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## The impact of metabolic syndrome and its components on perioperative outcomes after elective laparotomy - A prospective observational study

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## ABSTRACT

**Background:** Metabolic syndrome (MetS) represents a constellation of risk factors, including central obesity, elevated fasting blood glucose, high blood pressure and atherogenic dyslipidemia. This prospective observational study aimed to assess the impact of MetS on perioperative outcomes of patients undergoing elective abdominal surgery with laparotomy.

**Methods:** We included 105 consecutive non-diabetic patients undergoing elective abdominal surgery with laparotomy. Patients were divided into two groups based on MetS diagnosis. Perioperative adverse events were recorded according to the definitions of the European Perioperative Clinical Outcome guidelines.

**Results:** The prevalence of MetS was 57.1%. The presence of MetS was associated with a 2.64 higher odds (95% CI 1.18–5.95,  $P = 0.019$ ) for respiratory events and a 3.42 higher odds (95% CI 1.05–11.13,  $P = 0.041$ ) for superficial surgical site infections. Furthermore, regarding MetS patients, all individual components of MetS were associated with worse outcomes in an independent manner.

**Conclusions:** MetS as an entity along with its individual components are associated with an increased risk of perioperative events in patients undergoing elective abdominal surgery with laparotomy.

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## Introduction

Metabolic syndrome (MetS) is characterised by cardiovascular risk factors; these include hypertension, dyslipidemia (high triglyceride (TG) and low high-density lipoprotein cholesterol (HDL-C) levels), hyperglycemia and central obesity. The definition of MetS has been the subject of controversy as to its components and their individual contribution in establishing the diagnosis.<sup>1,2</sup>

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The prevalence of MetS varies worldwide, according to geographical region, study population (age, ethnicity and lifestyle) and MetS definition used.<sup>3–5</sup> For example, in the USA, the overall prevalence is 33% and it rises up to 46.7% among those  $\geq 60$  years of age.<sup>6</sup> Percentages are lower in Europe and in Southeast Asia (25% and 20%, respectively), while in China and Japan the prevalence is relatively low.<sup>7</sup>

The pathophysiology of MetS is still under investigation, although most investigators suggest a central role of insulin resistance along with abnormal adipose deposition and function.<sup>8</sup> Chronic inflammation, hypercoagulable state, endothelial dysfunction and chronic stress have been identified as processes closely associated with the syndrome.<sup>9</sup> Over the years, MetS has been linked with an increased risk of type II diabetes mellitus (DM) and vascular diseases (e.g. coronary heart disease, cerebrovascular disease, peripheral artery disease, abdominal aortic aneurysms and renal artery atherosclerotic disease) and chronic kidney disease.<sup>10</sup> Additionally, nonalcoholic fatty liver disease (steatosis) has been considered as the hepatic manifestation of MetS.<sup>11</sup>

MetS has been reported to be rather frequent among surgical patients, beyond 40% in some reports, but most of the evidence comes from retrospective studies.<sup>1</sup> There is a scarcity of data derived from prospective observational cohorts concerning the impact of MetS, either as an entity or its individual components, on perioperative adverse events in non-cardiac surgery patients.<sup>1</sup> Hence, we conducted a prospective observational study on patients undergoing elective abdominal surgery with laparotomy in order to evaluate the impact of MetS on perioperative outcomes.

## Patients and methods

Approval for this prospective observational study was provided by the Ethics Committee of the University Hospital of Ioannina, Greece. The study was registered at ClinicalTrials.gov (ID: NCT02447523). Written consent was obtained from each patient. The study population included consecutive patients who underwent elective laparotomy (colectomy: 55, Whipple: 8, hepatectomy: 5, gastrectomy: 17, nephrectomy: 9, removal of retroperitoneal mass: 5 and removal of pelvic mass: 6), for a variety of surgical procedures, in our hospital between September 2012 and December of 2014. All patients fulfilled the inclusion criteria: age  $> 18$  years and legally competent to consent, undergoing elective laparotomy with an estimated duration of operation  $> 1$  h, American Society of Anesthesiologists (ASA) physical status I–III<sup>12</sup> and receiving general anesthesia. Exclusion criteria were known end-stage cancer, pregnancy, DM and patients preoperatively admitted to the intensive care unit (ICU).

