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The Use of Pressure Recording Analytical Method in Patients Undergoing Endovascular Repair for Abdominal Aortic Aneurysm: The Impact on Clinical Decisions for the Appropriate Postoperative Setting and Cost-effective Analysis

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Abstract

Objective. To analyze the use of the Pressure Recording Analytical Method (PRAM), an hemodynamic monitoring system, in evaluating intraoperative and postoperative hemodynamic instability in patients undergoing endovascular repair for abdominal aortic aneurysm, and to evaluate if the decision to refer patients to a ordinary ward or to a Cardiac Step-Down Unit (CSDU) after the intervention on the basis of intraoperative hemodynamic monitoring could be more cost-effective. **Materials and Methods.** After preoperative clinical evaluation, 44 patients were divided in this non-randomised study into two groups according to their postoperative destination: Group 1-ward (N=22) and Group 2-CSDU (N=22). All patients underwent monitoring with PRAM during the intervention and in the 24 postoperative hours, measuring several indices of myocardial contractility and other hemodynamic variables. **Results.** According to the variability of two parameters, Stroke Volume Variation and Pulse Pressure Variation, patients were classified as stable or unstable. Unstable patients showed a significant alteration in several hemodynamic indices, in comparison to stable ones. According to the intraoperative monitoring, eight high risk patients could have been sent to an ordinary ward due to their stability, with a reduction in the improper use of CSDU and, consequently, in costs. **Conclusions.** Hemodynamic monitoring with PRAM can be useful in these patients, both for intraoperative management and for the choice of the more appropriate postoperative setting, possibly reducing the improper use of CSDU for hemodynamically stable patients who are judged to be at high risk preoperatively, and re-evaluating low surgical risk patients with an unstable intraoperative pattern, with a possible reduction in costs.

Key Words: Hemodynamic Monitoring ▪ Goal Directed Therapy ▪ Abdominal Aortic Aneurysm ▪ Endovascular Repair ▪ Postoperative Setting

Introduction

Hemodynamic monitoring is crucial in critically ill patients (1-3) as well as during and after major surgery (1, 4, 5-7), in order to promptly detect the occurrence of acute alterations, such as shock, that could lead to hypoperfusion and organ ischemia, and to evaluate the effects of pharmacological interventions.

In patients who are candidates for major vascular surgery, postoperative complications and death are more frequent among high risk and older patients, since they have multiple comorbidities, such as coronary artery disease, heart failure, diabetes mellitus and chronic renal dysfunction (8). In order to reduce cardiac perioperative complications in these patients, several authors have underlined the importance of a complete preoperative cardiac evaluation (9) and therapy optimization (10, 11), whereas the role of preoperative coronary revascularization is still debated (9, 12). In the last few years, therapy optimization, known as Goal-Directed Therapy (GDT), guided by data collected during hemodynamic monitoring, has been associated with a reduction in the incidence of surgical complications and length of hospital stay, even if the data regarding periprocedural mortality after major visceral/non-cardiac surgery are still controversial (6, 7, 13, 14). Nevertheless, even the NICE (National Institute for Health and Care Excellence) Guidelines recommend GDT for patients undergoing major vascular surgery (15).

The GDT cornerstone consists mainly in the monitoring of cardiac output in order to optimize perfusion and tissue oxygenation, and to improve postoperative outcomes, by guaranteeing adequate oxygen delivery (16, 17). This suggests that a safe hemodynamic monitoring system is required, and with this aim, several systems have been developed which can analyze variations in cardiovascular and hemodynamic parameters, and provide information on cardiac and vascular interaction (18).

Among them, the Pressure Recording Analytical Method (PRAM) system has been widely used in our Institution to evaluate hemodynamic parameters in several cardiac conditions, such as heart failure and acute myocardial infarction (19-21). PRAM is a minimally invasive monitoring system that provides, from the beat-to-beat analysis of the arterial waveform, measurement of the main hemodynamic variables, such as systemic blood pressures, stroke volume, cardiac output, and vascular resistances. Moreover, dynamic indices of fluid responsiveness are continuously displayed (17).

The aim of this prospective, single center study was to evaluate the impact of the use of this minimally invasive hemodynamic monitoring system on the prediction of postoperative hemodynamic instability after endovascular repair of an abdominal aortic aneurysm (AAA). Moreover, we compared the decision to refer patients to the postoperative ward or the Cardiac Step-Down Unit (CSDU) on the basis of preoperative assessment or intraoperative monitoring, to evaluate whether this latter decision could lead to a reduction in the improper use of CSDU. Finally, we performed a cost analysis of these two different strategies.

