

Donc, développement de modèles innovant tel que :
ERAS (Enhanced Recovery after Surgery Care Pathway)
PSH

Table 1. Main Items of the Enhanced Recovery after Surgery Care Pathway

Preoperative	Intraoperative	Postoperative
Patient counseling	No gastric tube	Exercise therapy
Administration of fluids and carbohydrates	Thoracic epidural anesthesia	No oral opioids
No fasting	Short-acting anesthetic drugs	Use of NSAIDS
Minimum bowel preparation	Goal-directed fluid therapy	PONV prevention
No premedication with benzodiazepines	Small incision	Stimulation of intestinal motility
	No drains	Early mobilization
	Body temperature control	Early oral intake

PONV = postoperative nausea and vomiting; NSAIDS = nonsteroidal antiinflammatory drugs.

Mais qu'est-ce que le PSH???

THE OPEN MIND



The Perioperative Surgical Home as a Future Perioperative Practice Model

From the Departments of *Anesthesiology & Perioperative Care, and
†Orthopedic Surgery, University of California Irvine, Irvine, California.

Zeev N. Kain, MD, MBA,* Shermeen Vakharia, MD, MBA,* Leslie Garson, MD,* Scott Engwall, MD, MBA,*
Ran Schwarzkopf, MD,† Ranjan Gupta, MD,† and Maxime Cannesson, MD, PhD*

May 2014 • Volume 118 • Number 5

The Perioperative Surgical Home (PSH)^{3,7} is a practice model that has been proposed as one of the potential solutions to our fragmented and costly perioperative system. The PSH is defined by the American Society of Anesthesiologists as “a patient-centered and physician-led multidisciplinary and team-based system of coordinated care that guides the patient throughout the entire surgical experience”.^{a,3,7,8} The overall goal of the PSH is to provide improved clinical outcomes and better perioperative service at lower cost. The purpose of this *The Open Mind* is to detail how the PSH model will achieve these goals and how the specialty of anesthesiology may benefit from this practice model.

- Concept très large ayant pour but une optimisation de la PEC et une diminution des coûts
- Optimisation de la PEC débute à la minute où est posée l'indication chirurgicale, et allant jusqu'au 30^{ème} jour après la sortie
- Associant des protocoles pré, per, et post chir minimisant les variations individuelles

Enhanced Recovery after Surgery Versus Perioperative Surgical Home: Is It All in the Name?

Maxime Cannesson, MD, PhD, and Zeev Kain, MD, MBA

From the Department of Anesthesiology & Perioperative Care, University of California Irvine, Orange, California.

www.anesthesia-analgesia.org
May 2014 • Volume 118 • Number 5

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May 2014 • Volume 118 • Number 5

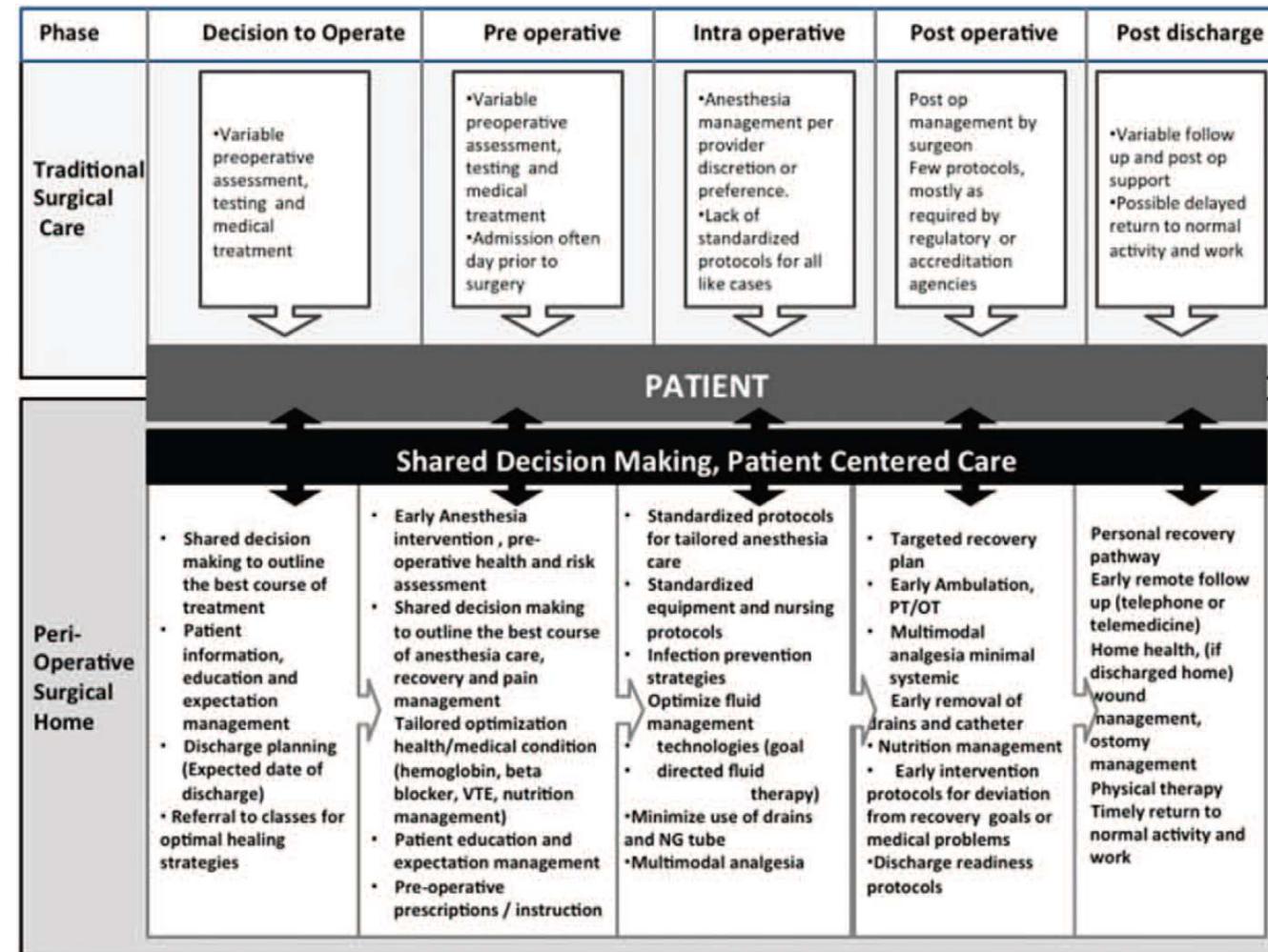


Figure 1. Existing versus suggested perioperative flow system.

The Perioperative Surgical Home as a Future Perioperative Practice Model

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May 2014 • Volume 118 • Number 5