## Laboratory evaluation

All participants were interviewed on the day before surgery when history and physical examination were recorded, including vital signs and physical characteristics (weight, height and waist circumference) and peripheral blood samples were collected after a 12 h fasting period. Laboratory measurements included complete blood cell count, standard serum biochemical analysis as well as total cholesterol, HDL-C, TG, glycated hemoglobin (HbA1C), insulin and coagulation assays. All biochemical analysis were performed by standardized methods using an Olympus AU600 (Olympus Diagnostica, Hamburg, Germany) clinical chemistry analyser at the Laboratory of Biochemistry at the University Hospital of Ioannina. The glomerular filtration rate (GFR-EPI) was calculated by using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula.<sup>13</sup> Insulin resistance (IR) was quantified by the glucose homeostasis model assessment (HOMA).<sup>14</sup>

## Diagnosis of MetS

MetS was diagnosed by implementing the 2009 Joint Interim Statement of the International Diabetes Federation and the American Heart Association/National Heart, Lung and Blood Institute (IDF-AHA/NHLBI) criteria.<sup>2</sup> The study population was divided into two groups (MetS and non-MetS) based on the following 5 laboratory and clinical criteria<sup>2</sup>: a) waist circumference 94 cm or higher, and 80 cm or higher for men and women, respectively as defined by the Joint Interim Statement of IDF task force<sup>2</sup> for people of Mediterranean origin, b) fasting glucose  $\geq 100$  mg/dL (5.6 mmol/L) or receiving treatment for elevated glucose, c) hypertension: blood pressure  $\geq 130/85$  mmHg or on antihypertensive drug treatment, d) TG  $\geq 150$  mg/dL (1.7 mmol/L) or on TG-lowering drugs, e) HDL-C  $< 40$  mg/dL (1.0 mmol/L) and  $< 50$  mg/dL (1.3 mmol/L) for men and women, respectively, or on drug treatment for low HDL-C. MetS was diagnosed when at least three of the aforementioned were present.

## Perioperative data recording

All operations were performed under general anesthesia and all patients received standard care according to treatment protocols implemented by the Department of Anesthesia, University Hospital of Ioannina. Standard monitoring was applied to each patient based on ASA recommendations. Data collection during surgery included duration of operation and anesthesia, fluid administration (type and total amount) and surgical complications. Perioperative adverse events were recorded according to the definitions of the European Perioperative Clinical Outcome (EPCO) guidelines.<sup>15</sup> The follow-up period lasted up to 30 days after surgery.

## Statistical analysis

Taking into consideration the available relevant literature<sup>16,17</sup> group sample sizes of 42 in the MetS group and 42 in the control group achieve 90% power to detect a difference in perioperative outcomes between the group proportions of 0.2500. The proportion in the MetS group is assumed to be 0.0500 under the null hypothesis and 0.3000 under the alternative hypothesis. The proportion in the control group is 0.0500. The two-sided Likelihood Ratio test is the test statistic used. The significance level of the test was targeted at 0.0500. The significance level actually achieved by this design is 0.0909. A total of 105 participants were finally enrolled, 45 and 60 in the non-MetS and MetS group, respectively. Continuous variables are presented as mean values  $\pm$  standard deviation (SD); qualitative variables are expressed as values and frequencies. Associations among categorical variables were explored by the chi square ( $\chi^2$ ) test. The Student t-test was used for comparisons between normally distributed continuous variables, whereas the Wilcoxon-Mann-Whitney tests were used for the asymmetrically distributed variables. Multiple logistic regression analysis was used to estimate the correlation between MetS (as an entity or its individual components) and perioperative complications. We used 95% confidence intervals (CI) with a significance level of 5% for all comparisons. Statistical analyses were performed using the IBM SPSS Statistics for Windows, Version 23.0 (Armonk NY, USA: IBM Corp.).

## Results

### General characteristics of the study population

A total of 105 patients were included. Patient characteristics, comorbidities and drug therapy are summarized in Table 1. MetS

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