Materials and Methods

From December 2019 to April 2020, all patients who were candidates to endovascular repair for AAA at our Department were prospectively enrolled and gave their informed consent for participation in the study. The inclusion criteria were: age over 18 years, the presence of an AAA with an indication for endovascular repair, and the possibility of radial arterial access. The exclusion criteria were: difficulty in obtaining an adequate arterial signal in the radial artery (for example, due to a disease affecting the subclavian artery), and the need for more complex procedures, such as fenestrated, branched or Chimney EVAR (FEVAR, BEVAR and ChEVAR, respectively). As previously reported in the study by Abebe et al., the incidence of hemodynamic instability in adult surgical patients in the post-anesthesia care unit ranges from 21.1% to 56.6% and is about three times higher in patients with high versus low risk (22). Hypothesizing an anticipated incidence of hemodynamic instability of 20% in low risk patients and a 60% incidence in high risk patients, considering a type I error of 0.05 and a type II error of 80%, the number of patients needed is 44, 22 in each group. The study protocol was drawn up in accordance with the ethical Guidelines of the 1964 Declaration of Helsinki and was an extension of a larger study concerning the use of PRAM in patients undergoing transcatheter aortic interventions, previously approved by the Ethics Committee of the Azienda Ospedaliero-Universitaria Careggi (reference number Cineca 11574).

Preoperative Assessment and Indications for Surgery

According to the Guidelines (23), the indication for elective surgery was the presence of asymptomatic infrarenal AAA ≥5.5 cm in male patients, whereas in females the threshold diameter for elective surgery was > 5 cm. Intervention was also considered if the diameter was under the threshold but one or more of the following conditions were present: rapid aneurysm growth (>1 cm annually or >0.5 cm within 6 months), and AAA morphology considered as high risk of rupture (i.e. saccular aneurysm or in the presence of blisters, blebs or inhomogeneous parietal thrombus).

All patients underwent computed tomography angiography of the entire thoraco-abdominal aorta. Preoperative evaluation assessing the feasibility of an endovascular procedure was performed using Aquarius iNtuition® software (TeraRecon, Foster City, California, USA). All patients underwent complete laboratory tests (blood count, creatinine, transaminases and coagulation) and a complete cardiovascular evaluation, including electrocardiography, echocardiography, stress test or coronary angiography when indicated, duplex ultrasonography of the supra-aortic trunks and lower extremities, and pulmonary function testing. A preoperative anesthesiology evaluation was performed to determine the need for perioperative and postoperative intensive monitoring. High risk patients were defined according to the EVAR-2 trial: recent acute myocardial infarction (<3 months), symptomatic congestive heart failure, unstable angina, severe valvular heart disease, cardiac arrhythmia, chronic obstructive pulmonary disease, and chronic kidney disease with a serum creatinine value of >2.26 mg/dL (24).

On the basis of the preoperative assessment, the patients were prospectively divided into two groups and in all cases the anesthesiologist followed the preoperative indications for postoperative monitoring: Group 1-ward (N=22), patients for whom postoperative CSDU was not required, and Group 2-CSDU (N=22), patients for whom postoperative CSDU was required. No random allocation into the two groups was performed. All patients underwent intraoperative monitoring with the minimally invasive PRAM system (25) using a MostCareUp® device (Vygon, Ecouen, France), both during the intervention and for the first 24 postoperative hours, both on the ward and in the CSDU.

Furthermore, the patients were divided on the basis of hemodynamic parameters detected intraoperatively into an "unstable" group and a "stable" group. The "unstable" group consisted of 18 patients in whom the variability of stroke volume variation (SVV) and pulse pressure variation (PPV) measured during the intervention and in the first subsequent 24 hours was greater than 15%, while the "stable" group consisted of 26 patients in whom the fluctuations in these parameters were less than 15% and were considered physiological, as previously reported in the literature (26-29).

PRAM System

The MostCareUp® monitoring system is a device that makes it possible to perform a beat-to-beat analysis, from which it is possible to obtain several hemodynamic variables and the parameters of myocardial contractility (heart-circulation interactions, variations in ventricular contractility, arterial stiffness, etc.) (Supplemental Figure 1). This medical device is CE marked (identification number CE 0476). This system does not require calibration, and does not use pre-estimated values obtained from statistical analyses or anthropometric data (i.e. gender or age) that belong to the patient monitored. For PRAM set-up, height and weight data are required in order to obtain body surface area which is necessary to obtain the parameters indexed in relation to the patient's size, such as cardiac index and stroke volume index. Therefore, the hemodynamic parameters detected by this system are influenced exclusively by the morphology of the pressure signal recorded in the patient analyzed. Consequently, when the clinical condition of the patient modifies the dynamic impedance of the cardiovascular system (changes in vascular tone due to the effect of vaso-active drugs, as well as variations in venous return, hematocrits, the rigidity of the vessels and heart circulation coupling, etc.), the system obtains the new information from the variation in the morphology of the pressure wave detected at the peripheral level. The PRAM method therefore provides a large amount of information about the patient's hemodynamic status, while keeping the level of invasiveness contained, thus being easily applicable to almost all patients, in particular in the field of vascular surgery.

For PRAM monitoring, a standard arterial catheter was inserted into the radial artery. A 150 cm pressure tube connection and transducer (Truwave PX-600F, Edwards Lifecsience, Irvine, CA, USA) were connected to the MostCareUp® monitoring system (Vygon, Ecouen, France). Pressure signals were sampled at 1000 Hz. An event marker of the signal pressure recordings was used to identify the phases of the study. The variables obtained by PRAM were displayed on the screen in real time and stored electronically (every 30 seconds) in the system.