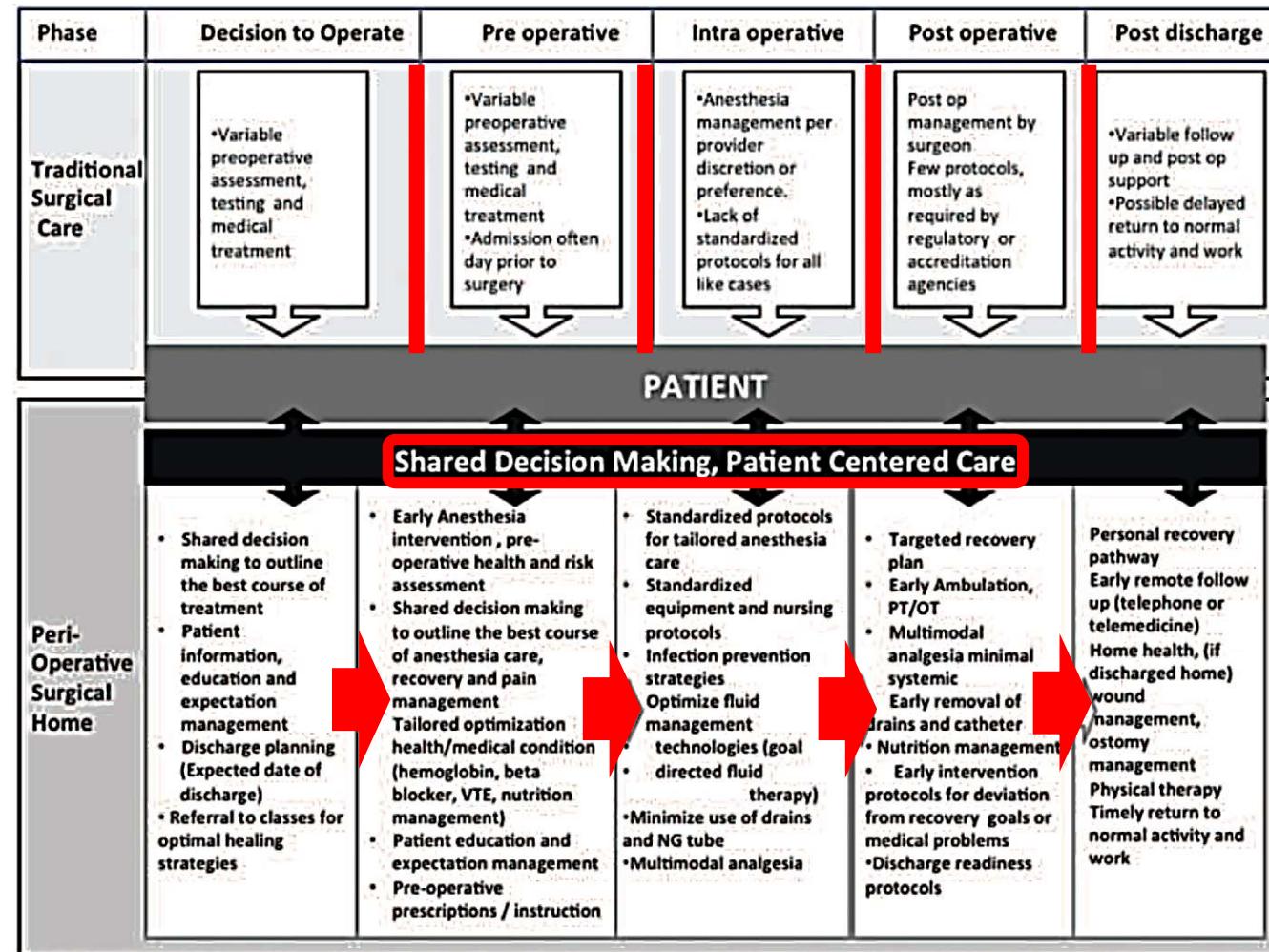


Figure 1. Existing versus suggested perioperative flow system.

En terme Financier, le PSH...

RESEARCH

Open Access

Total joint Perioperative Surgical Home: an observational financial review

Darren R Raphael^{1*}, Maxime Cannesson¹, Ran Schwarzkopf², Leslie M Garson¹, Shermeen B Vakharia¹, Ranjan Gupta² and Zeev N Kain¹



Raphael et al. *Perioperative Medicine* 2014, 3:6
<http://www.perioperativemedicinejournal.com/content/3/1/6>

Table 5 Benchmark cost comparison: average hospital cost excluding implants^a

	Total Joint-PSH	Benchmark [16]
TKA	\$10,042 ± 1,305	\$17,588
THA	\$9952 ± 1,294	\$16,267

PSH, perioperative surgical home; THA, total hip arthroplasty; TKA, total knee arthroplasty.

^aData are expressed as mean ± SD.

Conclusions

We found that direct hospital costs can be driven substantially below benchmark levels using the Total Joint-PSH pathway, and suggest that implementation of a PSH model of care could help institutions to better control process costs and identify unwarranted costs. In the case of the Total Joint-PSH, we have identified an opportunity to decrease variation in the cost of implants and the cost of PACU time.

16. Kozma CM, Slaton T, Paris A, Edgell ET: Cost and utilization of healthcare services for hip and knee replacement. *J Med Econ* 2013, 16(7):888–896.

EVOLUTION DES ROLES ???

Acte II

Anaesthesiology and perioperative medicine around the world: different names, same goals

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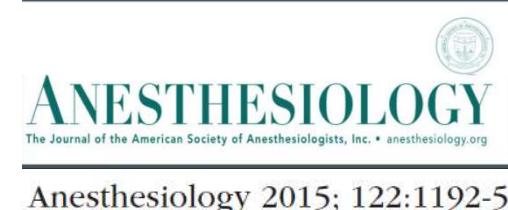
As most healthcare systems around the globe have been forced to find innovative ways to improve patients' outcome and satisfaction while reducing their cost,¹ many countries, including the USA, UK, France, the rest of Europe, and Australia, have developed strategies to increase the role of anaesthesiologists in perioperative medicine. These countries have responded to diminishing fiscal resources in their healthcare system with innovative models such as enhanced recovery after surgery (ERAS)² and perioperative surgical home (PSH).^{3 4} Regardless of what these clinical delivery models are called, they are all focusing on delivering care with better clinical outcome, better service, and more efficiency. This is achieved by reduced variability, standardized protocols, and improved coordinated care by leveraging information technology and evidence-based medicine.^{2 5 6} Interestingly, all of these systems are slowly but surely proving to be viable and sustainable solutions.^{7–9}

***Le PSH crée un besoin,
Nécessite d'un leader
afin de manager la
PEC pluridisciplinaire
tout au long de cette
ligne temporelle***

Future of Anesthesiology Is Perioperative Medicine

A Call for Action

Zeev N. Kain, M.D., M.B.A., Jane C. K. Fitch, M.D., Jeffrey R. Kirsch, M.D., Berend Mets, M.B., Ph.D., F.R.C.A., Ronald G. Pearl, M.D., Ph.D.



Anesthesiology 2015; 122:1192-5

Table 1. Proposed Competencies for the Perioperative Surgical Home

American College of Graduate Medical Education Competency	PSH-Specific Subcompetencies	Practice-based learning and improvement	Ability to evaluate EBM application: Biases in clinical trials, validity, emphasis, and critical evaluation for practice
Patient care	EBM-based preoperative risk reduction and optimization strategies (e.g., β blocker, statin, anemia corrections; carbohydrate loading) Practices EBM intraoperative management (goal-directed therapy, glycemic control, normothermia) Practices EBM postoperative management and EBM enhanced recovery strategies (e.g., early mobilization, venous thromboembolism prophylaxis, wound and skin care, urinary catheter removal) Primary consultant in general medical issues that commonly present in surgical patient population	Practice-based learning and improvement	Ability to improve own practice through continuous quality management tools: Practice assessment: dashboards, practice improvement plans Use of practice guidelines, parameters in own and relevant specialties (e.g., surgery care improvement process), in evaluating practice outcomes WHO Safe Surgery checklist implementation Understanding of practice model such as PSH, accountable care organization, and enhanced recovery after surgery Disruptive technology, change management Understands current payment models (e.g., bundled payments, acute care episode, gain sharing)
Patient care (technical skills required)	Electrocardiogram—advanced interpretation skills Surface ultrasound (ultrasound point of care) Pulmonary function tests including advanced interpretation skills Coronary artery stents management including perioperative management of anti-platelet therapy Cardiac pacemakers management including bedside interrogation Implantable cardioverter defibrillators management including bedside interrogation Insulin pumps management including rate adjustment Intrathecral pumps management including interrogation and refilling Thoracostomy tube placement	System-based practice	Systems approach to patient management—clinical pathway protocols Familiar with tools/principles for systems improvement in efficiency, cost reduction, quality: Lean, Six Sigma Basics of hospital organizations and finance (e.g., professional fee vs. technical fee) Principles of operating rooms management: block allocation, staffing plans, patient flow (value stream mapping) Principles of process flow and perioperative care coordination (value stream mapping) Transition of care (e.g., readmission, case management, discharge planning) Use of practice guidelines, parameters in own and relevant specialties Principles of patient safety (e.g., human factors, root cause analysis) Patient-centered communication skills
Medical knowledge (management includes preoperative evaluation and risk reduction as well as postoperative management should the complication occur)	Congestive heart failure Diabetes Pneumonia Sepsis Chronic obstructive pulmonary disease Acute kidney injury Urinary tract infection Venous thrombus embolus Stroke Asthma Acute coronary syndrome Delirium Goal-directed therapy and blood management Deep vein thrombosis Acute renal failure Skin and wound breakdown Postoperative prevention/management falls Myocardial infarction Prevention of “failure to rescue” Basic postoperative principles/need: Physical therapy, alternative pain techniques	Communication and interpersonal skills	Understand change management, Conflict resolution, Familiar with organizational learning: Double loop vs. single loop. Understands the principals of strategic planning Task management, team working and situational awareness Use of information technology to enhance continuity of care across the episode of care (e.g., hand-offs, posthospitalization patient-centered medical home) Transition of care Acquire skills to supervise healthcare extenders throughout the entire perioperative continuum Professional identity as a “perioperative medicine expert” Transparency of practice Focus on collaborative, trusting relationships with patients, other disciplines Patient-centered care within the context of the PSH (e.g., shared decision-making)
			Developed by the American Society of Anesthesiologists subcommittee of Perioperative Surgical Home Education. Chair: Zeev N. Kain, M.D., M.B.A.; membership: Amr Abouleish, M.D., Cynthia Anderson, M.D., Beverly P. Chang, M.D., Shubjeet Kaur, M.D., Gary Stier, M.D., M.B.A., Rebecca S. Twersky, M.D., M.P.H., Thomas Vetter, M.D., M.P.H., Neal Cohen, M.D. (Liaison, Committee on Academic Anesthesiology), Linda Mason, M.D. (Liaison, Committee on Academic Anesthesiology). EBM = evidence-based medicine; PSH = perioperative surgical home; WHO = World Health Organization.

