


# Endotracheal bioimpedance cardiography improves immediate postoperative outcome: a case-control study in off-pump coronary surgery

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Received: 20 September 2016 / Accepted: 26 January 2017 / Published online: 8 February 2017  
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**Abstract** The feasibility and clinical utility of the endotracheal cardiac output monitor (ECOM) to optimize intraoperative hemodynamics and improve short-term outcome in off-pump coronary artery bypass grafting (OPCAB) is unknown. We aimed to compare ECOM with a standard of care in that specific surgical setting. Twenty consecutive adult ECOM-monitored patients undergoing OPCAB were prospectively included (ECOM group) and retrospectively compared to 42 patients scheduled for similar surgery without ECOM monitoring (Control group). The primary endpoint was the global rate of postoperative admission to the intensive care unit (ICU). Secondary endpoints were the time to extubation, the length of stay in ICU and in hospital, the postoperative levels of lactate and troponin and the feasibility of ECOM. The rate of postoperative admission to the ICU was 38/42 (90%) in the Control group versus 11/20 (55%) in the ECOM group,  $P=0.008$ . None unexpected admission for hemodynamic instability was observed in the ECOM group. The time to extubation, the length of stay in ICU, and both troponin level at admission and lactate level at H6 were all significantly decreased in the ECOM group. On a scale ranging from 0 to 5, convenience and satisfaction regarding ECOM were  $4.30 \pm 1.17$  and  $3.45 \pm 0.68$ , respectively. The systematic

use of ECOM is associated with a significant reduction in the rate of admission to the ICU and an improvement in immediate outcome in OPCAB.

**Keywords** Endotracheal bioimpedance cardiography · Hemodynamic monitoring · Cardiac surgery · Off-pump coronary artery bypass grafting

## 1 Introduction

Intraoperative advanced hemodynamic monitoring is useful for moderate to high-risk patients undergoing cardiac surgery [1]. Hemodynamic optimization with early goal-directed therapy (EGDT) has proven its ability to reduce morbidity [2–6], time to extubation [7], and length of stay in the intensive care unit (ICU) [3, 8, 9]. EGDT strategies for elective cardiac surgical procedures usually rely on stroke volume and/or cardiac output optimization [1, 2]. Off-pump coronary artery bypass grafting (OPCAB) is a simplified surgical procedure avoiding cardiopulmonary bypass that could shorten postoperative rehabilitation [10–12]. Patients undergoing OPCAB are most often admitted postoperatively first to the Post Anesthesia Care Unit and then assessed for secondary admission either to the ward or to the ICU, depending of their hemodynamic and clinical status during the first postoperative hours. To date, there is no standardization regarding the choice of advanced hemodynamic monitoring in OPCAB, and systematic intraoperative cardiac output and/or stroke volume assessment by means of transeosophageal echocardiography (TEE) is not yet a routine practice in France.

The endotracheal cardiac output monitor (ECOM Medical, Inc., San Juan Capistrano, CA) is a new Food and Drug Administration-approved plug and play device that provides

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continuous cardiac output measurement via a specifically designed endotracheal tube using three-dimensional bioimpedance in conjunction with an arterial catheter [13]. This new mini-invasive cardiac output monitor was previously evaluated with encouraging results in seven human studies including 196 cardiac surgical patients and compared either to bolus thermodilution or echocardiography [14–20]. Recently, we reported a randomized controlled study suggesting that ECOM could be of clinical utility in coronary surgery with cardiopulmonary bypass [7]. Whether ECOM could also be of some usefulness in OPCAB is unknown.

Therefore, we conducted a new study aiming to assess both the feasibility and clinical utility of ECOM to optimize intraoperative hemodynamics in OPCAB surgery compared to a standard of care. We hypothesized that ECOM would improve overall intraoperative hemodynamic management and subsequently immediate postoperative outcome in that specific surgical setting.

## 2 Methods

### 2.1 Patient population

A case-control study was conducted over an 8-month period in a single University Teaching Hospital after approval from the local Research Ethics Committee (Chairperson Pr. J.F. Guérin, date of approval 26th of February 2015). Because data were collected during routine care that conformed to standard procedures currently used in the institution, authorization was granted to waive written informed consent. Verbal consent was however obtained from all participants. From March to April 2015, 20 consecutive ECOM-monitored adult patients (so-called the ECOM group) undergoing elective OPCAB were prospectively included in the study and compared to 42 consecutive controlled adult patients having undergone elective OPCAB by the same surgeon (FF) from September 2014 to February 2015 without ECOM monitoring (so-called the Control group). Inclusion criteria were elective OPCAB. Patients undergoing emergent surgery (less than 24 h) or

redo surgery, and patients with severe aortic valvular disease were not included into the study.