During monitoring the following variables were evaluated: systolic, diastolic, dicrotic and mean arterial pressure (mmHg); Heart Rate (HR, bpm); Stroke Volume (SV, mL); Stroke Volume Index (SVI); Cardiac Output (CO = SV x HR, L/min); Cardiac Index (CI); Systemic Vascular Resistances (SVR, dyne*s/cm); Stroke Volume Variation (SVV); Pulse Pressure Variation (PPV); and Cardiac Cycle Efficiency (CCE, units) that indicates the ability of the cardiovascular system to maintain homeostasis at different energy levels.

The reliability of the PRAM measurements has been previously analyzed and demonstrated (30). Given the results of that study in our Institution we use, in the presence of resonance artifacts, a dedicated transducer, manufactured for limiting resonance effects. Also, the validity of the hemodynamic parameters measured by PRAM has been previously analyzed and demonstrated in comparison with echocardiographic assessment of CO (31), non-invasive measurements of blood pressure values (32), thermodilution for assessment of CI (1), and with both thermodilution and another more invasive monitoring system for CO assessment (33).

Use of PRAM in Different Clinical Settings

In the last 20 years, the PRAM system has been used in different clinical conditions, both in our Center and in other Centers. In particular, in our Center it has been used to monitor patients with decompensated heart failure treated with ultrafiltration and diuretics (19, 20), as well as to evaluate the beneficial effects of levosimendan (34), in patients with atrial fibrillation undergoing electrical cardioversion (35), in patients with ST-Elevation myocardial infarction treated with primary angioplasty (21), to monitor patients undergoing transcatheter aortic valve replacement (36, 37), and in patients undergoing cardiac and vascular surgery, both intraoperatively (32) and in the postoperative course of cardiac surgery (4). In other Centers, the PRAM system has been used to monitor patients with septic shock (38), in patients undergoing major abdominal surgery (39) or cardiac surgery (1, 40). Moreover, PRAM has been also used in pediatric patients (41-43), in patients under spinal anesthesia for elective cesarean section (44), and in patients with veno-venous extracorporeal membrane oxygenation therapy (45).

Statistical Analysis

All data were recorded prospectively in a dedicated database, containing clinical and anatomic characteristics, intraoperative and postoperative variables detected with MostCareUp®, blood tests, length of stay and 30-day MACCE (Major Adverse Cardiac and Cardiovascular Events). The results were expressed as the means and standard deviation of the hemodynamic parameters in the intraoperative and 24-hour postoperative periods. Differences in percentages were analyzed by means of the Chi-square test or Fisher exact test for frequencies smaller that 5%, while differences in mean values were compared by means of the T-test for unpaired data. The mean values of the hemodynamic parameters measured in these two groups were then compared by means of the T-test for unpaired data. Finally, a cost analysis was performed in order to assess the potential savings associated with correcting the overuse of unnecessary postoperative CSDU stays. For this cost analysis we considered that in our Institution hospitalization in a surgical ward costs 766 euros per day, while it costs 1188 euros per day in the CSDU. Moreover, we estimated a cost of about 120 euros per patient for 72 hours hemodynamic monitoring with PRAM.

Results

Demographic and Clinical Features

The patients were predominantly male in both groups, with no significant difference in mean age or in the prevalence of cardiovascular risk factors and comorbidities. These were well balanced in the two groups, also with regard to the prevalence of coronary artery disease and peripheral occlusive arterial disease (Table 1). Regarding anatomical and technical features, the diameters of the aneurysm and the iliac arteries were similar in the two groups, and in about 1/3 of the cases a percutaneous approach was possible in both groups (Table 1), while in the remaining patients a surgical approach was required.

No statistically significant differences were found between the group 1-ward and group 2-CSDU patients in the hemodynamic variables assessed both intraoperatively and in the subsequent 24-hour monitoring (Table 2).

Table 1. Clinical, Anatomical and Procedural Characteristics of Patients Investigated

Characteristics	Group 1-ward	Group 2-CSDU	P
Clinical			
Age (mean ± SD)	74±6	77±6	0.105
Sex (M) (N; %)	21 (95.5)	20 (90.9)	0.550
Arterial Hypertension (N; %)	17 (77.3)	15 (68.2)	0.498
Diabetes Mellitus (N; %)	1 (4.5)	4 (18.2)	0.345
Hyperlipidemia (N; %)	12 (54.5)	12 (54.5)	1
COPD (N; %)	14 (63.6)	16 (72.7)	0.517
CAD (N; %)	4 (18.2)	9 (40.9)	0.099
POAD (N; %)	1 (4.5)	5 (22.7)	0.185
Anatomical and technical features			
AAA mm (mean ±SD)	52.9±7.3	56.2±8.5	0.174
R-CIA mm (mean ±SD)	19.4±6.2	17.5±4.4	0.248
L-CIA mm (mean ±SD)	17.7±6.7	18.7±5.8	0.599
Percutaneous access (N;%)	8/22 (36.4)	6/22 (27.3)	0.517

COPD=Chronic Obstructive Pulmonary Disease; CAD=Coronary Artery Disease; POAD=Peripheral Occlusive Arterial Disease; AAA=Abdominal Aortic Aneurysm; CIA=Common Iliac Artery; R=right; L=left.

Table 2. Intraoperative and 24 Hours Postoperative Hemodynamic Variables in the Two Groups, of Patients Analyzed, Ward (group 1) and CSDU (group 2).