Future of Anesthesiology Is Perioperative Medicine

A Call for Action

Zeev N. Kain, M.D., M.B.A., Jane C. K. Fitch, M.D., Jeffrey R. Kirsch, M.D., Berend Mets, M.B., Ph.D., F.R.C.A., Ronald G. Pearl, M.D., Ph.D.



Anesthesiology 2015; 122:1192-5

Quelle profession médicale regroupe toutes ces compétences???

Table 1. Proposed Competencies for the Perioperative Surgical Home

American College of Graduate Medical Education Competency	PSH-Specific Subcompetencies	Practice-based learning and improvement	System-based practice	Communication and interpersonal skills	Professionalism
Patient care	EBM-based preoperative risk reduction and optimization strategies (e.g., β blocker, statin, anemia corrections; carbohydrate loading) Practices EBM intraoperative management (goal-directed therapy, glycemic control, normothermia) Practices EBM postoperative management and EBM enhanced recovery strategies (e.g., early mobilization, venous thromboembolism prophylaxis, wound and skin care, urinary catheter removal) Primary consultant in general medical issues that commonly present in surgical patient population	Ability to evaluate EBM application: Biases in clinical trials, validity, emphasis, and critical evaluation for practice Ability to improve own practice through continuous quality management tools: Practice assessment: dashboards, practice improvement plans Use of practice guidelines, parameters in own and relevant specialties (e.g., surgery care improvement process), in evaluating practice outcomes WHO Safe Surgery checklist implementation Understanding of practice model such as PSH, accountable care organization, and enhanced recovery after surgery Disruptive technology, change management Understands current payment models (e.g., bundled payments, acute care episode, gain sharing)	Systems approach to patient management—clinical pathway protocols Familiar with tools/principles for systems improvement in efficiency, cost reduction, quality: Lean, Six Sigma Basics of hospital organizations and finance (e.g., professional fee vs. technical fee) Principles of operating rooms management: block allocation, staffing plans, patient flow (value stream mapping) Principles of process flow and perioperative care coordination (value stream mapping) Transition of care (e.g., readmission, case management, discharge planning) Use of practice guidelines, parameters in own and relevant specialties Principles of patient safety (e.g., human factors, root cause analysis) Patient-centered communication skills Understand change management, conflict resolution. Familiar with organizational learning: Double loop vs. single loop. Understands the principles of strategic planning Task management, team working and situational awareness Use of information technology to enhance continuity of care across the episode of care (e.g., hand-offs, posthospitalization patient-centered medical home) Transition of care Acquire skills to supervise healthcare extenders throughout the entire perioperative continuum Professional identity as a “perioperative medicine expert” Transparency of practice Focus on collaborative, trusting relationships with patients, other disciplines Patient-centered care within the context of the PSH (e.g., shared decision-making)		
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EBM = evidence-based medicine; PSH = perioperative surgical home; WHO = World Health Organization.



The Future of Anesthesiology: Should the Perioperative Surgical Home Redefine Us?



Richard C. Priell, MD, MBA, FCCM,* Robert C. Morell, MD,† Douglas B. Coursin, MD, FCCP,‡
Sorin J. Brull, MD, FCARCSI (Hon),§ Steven J. Barker, PhD, MD,|| Mark J. Rice, MD,¶
Jeffery S. Vender, MD, FCCM, FCCP, MBA, #** and Neal H. Cohen, MD, MS††

May 2015 • Volume 120 • Number 5

L'anesthésiste s'éloigne du BLOC?

Pression démographique
Pression institutionnelle
Nouveau rôle (PSH)

AUTOMATISATION DE L'ANESTHÉSIE?

Acte III



EDITORIAL

Closed-Loop Systems in Anesthesia: Reality or Fantasy?

Timothy E. Miller, MB, ChB, FRCA, and Tong J. Gan, MD, MHS, FRCA

Permet à l'anesthésiste de se concentrer sur d'autres tâches

Evite l'erreur humaine, les troubles de l'attention

Intérêt clinique pour garantir la profondeur d'anesthésie

Autres boucles fermées possibles?

Anesthésie en boucle

- Les débuts en 1950

ELECTROENCEPHALOGRAPHICALLY CONTROLLED ANESTHESIA IN ABDOMINAL SURGERY

CHARLES W. MAYO, M.D.
REGINALD G. BICKFORD, M.B.
and
ALBERT FAULCONER Jr., M.D.
Rochester, Minn.

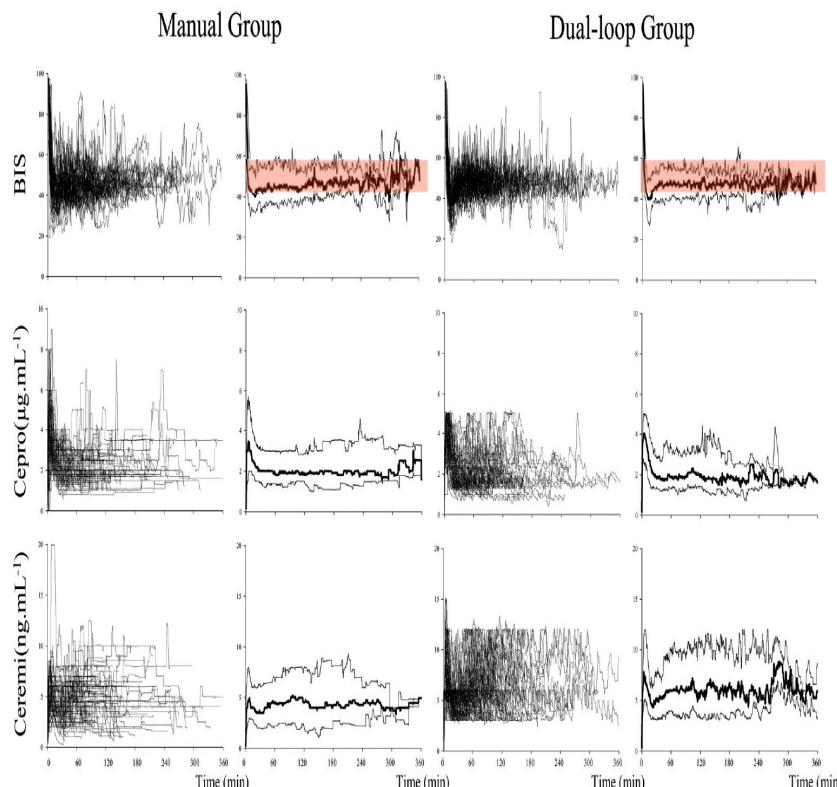
- Depuis, cela reste du domaine de la recherche clinique
- Boucle fermée, Closed-loop, Feed-back control
→ aucune intervention humaine

CME

Closed-Loop Coadministration of Propofol and Remifentanil Guided by Bispectral Index: A Randomized Multicenter Study

Ngai Liu, MD, PhD,* Thierry Chazot, MD,* Sophie Hamada, MD,* Alain Landais, MD,† Nathalie Boichut, MD,‡ Corinne Dussauzoy, MD,§ Bernard Trillat, MSc,|| Laurent Beydon, MD,§ Emmanuel Samain, MD,‡ Daniel I. Sessler, MD,¶ and Marc Fischler, MD,*

CONCLUSION: The controller allows the automated delivery of propofol and remifentanil and maintains BIS values in predetermined boundaries during general anesthesia better than manual administration. (Anesth Analg 2011;112:546–57)



Feasibility of Closed-loop Titration of Propofol and Remifentanil Guided by the Spectral M-Entropy Monitor

Ngai Liu, M.D., Ph.D.,* Morgan Le Guen, M.D.,* Fatima Benabbes-Lambert, M.D.,† Thierry Chazot, M.D.,* Bernard Trillat, M.Sc.,‡ Daniel I. Sessler, M.D.,§ Marc Fischler, M.D.||

Conclusion: Intraoperative automated control of hypnosis and analgesia guided by M-Entropy is clinically feasible and more precise than skilled manual control.

