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VIBe Scale: Validation of the Intraoperative Bleeding Severity Scale by Spine Surgeons

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ABSTRACT

Background: The Validated Intraoperative Bleeding Scale (VIBe Scale) was initially validated with surgeons who operate on cardiothoracic, abdominal, and pelvic cavities and fulfilled criteria for a clinician-reported scale. However, there is a need for a tool to aid in intraoperative blood management during spine surgeries. The purpose of the present study was to establish the reliability and consistency of the VIBe Scale as a tool for spine surgeons to assess intraoperative bleeding.

Methods: Orthopedic ($n = 16$) and neurological ($n = 9$) spine surgeons scored videos depicting surgical bleeding and assessed the VIBe Scale's relevance and clarity. Inter- and intraobserver agreement (Kendall's W) were calculated for all surgeons and pooled with responses from the original study to establish agreement across specialties.

Results: All of the spine surgeons indicated that the scale was clinically relevant for evaluating hemostasis and could be implemented in a clinical study. Twenty-two spine surgeons (88%) reported that the scale represents the range of bleeding site sizes and severities expected in their practice. Twenty-four spine surgeons (96%) indicated that the scale would be useful in communicating bleeding severity with other members of the surgical team. Interobserver agreement was acceptable (0.79) for orthopedic specialists, appreciable (0.88) for neurological specialists, and appreciable (0.88) for the combined specialists. Intraobserver agreement was excellent for orthopedic (0.91) and neurological (0.91) spine surgeons and excellent (0.96) for the combined specialists.

Conclusions: The results highlight the reliability of the VIBe Scale and potential utility for quantifying intraoperative blood loss in spine surgery.

Level of Evidence: 3.

Clinical Relevance: The VIBe Scale may be useful for evaluating the efficacy of untested intraoperative hemostatic agents and for comparing the relative efficacy of 2 or more analogous agents. It may also prove useful for intraoperative staff by quantifying ongoing intraoperative blood loss and correlating losses with the potential transfusion and intraoperative hemostatic agent requirements.

Other and Special Categories

Keywords: bleeding, hemostasis, scale, spine, surgery, validation, VIBe

INTRODUCTION

The volume of spine procedures performed in the United States has increased dramatically, with spinal fusion procedures increasing over 220% from 1998 to 2008. During the same period, aggregate charges for these surgeries increased by 690%.[1] In a retrospective analysis, Stokes et al found that bleeding-related complications and/or transfusions occur in 15% of spine surgeries and are associated with a doubling of cost, demonstrating the clear need for effective hemostasis.[2] These estimates may underestimate the reality in some spine surgeries.[2] For instance, revision surgeries to treat spinal deformity have reported rates of transfusion as high as 30%.[3] The need for transfusion poses multiple risks and negatively impacts mortality and morbidity,[4–7] and earlier time to hemostasis limits mortality and complications.[8] Clinical evaluation tools are critical to improving patient care; they can facilitate active communication to plan for anticipated blood loss and intraoperative hemostasis.

Multiple strategies to reduce blood loss are regularly employed in spine surgery practice.[3] Current evidence supports the safety of preoperative discontinuation of medications and supplements that might limit coagulation intraoperatively.[3] Intraoperatively, surgeons have a number of tools that may be employed to limit blood loss.[9–11] These include patient positioning[12] and control of arterial pressure.[13] In spine surgery, numerous agents have been developed to achieve hemostasis; these include passive agents such as bone wax, oxidized regenerated cellulose, and gelatin-based sponges; and active agents such as antifibrinolytics and flowable hemostats.[3,14–17] Notably, the use of flowable hemostats has been demonstrated to reduce time to hemostasis, length of hospital stay, and consumption of health resources by patients undergoing spinal surgical procedures.[18,19]

Despite the apparent benefits of hemostatic agents, clear differentiation of their clinical utility is challenging in clinical studies, as standardized definitions for intraoperative bleeding severity or hemostasis are limited.[16,20] Prompted by US Food and Drug Administration requirements that a validated scale be used in clinical studies of hemostatic agents, a clinician-reported, intraoperative bleeding scale (Validated Intraoperative Bleeding Scale [VIBe Scale]) was developed and validated.[21] The VIBe Scale incorporates 5 visually estimated levels of bleeding to encompass the absence of bleeding (0–1.0 mL/min) through life-threatening blood loss (>50 mL/min). Validation of the VIBe Scale included surgeons who operate on cardiothoracic, abdominal, and pelvic cavities, and utilized videos of soft tissue bleeding. In each phase of development and validation, the scale fulfilled criteria for a clinician-reported scale by demonstration of high inter- and intraobserver agreement. In addition, there was unanimous agreement that the scale could be successfully implemented in clinical studies. Orthopedic and neurological spine surgeons were not included in the development or validation of the VIBe Scale, as the videos employed omitted bleeding from hard tissues, which would be of relevance to orthopedic surgeons. The objective of the following study was to establish the VIBe Scale as a reliable and consistent tool applicable to multiple surgical specialties by validating the scale for use by neurologic and orthopedic surgeons.

