



Defining Major Surgery: A Delphi Consensus Among European Surgical Association (ESA) Members

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Abstract

Background Major surgery is a term frequently used but poorly defined. The aim of the present study was to reach a consensus in the definition of major surgery within a panel of expert surgeons from the European Surgical Association (ESA).

Methods A 3-round Delphi process was performed. All ESA members were invited to participate in the expert panel. In round 1, experts were inquired by open- and closed-ended questions on potential criteria to define major surgery. Results were analyzed and presented back anonymously to the panel within next rounds. Closed-ended questions in round 2 and 3 were either binary or statements to be rated on a Likert scale ranging from 1 (strong disagreement) to 5 (strong agreement). Participants were sent 3 reminders at 2-week intervals for each round. 70% of agreement was considered to indicate consensus.

Results Out of 305 ESA members, 67 (22%) answered all the 3 rounds. Significant comorbidities were the only preoperative factor retained to define major surgery (78%). Vascular clamping or organ ischemia (92%), high intraoperative blood loss (90%), high noradrenalin requirements (77%), long operative time (73%) and perioperative blood transfusion (70%) were procedure-related factors that reached consensus. Regarding postoperative factors, systemic inflammatory response (76%) and the need for intensive or intermediate care (88%) reached consensus. Consequences of major surgery were high morbidity (>30% overall) and mortality (>2%).

Conclusion ESA experts defined major surgery according to extent and complexity of the procedure, its pathophysiological consequences and consecutive clinical outcomes.

David Martin and Styliani Mantziari shared first authorship.

Collaborators of the ESA Study Group are co-authors of this study and can be found under the heading Acknowledgements.

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Introduction

What constitutes major surgery has been a matter of debate since the beginning of surgical practice. As early as 1917, Dr. R. Earl was preoccupied by this lack of clear definition and its impact on the surgical profession, as at the time osteopaths were allowed to perform ‘minor surgery’ [1]. To his relevant inquiry, he received the following response: ‘major surgery includes all work requiring a general anesthetic; all operations which involve openings into the great cavities of the body; all operations in the course of which hazards of severe hemorrhage are possible; all conditions in which the life of the patient is at stake; all

conditions which require for their relief manipulations, for the proper performance of which special anatomical knowledge and manipulative skill are essential' [1]. In 1965, a broad-scale survey was conducted among American surgeons to define criteria for major surgery [2]. Twelve variables stood out, including the severity of surgical trauma, patient status, potential morbi-mortality and long-term sequelae, as well as the infrastructure and expertise needed. No other attempt to reach a consensual definition of major surgery has been published since.

Many healthcare providers argue to this day the existence of 'minor surgery,' as even a minor intervention may have serious side effects on some occasions. Nonetheless, 'major surgery' remains a term widely used, though poorly defined, which may have direct implications on healthcare management, adequate preoperative patient selection and preparation and even on residents' and surgeons' training [3–5]. Furthermore, this lack of standard definition, particularly in clinical trials, may confound the interpretation of surgical outcomes.

Generally, an expert is a person who, in addition to having a theoretical knowledge of a defined area, has acquired advanced practical competence and recognized by his peers in the field. These skills seemed interesting to us to establish a definition of major surgery. The European Surgical Association (ESA) was founded in 1993 and currently represents one of Europe's most prestigious surgical organizations, regrouping expert surgeons from leading medical institutions. The aim of the present study was to reach a consensus in the definition of major surgery within this panel of expert surgeons by means of a 3-round Delphi process.

Materials and methods

Participants and study design

ESA members include the continent's most prominent surgeons from the country's leading academic medical institutions, many of whom are Chairs of Surgery Department at these institutions. Membership also includes some leading surgeons from around the world.

All ESA members ($n = 305$) were invited to take part in a 3-round Delphi process, by means of electronic mail invitations and questionnaires delivered via a dedicated online platform (Survey Monkey®, Palo Alto, CA, USA). The Delphi process involves completion of a series of questionnaires interspersed with summary and feedback derived from previous responses [6]. It allows free discussion without the influence of personal status, enables the alteration of personal views without embarrassment and provides a means to combine opinions from experts who

are geographically dispersed [6–8]. This method has been widely used in surgery research.