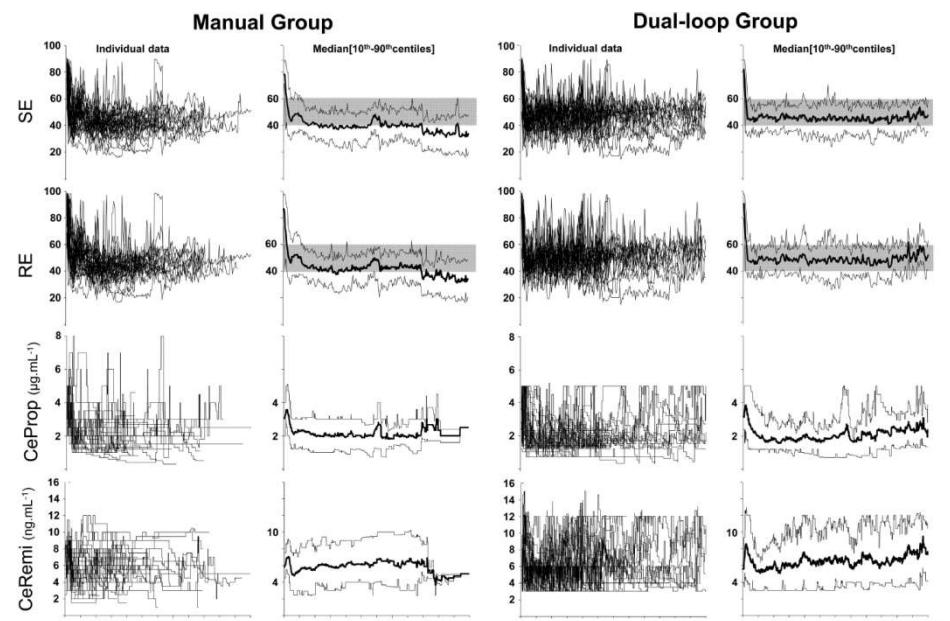


Fig. 3. State entropy (SE) and response entropy (RE) values and calculated effect-site concentration of propofol (CeProp) and remifentanil (CeRemi) from induction to discontinuation of these drugs. All individual values are shown; data are averaged for graphical representation with a moving average filter of 1 min duration. Median values (thick line) are presented with 10th and 90th percentiles (thin line). Dual-loop = closed-loop control of propofol and remifentanil; Manual = manual group guided by spectral entropy.

L'administration automatisée des médicaments : une aide pour l'anesthésiste réanimateur militaire.

E. Batjom^a, N. Liu^b, T. Chazot^b, B. Lenoir^c.

^a Service d'anesthésie-réanimation, HIA Bégin, 69 avenue de Paris – 94120 Saint-Mandé Cedex.

^b Service d'anesthésie-réanimation, Hôpital Foch – 92150 Suresnes.

^c Service d'anesthésie-réanimation, HIA Percy, BP 406 – 92141 Clamart Cedex.

Article reçu le 17 décembre 2008, accepté le 19 avril 2010.

Conclusion.

Les boucles fermées peuvent prendre tout leur intérêt dans de nombreuses situations rencontrées par les médecins militaires, en particulier les anesthésistes-réanimateurs, en prenant une part de la charge des soins tout en améliorant leur qualité. Ces boucles fermées peuvent permettre par exemple la perfusion automatisée des agents de la sédation ou de l'anesthésie ou l'optimisation de la ventilation mécanique. Actuellement, ces outils sont encore du domaine de la recherche clinique mais ils ne doivent pas être négligés par le Service de santé des armées, car ils devraient se généraliser dans les années à venir en médecine civile, et espérons le, avoir des applications concrètes pour les médecins militaires.

Autre type de boucles fermées



Evaluation of a novel closed-loop fluid-administration system based on dynamic predictors of fluid responsiveness: an *in silico* simulation study

Joseph Rinehart¹, Brenton Alexander¹, Yannick Le Manach^{2,3}, Christoph K Hofer⁴, Benoit Tavernier⁵, Zeev N Kain¹ and Maxime Cannesson^{1*}

LIR : Learning Intravenous Resuscitator

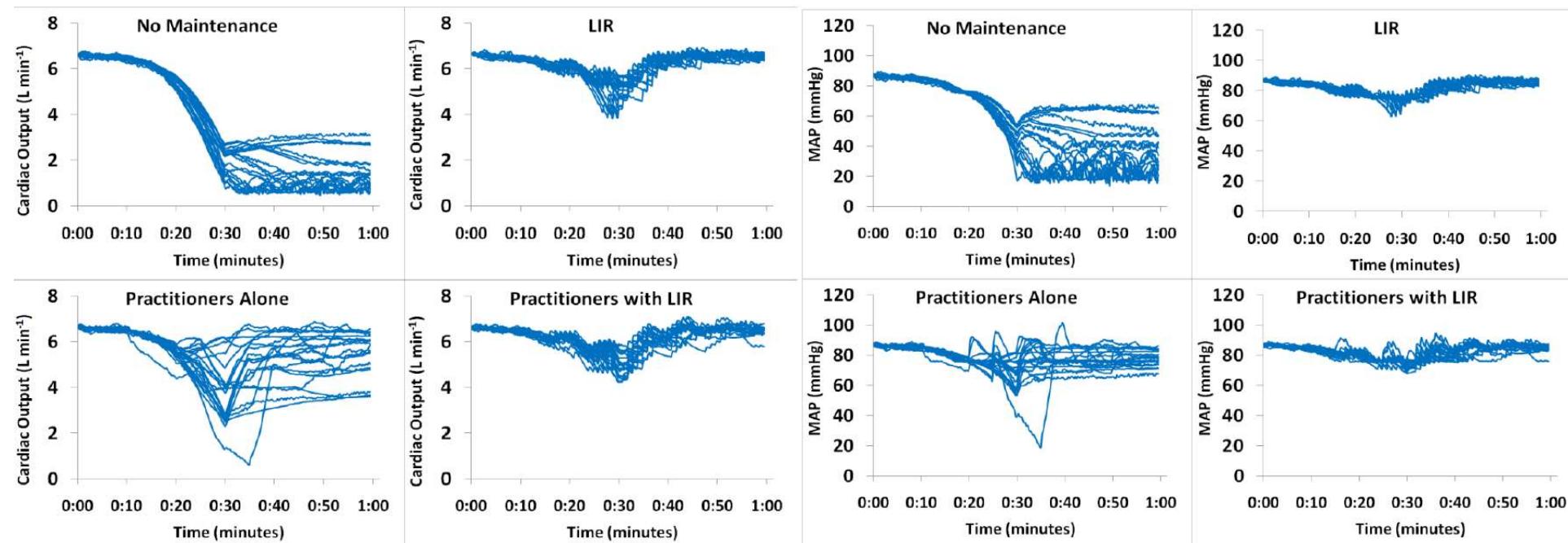


Figure 2 Cardiac output in Phase 2 groups; closed-loop system versus practitioner management during a simulated hemorrhage scenario. Each line represents a single case. Once the hemorrhage began, the LIR-managed groups intervened significantly earlier than the practitioner group and gave more total fluid. The mean, minimum, and final cardiac output was higher in both LIR-managed groups than in the practitioner group, and the coefficient of variance was lower. LIR, Learning Intravenous Resuscitator.

Figure 3 Mean arterial pressure in Phase 2 groups: closed-loop system versus practitioner management during a simulated hemorrhage scenario. Each line represents a single case. We observed no difference in mean arterial pressure between intervention groups, but all were significantly higher than those in the unmanaged group.

Conclusion: These data demonstrate that LIR is an effective volumetric resuscitator in simulated hemorrhage scenarios and improved physician management of the simulated hemorrhages.

Closed-Loop Fluid Administration Compared to Anesthesiologist Management for Hemodynamic Optimization and Resuscitation During Surgery: An In Vivo Study



Joseph Rinehart, MD,* Christine Lee, BS,* Cecilia Canales, MPH,* Allen Kong, MD,†
Zeev Kain, MD, MBA,* and Maxime Cannesson, MD, PhD,*

METHODS: Sixteen Yorkshire pigs underwent a 2-phase hemorrhage protocol and were resuscitated by either the Learning Intravenous Resuscitator closed-loop system or an anesthesiologist. Median hemodynamic values and variation of hemodynamics were compared between groups.

