

POSTOPERATIVE CARE

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Use of the surgical Apgar score to guide postoperative care

Collaborators

Steering committee: JB Haddow, H Adwan, SE Clark, S Tayeh, SS Antonowicz, P Jayia, DW Chicken, T Wiggins, R Davenport, S Kaptanis, M Fakhry and CH Knowles *Local investigators*: AS Elmetwally, E Geddoa, MS Nair, I Naeem, S Adegbola and LJ Muirhead

London Surgical Research Group

ABSTRACT

INTRODUCTION The surgical Apgar score (SAS) can predict 30-day major complications or death after surgery. Studies have validated the score in different patient populations and suggest it should be used to objectively guide postoperative care. We aimed to see whether using the SAS in a decisive approach in a future randomised controlled trial (RCT) would be likely to demonstrate an effect on postoperative care and clinical outcome.

METHODS A total of 143 adults undergoing general/vascular surgery in 9 National Health Service hospitals were recruited to a pilot single blinded RCT and the data for 139 of these were analysed. Participants were randomised to a control group with standard postoperative care or to an intervention group with care influenced (but not mandated) by the SAS (decisive approach). The notional primary outcome was 30-day major complications or death.

RESULTS Incidence of major complications was similar in both groups (control: 20/69 [29%], intervention: 23/70 [33%], p=0.622). Immediate admissions to the critical care unit was higher in the intervention group, especially in the SAS 0–4 subgroup (4/6 vs 2/7) although this was not statistically significant (p=0.310). Validity was also confirmed in area under the curve (AUC) analysis (AUC: 0.77).

CONCLUSIONS This pilot study found that a future RCT to investigate the effect of using the SAS in a decisive approach may demonstrate a difference in postoperative care. However, significant changes to the design are needed if differences in clinical outcome are to be achieved reliably. These would include a wider array of postoperative interventions implemented using a quality improvement approach in a stepped wedge cluster design with blinded collection of outcome data.

KEYWORDS

Postoperative complications - Decision support techniques - Prognostic impact study

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CORRESPONDENCE TO James Haddow, E: jameshaddow@nhs.net

Prognostic studies are performed in many areas of medicine where the broad aim is to provide information that may eventually stratify or personalise treatment to yield patient benefit.^{1–5} In surgery, several clinical risk scoring systems exist. Their aim is to predict surgical outcomes. The American Society of Anesthesiologists (ASA) grading system is employed widely. However, it has been shown to be of little use in predicting individual patient outcome (positive predictive value for complications 57%, negative predictive value 80%).⁴ Other more accurate scores such as POSSUM (Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity) exist but, owing to their complex nature, they have not been adopted into routine clinical practice.

In contrast, the surgical Apgar score (SAS) is a simple, objective and economical ten-point postoperative prognostic scoring system based on three readily recorded intraoperative variables: lowest heart rate, lowest mean arterial pressure and estimated blood loss (Table 1). Following development by Gawande *et al* in 2007,⁵ the score was first validated in 4,119 patients undergoing general or vascular surgery and showed a strong correlation with the occurrence of major complications or death within 30 days of surgery: a lower score on a scale of 0 to 10 predicts a poorer prognosis.

The SAS has since been validated externally by several other groups in patients undergoing general, vascular, urological, gynaecological, orthopaedic and pancreatic surgery, and neurosurgery.^{6–14} A large multicentre prospective study across 8 countries also validated the score in 5,909 adults undergoing non-cardiac operations¹⁵ and in the largest study to date, the score was validated retrospectively in 101,907 patients across a wide range of surgical subspecialties in a single American centre.¹⁶ However, this was for mortality only. The SAS has also been shown to

Table 1 The ten-point surgical Apgar score (SAS): The SAS is calculated at the end of any general or vascular surgery operation from the estimated blood loss, lowest mean arterial pressure and lowest heart rate entered in the anaesthesia record during the operation. The score is the sum of the points from each category.