Hemodynamic variables	Intraoperative			24 hours postoperative		
	Group 1 -ward	Group 2 -CSDU	P*	Group 1-ward	Group 2 -CSDU	P*
Systolic pressure (mmHg)	119.5±17.5	125.0±22.8	0.375	135.9±17.4	138.4±15.8	0.620
Diastolic pressure (mmHg)	61.4±6.7	62.3±11.2	0.748	61.9±10.3	65.1±7.9	0.254
Heart rate (bpm)	60.9±7.5	65.6±9.0	0.067	71.9±17.4	71.8±19.0	0.986
Systemic vascular resistances (dyne·s/cm^5)	1233.9±196.2	1327.9±227.9	0.150	1388.3±250.3	1436.5±209.7	0.493
CCE (units)	0.036±0.02	0.005±0.30	0.631	0.080±0.30	-0.010±0.30	0.325
Cardiac Output (L/min)	4.6±0.6	4.6±0.6	1	4.6±0.6	4.6±0.7	1
Stroke volume (mL)	74.9±13.1	77.2±11.1	0.533	68.0±13.1	71.0±23.1	0.599
SVV (%)	12.6±5.8	11.8±4.9	0.624	13.6±6.3	13.7±3.7	0.949
PPV (%)	17.9±1.6	15.3±7.6	0.124	19.4±13.7	16.8±8.7	0.457

*T test for unpaired data was used to compares the means of the two groups; CSDU=Cardiac Step Down Unit; CCE=Cardiac Cycle Efficiency; SVV=Stroke Volume Variation; PPV=Pulse Pressure Variation.

Hemodynamic Variables ("Unstable" vs. "Stable" group)

Comparing the two groups of unstable vs. stable patients, no significant differences were observed in mean systolic and diastolic pressure values, while heart rate, SVR, CCE, CO and SV differed significantly between these two groups, both in the intraoperative and in the 24-hour postoperative phase (Table 3). Interestingly, the average CCE in the "unstable" group was negative both during surgery and in the 24-hour postoperative monitoring.

Considering this division, 18 patients belonging to group 1-ward were considered "stable" and four "unstable" according to our criteria, while in group 2-CSDU, eight patients were deemed to be "stable" and 14 "unstable" (Figure 1).

A significant difference was observed in unstable patients between group 1–ward and group 2–CSDU patients (18.2% vs. 63.6%, P=0.002). In 5/44 unstable patients (11.4%), vasopressors were required for persistent hypotension.

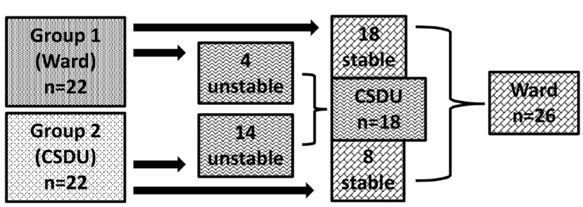

Figure 1. Real and hypothetical subdivision of patients destination, ward or CSDU, on the basis of preoperative assessment and after hemodynamic variables monitoring.

From this study it emerges that there were 4/22 (18.2%) patients referred to the non-monitored ordinary ward who could have benefited from postoperative monitoring. On the other hand, eight patients (36.4%) who were referred to the CSDU were very stable and could have been sent to the ward according to the intraoperative hemodynamic monitoring evaluation. In fact, taking into account a hypothetical subdivision carried out with the contribution of intraoperative hemodynamic variables, we would have sent 26 (18+8) patients to the ordinary ward, and 18 (4+14) patients to CSDU (Figure 1).

In Figure 2 we present the trends of the CCE-curves obtained intraoperatively and in the postoperative 24 hours in two paradigmatic patients: on the left a "stable" patient sent to CSDU and on the right an "unstable" patient sent to the ward, on the basis of preoperative evaluation.

The patient on the left, sent to the CSDU after preoperative evaluation, shows a regular trend in both intraoperative and postoperative parameters, a sign that his cardiovascular system was able to compensate for the perturbations induced by anesthesia and surgery. On the other hand, the patient on the right, sent to the non-monitored ward, shows significant variability in both intraoperative and postoperative hemodynamic parameters, which means the reduced compliance of his cardiovascular system, a condition with a higher risk of complications (Supplemental Figures 2 and 3).

During 30-day follow-up we did not observe any perioperative deaths, and none of the 44

Table 3. Intraoperative and 24 Hours Postoperative Hemodynamic Variables in the Two Groups, of Stable and Unstable Patients

Hemodynamic variables	Intraoperative			24 hours postoperative		
	Unstable	Stable	P*	Unstable	Stable	P*
Systolic pressure (mmHg)	121.3±21.1	122.8±8.9	0.760	133.5±19.8	139.7±17.5	0.277
Diastolic pressure (mmHg)	64.9±10.9	59.6±8.5	0.079	66.9±11.1	65.1±7.9	0.539
Heart rate (bpm)	67.9±7.2	59.2±8.9	0.0009	78.6±19.1	65.9±13.4	0.014
Systemic vascular resistances (dyne·s/cm^5)	1418.6±236.7	1178.8±192.2	0.0006	1544.3±235.2	1314.2±113.1	0.0002
CCE (units)	-0.212±0.2	0.184±0.2	0.0001	-0.201±0.2	0.210±0.1	0.0001
Cardiac Output (L/min)	4.3±0.5	4.8±0.6	0.0045	4.3±0.5	4.9±0.6	0.0008
Stroke volume (mL)	70.2±9.8	77.9±14.1	0.042	59.0±17.1	77.1±16.9	0.001

*T test for unpaired data was used to compares the means of the two groups; Unstable patients were defined as those who showed values of SVV and PPV higher than 15%. CCE=Cardiac Cycle Efficiency.