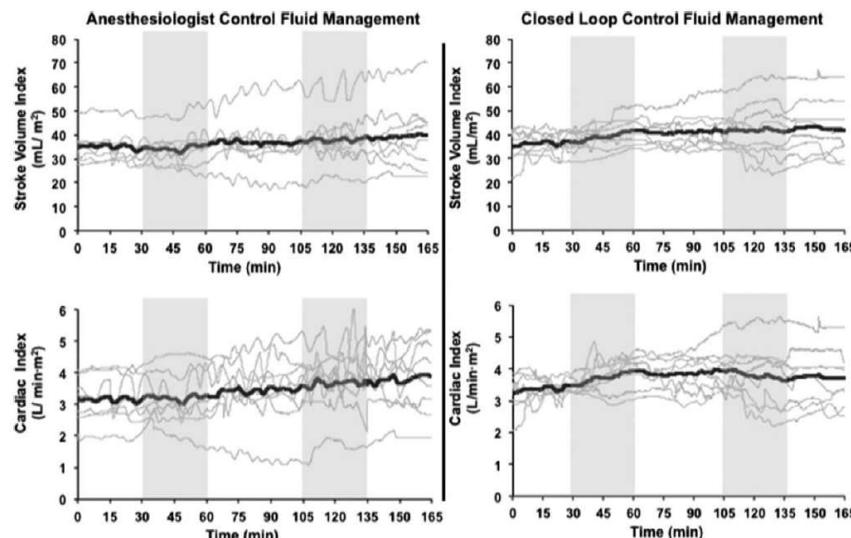


Figure 2. Stroke volume index and cardiac index for both groups during the study protocol. Each line represents 1 case, with 1 bold line representing the average of all the cases. Data are shown as absolute values. The gray regions in the graphs highlight hemorrhage periods.

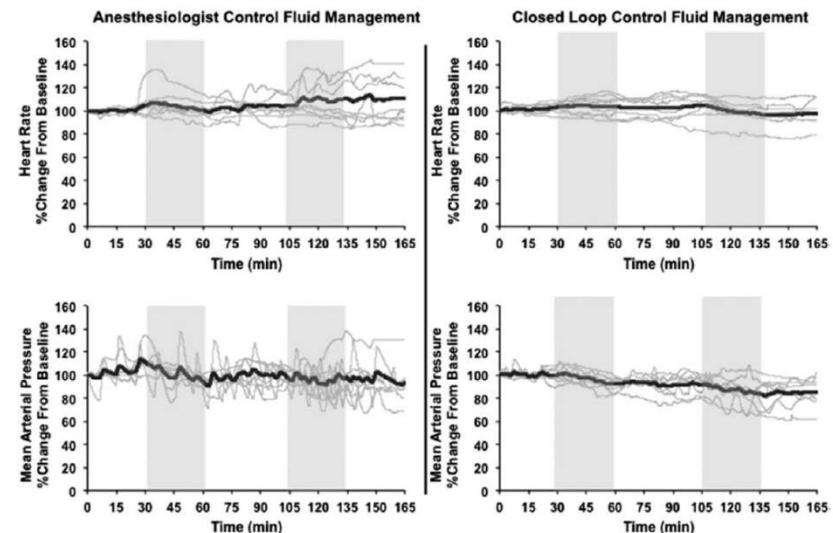


Figure 3. Heart rate and mean arterial pressure for both groups during the study protocol. Each line represents 1 case, with 1 bold line representing the average of all the cases. Data are shown as percentage change from baseline values. The gray regions in the graphs highlight hemorrhage periods.

CONCLUSION: This in vivo study building on previous simulation work demonstrates that the closed-loop fluid management system used in this experiment can perform fluid resuscitation during mild and severe hemorrhages and is able to maintain high cardiac output and stroke volume while reducing hemodynamic variability. (Anesth Analg 2013;117:1119–29)

CME **Closed-Loop Control of Anesthesia: A Primer for Anesthesiologists**

Guy A. Dumont, PhD, PEng*† and J. Mark Ansermino, MBBCh, MSc (Inf), FFA (SA), FRCPC†

Table 1. Engineering Steps Required for the Development of an Anesthesia Closed-Loop Control System Suitable for Clinical Trials

Step	Particulars
System identification	Nominal model Uncertainty characterization
Specifications	Induction Maintenance Performance Robustness
Controller design	Stability analysis Robustness analysis Fallback modes
Computer simulations	Monte-Carlo or similar simulations Computation of performance metrics
System integration and development	Definition of hardware and software platform Integration of pumps and monitors Graphical user interface (GUI) Rigorous, traceable, and verifiable software development GUI testing
Usability studies	Identification of usability issues Risk mitigation and minimization
Hardware-in-the-loop simulations	Extremes of performance Multivariable integration Training
Application for regulatory body and research ethics approval to proceed to clinical trials	Good to go!

CONCLUSIONS

The introduction of automation promises to reduce the variability and increase the safety of many processes in anesthesia, including automated anesthetic drug delivery. The ubiquitous real gains in performance promised by adoption of feedback control can be realized in anesthesia but will necessitate a strong engineering approach to the design, analysis, validation, and verification of closed-loop systems. Given that these elements are secured, and if major suppliers of anesthesia equipment are engaged in participating in the development and testing of such a system, we may in a few years see widespread use of closed-loop control of anesthesia and analgesia in daily clinical practice. ■



Closed LOOP ou automatisation de l'anesthésie

- Boucle fermée propofol : BIS
- Boucle fermée analgésique : ANI
-

ET LE MONITORAGE???

Acte IV

- **Changement d'organisation :**
→optimisation de l'efficience

- **Elargissement du rôle de l'anesthésiste**

Future of Anesthesiology Is Perioperative Medicine

A Call for Action

Zeev N. Kain, M.D., M.B.A., Jane C. K. Fitch, M.D., Jeffrey R. Kirsch, M.D.,
Berend Mets, M.B., Ph.D., F.R.C.A., Ronald G. Pearl, M.D., Ph.D.



- **Mise en pratique des RFE**
- **Closed Loop? Ou Closed IADE Loop?**
- **Monitorage à la hauteur du défi**

“The discovery of a technically simple and nontraumatic way of estimating the output of the heart per beat is something of an El Dorado.”

Donald A. McDonald, 1960

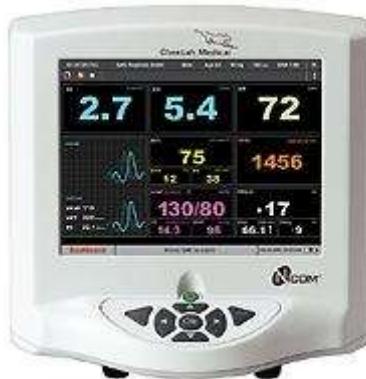
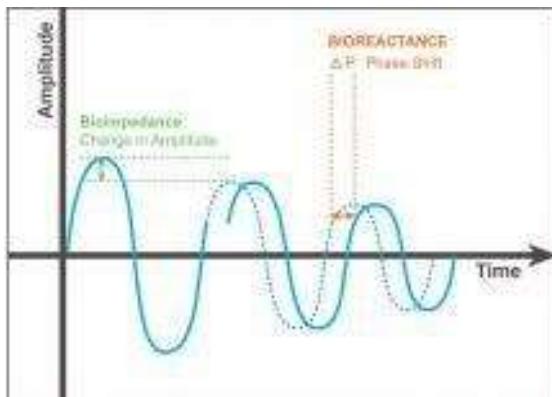
Monitorage idéal

- *moins invasif et iatrogénique possible*
- *fournir une information continue*
- *être automatique et ne pas nécessiter d'étalonnage*
- *Facile à utiliser*
- *permettant une adaptation thérapeutique*
- *Précis*
- *Reproductible*
- *Temps de réponse rapide*
- *Mesure fiables des variations*
- *Non opérateur dépendant*
- *N'engendrer qu'un surcoût tolérable pour l'utilisateur*
- *Bénéfique en terme de morbi-mortalité*

→ impose qu'il y ait **une stratégie derrière le monitorage**

L'Avenir?