	Number of po	Number of points					
	0	1	2	3	4		
Estimated blood loss (ml)	>1,000	601-1,000	101–600	≤100			
Lowest mean arterial pressure (mmHg)	<40	40–54	55–69	≥70			
Lowest heart rate (bpm)	>85*	76–85	66–75	56–65	≤55*		

*Occurrence of pathological bradyarrhythmia (including sinus arrest, atrioventricular block of dissociation, junctional or ventricular escape rhythms) and asystole also receives 0 points for lowest heart rate. Source: Gawande, 2007.⁵

predict complications that arise after an uncomplicated discharge following colorectal resection.¹⁷ Contrarily, two studies have not demonstrated the predictive value of the SAS.^{18,19}

With greater numbers of high-risk patients in the UK undergoing surgery, for which the mortality is 85%,²⁰ identifying these patients and reducing their perioperative risk is vital. Furthermore, strategies to reduce 30-day postoperative complications are important as it has been shown that their occurrence significantly reduces long-term survival.²¹ Although the SAS cannot be calculated preoperatively to offer insight into the decision for surgery, authors have proposed that the score should be used to aid communication between care teams and to direct the clinical management in the postoperative phase.^{6–8,11–17}

The utility of the SAS is promising but so far it has not been tested in an impact study. It has therefore not yet been demonstrated whether the SAS can be used to guide postoperative care and consequently benefit outcome. In the first step to address this research question, we conducted a pilot study as a prelude to a multicentre randomised controlled trial (RCT). The aims were:

- > to see whether using the SAS in a decisive approach in a future RCT would be likely to demonstrate an effect on: a) postoperative care; and b) clinical outcome
- > to determine the feasibility and validity of conducting a RCT impact study.

Methods

Surgical registrars in nine hospitals in the UK were recruited as investigators through a trainee-led research collaborative. These investigators established the project at their sites and were responsible for recruiting patients, obtaining informed consent, administering the protocol and collecting the data. Recruitment into the trial was approved by East London Research Ethics Committee 3. The trial was registered on the ClinicalTrials.gov website (number NCT01799369).

Eligibility for the study was kept similar to the original validation study:¹⁴ limited to adults undergoing emergency or elective general or vascular surgery who required routine outpatient follow-up. Those without capacity to consent to involvement in the trial were excluded. Patients were identified and recruited with written consent when they were placed on the operating waiting list or when consent for the operation was obtained. For this pilot, an arbitrary study end of 200 participants or one year of recruitment, whichever being the earliest, was set.

Design

This pilot impact study was designed as a multicentre, single blinded RCT. Demographic and perioperative patient data were collected prospectively from the medical records. Randomisation was conducted by the surgeon at the end of the operation and after the data to calculate the SAS had been collected. A computer generated block randomisation method (block size of four) was accessed through a secure website (ALEA version 2.2; Netherlands Cancer Institute, Amsterdam, Netherlands) to allocate an equal number of patients to either a control or a stratified intervention group. Randomisation was stratified by ASA grades 1-2 or 3-5 and by emergency or elective surgery. Patients were blinded to the randomisation outcome but healthcare professionals were not. Patient characteristics were recorded, including age, sex, ASA grade, type of operation (emergency or elective) and operation class (minor, intermediate, major, extensive).

Interventions

In designing the interventions, we considered the work of Moons *et al*, who stressed that prediction models are not meant to take over the job of the doctor.²² They are instead intended to help doctors make decisions by providing objective estimates of probability as a supplement to other relevant clinical information. Impact studies, such as ours, may use an assistive approach that simply provides the model's predicted probabilities of an outcome between 0% and 100% or a decisive approach that explicitly suggests decisions for each probability category.²⁵

We chose to employ a decisive approach as this was likely to have greater effect. For patients in the intervention group, the SAS was calculated by hand using a reference table (Table 1). The SAS was used to stratify the patients into three probability categories. As poor scoring patients (SAS 0–4) are 16 times more likely to experience a major complication than patients with the highest scores (9-10),⁵ we chose the probability categories for our study as SAS 0-4, 5-8 and 9-10. Absolute risks of major complications were estimated for each probability category from the original validation data¹⁴ at 60%, 15% and 5% respectively. These absolute risk estimates, along with a review of the background literature concerning the SAS, were provided to the surgeons in advance so they understood the implication of the scores. Surgeons were to provide this information with explanation during communications and handovers.

