



# Basic Features and Clinical Applicability of 'Preliminary Universal Surgical Invasiveness Score' (pUSIS): A Multi-Centre Pilot Study

Evrensel Cerrahi İnvazivlik Başlangıç Skoru (ECİBS)'nin Temel Özellikleri ve Klinik Uygulanabilirliği: Çok Merkezli Bir Pilot Çalışma

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**Objective:** There is still a lack of a universally applicable and comprehensive scoring system for documenting the invasiveness of surgical procedures. The proposed preliminary 'Universal Surgical Invasiveness Score' (pUSIS) is intended to fill this gap.

**Methods:** We used the recently developed pUSIS to obtain values from 8 types of surgery and 80 individual interventions. The results were analysed using descriptive statistical methods. The degree of difficulty on a scale from 0 (very easy) to 10 (extremely difficult) and time expenditures for assessing pUSIS were documented.

**Results:** Individual pUSIS values ranged from 8 in a laparoscopic cholecystectomy case to 36 in a total hip replacement case. The lowest median pUSIS value of 11.5 was found for laparoscopic cholecystectomy and the highest value of 24.5 was found for open thoracic surgery. The correlation between pUSIS values and the duration of surgery resulted in a tight linear regression ( $R^2=0.6419$ ). The lowest mean ( $\pm$ SD) difficulty level to obtain pUSIS values was  $1.6\pm 0.6$  for sleeve gastrectomy and the highest one was  $2.9\pm 0.6$  for knee replacement. The duration to finalise the calculations was  $4.1\pm 1.1$  min for video-assisted thoracoscopy (VATS) and  $9.4\pm 1.3$  min for sleeve gastrectomy.

**Conclusion:** We concluded that pUSIS has the potential to be a useful, simply obtainable and universal assessment tool for quantification of the magnitude and invasiveness of individual surgical operations and can serve as a means to quantify surgical interventions for outcome research and evaluate surgical performance.

**Keywords:** Surgical invasiveness, score, surgical risk, outcome

**Amaç:** Cerrahi işlemlerin invazivlik derecesini belgelendirmek konusunda halen evrensel olarak uygulanabilir ve kapsamlı bir skorlama sistemi eksikliği bulunmaktadır. Önerilen 'Evrensel Cerrahi İnvazivlik Başlangıç Skoru' (ECİBS) bu boşluğu doldurmayı amaçlamaktadır.

**Yöntemler:** Sekiz tip cerrahi ve 80 müdahaleden veri elde etmek amacıyla son zamanlarda geliştirilen ECİBS'i kullandık. Sonuçlar tanımlayıcı istatistik yöntemleri kullanılarak değerlendirildi. 0 ile 10 değerleri arasında değişen bir ölçekte zorluğun derecesi ve ECİBS'i değerlendirmek için harcanan zaman rapor edildi.

**Bulgular:** Bireysel ECİBS değeri 8 ile (laparoskopik kolesistektomi vakası) 36 (total kalça protezi vakası) arasında değişiklik gösterdi. En düşük ortalama ECİBS değeri 11,5 olarak laparoskopik kolesistektomide ve en yüksek ortalama ECİBS değeri 24,5 olarak açık torasik ameliyatta bulundu. ECİBS değerleri ile ameliyat süresi arasındaki korelasyon sıkı bir doğrusal regresyona neden oldu ( $R^2=0,6419$ ). ECİBS değerlerini elde etmek için ortalama ( $\pm$ SS) en düşük zorluk düzeyi sleeve gastrektomi için  $1,6\pm 0,6$  iken, en yüksek zorluk düzeyi diz replasmanı için  $2,9\pm 0,6$  idi. Hesaplamaları sonuçlandırmak için harcanan süre video yardımcı torakoskopi (VATS) için  $4,1\pm 1,1$  dakika, sleeve gastrektomi için  $9,4\pm 1,3$  dakika olarak bulundu.

**Sonuç:** Çalışmada ECİBS'in cerrahi girişimlerin büyüklüğü ve invazivliğinin ölçülmesi için faydalı, kolaylıkla elde edilebilir ve evrensel bir değerlendirme aracı olma potansiyelinin olduğu ve de sonuçların araştırılması için cerrahi müdahalelerin niceliklerini belirlemek ve cerrahi performansı değerlendirmek amacıyla kullanılabileceği sonucuna ulaşılmıştır.