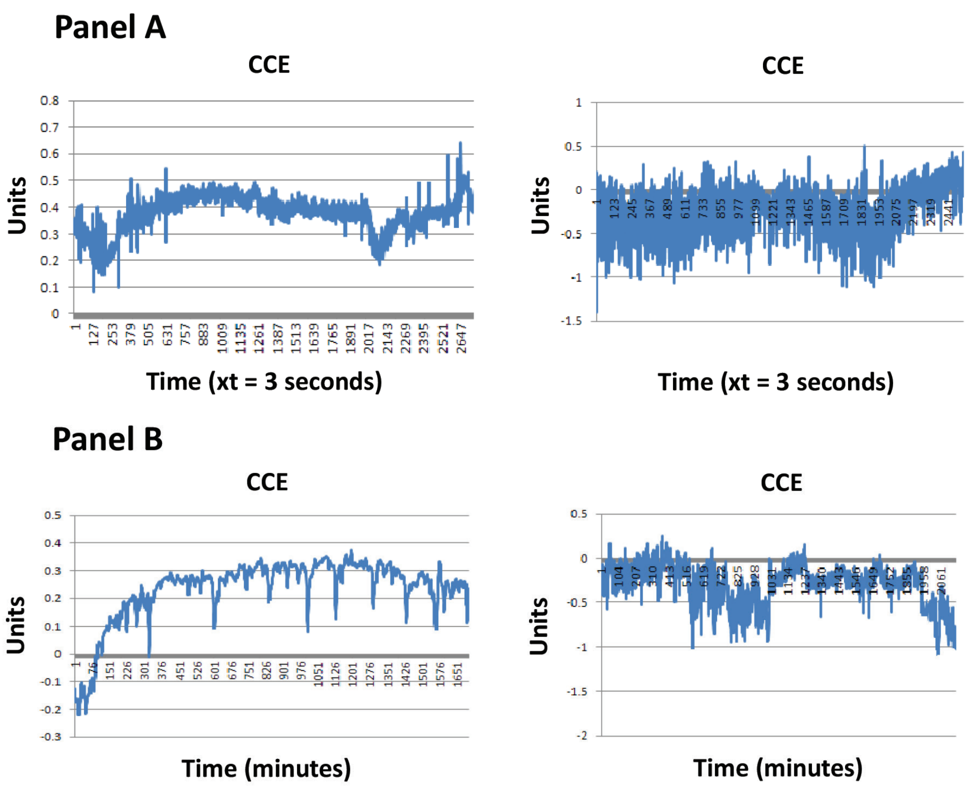

Figure 2. Trends of the CCE curves in the intraoperative phase (panel A) and in the 24 postoperative hours (panel B) of two paradigmatic patients: on the left a «stable» patient sent to the CSDU and on the right an «unstable» patient sent to the ward on the basis of preoperative evaluation.

patients had postoperative cardiac complications. The mean length of hospital stay was 4.28 days in group 1 and 5.26 days in group 2.

Cost Analysis

Considering the different costs of hospital stay per day at our Institution in a ordinary surgical ward (766 euros) and in the CSDU (1188 euros), we can calculate that the improper referral of a patient to the CSDU costs 422 euros per day more than if he was sent to the ward. According to our study, eight patients were improperly referred to the CSDU, with an estimated increase in costs of 3376 euros. Considering that 44 patients undergoing endovascular treatment are admitted over five months, we can assume that we treat 106 AAA patients in one year at our Institution, of whom about 20 are improperly referred to the CSDU after preoperative assessment, with an additional cost of 8440 euros per year in this selected group of patients. It is likely that this strategy could also be applied to other diseases in order to improve cost savings. The counterpart of our study is, however, represented by the group of patients sent to the ward according to preoperative evaluation but who would have benefited from CSDU according to hemodynamic monitoring. Assuming a cost of about 120 euros per each patient for PRAM monitoring, we can estimate an annual expense of approximately 2400 euros for 20 patients that must be deducted from the total profit.

Discussion

In the present study we report the feasibility and effectiveness of hemodynamic monitoring in patients undergoing endovascular repair for AAA, in order to choose the appropriate postoperative setting and its possible impact on costs. To date, this choice at our Institution has been mainly based upon clinical and instrumental preoperative evaluation, guided by our previous studies (46, 47) in accordance with the current Guidelines (23).