In keeping with a decisive approach, actions were therefore stipulated but clinical interventions were not compulsory and doctors were free to exercise their own clinical judgement at all times. In deciding the stipulated clinical actions, we acknowledged that postoperative critical care admission is associated with improved survival.²⁴ Many clinicians believe that, despite limited evidence, high risk patients undergoing major non-cardiac surgery would benefit from routine postoperative admission to the critical care unit²⁵ and there is evidence of a systematic failure in the process of allocation of critical care resources in Europe, including in the UK.²⁶ Consequently, consideration for admission to the critical care unit was included. Other actions were included after considering the more common major postoperative complications (surgical site infection, deep vein thrombosis and stress ulcers). The actions, shortlisted and refined by the steering committee after review by peers, were:

- > SAS 9–10: no additional actions required
- > SAS 5–8: prescribe antibiotic, stress ulcer and venous thromboembolism prophylaxis if considered beneficial, handover to a surgical colleague to review the patient in eight hours (specifically including review of vital signs, urine output and pain) and then plan twice daily review for the next two days
- > SAS 0-4: in addition to the above actions, seek the opinion of an intensivist to consider admission to critical care unit and plan an additional review in four hours
- > For patients in the control group, the SAS was not calculated (to prevent contamination effects [ie interventions being applied in control patients]) and their management continued as per local standard clinical care.

Outcomes

Outcome data were collected after 30 days during an outpatient consultation (or if still an inpatient, during a ward consultation). Observer blinding was not feasible in this pilot study owing to limited resources. Patients lost to follow-up were consulted by telephone.

Although this was a pilot, notional primary and secondary outcomes were defined. The primary outcome was the same as in the original validation paper:¹⁵ major complications or death within 30 days of surgery (a composite binary outcome). Major complications, as defined by the American College of Surgeons National Surgical Quality Improvement Program, were included; these comprised acute renal failure, bleeding that required a transfusion of \geq 4 units of red blood cells within 72 hours after surgery, cardiac arrest requiring cardiopulmonary resuscitation, coma of \geq 24 hours, deep vein thrombosis, myocardial infarction, unplanned intubation, ventilator use for \geq 48 hours, pneumonia, pulmonary embolism, stroke, wound disruption, deep or organ/space surgical site infection, sepsis, septic shock, systemic inflammatory response syndrome and vascular graft failure.²⁷ Other complications of Clavien grade III and greater²⁸ were also included. Superficial surgical site infection and urinary tract infection were not considered major complications.

Secondary outcomes were all complications, immediate and delayed admissions to the critical care unit with length of stay, duration of therapeutic antibiotics (course lasting more than 24 hours), number of additional operations under general anaesthesia to treat complications, all within 50 days of the primary operation, and overall length of postoperative stay.

All data were collected on paper proformas before being inputted into a local Access[®] database (Microsoft, Redmond, WA, US). Data completeness was verified, and patient and site identifiable information was removed before being combined for analysis.

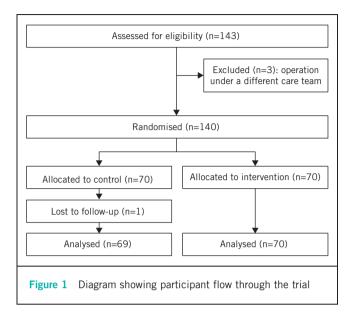
Statistical analysis

The combined anonymised dataset was coded appropriately. All statistical analyses were performed on Stata[®] 10 (StataCorp, College Station, TX, US). Continuous variables were analysed using two-sided t-tests; when distributions were apparently skewed, the two-sample Mann–Whitney U test was used. Categorical variables were analysed using chi-squared tests. The area under the receiver operating characteristic curve (AUC) was used to quantify the performance of the score. Univariate logistic regression was used to compare outcomes in the two groups.