In round 1, experts were presented with open- and closed-ended questions to define major surgery and determine its different aspects. Preoperative, intraoperative and postoperative parameters, as well as patient- and intervention-related criteria were considered. Significant comorbidities were defined as Charlson index > 3 and/or ASA score > 2 [9, 10]. The authors developed these parameters which seemed relevant to the perioperative phase, but all participants were asked to propose any additional criteria or reflexions they considered important in free-text fields. Results were analyzed and summarized in rounds 2 and 3, where only closed-ended questions were included, either binary (*yes/no answer*) or statements to be rated on a 5-scale Likert scale (1: strong disagreement, 5: strong agreement). The top 5 responses from the previous round were presented in return. For some pertinent factors, cutoffs have been proposed, and always with the possibility of choosing a proposed cutoff or proposing one in a free-text field. Participants were sent 3 reminders at 2-week intervals for each round, with four-week intervals between rounds for result analysis and preparation of the next step. The whole process started on June 1, 2018, and was completed on February 1, 2019. All responses were treated anonymously, while participant's demographics were recorded. In accordance with previous studies, consensus was obtained when a statement was agreed or strongly agreed (*Likert scale* ≥ 4), or a binary question answered 'yes' or 'no' by $\geq 70\%$ of the experts [11, 12].

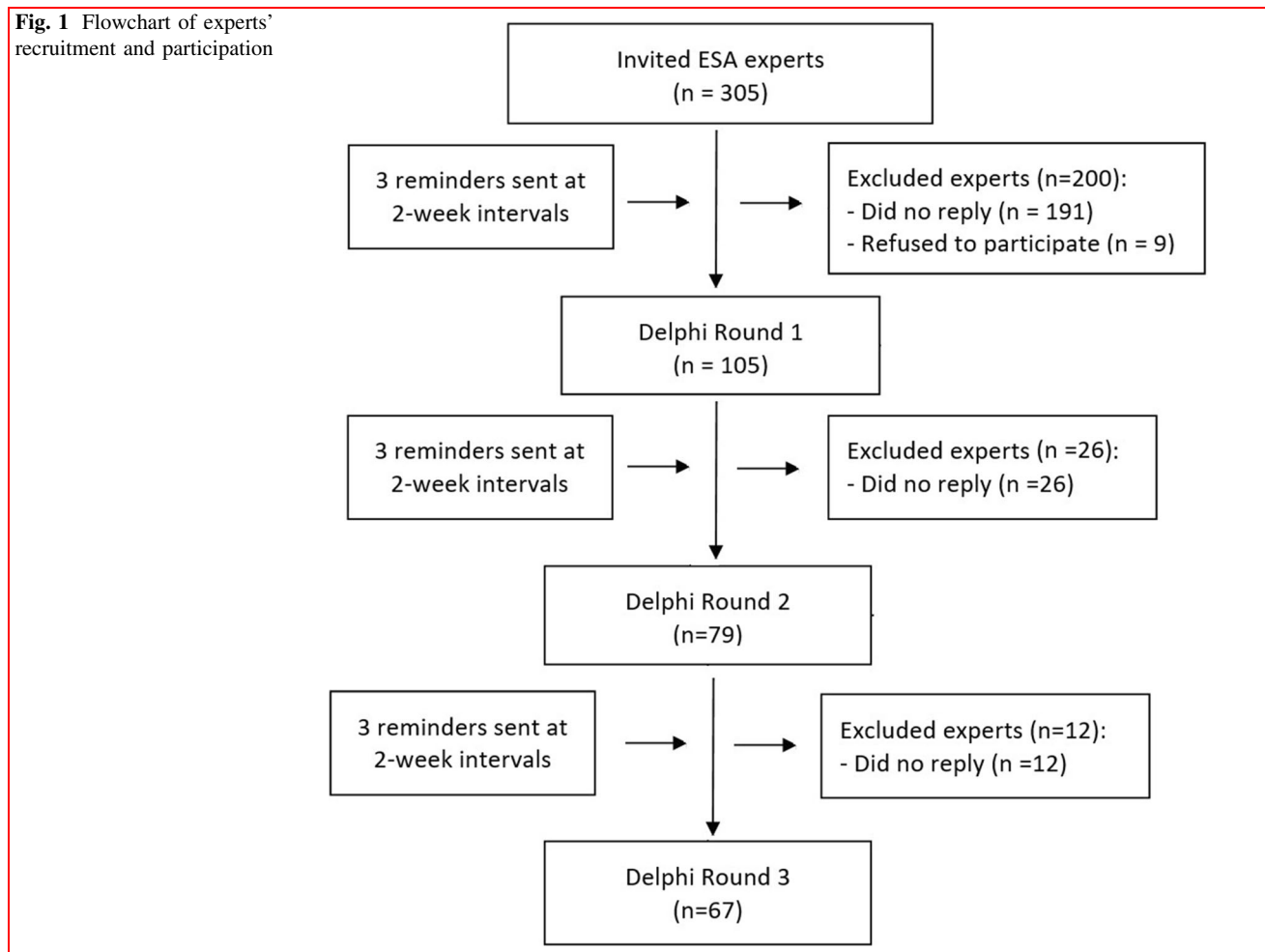
The study did not require approval by the local ethics committee as no patients were enrolled.