**Anahtar kelimeler:** Cerrahi invazivlik, skor, cerrahi risk, sonuç

## Introduction

For the estimation of postoperative outcome, it is important to have a clear picture about the magnitude and invasiveness of the involved surgery as an essential factor in addition to 2 conditions: the pre-existing health condition of the patient and the type and quality of anaesthesiological care. Unfortunately, there is a lack of a simple and universal denominator for the magnitude of surgical invasiveness, which is independent of the patient's pre-existing morbidity and the applied anaesthesia. In particular, there is no simple assessment tool that encompasses both, spatial and temporal aspects of surgical interventions, as well as the qualitative distinction between different organs and tissues. A parameter that considers all these characteristics of a surgical operation in a quantitative manner would certainly be useful in order to facilitate or even permit comparisons among surgical cases. It would also enable the classification and prediction of certain aspects of postoperative recovery as well as the evaluation of different surgeons and teams performing the same type of surgery. Furthermore, in retrospect, a tool of this kind would add a valuable possibility for assessing the surgical risk of each procedure as well as the average pUSIS values of each type of surgery.

The assessment of the magnitude of a surgical intervention is mostly based on the involved surgeon's 'gut-feeling' about the operative course, which is not only subjective but also far from yielding a quantitative aspect (1). Nevertheless, there is no doubt about the contribution of intraoperative management to the overall outcome in general. In the past, there have been a number of attempts focusing on the evaluation of surgical stress. The closest one to achieve this goal is the 'Surgical Apgar Score' (SAS), which has been introduced in 2008 (2, 3). In its original form, it is a 10-point scale based on intraoperative blood loss, heart rate and blood pressure. The authors state that their scoring system may detect differences in intraoperative management and convey prognostic information that even translates into the postoperative outcome. However, SAS has two major limitations: the assessed parameters are also related to the pre-existing patients' morbidity (which may interfere with the impact of intraoperative events) and it ignores tissue manipulation and traumatization during surgery (which otherwise is the main determinant of surgical invasiveness). There are also scoring systems assessing surgical characteristics, which have been tailored for specific interventions such as spine surgery (4, 5). A totally different and quantitative approach to assess surgical invasiveness has been introduced by Wennervirta et al., who presented the Surgical Stress Index (SSI) that is computed from finger photo-plethysmographic waveform amplitudes and pulse-to-pulse intervals (6-9). This technique is objective, but because it is limited as an indicator for the balance between nociception and anti-nociception only, it remains more dependent on the amount and quality of anaesthesia than on the impact of surgery; the biggest

concern is that one cannot distinguish between the influence of these 2 factors. The online accessible Surgical Outcome Risk Tool (SORT) is a pre-operative risk prediction tool to estimate the probability of death within 30 days of surgery (10). It has been developed and validated only for use in inpatient non-neurological, non-cardiac surgery.

In contrast to all these reported evaluation systems, a novel tool intended to assess the invasiveness of surgery alone would necessarily include all possible stressing effects of the intervention on the targeted organs/tissues as well as on the whole body and would strictly focus on the surgical intervention alone. The result should be expressed as a numerical value that is applicable to any type of surgery. For this purpose, our scoring system called the 'Universal Surgical Invasiveness Score' (USIS) has been created and recently proposed (11). This purely observational assessment tool has been created according to plausible considerations based on experience. In order to offer an easily accessible and immediately available result at the end of surgery, it explicitly avoids to incorporate stress-related parameters that have to be provided by laboratory tests (e.g. plasma stress hormones) and purely relies on observation. USIS is intended to be applicable to all types of surgical interventions in adults. The main limitation of its actual version is that the choice and weight of its components are still based on its creators' experience as well as on plausibility matters, but it is not yet clinically validated. Therefore, we added the prefix 'preliminary' to the name 'Preliminary Universal Surgical Invasiveness Score' (pUSIS) as its recent denomination.

To overcome this provisory status of the scoring system, a 3-phased plan for establishing its definitive version has been drawn: 1) This recent pilot study is the first step to prove the feasibility of pUSIS in a limited number of routine elective surgical cases. This will be followed by 2) a 'Delphi Exercise' for which a group of experienced surgeons and anaesthesiologists will discuss and re-evaluate the components of pUSIS in the light of the results from this pilot study. Finally, 3) a prospective multi-centre validation study will be conducted on a large number of cases, which will lead to the definitive version of the scoring system. Only this version will permit the removal of the term 'preliminary' from its recent denomination. This definitive version of USIS will be suitable to become a productive means of assessing the invasiveness of individual surgeries. This pilot investigation only represents the first step in the implementation process.