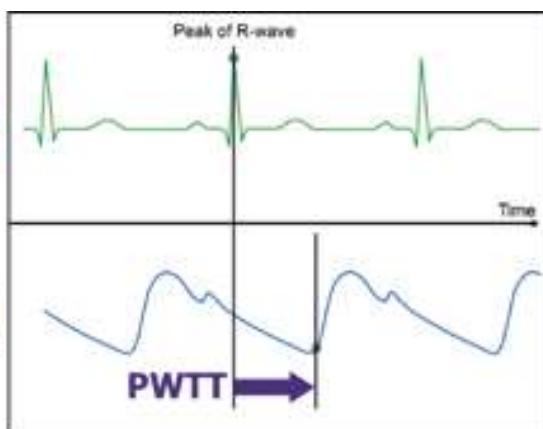
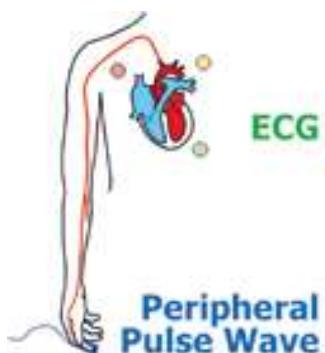
Bio Réactance



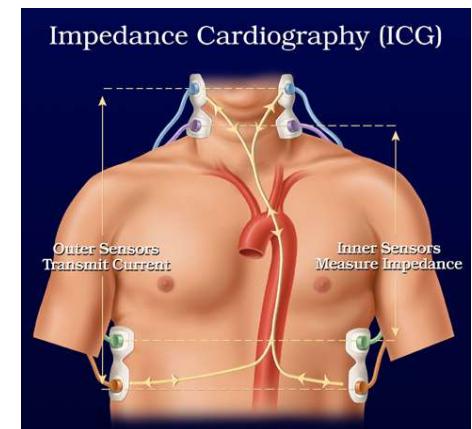
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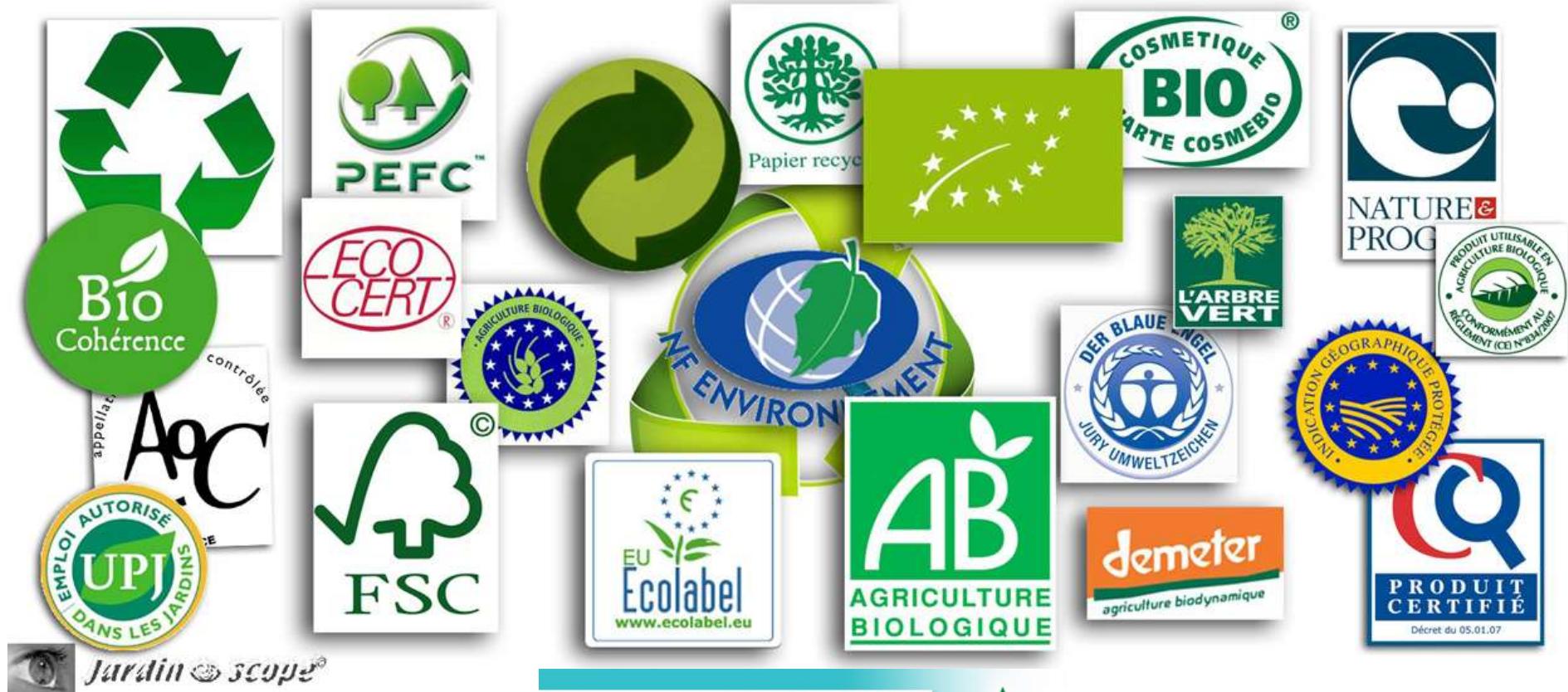
Bio Impédance



PRESQUE LA FIN

Acte préfinal

Bio BLOC Ecoresponsable



The Lancet Countdown on health and climate change: from 25 years of inaction to a global transformation for public health

Nick Watts, Markus Amann, Sonja Ayeb-Karlsson, Kristine Belesova, Timothy Bouley, Maxwell Boykoff, Peter Byass, Wenjia Cai, Diarmid Campbell-Lendrum, Jonathan Chambers, Peter M Cox, Meaghan Daly, Niheer Dasandi, Michael Davies, Michael Depledge, Anneliese Depoux, Paula Dominguez-Salas, Paul Drummond, Paul Ekins, Antoine Flahault, Howard Frumkin, Lucien Georgeson, Mostafa Ghanei, Delia Grace, Hilary Graham, Rébecca Grojsman, Andy Haines, Ian Hamilton, Stella Hartinger, Anne Johnson, Ilan Kelman, Gregor Kiesewetter, Dominic Kniveton, Lu Liang, Melissa Lott, Robert Lowe, Georgina Mace, Maquins Odhiambo Sewe, Mark Maslin, Slava Mikhaylov, James Milner, Ali Mohammad Latifi, Maziar Moradi-Lakeh, Karyn Morrissey, Kris Murray, Tara Neville, Maria Nilsson, Tadj Oreszczyn, Fereidoon Owfi, David Pencheon, Steve Pye, Mahnaz Rabbaníha, Elizabeth Robinson, Joacim Rocklöv, Stefanie Schütte, Joy Shumake-Guillemot, Rebeca Steinbach, Meisam Tabatabaei, Nicola Wheeler, Paul Wilkinson, Peng Gong*, Hugh Montgomery*, Anthony Costello*



THE LANCET

International journal of medical science and practice

Published online October 30, 2017

Rapport 2017 du « Compte à rebours santé et changement climatique » du Lancet

Après 25 ans d'inaction, une transformation globale en faveur de la santé publique est lancé

Les symptômes humains du changement climatique sont sans équivoque et potentiellement irréversibles, touchant dès aujourd'hui la santé des populations dans le monde entier. Bien que ces effets affectent majoritairement les populations les plus vulnérables de la société, toutes les communautés seront touchées.

Le retard de la réponse au changement climatique ces 25 dernières années a mis en péril la vie humaine et les moyens de subsistance.

Il est essentiel que les professionnels de santé fassent entendre leur voix afin de stimuler les progrès en matière de lutte contre le changement climatique et de tirer les bénéfices associés pour la santé.



[http://dx.doi.org/10.1016/S0140-6736\(17\)32464-9](http://dx.doi.org/10.1016/S0140-6736(17)32464-9)

The Lancet Countdown on health and climate change: from 25 years of inaction to a global transformation for public health



THE LANCET
International journal of medical science and practice
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Nick Watts, Markus Amann, Sonja Ayeb-Karlsson, Kristine Belesova, Timothy Bouley, Maxwell Boykoff, Peter Byass, Wenja Cai, Diarmid Campbell-Lendrum, Jonathan Chambers, Peter M Cox, Meaghan Daly, Niheer Dasandi, Michael Davies, Michael Depledge, Anneliese Depouy, Paula Domínguez-Salas, Paul Drummond, Paul Ekins, Antoine Flahault, Howard Frumkin, Lucien Georgeson, Mostafa Ghanei,

Delia Grace, Hilary
Dominic Kniveton,
Ali Mohammad L
David Pencheon, S
Rebecca Steinbach

Panel 1: Progress towards climate change goals
In 2015, we made progress but still have work to do.
Recommendations for health research and action.
Since 2007, the climate change
Recommendations for health system
Spending on health care (US\$16 billion) has been global development's all-time high. (Indicator 4.9)
Recommendations for fossil fuel capacity
In 2015, more fossil fuel capacity was installed than ever before. Global annual installations reached 2000 gigawatt, recently added (Indicator 3.2), increased substantially in 2015. (Indicator 3.2)
Recommendations for electric vehicle
Despite historical trends, electric vehicle sales are not expected to reach 1% of new car sales by 2020. (Indicator 4.1)
Recommendations for energy efficiency
Energy efficiency, unlock potential from this transition. Every year since 2007, energy efficiency has been the global leader in energy efficiency.