Statistical analysis

Descriptive statistics for categorical variables were reported as number and percentage, while continuous variables were reported as means and standard deviation (SD).

Results

Out of 305 ESA members, 67 (22%) answered all the 3 rounds (Fig. 1). Participant demographics are shown in Table 1. Mean age was 59 years (SD 9), 100% were males, 40% were specialized in HPB surgery, 75% had more than 20 years of practice and most of them practice in university hospitals (91%). Among the experts, answering all three rounds, 40% were specialized in HPB surgery, 21% in upper gastrointestinal surgery and 18% colorectal surgery. A distinction between major and minor surgery was considered as important by 99% of ESA experts. There was no significant difference in demographics between the

Fig. 1 Flowchart of experts' recruitment and participation

participants who responded to the 3 rounds and those who answered the 1st or 2 first rounds. The 3-round questionnaires are available in Online Appendices 1, 2 and 3, respectively.

Among all the patient-related factors, only severe comorbidity, defined by a Charlson index > 3 or American Society of Anesthesiologists (ASA) class >2, was consensually related to major surgery through all three rounds. Poor nutritional status and the need for preoperative nutritional support were considered important by 69% and 66% of the participants, during rounds 1 and 2, respectively.

Several types of interventions were proposed as examples of 'major' and 'minor' surgery (Online Appendix 4). Vascular clamping or organ ischemia (92%), high intraoperative blood loss (90%), intraoperative vasopressor support (>10 mcg/min noradrenalin) (77%), long operative time (73%) and perioperative blood transfusion (70%) were the parameters that reached consensus (Fig. 2). In particular, operative time >4 h and blood loss >1000 mL were

associated with a major intervention by 68% and 86% of the experts, respectively.

Postoperatively, morbidity (94%), mortality (91%) and the need for intensive or intermediate care (88%) were the factors most consensually related to major surgery, with thresholds defined at >30% for 30-day overall morbidity and >2% for mortality. Postoperative systemic inflammatory response was also highly related by the experts to the magnitude of surgery (76%). Biomarkers C-reactive protein (CRP) (77%) and lactate (78%) were related to metabolic stress by most participants, although there was no consensus on their precise cutoffs to define major surgery (Fig. 3). Other markers did not reach consensus, such as leukocytes, procalcitonin, albumin, fibrinogen, IL-1, IL-6 and TNF-alpha.

The expert panel was asked about the surgeon's subjective perception of major surgery. A feeling of stress was reported by 40%, tiredness by 39% and happiness/satisfaction by 20% of participants. A strong consensus was obtained on the necessity of surgical expertise (90%), multidisciplinary management (87%) and high volume

Table 1 Demographics of ESA experts

	Overall, <i>n</i> = 67
Mean age (SD)	59 (9)
Male gender	67 (100%)
Surgical specialty ^a	
Hepato-pancreato-biliary	42 (40%)
Upper gastrointestinal	22 (21%)
Colorectal	19 (18%)
Transplantation	8 (7%)
Thoracic	4 (4%)
Endocrine surgery	4 (4%)
Vascular	3 (3%)
Plastic	1 (1%)
Orthopedic	1 (1%)
Bariatric	1 (1%)
Years of practice	
0–10 years	2 (3%)
10–20 years	15 (22%)
>20 years	50 (75%)
Hospital structure ^a	
University hospital	69 (91%)
Community hospital	1 (1%)
Private practice	6 (8%)

^aParticipants could give several answers; the percentages are adapted to the total of the answers

center (84%) in order to perform major surgery; 64% of the experts stipulated that a major intervention can be taught to a trainee, and 87% stated that it cannot be performed as a day-case procedure.

A detailed list of statements that did not reach consensus in rounds 1 and 2 is available in Online Appendix 5.