In fact, in one of our previous studies, the importance of a complete preoperative cardiac evaluation in patients undergoing abdominal aortic surgery was underlined and, in particular, we demonstrated that patients with a positive ergometric test could benefit from endovascular treatment to reduce the cardiac complications associated with open surgery (46). Moreover, in another study (47) we compared two different strategies of preoperative cardiac evaluation: one considering each patient's cardiovascular risk, and another applying the Lee criteria (48). This study did not demonstrate any significant difference between the two strategies in either morbidity or mortality, and suggested that routine use of ergometric testing should be avoided, since in most cases coronary angiography and myocardial revascularization do not lead to any significant improvement in morbidity and mortality. These studies were in line with the recent recommendations of the European Society of Vascular Surgery, suggesting that further cardiac assessment should be reserved only for patients with an acute cardiovascular disease, such as unstable angina, decompensated heart failure, severe valvular disease, and significant arrhythmias. In the absence of these diseases, clinical cardiovascular risk factors and the patient's functional capacity should be evaluated, and invasive coronary angiography should follow the same indications as in a non-surgical setting and not be routinely used for perioperative risk assessment before aortic surgery (23).

As far as intraoperative and postoperative management is concerned, fluid therapy and vasoactive drugs during interventions have been shown to play a pivotal role in these patients' outcomes (49). In order to improve intraoperative management, in the last few years the concept of Goal-Directed Therapy has progressively emerged (5, 13, 14, 16), and is also applied to vascular surgical patients (50, 51). For this purpose, hemodynamic monitoring is necessary, for which several devices have been developed (17, 18). Among them are the "Pulse Contour Methods" (PCMs) systems which are based on the principle that the volume of blood ejected from the left ventricle in systole (Stroke Volume, SV) could be estimated by dividing the area subtended by the pressure curve by the dynamic impedance of the arterial system. PCMs system can be classified into three categories: PCMs that require extreme calibration, through the dilution of an indicator; PCMs using the anthropometric and demographic data of the patient under study, and PCMs that do not require calibration or pre-estimated data. The MostCareUp® belongs to the third group of PCMs and uses the PRAM (Pressure Recording Analytical Method) system, based on the physical principle of perturbation, according to which every physical system subjected to perturbation tends to react by seeking a new condition of stability (i.e. a condition of minimum energy required).

This device has been previously explored at our Institution in several acute cardiac conditions, such as heart failure (19, 20) and ST-segment Elevation Myocardial Infarction (21), as well as in the postoperative phase of cardiac surgery. In the latter study, reduced perioperative values of Cardiac Cycle Efficiency demonstrated a negative prognostic impact at six months follow-up (4).

In the present study, we used this device to monitor two groups of patients undergoing endovascular repair for AAA: group 1 consisted of patients at low risk from preoperative assessment, who were referred to an ordinary ward after the intervention, and group 2 were those for whom postoperative CSDU monitoring was planned.

Comparing the results obtained from group 1 and 2 patients, no statistically significant difference was found in any of the variables analyzed with PRAM (MostCare®-UP), either during intraoperative monitoring or in the 24 hours after the intervention. However, the standard deviations of the hemodynamic parameters measured were wide, indicating the high variability of data collected, and suggesting that hemodynamic parameters varied greatly from patient to patient during surgery, independently of the destination assigned on the basis of the preoperative evaluation.

On the basis of these results, we systematically re-evaluated the trends of all the parameters analyzed in each patient, and observed that patients who showed a stable trend in hemodynamic variables during surgery remained stable even in the 24 postoperative hours, and were classified as "stable". On the other hand, patients who showed a higher degree of hemodynamic parameter variability during surgery maintained that variability in the postoperative period, and were defined as "unstable".

Therefore, according to their hemodynamic measurements, we divided patients into stable and unstable groups, a classification that did not exactly correspond to the group 1-ward and group 2-CSDU classification obtained according to risk stratification after preoperative evaluation. This may reflect the difficulties often found in cardiac risk stratification in patients who are candidates for vascular surgical interventions, suggesting the utility of a continuous and minimally invasive intraoperative monitoring system that could further help in guiding anesthetists in the choice of the more appropriate postoperative setting.

In particular, patients judged to be at low surgical risk following multidisciplinary preoperative evaluation, but who showed "latent" cardiovascular hemodynamic alterations, as highlighted by the reduced compliance of the cardiovascular system assessed with PRAM during surgery, could be referred to the CSDU in order to avoid perioperative complications and prevent their occurrence. On the other hand, this study also demonstrated that there are patients deemed to be at intermediate or high surgical risk after preoperative clinical and instrumental evaluation that show markedly stable hemodynamic parameters during intraoperative monitoring, and that could be referred to an ordinary ward instead of the CSDU.

This could also have an impact on costs: in fact, according to our cost analysis, in the present study we estimated a cost saving of approximately 6000 euros per year by avoiding the improper use of the CSDU, thus leading to the creation of a model that could also be applied to other clinical conditions in addition to AAA endovascular repair, with a further reduction in costs.

Our study does not seek to underestimate the importance of preoperative evaluation, as confirmed by the higher prevalence of unstable patients observed in group 2 (high risk) vs. group 1 patients (63.6 vs. 18.2%, P=0.002). Interestingly, our study also provides data about hemodynamic instability in a group of patients treated with an elective endovascular repair procedure, for whom hemodynamic monitoring data are scarce, since they were mainly analyzed in the context of a ruptured AAA, as demonstrated in a previous meta-nalysis (52).