### 2.2 Perioperative management

General anesthesia and postoperative management followed institutional standards and were similar in all patients. Briefly, intraoperative monitoring techniques included continuous five-lead electrocardiogram with computerized analysis of repolarization, pulse oximetry, invasive arterial blood pressure by means of a radial artery catheter and central venous pressure by means of a jugular central venous catheter. In addition, monitoring of the depth of anesthesia by means of the Bispectral Index™ (Covidien, Mansfield, MA, USA), a cell salvage machine, and forced-air warming were used in all patients. Standardized total intravenous anesthesia (i.e., target-control propofol and remifentanyl or sufentanil infusion, and cisatracurium) or inhaled sevoflurane in order to maintain a BIS value between 40 and 60 were used at the discretion of the attending practitioners. All patients were intubated with a 7.5 mm endotracheal tube after induction of general anesthesia. In the ECOM group, we used a specially designed endotracheal tube (ECOM-ETT 7.5G, ECOM Medical, Inc., San Juan Capistrano, CA) which contains seven silver electrodes on the cuff and tube that continuously measured the bioimpedance signal from the ascending aorta, in close proximity to the trachea (Fig. 1) [13]. The ECOM pressure monitor was connected to the radial arterial line and then to the ECOM endotracheal tube impedance wires. All pressure monitors were zeroed at the mid-axillary line. After processing, it provides real-time continuous stroke volume and cardiac index together with respiratory stroke volume variations as a dynamic test aiming to predict fluid responsiveness, and systemic vascular resistance calculation as an afterload valuable parameter. No previous adverse event was reported with the use of ECOM over a 24-h period [21] and it did not add any new invasive procedure when compared with the Control group. In the ECOM group, the device was available within the whole intraoperative period in order to help practitioners, familiar with the concept, in conducting

**Fig. 1** The ECOM endotracheal tube and the ECOM monitor. Figure from ECOM® Medical, Inc. Copyright © 2016



their own EGDT strategy on a case-by-case basis. Mechanical ventilation was in accordance with the actual standards of care (tidal volume 6–8 ml/kg of predicted body weight and a positive end-expiratory pressure of 5 cmH<sub>2</sub>O). The same surgical technique including similar successive steps by a single surgeon (FF) was used in all patients: incision, sternotomy, harvesting of the grafts, stabilization of the heart (ACROBAT-i Stabilizer System, MAQUET Holding B.V. & Co. KG, Germany), coronary artery bypass, hemostasis and sternal fixation.

All patients were admitted postoperatively to the Post Anesthesia Care Unit for at least 2 h and then carefully assessed for admission either to the ward or to the ICU, at the discretion of attending physicians not involved in the study protocol and blinded to all study endpoints. Indeed, if they were aware of the availability of ECOM in the operative room and its possible use by the anesthesiologists to conduct EGDT, they did not know both primary and secondary study endpoints, so that the decision to admit or not a patient to the ICU could not be influenced by the study itself. The decision to admit a patient to the ICU was either preoperatively anticipated (in accordance with patients' comorbidities and risk stratification) or postoperatively based on unexpected hemodynamic instability, bleeding, respiratory failure or early reoperation.

Patients' demographic and clinical characteristics were collected preoperatively, as well as intraoperative hemodynamic parameters and postoperative outcomes. Acute renal failure was defined as an increase in peak postoperative creatinine of at least 30%. To assess the feasibility of ECOM monitoring in that specific surgical setting, we asked attending anesthesiologists at the end of surgery for convenience, satisfaction, and quality of ECOM signal by means of three different scales ranging from 0 to 5 (Appendix 1).

### 2.3 Study endpoints

The primary endpoint of the study was the all-cause rate of postoperative admission to the ICU (both preoperatively anticipated and postoperatively unexpected). Secondary endpoints were the unexpected rate of postoperative admission to the ICU for hemodynamic instability, the time to extubation, the length of stay in ICU and in hospital, the postoperative levels of lactate and troponin at the admission in ICU and 6 h later (H6), and the feasibility of ECOM in that specific surgical setting.