Results

The study profile is summarised in Figure 1. Patients were recruited between April 2011 and March 2012. All of the 143 patients approached gave their consent to participate. Three subsequently had their operation under a different care team and were therefore excluded from the trial, and one was lost to follow-up. This left 139 patients for analysis (control: 69, intervention: 70). The characteristics of the patients were similar in each group (Table 2).

Outcomes for each group are summarised in Table 3. There was no difference in major complications between the groups (control: 20/69 [29%], intervention: 23/70 [33%]; odds ratio: 1.20, 95% confidence interval [CI]: 0.58–2.46, p=0.622). Comparison of the outcome by SAS subgroup also did not reveal any significant differences or trends. A single death occurred within 30 days. This was observed in the intervention group in a patient with ASA grade 5 undergoing an emergency intermediate operation. The patient's SAS was 0. The five most common major complications were sepsis, wound disruption, pneumonia, deep or organ/space surgical site infection and acute renal failure.



Trends in the secondary outcomes were revealed. The incidence of any complication, (minor, major or death) was lower in the intervention group (28 [40%] vs 35 [51%]). Immediate admissions to the critical care unit were higher in the intervention group (18 vs 13), especially in the SAS 0–4 subgroup where 4/6 patients (67%) were admitted compared with 2/7 (29%) in the control group. Despite this, the median total length of stay in the critical care unit was lower in the intervention group (2 vs 3 days). However, none of these differences reached statistical significance. There were no obvious trends in delayed admission to the critical care unit, use of therapeutic antibiotics, additional general anaesthetic operations or median post-operative length of stay.

The validity of the SAS as a predictor of major complications or death was confirmed. In AUC analysis in the control group only, the score demonstrated good discrimination with an AUC of 0.77 (95% CI: 0.65–0.89) for major complications or death (Fig 2).

In the intervention group, the SAS was calculated correctly in 63 patients (90%). Of the seven miscalculations, six were underestimations (ie the calculated score was lower than the correct score). Only in two cases did a miscalculation result in misclassification: one to the SAS 0–4 subgroup and one to the SAS 9–10 subgroup.

Discussion

This is the first study of the use of the SAS prognostic model in clinical practice. In our pilot, we aimed to see whether using the SAS in a decisive approach in a future RCT would be likely to demonstrate an effect on: a) postoperative care; and b) clinical outcome.

Regarding postoperative care, in the intervention SAS 0–4 subgroup, where all patients were discussed with an intensivist, there was a non-significant trend towards more immediate admissions to the critical care unit (4/6 [67%]

Table 2 Patient characteristics					
	Control (<i>n</i> =69)	Intervention (<i>n</i> =70)			
Mean age in years	59.6 (SD: 18.3)	59.3 (SD: 16.9)			
Female	34 (49%)	36 (51%)			
ASA grade					
1	19 (28%)	17 (24%)			
2	27 (39%)	30 (43%)			
3	20 (29%)	20 (29%)			
4	3 (4%)	2 (3%)			
5	0	1 (1%)			
Emergency operation	10 (14%)	16 (23%)			
Operation class					
Minor	6 (9%)	4 (6%)			
Intermediate	11 (16%)	15 (21%)			
Major	49 (71%)	44 (63%)			
Extensive	3 (4%)	7 (10%)			
Surgical Apgar score*					
0–4	7 (10%)	6 (9%)			
5–8	48 (70%)	44 (63%)			
9–10	14 (20%)	20 (29%)			
Mean estimated blood loss in ml	400 (SD: 620)	375 (SD: 547)			
Mean lowest MAP in mmHg	60.3 (SD: 9.9)	62.3 (SD: 12.8)			
Mean lowest heart rate in bpm	57.6 (SD: 11.3)	60.3 (SD: 10.7)			
SD = standard deviation; ASA = American Society of Anesthesiologists; MAP = mean arterial pressure *Calculated post hoc for the control group					

vs 2/7 [29%]). If this trend continued in a RCT, a significant effect of the SAS on postoperative care (namely, admission to the critical care unit) might be found.