Discussion

There is not a common understanding among surgeons of what major surgery means. According to the panel of experts from the ESA working group, a consensus (>70% of agreement) was reached in the following criteria defining major surgery; significant patient comorbidity, key surgical parameters (long operative duration, organ ischemia, blood loss >1000 mL, high vasopressor use), postoperative metabolic stress response, 30-day morbidity >30%, mortality >2% and the need for intermediate or intensive care. These criteria should be distilled now into a concise and easy-to-use definition in order to enable widespread use in both clinical practice and medical research.

In the present study, the only preoperative factor retained for the definition of major surgery was significant comorbidity of patients, defined as a Charlson score >3 or ASA class >2. Comorbidity is associated with worse health outcomes, more complex clinical management and

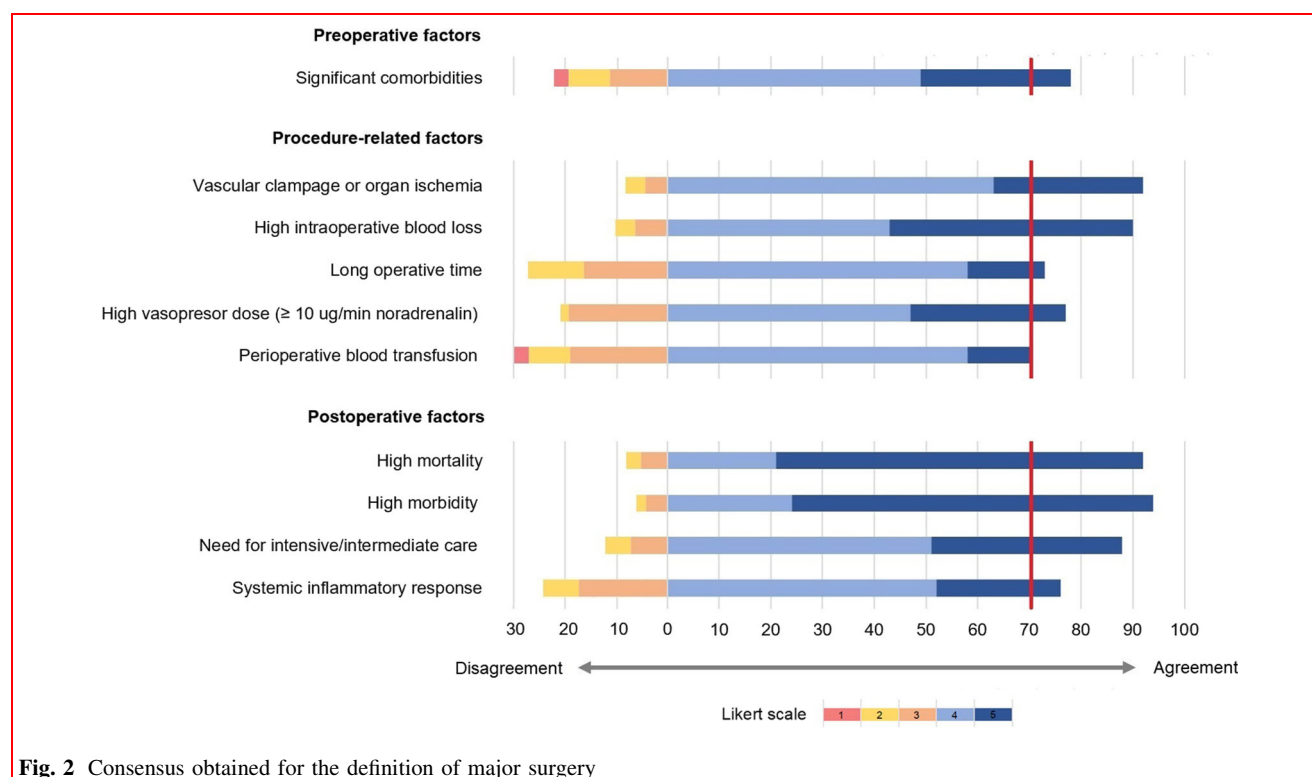


Fig. 2 Consensus obtained for the definition of major surgery

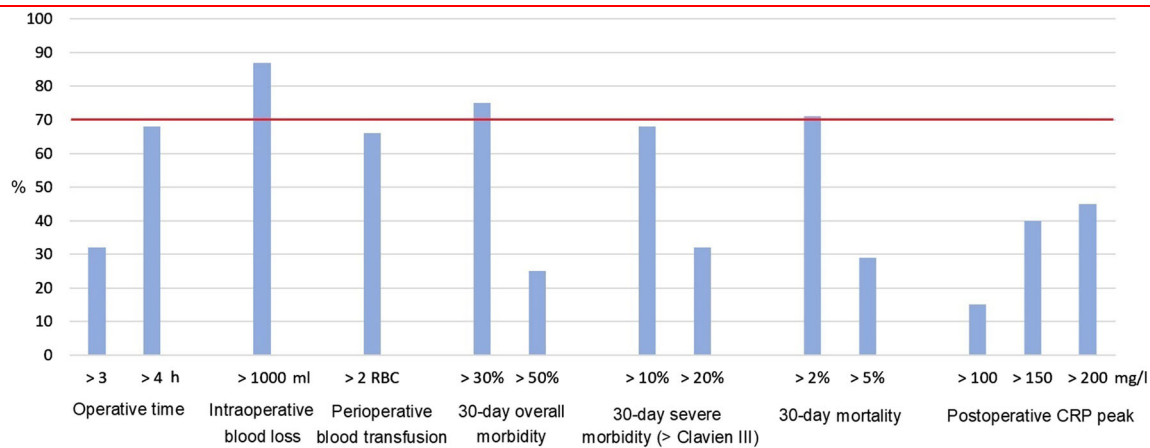


Fig. 3 Cutoffs of factors having reached consensus for the definition of major surgery

increased healthcare costs; however, there is no agreement on the meaning of the term [13]. Preexisting comorbidity was linked to increased risk of complications after major surgery in several papers published between 2009 and 2011 [14–16]. Several scoring systems have been developed to assess this risk, such as the Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity (POSSUM) and the Charlson index [9, 17]. The ASA score is widely used and easy to apply but remains prone to inter-observer variations [18, 19]. Patient age was not consensually considered as a major surgery criterion in the present study, although it has previously been described as a risk factor for morbidity and mortality after high-risk interventions [20, 21]. In a recent large-scale cohort study of 24,747 patients after major gastrointestinal surgery, overall perioperative morbidity increased twofold and mortality by 6.7 times for patients >75 years compared to younger patients [22]. There is thus a gap between experts' impression and previous scientific reports. A potential explanation for this fact could be that age cutoffs for 'elderly' vary significantly among the different studies between 65 and 80 years [20]. In addition, experts seemed to consider operative complexity and surgery-related characteristics as the principal determinant of major surgery, while opinions diverged as to the impact of specific patient-related factors.