METHODS

The Food and Drug Administration has provided specific criteria that must be fulfilled for a scale to be considered acceptable and valid.[22] These criteria include the ability to detect change, clarity, construct validity, relevance, repeatability, reproducibility, response range, and usability. Creation, development, and validation of the VIBe Scale (Table 1) according to these criteria involved surgeons from a variety of specialties and have been published.[21]

Participant Recruitment

For evaluation of the scale for use in spine surgery, board-certified orthopedic and neurological spine surgeons were recruited. Surgeons were not recruited based on consultancy agreements, product usage, or industry affiliations.

Study Procedure

The study was performed using the online data collection tool used in the primary report detailing the creation, development, and validation of the scale.[21] This tool was designed and implemented by BioMedCom Partners, Inc (New York, NY) and provided training on the use of the scale followed by review and assessment of videos of surgical bleeding. All animal activities were performed in compliance with the applicable US Animal Welfare Regulations in an institution accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International following Institutional Animal Care and Use Committee approval. These videos were obtained during surgeries on a porcine animal model to measure blood loss outside of the clinical setting; this model was selected due to the similarity of its anatomical size and organ structure to that of humans and afforded the ability to create videos of standardized quality. No adjunctive hemostatic agents were used in the videos, and bleeding rate was measured by collecting blood from each individual lesion with gauze that was weighed before use and after blood collection (1 g was equated to 1 mL). Selected videos were edited to be 15 seconds in duration.

Surgeons were familiarized with the online data collection tool by responding to a set of general questions regarding each participant's background, training, and

Table 1. Validated Intraoperative Bleeding Scale.

Grade	Visual Presentation	Anatomical Appearance	Qualitative Description	Visually Estimated Rate of Blood Loss (mL/min)
0	No bleeding	No bleeding	No bleeding	≤1.0
1	Intermittent flow or continuous ooze	Capillary-like bleeding	Mild	>1.0–5.0
2	Continuous flow	Venule- and arteriolar-like bleeding	Moderate	>5.0–10.0
3	Controllable spurting and/or overwhelming flow	Noncentral venous- and arterial-like bleeding	Severe	>10.0–50.0
4	Uncontrollable spurting or gush	Central arterial- or venous-like bleeding	Life-threatening[a]	>50.0

[a]Systemic resuscitation is required (eg, volume expanders, vasopressors, blood products, etc).

surgical practice. Surgeons were then trained on the use of the VIBe Scale by being presented with 10 training videos, with 2 videos for each grade. Surgeons were required to view a minimum of a single video for each grade and could view any of the videos within each grade multiple times. After training on the use of the scale, surgeons were presented with 20 videos that they could score. The first 2 videos were to practice using the interface and were not included in the validation data. The surgeons then used the scale to score 18 videos not necessarily related to their surgical specialty to evaluate both intra- and interobserver agreement. There were 12 unique videos. Of these, 10 videos were retained from the previous study,[21] and 2 were new videos added to reflect bleeding encountered during spinal surgery. Five of the retained videos and 1 of the new videos were presented twice.

Agreement Between Specialties

To further validate the scale for use in spine surgery, the scores of the 10 retained videos from the spine surgeon participants were next pooled with data from the previous study of general surgical specialists,[21] and rate of agreement was calculated.

Statistical Methods

Sample size was calculated wherein a sample size of 20 subjects per specialty assessing 10 videos achieves >80% power to detect a Kendall's *W* of 0.80 for interobserver agreement, and assessing 5 videos twice achieves >80% power to detect a Kendall's *W* of 0.80 for intraobserver agreement. The Kendall's *W* coefficient of concordance was calculated for each of 10,000 simulations, and the proportion of simulations calculated at each agreement level was the calculated empirical power that could detect the associated Kendall's *W*.[23] Acceptable agreement between specialties was assessed at a coefficient of 0.70 to <0.80, a coefficient of ≥0.80 to <0.90 was interpreted as appreciable agreement, ≥0.9 was interpreted as excellent agreement, and 1.00 as perfect agreement between specialists.