The aim of the study was to obtain the first collection of real-life pUSIS data from a group of different types of surgery, although we can already concede that this pilot study does not intend to cover all surgical disciplines. The primary endpoint was the magnitude, distribution and spread of points among these interventions and the effort necessary to calculate these values.

## Methods

### Assessment of pUSIS for individual surgeries

The system is composed of 3 cumulative parts (Figure 1):

- Surgical access by considering the location, size of the incision(s) as well as type of access to the targeted operation site (either open or endoscopic).
- Magnitude of the targeted organ/tissue trauma due to surgical manipulation by considering the location and duration of the surgical activity on the affected organ/tissue.
- Associated factors that have an impact on the postoperative outcome, such as blood loss and the location and number of inserted drainages.

The sum of the collected points from A, B and C yields the final pUSIS score. The anaesthesiologist in-charge of the assessed surgery calculated pUSIS towards the end of the operation. The evaluation procedure and data collection were exclusively observational and encompassed only clearly visible movements during the surgical procedure.

### Data acquisition

After obtaining a 'non-objection' declaration from the local Ethics Committee (No. 106-2015, chair Pr. Meyer-Abt) for performing this investigation, we have set up a prospective multi-centre observational pilot study to harvest pUSIS data from different surgical procedures. In 6 different surgical centres in 3 countries, a group of 8 distinct types of surgical interventions was chosen to be investigated. From each type

Surgical measure	Calculation	
1. Size of skin incision	1 point per 5 cm length of incision	<b>A</b> Surgical access
2. Size of soft tissue incision	1 point per 5 cm length of incision	
3. Opening of a body cavity by endoscopy	1 point for head/neck region 1 point for uterus, bladder 2 points for abdomen 3 points for thorax	
4. Opening of a body cavity by incision	2 point for head/neck region 3 points for uterus, bladder 4 points for abdomen 6 points for thorax	
5. Target organ/tissues	<b>1 point per hour of operating the targeted organ/tissue multiplied with the organ/tissue-factor as follow:</b>	<b>B</b> Organ/tissue trauma
Head/neck	x1 for brain and nervous system x1 face/neck structures ex. Cavities x2 sinuses, maxilla, mandibula x3 sensory organs (eyes, ears) x4 oral/nasal cavity, pharynx, larynx,	
Thorax	x2 heart, mediastinal organs x3 lungs, pleura	
Abdominal region	x3 abdominal organs x2 retro-peritoneal organs	
Perineum	x2 urogenital systems	
Vascular	x3 aorta, carotides x2 porto-caval vessels x1 peripheral vessels	
Musculo-skeletal system (bones, muscles, tendons, ligaments)	x3 pelvis x2 vertebral column x2 femur, humerus and large joints x1 other	
1. Blood loss	1 points per 250 mL blood loss	<b>C</b> Associated factors
2. Drainages	2 points per soft tissue drainage 3 points per abdominal cavity drainage 4 points per thoracic cavity drainage	
<b>Final SIS value at end of surgery=sum of points in A + B + C</b>		

Figure 1. Synopsis of pUSIS to calculate the score of individual surgical interventions

of surgery, which was performed by different surgical teams, 10 consecutive individual cases were documented. This is the list of the investigated types of surgery:

- Total hip replacement
- Open colon surgery
- Mastectomy
- Video-assisted thoracoscopy (VATS)
- Open thoracic surgery
- Total knee replacement
- Laparoscopic cholecystectomy
- Laparoscopic sleeve gastrectomy

All participating academic surgical centres denominated a local anaesthesiologist to be responsible for the locally performed study. Before commencing the data collection, the involved anaesthesiologists were thoroughly briefed about the details and methodology of pUSIS assessments in order to obtain comparable results for the different surgeries from all locations. Subsequently, the data harvesting started in October 2015 and was concluded by January 2016.

The included cases were elective surgeries on adult patients (>18 years of age) of both genders, who gave their informed consent to be included into this study. Emergency cases or operations on infants and pregnant women were excluded. In addition to the pUSIS value, the subjective difficulty level to obtain pUSIS (according to a subjective rating scale ranging from 0=easy to 10 very difficult) as well as the time necessary to calculate the individual scores was evaluated. No further patient details, clinical data, laboratory analysis or patient monitoring was involved. The data acquisition did not yield anything that could identify the patient, date, location of the intervention or identity of the involved surgical personnel.