However, in terms of clinical outcome (ie major complications and death within 30 days), there was neither a difference nor a discernible trend between the groups (control: 20/69 (29%), intervention: 23/70 (33%), p=0.622). This result suggests there is a substantial risk that a RCT using the current methodology will not demonstrate a significant effect on clinical outcome.

A number of factors may explain this. There was a low prevalence (9%) of patients in the highest risk subgroup (SAS 0-4), where the greatest opportunity to benefit outcomes arguably lay. Furthermore, almost a quarter of the patients had a score of 9–10 and therefore received the same care in both groups. The prevalence of lower scores could potentially be increased by adjusting the inclusion and exclusion criteria to select a higher risk population.

Table 3 Outcomes for	patients within 30	days of operation
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	Control (<i>n</i> =69)	Intervention (n=70)	OR (95% CI) ^a	<i>p</i> -value ^a			
Major complications or death	20 (29%)	23 (33%)	1.20 (0.58–2.46)	0.622			
SAS 0-4	4/7 (57%)	5/6 (83%)	3.75 (0.27–51.37)	0.322			
SAS 5–8	11/48 (31%)	13/44 (36%)	1.41 (0.55–3.58)	0.470			
SAS 9–10	5/14 (36%)	5/20 (25%)	0.60 (0.14–2.66)	0.502			
Most common major complications							
Sepsis	9 (13%)	4 (6%)	0.40 (0.19–1.38)	0.148			
Wound disruption	5 (7%)	7 (10%)	1.42 (0.43–4.72)	0.565			
Pneumonia	6 (9%)	6 (9%)	0.98 (0.30–3.22)	0.979			
Deep or organ/space SSI	5 (7%)	6 (9%)	1.20 (0.35–4.13)	0.773			
Acute renal failure	5 (7%)	3 (4%)	0.57 (0.13–2.50)	0.459			
Any complication ^b	35 (51%)	28 (40%)	0.66 (0.34–1.30)	0.235			
Immediate admission to critical care	13 (19%)	18 (26%)	1.52 (0.68–3.40)	0.310			
SAS 0-4	2/7 (29%)	4/6 (67%)	5.00 (0.47–52.96)	0.181			
SAS 5-8	8/48 (17%)	12/44 (27%)	1.88 (0.68–5.14)	0.222			
SAS 9–10	3/14 (21%)	2/20 (10%)	0.41 (0.06–2.84)	0.364			
Delayed admission to critical care	2 (3%)	4 (6%)	2.03 (0.36–11.46)	0.423			
Median total critical care length of stay in days (IQR) ^c	3 (2–3)	2 (1.5–2)	-	0.216			
Therapeutic antibiotics (>24h)	29 (42%)	26 (37%)	0.81 (0.41–1.61)	0.555			
Additional GA operations	10 (14%)	7 (10%)	0.66 (0.23–1.83)	0.421			
Median postoperative length of stay in days (IQR)	7 (4–11)	7 (3–13)	-	0.658			

OR = odds ratio; CI = confidence interval; SAS = surgical Apgar score; SSI = surgical site infection; GA = general anaesthesia ^ap-values, ORs and 95% CIs obtained from univariate logistic regression (binary outcomes) and two-sample Mann–Whitney U test (length of stay)

^bOccurrence of any complication: minor, major or death

^cFor admissions to critical care unit

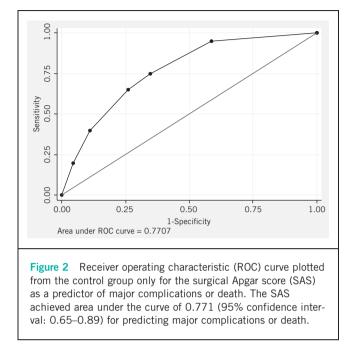
On the other hand, this would impact on recruitment and degrade external validity.