Tables depicting the frequency of surgeon responses were generated for the spine specialists and pooled surgical specialists. Kendall's *W* coefficient of concordance was calculated and used to measure inter- and intraobserver agreement. Interobserver agreement measures reproducibility or the ability of surgeons across surgical specialties to consistently place unique videos within the scale. Intraobserver agreement measures test-retest outcome or the ability of an individual surgeon to reliably score a unique video using the scale. The interobserver agreement was calculated for spine surgeons using 12 unique videos and the pooled specialists using 10 videos common to both studies. Intraobserver reliability was calculated for spine surgeons using the 6 videos that were repeated, and for the pooled specialists using 5 videos that were repeated across the 2 studies.

The ability to detect change was evaluated using the frequency tables in relation to the surgeon's ability to utilize each grade of the scale. Response range was assessed as the surgeon's ability to use both ends of the scale. A questionnaire assessed each surgeon's evaluation of the clarity of items within the scale and the relevance (ie, acceptability and ability to use items within the scale) of the scale. The questionnaire is presented in Supplemental Table 1.

Table 2. Participant background and general information.

Participant Background	*n*	%
Use of hemostatic agents in practice		
Yes	25	100
No	0	0
Anatomical focus		
Cervical, lumbar	5	20
Cervical, thoracic, lumbar	6	24
Cervical, thoracic, lumbar, sacral	10	40
Lumbar	2	8
Thoracic, lumbar	1	4
Thoracic, lumbar, sacral	1	4
Surgical specialty		
Neurological	6	24
Orthopedic	19	76
Surgical subspecialty		
Deformity	1	4
Deformity, degenerative	1	4
Deformity, degenerative, minimally invasive	8	32
Deformity, degenerative, minimally invasive, trauma	5	20
Deformity, degenerative, minimally invasive, tumor	1	4
Deformity, tumor	1	4
Degenerative	2	8
Degenerative, minimally invasive	3	12
Degenerative, minimally invasive, trauma	1	4
Degenerative, minimally invasive, trauma, tumor	1	4
Degenerative, trauma	1	4
Practice setting		
Academic	6	24
Academic, nonprofit	2	8
Academic, private	3	12
Nonprofit	4	16
Private	9	36
Private, nonprofit	1	4

RESULTS

Twenty-five spine surgeons participated in the study, of whom 6 (24%) reported a neurological specialty and 19 (76%) reported an orthopedic specialty (Table 2). In total, 17 (68%) surgeons indicated deformity surgery as part of their clinical practice (92% degenerative, 32% trauma, and 12% tumor). The combined cohort had a mean (SD) of 13.64 (8.95) years in practice, with 59.21% (25.89) of the reported caseload performed in an open fashion. All of the spine surgeons reported that they used topical hemostatic agents.

All 25 of the participating spine surgeons indicated that the scale was clinically relevant for evaluating hemostasis and could be implemented in a clinical study. Of that, 24 (96%) suggested that the scale could be used to differentiate hemostatic agents. And 22 (88%) spine surgeons reported that the scale represents the range of bleeding site sizes and severities expected in their practice. The scale was reported by 18 (72%) spine surgeons to use nonoverlapping terms, with only 1 (4%) surgeon reporting that term overlap would prevent using the scale. Nearly all of the spine surgeons reported that the scale was very (44%) or mostly (52%) self-explanatory, and 23 (92%) reported that the scale used objective terms. No spine surgeon felt that the terms used in the scale would prevent use of the scale. All of the spine surgeons confirmed that the scale could be used to describe intraoperative bleeding in communication. The greatest proportion (44%) reported that the scale could be used effectively in communication with all available selections of surgeons, surgical physician assistants, registered nurses, anesthesiologists, and industry representatives. The remainder selected a subset of the available selections, with 21 (84%) including anesthesiologists in their selection. Only a single (4%) surgeon reported that the scale would only be a useful communication tool between surgeons. Additional participant responses are presented in Supplemental Table 2.