The final set of data from the reported 80 individual surgeries was collected in an electronic spreadsheet that enabled descriptive statistical analysis. Data were analysed using Excel (Microsoft, Seattle). Continuous data were expressed as mean±standard deviation, and discontinuous data were expressed as median, quartiles and range.

**Results**

The obtained pUSIS values from all 80 surgeries ranged from 8 to 36. The median values and ranges for the 8 different types of surgery are listed in Table 1.

The lowest median pUSIS value of 11.5 was found for laparoscopic cholecystectomy, while the highest value of 24.5 was found for open thoracic surgery. With regard to the range, we found the lowest score of 8 in a laparoscopic cholecystectomy case and the highest score of 36 in a total hip replacement case. The mean durations of surgery ranged from 37±15 min for laparoscopic cholecystectomy to 162±45 min for laparoscopic sleeve gastrectomy. An illustrative distribution of the pUSIS results for all 8 different types of surgery is summarised in Figure 2.

The spread of pUSIS values as well as durations of each type of surgery show to what extent the operations were uniform in intensity and time. A good marker for this characteristic is the ratio between the standard deviation and respective mean value; for pUSIS values, these range from 0.10 for knee replacement to 0.39 for hip replacement, and for the duration of surgery, these range from 0.19 for knee replacement to 0.48 for hip replacement as well as for colon surgery. The correlation between pUSIS values and duration of surgery resulted in a linear regression coefficient for pUSIS=0.0809+9.1926 min, R<sup>2</sup>=0.6419 (Figure 3).

The average subjective level of difficulty to obtain the individual pUSIS values was 1.6±0.6 with a range of 0.2±0.4 for sleeve gastrectomy to 2.9±0.6 for knee replacement, while the average duration to finalise the calculations was 4.1±1.1 min with a range of 1.9±0.6 min for VATS to 9.4±1.3 min for sleeve gastrectomy (Table 2).

**Discussion**

Surgical stress influences the recovery time and quality as well as the occurrence of postoperative complications, morbidity and probably even mortality. Attempts to correlate outcome with perioperative circumstances are hindered by a marked variability in patients' health condition and intraoperative factors such as the quality of anaesthesiological care. These variables are additionally obfuscated by the invasiveness of surgery and the quality of surgical performance. Therefore, the extent to which the degree of surgical trauma further contributes to patients' risk of complications and postoperative recovery remains unclear (12).

Our data cover only a partial segment of the spectrum of possible invasiveness and omit the extremes (very low invasiveness in ophthalmic surgery and very high invasiveness in multi-body cavity interventions such as oesophagectomy) but give a good insight into the spread

Table 1. Main results of the survey, including distribution, range and spread of pUSIS values as well as durations of the investigated types of surgery

Type of surgery	pUSIS Median	pUSIS Range (min/max)	Duration of surgery (min; mean±SD)
Total hip replacement	16.5	12/36	106±51
Total knee replacement	19.5	17/24	135±25
Colon surgery (open)	20.5	16/28	110±52
Mastectomy	15.5	9/20	96±44
Thoracic surgery (open)	24.5	16/32	144±64
Video-assisted thoracoscopy	14.5	13/21	100±44
Laparoscopic cholecystectomy	11.5	8/12	37±15
Laparoscopic sleeve gastrectomy	20.0	13/27	162±45
All	17.5	8/36	111±56