Conclusion

In patients with AAA who are undergoing endovascular repair, intraoperative hemodynamic assessment with PRAM could represent a helpful strategy for surgical risk stratification and, in particular, could be useful for choosing the better clinical postoperative setting for each patient, together with the preoperative clinical and instrumental evaluation. The consequent reduction in the improper use of the CSDU could also have a beneficial impact on costs.

What Is Already Known on This Topic:

Hemodynamic monitoring is crucial in critically ill patients, both during and after major surgery, in order to promptly detect the occurrence of acute alterations that could lead to hypoperfusion and organ ischemia, and to evaluate the effects of pharmacological interventions. In patients who are candidates for major vascular surgery, postoperative complications and death are more frequent among high risk and older patients, since they have multiple comorbidities. A complete preoperative cardiac evaluation and therapy optimization have a crucial role in reducing cardiac perioperative complications. In the last few years, therapy optimization guided by hemodynamic monitoring, the Goal-Directed Therapy (GDT), has been associated with a reduction in surgical complications and the length of hospital stay. The GDT consists mainly in cardiac output monitoring to optimize perfusion and tissue oxygenation, and to improve postoperative outcomes. With this aim, several hemodynamic monitoring systems have been developed, such as the Pressure Recording Analytical Method (PRAM) system.

What This Study Adds:

Hemodynamic monitoring with PRAM in patients undergoing endovascular repair for abdominal aortic aneurysm can be useful, both for intraoperative therapeutic management and for the choice of the more appropriate postoperative setting for each patient, which is usually decided on the basis of preoperative clinical and instrumental evaluation.

This strategy could lead to avoiding the improper use of the Cardiac Step-Down Unit (CSDU) in stable patients judged to be at high surgical risk preoperatively, and to re-evaluate low surgical risk patients who show an unstable pattern during intraoperative monitoring. The reduction in the improper use of the CSDU could also have a beneficial impact on costs.

Authors' Contributions: Conception and design: EG, SMR and CP; Acquisition, analysis and interpretation of data: WD, CG, NM and AC; Drafting the article: EG, SMR, CP and EC; Revising it critically for important intellectual content: WD, CG and TAF; Approved final version of the manuscript: NM, RP and EC.

Conflict of Interest: Dr. Salvatore Mario Romano is the owner of the patent of the Pressure Recording Analytical Method.