Systemic inflammatory response syndrome (SIRS) is a serious condition related to systemic inflammation, organ dysfunction and organ failure [23]. It is a subset of cytokine storm that can occur after major surgery. Metabolic stress response has been extensively related to the magnitude of surgery in the literature, due to the hyperdynamic and hypermetabolic induced by surgical trauma [24]. In the present survey, systemic inflammatory response was identified as a key element to this definition. As suggested since

1975, tissue injury and ischemia–reperfusion have a systemic impact, by blunting of the cell-mediated immune system and the cascade of pro-inflammatory cytokines such as TNF- α , IL-6, IL-8 and IL-10 [19, 25–28]. Systemic inflammation seems to be less severe or even absent during abdominal surgery without tissue ischemia [27]. What is less well studied is the biomarkers that accurately reflect surgical trauma. In a recent prospective series of patients after major abdominal surgery, a decrease in serum albumin correlated with the extent of surgery, its metabolic response and with adverse outcomes such as complications and length of stay [29]. CRP and procalcitonin have also been proposed as predictors for adverse outcomes and may be used as additional criteria of discharge [30, 31]. In the present study, experts identified only lactate and CRP as biomarkers associated with the magnitude of surgery, without reaching a consensus on a precise cutoff. Metabolic stress after surgery is closely linked to intraoperative tissue damage and ischemia.

The expert panel identified intraoperative blood loss >1000 mL, hemodynamic instability, operative duration and organ ischemia as criteria to define major surgery. Previous studies have also identified severe intraoperative hemorrhage as a major risk factor for postoperative mortality [32]. Significant blood loss may trigger the cascade of inflammatory response as early as 30 min after the initial injury, initiating a process of multiple organ dysfunction [33, 34]. Long operative time was also selected as a criterion for major surgery in this present survey, but no cutoff could be defined. In the literature, postoperative metabolic stress has been related to the magnitude of surgery, rather than the duration of the procedure itself [35]. Intraoperative use of high-dose vasopressors, indicating hemodynamic instability, was another item retained by the expert group, although it remains difficult to clearly define

intraoperative instability and ‘high’ vasopressor doses. Data from cardiac surgery showed that vasopressor dependence was associated with postoperative renal failure, difficulty to wean from the mechanical ventilation and a longer length of stay in the intensive care unit (ICU) [36].