### 2.4 Statistical analysis

We performed a post hoc power calculation on the basis of a decrease in at least 40% of the rate of postoperative admission to the ICU in the ECOM group when compared

with the Control group at a 5% type I error rate and a 20% type II error rate. Thus, the sample size revealed 62 patients divided into 21 patients in the ECOM group and 41 patients in the Control group, corresponding to a ratio case/control group of 1/2.

Variables are expressed as mean  $\pm$  SD or median (extremes) for non-normally distributed variables (D'Agostini Pearson test) or number, as appropriate. Comparisons between both groups were made by independent samples *t* test or Mann–Whitney test according to the distribution for continuous variables and Fischer's exact test for categorical variables. We performed a multiple regression to look for potential statistical correlations between the primary endpoint and independent confusing variables.

A *P* value of <0.05 was considered as statistically significant and all *P* values were two-tailed. Statistical analyses were performed using MedCalc Statistical Software version 14.10.2 (MedCalc Software bvba, Ostend, Belgium; <http://www.medcalc.org>; 2014).

## 3 Results

One patient was excluded because of the unavailability of the ECOM endotracheal tube at the time of intubation. Sixty-two patients were included within the 8-month period and divided into 20 patients in the ECOM group and 42 patients in the Control group.

Demographic and clinical characteristics are indicated in Table 1. No statistical difference was observed between both groups, except for the rate of preoperative diuretics use, the duration of surgery, and the number of grafts. Intraoperative variables and hemodynamic parameters are summed up in Table 2. Minimal heart rate and vasoactive support were significantly lower in the Control group when compared with the ECOM group. Postoperative data and outcomes are reported in Table 3. As a primary endpoint, the all-cause rate of postoperative admission to the ICU was reduced by 61% in the ECOM group: 11/20 (55%) versus 38/42 (90%), *P*=0.008. While the preoperative anticipated rate of admission was similar in both groups [24/42 (57%) versus 10/20 (50%), *P*=0.785, respectively], the unexpected rate of admission related to hemodynamic instability markedly differed between Control: 12/42 (29%) versus ECOM: 0/20 (0%), *P*=0.006 (Table 3). As other secondary endpoints, the extubation time, the length of stay in ICU, and both troponin level at admission and lactate level at H6 were all significantly decreased in the ECOM group when compared with the Control group. Mediastinal bleeding was also significantly decreased in the ECOM group when compared with the Control group (Table 3).

The multiple regression showing the correlation between significant clinical variables and the primary endpoint is

**Table 1** Demographic and clinical characteristics (N = 62)

	Control N=42	ECOM N=20	P value
Age (year)	65 ± 11	62 ± 10	0.343
Sex (M/F)	34/8	16/4	1.000
Body mass index (kg/m <sup>2</sup> )	27.3 (17.8–39.3)	26.2 (20.0–45.0)	0.159
EuroSCORE	4.7 ± 3.1	4.6 ± 2.7	0.923
Left ventricular ejection fraction (%)	49 ± 14	56 ± 12	0.090
Hypertension	26	12	1.000
Atrial fibrillation	4	1	1.000
Chronic obstructive pulmonary disease	8	1	0.249
Stroke	3	4	0.198
Peripheral vascular disease	9	4	1.000
Diabetes mellitus	18	5	0.261
Chronic renal failure	12	5	1.000
Filtration glomerular rate (ml/min/1.73 m <sup>2</sup> )	73 (4–104)	81 (6–115)	0.387
Beta blockers	36	13	0.094
Renin angiotensin system inhibitors	21	12	0.588
Nitrates	11	4	0.755
Diuretics	19	3	0.025
Statins	35	15	0.499
Antiplatelet agents	37	17	0.705
Number of grafts	2.7 ± 0.8	3.2 ± 0.9	0.049
Duration of surgery (min)	125 (52–215)	146 (82–316)	0.032