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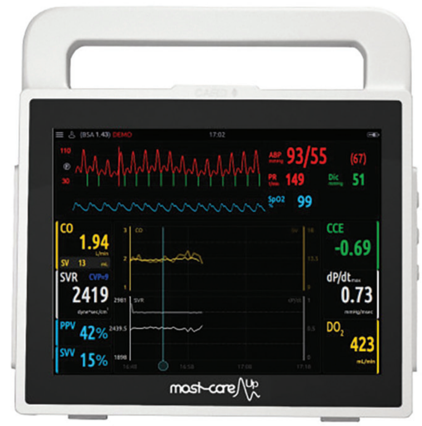
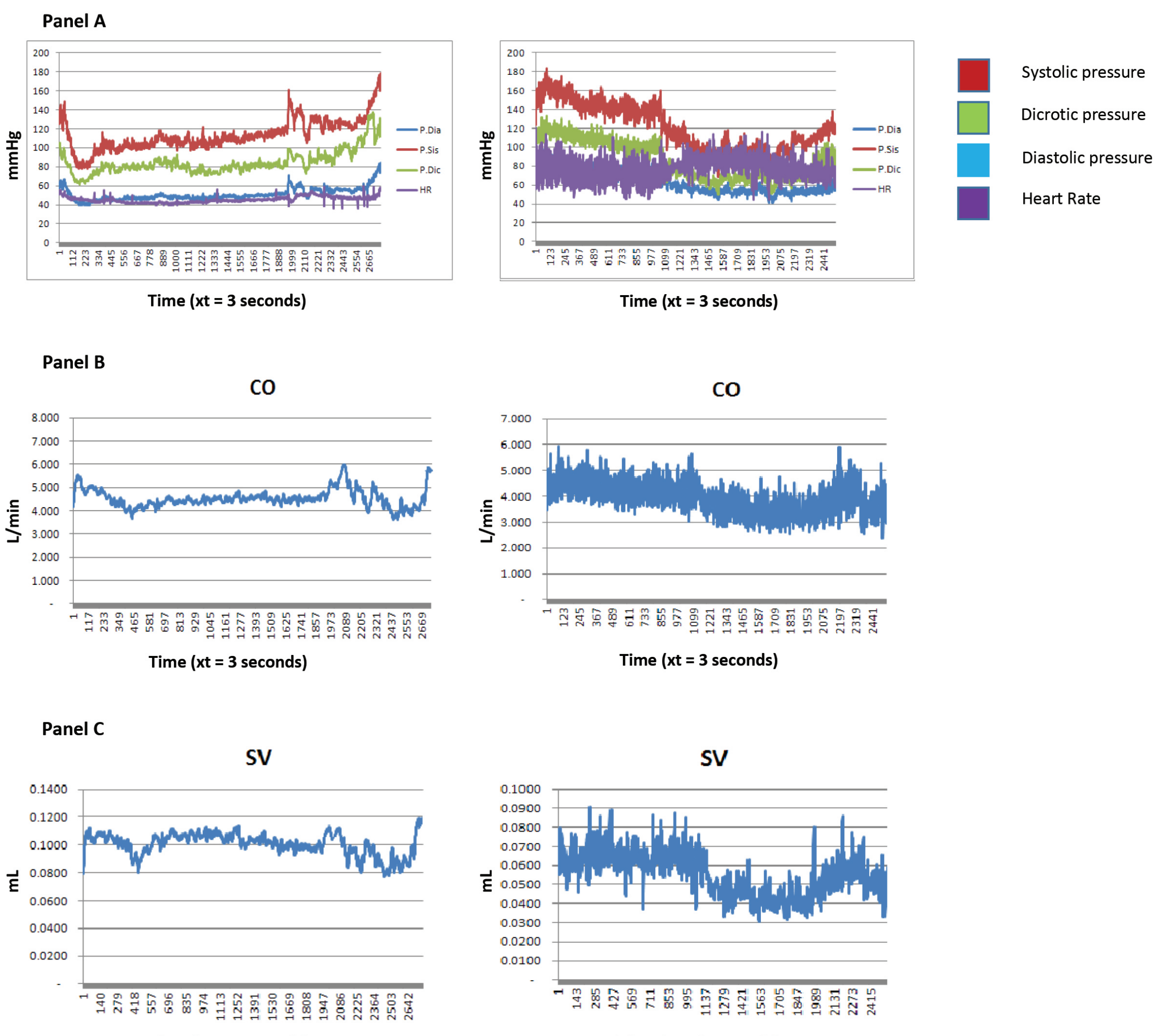
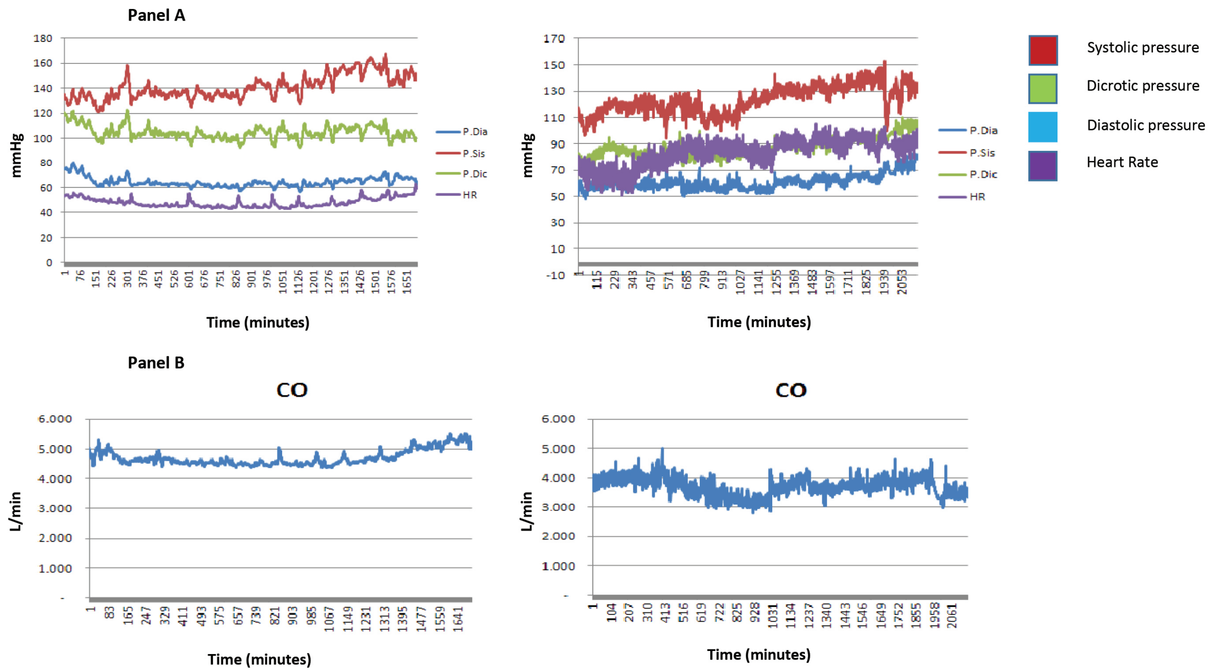
Supplementary Figures



Supplemental Figure 1. Image of MostCareUp® showing the main hemodynamic variables and indices of myocardial contractility assessed with PRAM algorithm.



Supplemental Figure 2. Trends of hemodynamic variables (systolic, dicrotic and diastolic pressure and heart rate) (panel A), of CO (panel B) and of SV (panel C) in the intraoperative phase of two paradigmatic patients: on the left a «stable» patient sent to the CSDU and on the right an «unstable» patient sent to the ward on the basis of preoperative evaluation.



Supplemental Figure 3. Trends of hemodynamic variables (systolic, dicrotic and diastolic pressure and heart rate) (panel A) and of CO (panel B) in the 24 postoperative hours of two paradigmatic patients: on the left a «stable» patient sent to the CSDU and on the right an «unstable» patient sent to the ward on the basis of preoperative evaluation.