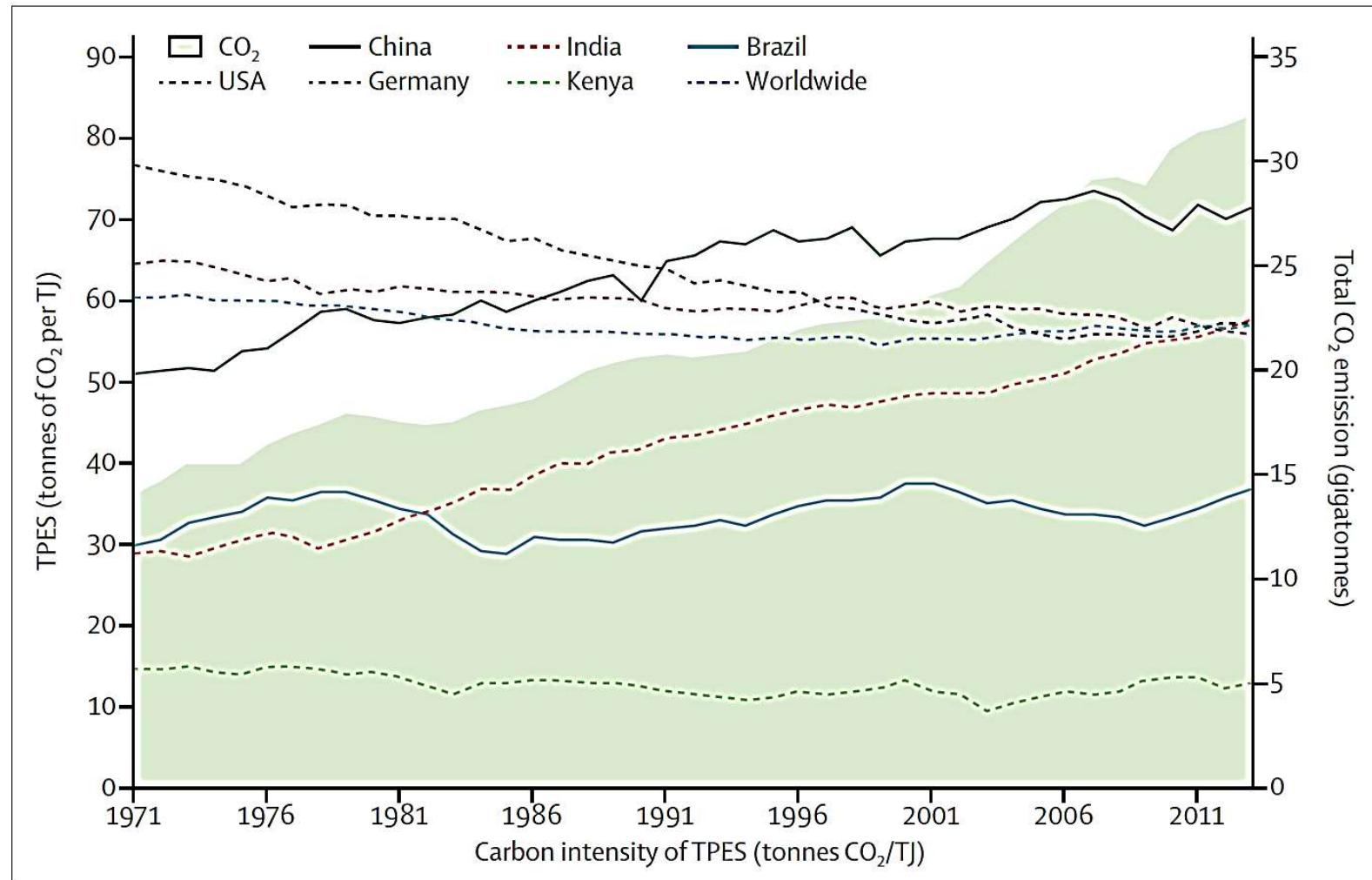


Figure 17: Carbon intensity of total primary energy supply (TPES) for selected countries and total carbon dioxide (CO₂) emissions

Total CO₂ emission is shown as the shaded area against the secondary Y axis.



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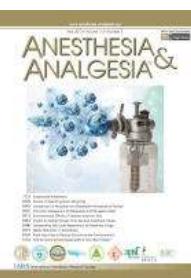
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Assessing the Impact on Global Climate from General Anesthetic Gases

Mads P. Sulbaek Andersen, PhD,* Ole J. Nielsen, PhD,† Timothy J. Wallington, PhD,‡
Boris Karpichev, PhD,* and Stanley P. Sander, PhD*

May 2012 • Volume 114 • Number 5

Table 1. Summary of Radiative Properties, Atmospheric Lifetimes, and Global Warming Potentials for Nitrous Oxide and the Halogenated Anesthetic Gases

Compound	Atmospheric lifetime (y)	Radiative efficiency (W m ⁻² ppb ⁻¹)	GWP			
			20-y time horizon	100-y time horizon	500-y time horizon	Ozone depletion potential
Nitrous oxide, N ₂ O	114 ⁸	0.00303 ⁸	289 ⁸	298 ⁸	153 ⁸	0.017 ¹⁷
Halothane, CF ₃ CHClBr	1.0 ⁸	0.165 ^a	190 ^a	50 ^{a,b}	20 ^a	0.4 ^{a,c}
Enflurane, CHFCICF ₂ OCF ₂ H	4.3 ⁸	0.447 ^a	2370 ^a	680 ^{a,d}	210 ^a	0.01 ^{a,c}
Isoflurane, CF ₃ CHClOCHF ₂	3.2 ¹³	0.453 ¹³	1800 ¹³	510 ¹³	160 ¹³	0.01 ^{a,c}
Desflurane, CF ₃ CHFOCHF ₂	14 ³	0.469 ¹³	6810 ³	2540 ³	130 ³	0 ^{a,c}
Sevoflurane, (CF ₃) ₂ CHOCH ₂ F	1.1 ³	0.351 ¹³	440 ³	130 ³	40 ³	0 ^{a,c}

GWP = global warming potential.

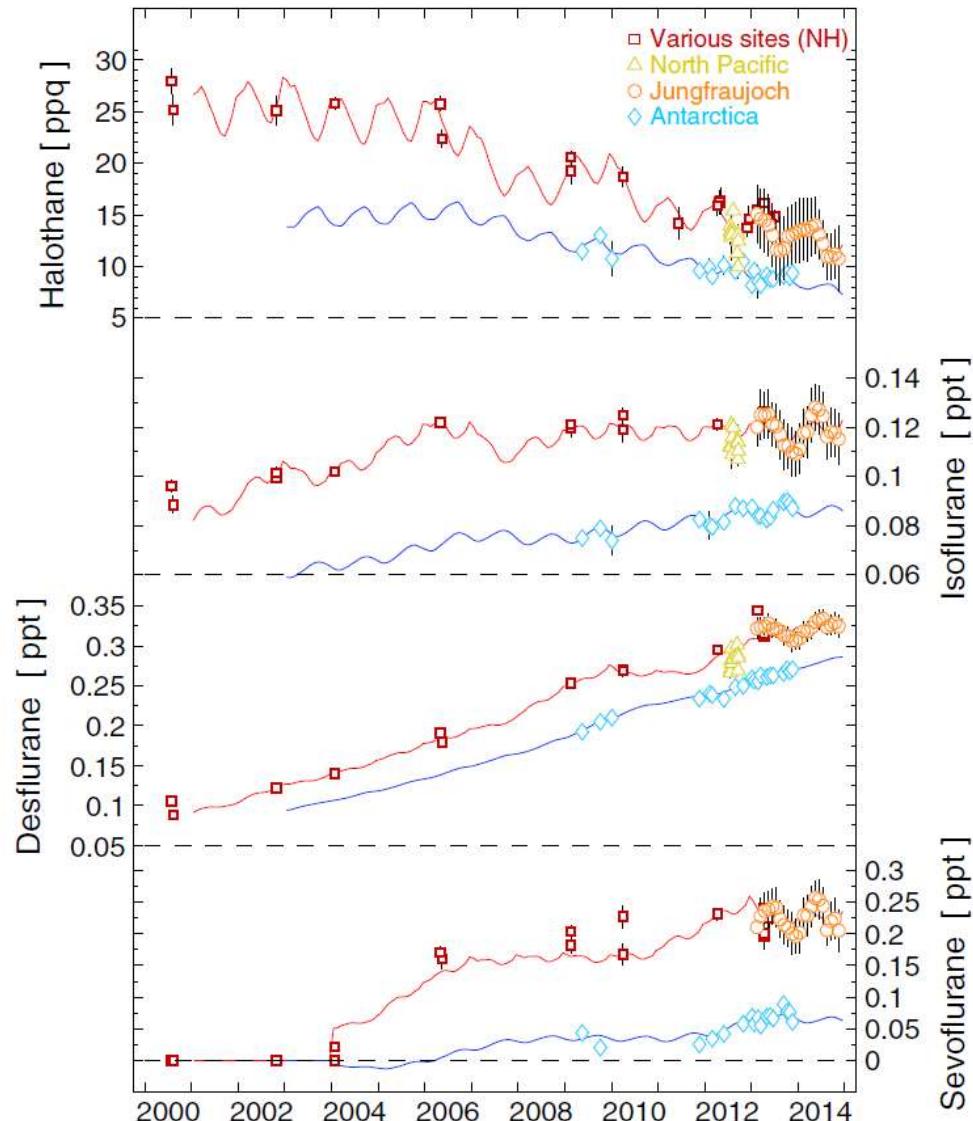
^a Determined in this work.