Other factors involved may have been observer bias and the Hawthorne effect²⁹ as well as contamination effects, where investigators applied the interventions in the control group as a result of increased awareness brought about by the trial itself. Blinded follow-up and a stepped wedge cluster design need to be considered to avoid these issues.

The effect of our interventions might have been improved if they had been applied in a mandatory fashion rather than a decisive approach (eg requiring all patients with SAS 0–4 to be admitted to the critical care unit). However, this would have affected the pilot's pragmatism as clinicians might not have been comfortable about losing their autonomy in applying their clinical judgement. Moreover, results from a future RCT that has relied on mandatory protocol are likely to have a lower potential to translate successfully into routine practice.

Instead, a future RCT needs to be suitably large and retain the pragmatism of a decisive approach to care based on the SAS as well as featuring a quality improvement approach to implementing a wide range of postoperative interventions and improvements in care. These would follow published guidelines (eg those from The Royal College of Surgeons of England) and feature items such as an end of surgery care bundle, where arterial blood gases are checked, a goal directed fluid therapy plan is made, muscle relaxants are reversed with the use of a nerve stimulator, hypothermia is corrected and a decision on the level of care is made with input from an intensivist (eg enhanced ward monitoring, high dependency or intensive care).⁵⁰

Following this, further items in addition to our protocol might include improved glycaemic monitoring and control, early nutritional assessment and input, and early physiotherapy and mobilisation. The quality improvement approach would be possible in a cluster design and would address organisational barriers to providing these items. Local plans would adapt to local needs but might address issues such as availability of higher levels of care, weekend and evening availability of key staff, training needs and cultural challenges.



It is also possible that mitigating major complications or death after the main physiological insult (the operation) has occurred only has a minor effect on clinical outcome. Analogously, enhanced recovery pathways appear to reduce postoperative morbidity.⁵¹ However, although these pathways include interventions in the postoperative phase, most are administered before and during the operation, and some studies have suggested that a reduced morbidity is due to a resultant attenuated postoperative stress response. For the SAS, the presumption that prediction of prognosis at the end of surgery presents an opportunity to intervene effectively in the postoperative phase may simply not hold. This is what needs to be addressed by a future RCT but if this transpires to be the case, then the SAS may be more valuable as an indicator of surgery and anaesthesia quality rather than as a postoperative predictor of individual outcome.

We also aimed to determine the feasibility and validity of conducting a RCT impact study. The successful completion of this pilot by a trainee-led research collaborative without a funded infrastructure demonstrated feasibility from a recruitment perspective (143 participants were recruited in one year). It was shown that the SAS was easy to calculate by hand by clinicians in a busy clinical setting. Where miscal-culations happened, most were minor underestimations. Our results also confirmed the validity of the score in a UK patient population (AUC: 0.77), despite the small sample size, and our findings were in line with those of previous studies from different countries and patient populations.

Conclusions

This pilot study found that a future RCT to investigate the effect of using the SAS in a decisive approach may demonstrate a difference in postoperative care (namely, admission to the critical care unit). It also demonstrated

feasibility and validity. However, there need to be significant changes to the design if differences in clinical outcome (major complications and death within 30 days of surgery) are to be achieved reliably. A wider array of postoperative interventions stratified by the SAS needs to be included and implemented using a quality improvement approach in a stepped wedge cluster design with blinded collection of outcome data. Evaluating a complex intervention such as this will therefore require the rigour detailed in the guidance from the Medical Research Council.³²

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