Values are mean ± SD or median (extremes) or number

**Table 2** Intraoperative variables and hemodynamic parameters (N = 62)

	Control N=42	ECOM N=20	P value
Difficult intubation	7	2	0.705
Minimal BIS value	24 (1–41)	24 (8–43)	0.874
Duration of BIS < 40 (min)	55 (0–171)	32 (0–130)	0.228
Intraoperative hemodynamic monitoring			
Transesophageal echocardiography	1	1	0.544
Pulmonary artery catheter	1	0	1.000
Continuous central venous oxygen saturation	1	3	0.095
Near-infrared spectroscopy	1	0	1.000
ECOM	0	20	<0.001
Intraoperative hemodynamic parameters			
Maximal heart rate (beats/min)	83 ± 15	83 ± 13	0.965
Minimal heart rate (beats/min)	46 ± 10	52 ± 9	0.032
Minimal systolic blood pressure (mmHg)	72 ± 11	71 ± 8	0.878
Minimal mean blood pressure (mmHg)	52 ± 7	52 ± 6	0.793
Minimal diastolic blood pressure (mmHg)	43 ± 6	41 ± 6	0.281
Intraoperative hemodynamic management			
Total fluid volume (ml)	1150 (500–2000)	1500 (500–3500)	0.110
Transfusion requirement	6	1	0.412
Inotropic support with dobutamine	3	1	1.000
Vasoactive support with norepinephrine or phenylephrine	27	19	0.012

Values are mean ± SD or median (extremes) or number

BIS bispectral index, ECOM endotracheal cardiac output monitor

**Table 3** Postoperative data and outcomes (N=62)

	Control N=42	ECOM N=20	P value
All-cause admission to the ICU	38	11	0.008
Preoperatively anticipated	24	10	0.785
Unexpected hemodynamic instability	12	0	0.006
Unexpected bleeding	1	0	1.000
Unexpected early reoperation	1	0	1.000
Unexpected respiratory failure	0	1	0.322
Acute renal failure	13	2	0.112
Mediastinal bleeding (ml)	490 (125–1970)	317 (175–700)	<0.001
SAPS 2 score	27 ± 11	23 ± 10	0.352
Lactate at the admission (mmol/l)	1.6 ± 0.6	1.5 ± 0.5	0.634
Troponin at the admission (ng/ml)	944 (265–1518)	546 (0–275)	0.028
Lactate at H6 (mmol/l)	2.0 ± 0.6	1.5 ± 0.4	0.043
Troponin at H6 (ng/ml)	1221 (138–83686)	1507 (2–6743)	0.635
Extubation time (h)	4 (0–696)	2 (0–7)	<0.001
Length of stay in ICU (day)	1.0 (0–29)	0.5 (0–10)	0.002
Hospital discharge (day)	9.5 (6–29)	11.0 (2–25)	0.336
In-hospital mortality	2	0	1.000

Values are mean ± SD or median (extremes) or number  
 ICU intensive care unit, SAPS simplified acute physiologic score

**Table 4** Multiple regression showing the correlation between significant clinical variables and the admission to the intensive care unit

Independent variables	r <sub>partial</sub>	P value
Diuretics	0.075	0.586
Number of grafts	−0.109	0.428
Duration of surgery	0.061	0.658
Mediastinal bleeding	0.234	0.085

Coefficient of determination R<sup>2</sup>=0.122

Analysis of variance: P=0.216

None variable was significantly correlated with the admission to the intensive care unit

reported in Table 4. None independent variable was correlated with the all-cause rate of admission to the ICU. The coefficient of determination R<sup>2</sup> was 0.122 and the analysis of variance accepted the absence of significant relationship (P=0.289).

The feasibility of ECOM monitoring in OPCAB is depicted in Table 5. Both quality of signal and satisfaction were acceptable whereas the convenience was good.

#### 4 Discussion

The main findings of the present case-control study are that the systematic availability of continuous intraoperative advanced hemodynamic monitoring by means of ECOM in

**Table 5** Feasibility of ECOM monitoring in 20 patients undergoing OPCAB surgery

Scales (0–5)	Scores
Convenience	4.30 ± 1.17
Satisfaction	3.45 ± 0.68
Quality of signal	3.30 ± 0.98

Values are mean ± SD

ECOM endotracheal cardiac output monitor, OPCAB off-pump coronary artery bypass

an anesthesiologist staff familiar with the EGDT concept, is associated with both a marked decrease in the all-cause rate of postoperative admission to the ICU and an improvement in immediate postoperative outcome following OPCAB when compared with a standard of care.