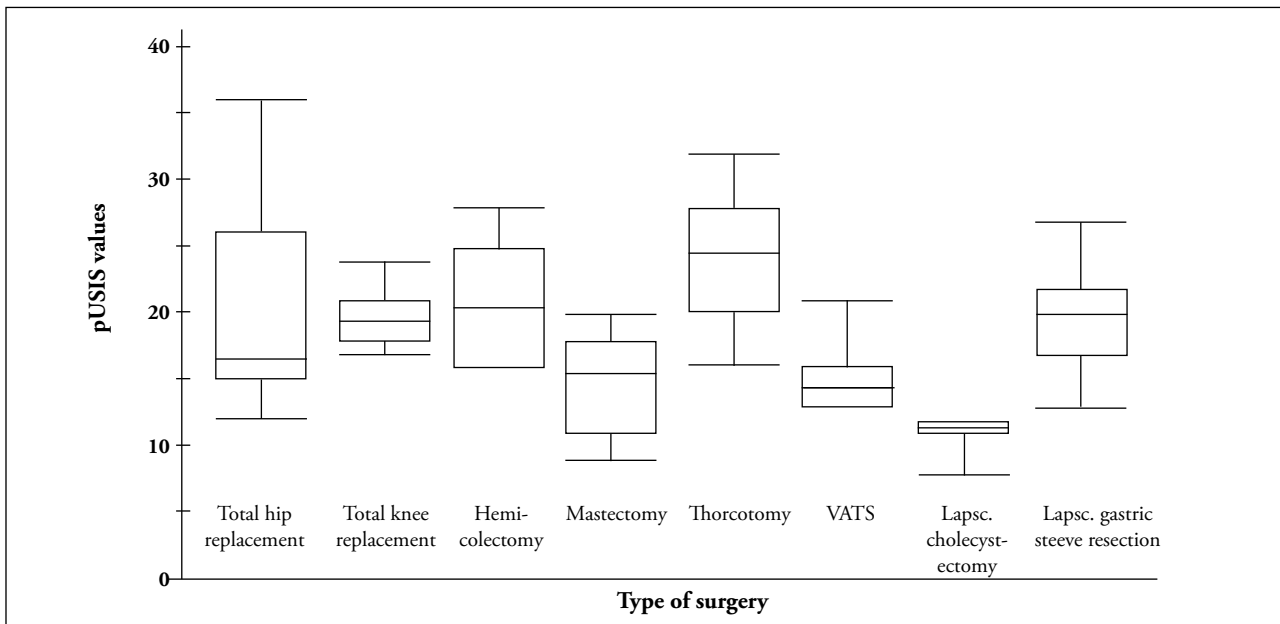


Figure 2. Variation of pUSIS by type of surgery. Boxplots represent the magnitudes (median), spread (1<sup>st</sup> and 3<sup>rd</sup> quartiles) and ranges (whiskers) of pUSIS values obtained from 8 different types of surgery (n=10 interventions operation type, total n=80 s)

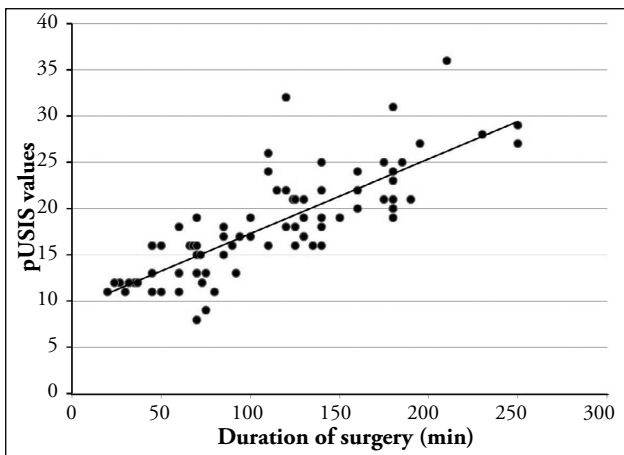


Figure 3. Correlation between pUSIS and duration of surgeries (n=80, min=minutes)

of pUSIS values in moderate to large surgery. For a first clinical trial in the sense of a pilot, this may be acceptable, but it certainly needs to be tested on a broader variety of surgeries. pUSIS represents a lesser objective means of assessment than SSI (6-9), but it is easier to perform, is available anytime and most importantly, clearly avoids to confound the influence of anaesthesia and surgery on the incurred stress level. The main difference between pUSIS and SORT is that SORT has to be applied before surgery and does not take into account what really happens during the intervention. Finally, in contrast to SAS, pUSIS exclusively deals with effects of surgery on the body and the targeted organs alone, thereby ignoring other factors (e.g. patients' morbidity) that can be otherwise quantified with other specific methods.

Table 2. Results based on the difficulty level to calculate and time interval to assess pUSIS

Type of surgery	Subjective difficulty degree (VRS 0 to 10)	Time interval for completion (min)
Total hip replacement	1.1±1.4	4.7±1.4
Total knee replacement	2.9±0.6	5.3±1.8
Colon surgery (open)	2.2±1.0	3.5±2.5
Mastectomy	1.8±0.6	2.5±1.2
Thoracic surgery (open)	2.1±0.7	2.6±0.8
Video-assisted thoracoscopy	1.9±0.7	1.9±0.6
Laparoscopic cholecystectomy	0.5±0.5	2.5±0.8
Laparoscopic sleeve gastrectomy	0.2±0.4	9.4±1.3
All	1.6±0.8	4.1±1.3

All values are expressed as mean±SD. VRS: verbal rating scale.