The attempt to identify certain types of operations as ‘major’ and ‘minor’ revealed a surprising heterogeneity as to how experts perceive different kinds of interventions (Online Appendix 4). The experts were discrepant in about 50% of procedures. A common argument provided was that any seemingly ‘minor’ procedure may occasionally have major consequences, as was also previously suggested by Small et al. [2].

Postoperative morbidity >30% and mortality >2% were set as a threshold for major surgery by the participants. Although these cutoffs remain somewhat arbitrary, they gathered a high rate of agreement among experts from different subspecialties. Previous studies have also suggested a threshold of mortality >1% related to major surgery [37]. Perioperative care is another element closely related to the magnitude of surgery, as multidisciplinary patient management in high-volume center has been shown to reduce short- and long-term complications in high-risk surgery [38, 39]. The present survey reinforces the importance of the expertise of both surgeon and center when endeavoring major interventions, as underlined by >90% of experts.

One direct implication of defining an intervention as ‘major’ would be the level of postoperative surveillance needed. Routine increased surveillance (intermediate or intensive care) after high-risk procedures may allow for prompt recognition and management of postoperative complications, thereby limiting added morbidity and mortality [40]. A British nationwide study including more than 4 million surgical procedures showed that high-risk surgical population accounts for 12.5% of procedures but for more than 80% of deaths, and only 15% of these patients were admitted to the ICU [41]. However, it is important to consider the fact that high-dependency units are very different from country to country.

Data about surgeons’ emotions are sparse in the literature, and it remains unclear what role emotions play in surgical practice [42]. In the present study, a feeling of stress, tiredness and happiness/satisfaction were reported by a minority of surgeons. The few available studies have mainly focused on feelings occurring in the context of stress, due to either an adverse event in the operating room or the occurrence of a severe postoperative complication [43, 44]. In a recent review exploring how surgeons described their practice, a gap between the myth of the surgeon (idealized image of surgeons as non-introspective, isolated, cold technicians, derived from the culture of

surgeons) and their actual experience has been showed [45].

Several limitations of the present study need to be addressed. A potential selection bias could be introduced, insofar as certain parameters have been proposed by authors. However, participants had the possibility to suggest other items in free-text fields. The expert panel was a highly selected group of European academic surgeons with a majority specialized in HPB surgery, which could limit the ability to extrapolate the proposed definition to other disciplines. Intraoperative blood loss, hemodynamic instability and organ ischemia as criteria to define major surgery may be applied for major hepatic surgery, but not necessary for other types of surgery, such as rectal resection for example. Moreover, other specialists have assessed criteria of other specialties, without their competence in the field being evaluated. Furthermore, it is difficult to assess how representative the answers are, to the extent that the opinion and demographic characteristics of the 238 experts who did not answer are not known. In addition, as this survey included mostly academic surgeons (91%), some findings may not be applicable to smaller structures, such as peripheral hospitals or private hospitals. The response rate was unfortunately low (22%) to provide a robust extrapolation of the results to the general surgical population. The target surgeon group was chosen to include expert and experienced surgeons, aiming to provide a well-founded basis for major surgery definition. Although further validation of these results is warranted in different surgeon populations and subspecialties, this study addresses the question in a methodologically robust and clinically relevant manner. A baseline definition of what expert surgeons consider as a ‘major’ intervention seems to exist, and precisely the most interesting aspect of this definition is its generalizability in different types of health systems and surgery type. This preliminary proposal of a highly expert group could serve as a basis for further elaboration of this widely used, but so poorly defined term of ‘major’ surgery. The Delphi technique is a widely used and accepted method for achieving convergence of opinion among experts within specific questions or issues. This method was designed to transform opinion into group consensus [8, 46]. One of the primary characteristics and advantages of the Delphi process is subject anonymity which can reduce the effects of dominant individuals which often is a concern when using group-based processes used to collect and synthesize information [7].

In conclusion, ESA experts defined major surgery according to preexisting comorbidity of the patients, extent and complexity of the procedure, its pathophysiological consequences and consecutive clinical outcomes. Further assessment of these criteria needs to be obtained in order to

validate and refine the definition for applicability in both clinical practice and medical research.

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Compliance with ethical standards

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

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