Although the preoperative anticipated admission rate to the ICU was similar in both groups, no more admission related to unexpected hemodynamic instability was observed in the ECOM group, fully explaining the main result of the study. The ECOM device provides real-time cardiac output, preload dependency, and left ventricular afterload information that probably helped anesthesiologists to improve and/or stabilize patient’s hemodynamic status. Thus, the continuous knowledge of cardiac output/stroke volume values at any moment of the surgical procedure could have facilitated the decision to administrate more vasopressors, as suggested by the current results. As well, we observed a trend toward more fluid volume

(+350 ml) in the ECOM group. Taken together, these changes in individual hemodynamic strategies could have contributed to immediate postoperative stability and the decision by attending physicians not to admit patients in the ICU. As no institutional EGDT protocol was suggested to practitioners, it may be that other non-measured hemodynamic variables differed between both groups, explaining the improvement in immediate postoperative outcome. It is noteworthy that almost all secondary endpoints were significantly improved in the ECOM group: extubation time and the length of stay in ICU were reduced, whereas troponin measurement at the admission in ICU and lactate at H6 were decreased when compared with the Control group, further suggesting that overall hemodynamic management was improved by the systematic availability of continuous intraoperative ECOM monitoring. These results are in accordance with a previous published study from our group suggesting a potential role for ECOM in coronary surgery patients [7]. As far as we acknowledge, no other data are available in the literature regarding the clinical utility of ECOM.

No standardization regarding the choice of advanced hemodynamic monitoring in OPCAB exists at the present time, and systematic intraoperative continuous cardiac output monitoring is far to be easy in that specific setting. It usually relies on TEE [22] and/or transpulmonary thermodilution [23, 24]. TEE images are however either partially unavailable or somewhat difficult to interpret during some crucial phases of the surgical procedure (as during luxation of the heart), and do not permit a true continuous hemodynamic monitoring. It is noteworthy that the use of TEE was uncommon in the present study, even in the Control group. Conversely, hemodynamic parameters given by ECOM were continuously available all along surgery. Thus, ECOM could meet many important theoretic characteristics of the ideal hemodynamic monitoring device, as operator independency, mini-invasiveness, and convenience [13]. The current results about convenience, quality of signal and satisfaction outline that practitioners trust the device and use it easily when available at the bedside.

Some comments are necessary concerning the limitations of the present study. First, we only investigated a small cohort of patients in a monocenter case-control study. As there is at the present time no literature available on this specific topic, and as we were uncertain if such an advanced hemodynamic monitoring tool could be of some clinical interest in that subtype of high-risk surgical cardiac patients, we believe however our study design was adapted to provide preliminary results in that setting. Subsequently, the level of evidence suggesting there is a role for ECOM at the bedside remains low, and further randomized outcome studies are mandatory before recommending a wider use in routine practice. Second, the

physicians assessing patients for postoperative admission either to the ICU or to the ward were not blinded to the use of ECOM in our study. They were however blinded to all study endpoints. As well, some significant clinical differences exist between the two groups of patients which could have partially explained our results, especially the decrease in postoperative mediastinal bleeding in the ECOM group. Subsequently, we performed a multiple regression to look for potential statistical correlations between the primary endpoint and independent confounding variables. We found that none independent variable was correlated with the all-cause rate of admission to the ICU, reinforcing the internal validity of our results. However, the decrease in postoperative mediastinal bleeding in the ECOM group could have influenced some secondary endpoints, as extubation time and length of stay in ICU. Again, future studies including more patients monitored with ECOM during major surgeries are warranted to confirm the potential improvement in outcome when using ECOM. Finally, we did not provide an institutional EGDT strategy based on ECOM in the present study but only gave the opportunity to systematically use (or not) hemodynamic parameters given by the ECOM device in order to guide the clinical decision making process. We actually do not know if practitioners did it or not and if they did, how do they did. A next step would be to evaluate the clinical interest of ECOM-induced EGDT strategies in the specific setting of OPCAB and other surgical subtypes of high-risk patients.

In conclusion, this case-control study suggests that intraoperative advanced mini-invasive hemodynamic monitoring by means of ECOM could reduce the admission rate in ICU and improve immediate postoperative outcome in OPCAB when compared to a standard of care. Considering the modern pattern of rapid postoperative rehabilitation following cardiac surgery, such results are encouraging while necessitating being further confirmed in well-designed randomized outcome studies before a wider use in clinical practice. Further studies are also mandatory to better assess both the economic and clinical impact of such a mini-invasive advanced monitoring tool in various clinical settings.

**Acknowledgements** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

**Funding** Departmental funding only.

**Compliance with ethical standards**

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of

the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Verbal consent was obtained from all individual participants included in the study.

## Appendix 1: Scales for feasibility of ECOM in off-pump coronary surgery

Difficulty encountered: 0 (no difficulty) to 5 (worse difficulty)

0 1 2 3 4 5

Satisfaction: 0 (not at all) to 5 (totally satisfied)

0 1 2 3 4 5

Quality of signal: 0 (very bad) to 5 (very good)

0 1 2 3 4 5

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