We assume that if all non-surgical factors such as the patient's morbidity and quality of anaesthesiological care are known and accordingly stratified, pUSIS would become a powerful tool to assess the variable impact of surgery, which in turn could be easily correlated with outcome results. Besides being exclusively of surgical nature, the score is universal and not limited to certain surgical procedures. Besides, it is simple enough to be assessed by an observer during or towards the end of an operation of any setting, regardless of the resource and technological capacity.

The included types of surgery were chosen in order to cover different specialties and types of operations, e.g. open and



endoscopic procedures, as well as interventions in different body parts and of various levels of complexity and invasiveness. Each investigated type of surgery represented the unaffected local techniques and customs. Nevertheless, we found variation spreads in pUSIS values as well as surgery durations within the same type of surgery, which probably represents differences between the individual surgical cases due to the intraoperative findings during the intervention and differences between the performance of surgeons as well (13). This variation is best illustrated by the spread of values of each type of surgery (Figure 1).

As expected, the subjective observation of the 'magnitude' of surgical interventions is echoed by the size of and the inter-individual variation in pUSIS values, which systematically incorporate all contributing factors that make up the 'invasiveness' of an operation. In particular, both spatial and temporal factors are included, avoiding the less-representative 1-dimensional aspect of duration of surgery alone as well as the similarly 1-dimensional determination of the operation target. However, there is a strong correlation between pUSIS and duration of surgery, which reflects the relevance of time (Figure 2).

The distribution of points among the 3 components forming the final pUSIS (A: surgical access; B: tissue traumatization and C: associated factors) that resulted in an average representation of A=53%, B=26% and C=21% may initially appear as being strongly access-dominated. This may be partially caused by not including rather short surgeries (the longest duration was 250 min, while the average duration was  $111 \pm 56$  min only), thereby limiting, in particular, the impact of tissue traumatization (B) that is strongly dependent on the temporal dimension. However, the distinction between open and endoscopic surgeries is clearly illustrated in the different proportion of A vs. B values, which were distributed as A=61%, B=19% and C=20% in open surgery in comparison with A=43%, B=33% and C=24% in endoscopic interventions. This circumstance is at least a positive indicator of the sensitivity of pUSIS for the differentiation of access-dependent as well as tissue traumatization-related aspects of surgical operations. It also underlines the ability of pUSIS to reflect various combinations of invasiveness-related circumstances as they appear in different combinations. However, the true weight of each component of USIS is still to be determined in the future phases 2 (panel of experts during a Delphi Exercise) and 3 (extended validation trial) of its evaluation.

The necessary effort to obtain a pUSIS value at the end of surgery turned out to be very small. An average difficulty level of 1.6 on a scale up to 10 can be considered as considerably low, thereby not representing a hindrance to its widespread application. In addition, the time expenditure necessary to sum up the final pUSIS value was not really incriminatory (4.1 min). The only precondition to be able to calculate the score in a reliable fashion is to have a good overview of what has happened on the operation site while gaining access to the

targeted tissue and the observation of main aspects of surgical manipulation. The ease and expedience of filling the questionnaire would encourage the anaesthesiologist in-charge of the case to cover this task without hesitance.

With regard to limitations, we have to emphasise on the preliminary nature of pUSIS, which still lacks validation, as well as the orienting nature of this pilot assessment. However, this multi-centre pilot investigation was necessary to obtain initial results for the whole idea of a universal scoring system, which in turn will be used as a starting point for the 2<sup>nd</sup> phase (the Delphi Exercise) to find an agreement among experts for the relevance and weight of each component of the scoring system, and a 3<sup>rd</sup> phase that will be tailored as a multi-centre validation study on a large number of cases. The absence of certain types of surgery, such as neurosurgery, cardiovascular and head-neck surgery, was not caused by deliberate exclusion. We included surgeries that were available in the centres that agreed to participate. We consider that our partial variety of surgeries was sufficient to cover the limited scope of this pilot study.

We can conclude that pUSIS promises to be a first step in the introduction of a useful, simply obtainable universal assessment tool for quantification of the magnitude and invasiveness of individual surgical operations. Potential benefits of having a finally validated and approved scoring system for surgical interventions are manifold in the context of decision making, outcome research and evaluation of surgical performance.

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