^b Previous literature values were 40¹⁰ and 220¹¹ with both values converted from HGWP (halocarbon global warming potential) values relative to CFC-12, using GWP (CFC-12) = 10,890.²

^c Estimated using the semiempirical method with fractional halogen release values (describes the fraction of the halogenated gas that has undergone photochemical degradation and released its halogen atoms by some time at a given stratospheric location)⁸ for enflurane and isoflurane assumed equal to the average (0.21) for hydrochlorofluorocarbons given in Table 5-1 in the World Meteorological Organization Ozone Assessment Report.⁸ Fractional release value for halothane was equated to that for CH₃Br (0.6).

^d Previous literature values were 440¹⁰ and 870¹¹, with both values converted from HGWP values relative to CFC-12, using GWP (CFC-12) = 10,890.²

GWP (Global Warming Potentials) = PRG (Potentiel de Réchauffement Global)
Rapport entre le GES et CO₂



Modern inhalation anesthetics: Potent greenhouse gases in the global atmosphere

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Received 8 DEC 2014

Accepted 9 FEB 2015

Accepted article online 12 FEB 2015

Published online 13 MAR 2015

Figure 1. Atmospheric records of halogenated anesthetics: The four anesthetics halothane, isoflurane, desflurane, and sevoflurane in samples collected in the Northern Hemisphere at various locations during clean air conditions, from the North Pacific, from Jungfraujoch, and from the Korean Antarctic Station King Sejong. Vertical bars for the flask samples denote measurement precisions ($\pm 1\sigma$) and, if not seen, are smaller than the symbol size. Jungfraujoch data are monthly means of background-filtered measurements with vertical bars denoting ($\pm 1\sigma$) variability. The solid lines are modeled mole fractions for the model surface boxes 30°N to 90°N (in red) and 30°S to 90°S (in blue).

**EN GUISE DE
CONCLUSION**

postbulle

Prédire L'avenir... difficile???

METEO FRANCE
Samedi 18 Novembre

Région ▾

★ (0/5) ▾

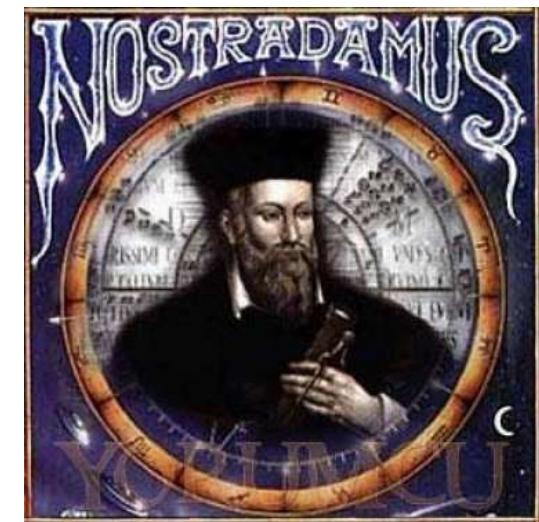
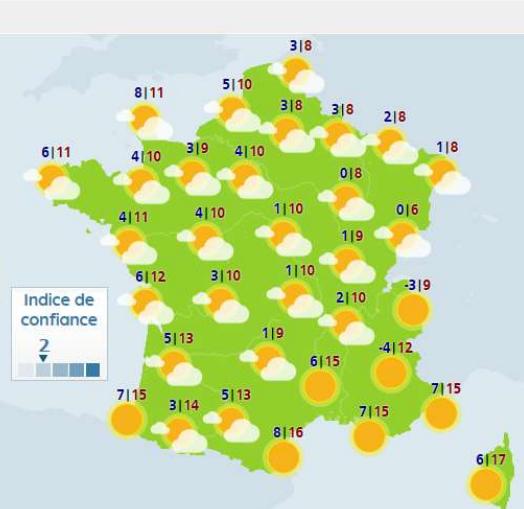
Prévisions

Vents

- lundi
- mardi
- mercredi
- jeudi
- vendredi
- samedi
- dimanche

▼ Tendances jours suivants

- lundi
- mardi
- mercredi
- jeudi
- vendredi
- samedi
- dimanche



Prédire L'avenir... Telle est la difficulté

Acta Anaesthesiol Scand 2000; 44: 3–8
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ACTA ANAESTHESIOLOGICA SCANDINAVICA
ISSN 0001-5172

Editorial

Anaesthesiology into the new millennium

J. C. RÆDER

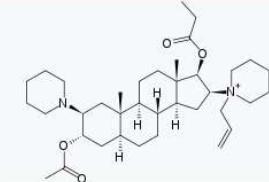
Dept. of Anaesthesia, Ullevaal University Hospital, Oslo, Norway

Key words: Anesthesia; anesthetic drugs; anesthetic equipment.

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**Curare : recherche un curare non
dépolarisant d'action rapide et de
courte durée d'action →
Rapacuronium (aux USA)**

Rapacuronium



Identification

Propanoate de [(2S,3S,5S,8R,9S,10S,13S,14S,16S,17S)-3-acétyloxy-10,13-diméthyl-2-(1-pipéridyl)-16-(1-prop-2-ényl-3,4,5,6,7,8,9,11,12,14,15,16,17-tétradécahydro-1*H*-cyclopenta[a]phénanthrén-17-yl)]

Nom 2-(1-pipéridyl)-16-(1-prop-2-ényl-3,4,5,6,7,8,9,11,12,14,15,16,17-tétradécahydro-1*H*-cyclopenta[a]phénanthrén-17-yl]

UICPA

N° CAS 156137-99-4

PubChem 5311398 [archive]

SMILES [Afficher]

InChI [Afficher]

Propriétés chimiques

Formule brute C₃₇H₆₁N₂O₄⁺ [Isomères]

Masse molaire ¹ 597,8912 ± 0,0355 g/mol
C 74,33 %, H 10,28 %, N 4,69 %,
O 10,7 %.

Unités du SI et CNTP, sauf indication contraire.

VOLUNTARY MARKET WITHDRAWAL

Adverse Drug Reaction

March 27, 2001

Re: RAPLON (rapacuronium bromide) for Injection

ALL BATCHES

NDC 0052-0490-15 (100 mg)

NDC 0052-0495-16 (200 mg)

NDC 0052-0490-86 (100 mg sample)

In light of the recent safety issues raised, regarding RAPLON ^{AE} and its possible association with the occurrence of bronchospasm, we are voluntarily withdrawing the product. We feel a strong responsibility to the clinicians that not only use our products, but also entrust the lives of their patients on the reliability of these products. Our primary concern and goal in this endeavor is to ensure the safety of each patient.

The Food and Drug Administration (FDA) was notified immediately of this decision and the planned market withdrawal of all unused product.

The RAPLON ^{AE} package insert lists bronchospasm as an adverse event which occurred in 3.2% of patients in premarketing clinical trials. We have now received reports of several serious adverse bronchospasm events including a few unexplained fatalities. In each of these cases the cause is unknown, as there were multiple drugs administered and other conditions present. From our surveillance of postmarketing spontaneous reporting, it appears that the incidence is within labeling, however, the severity of these events, up to and including mortality that has been reported postmarketing, was not seen in clinical trials. These reports are made voluntarily from a population of unknown size and the exact frequency can not be determined.

Please examine your stock immediately to determine if you have any RAPLON in your inventory. If so, discontinue using the material and have your hospital pharmacy or wholesaler promptly return via parcel post to our West Orange facility: ATTENTION: RETURN MARKET WITHDRAWAL.

You will be reimbursed by credit memo for the returned goods and postage.



**ANESTHÉSIE DE DEMAIN
INSIDE OR OUTSIDE?**