The distribution of spine surgeon responses to the 12 unique videos used to validate the scale is shown in Table 3. At least 17 (68%) surgeons suggested that 9 of the videos depicted clinically significant bleeding. The 3 videos with the fewest responses (≤24%) indicating clinical significance all depicted grade 0 (0–1 mL/min) or grade 1 (>1.0–5.0 mL/min) bleeding. The surgeons' responses spanned the range of grades in the scale. For the grade 0 videos depicting a 0.2 and 0.7 mL/min bleed rate, 19 (76%) surgeons responded with grade 0 in both (20% and 16% responded with grade 1, respectively). For the grade 1 video depicting a 1.6 mL/min bleed rate, 21 (84%) surgeons responded with grade 1 (12% responded with grade 0). The highest bleed rate depicted in the videos was 366.7 mL/min. For this grade 4 (>50 mL/min) video, 18 (72%) responded with grade 4 and the remainder (28%) with grade 3. These findings demonstrate that spine surgeons utilized the full response range of the scale and were able to detect changes in bleeding

Table 3. Spine surgeon Validated Intraoperative Bleeding Scale responses and associated video bleeding rate.

Specialty	Video Bleeding Rate, mL/min	VIBe Scale Response, *n* (%) 0	1	2	3	4
Orthopedic						
	0.2	13 (68.42)	5 (26.32)	1 (5.26)	0	0
	0.7	14 (73.68)	4 (21.05)	0	1 (5.26)	0
	1.3	0	10 (52.63)	9 (47.37)	0	0
	1.6	2 (10.53)	16 (84.21)	1 (5.26)	0	0
	6.4	0	3 (15.79)	14 (73.68)	2 (10.53)	0
	7.3	0	11 (57.89)	6 (31.58)	2 (10.53)	0
	9.7	0	0	6 (31.58)	13 (68.42)	0
	11.4	0	0	0	12 (63.16)	7 (36.84)
	27	0	2 (10.53)	12 (63.16)	5 (26.32)	0
	38.7	1 (5.26)	2 (10.53)	7 (36.84)	9 (47.37)	0
	142.4	0	0	8 (42.11)	8 (42.11)	3 (15.79)
	366.7	0	0	0	4 (21.05)	15 (78.95)
Neurological						
	0.2	6 (100.00)	0	0	0	0
	0.7	5 (83.33)	0	1 (16.67)	0	0
	1.3	0	3 (50.00)	3 (50.00)	0	0
	1.6	1 (16.67)	5 (83.33)	0	0	0
	6.4	0	1 (16.67)	3 (50.00)	2 (33.33)	0
	7.3	0	5 (83.33)	1 (16.67)	0	0
	9.7	0	0	1 (16.67)	5 (83.33)	0
	11.4	0	0	1 (16.67)	4 (66.67)	1 (16.67)
	27	0	1 (16.67)	4 (66.67)	1 (16.67)	0
	38.7	1 (16.67)	1 (16.67)	3 (50.00)	1 (16.67)	0
	142.4	0	0	1 (16.67)	3 (50.0)	2 (33.33)
	366.7	0	0	0	3 (50.00)	3 (50.00)

Abbreviation: VIBe Scale, Validated Intraoperative Bleeding Scale.

Table 4. Pooled surgical specialists VIBe Scale responses and associated video bleeding rate.

Video Bleeding Rate, mL/min	Participant Group	VIBe Scale Response, *N* (%)				
		0	1	2	3	4
0.2	Spine surgeons	19 (76.00)	5 (20.00)	1 (4.00)	0	0
	All surgeons	98 (77.17)	26 (20.47)	3 (2.36)	0	0
0.7	Spine surgeons	19 (76.00)	4 (16.00)	1 (4.00)	1 (4.00)	0
	All surgeons	114 (89.76)	10 (7.87)	2 (1.57)	1 (0.79)	0
1.3	Spine surgeons	0	13 (52.00)	12 (48.00)	0	0
	All surgeons	0	58 (45.67)	69 (54.33)	0	0
1.6	Spine surgeons	3 (12.00)	21 (84.00)	1 (4.00)	0	0
	All surgeons	9 (7.09)	115 (90.55)	3 (2.36)	0	0
6.4	Spine surgeons	0	4 (16.00)	17 (68.00)	4 (16.00)	0
	All surgeons	0	13 (10.24)	94 (74.02)	20 (15.75)	0
7.3	Spine surgeons	0	16 (64.00)	7 (28.00)	2 (8.00)	0
	All surgeons	2 (1.57)	82 (64.75)	41 (32.28)	2 (1.57)	0
9.7	Spine surgeons	0	0	7 (28.00)	18 (72.00)	0
	All surgeons	0	0	16 (12.60)	102 (80.31)	9 (7.09)
27	Spine surgeons	0	3 (12.00)	16 (64.00)	6 (24.00)	0
	All surgeons	0	5 (3.94)	94 (74.02)	28 (22.05)	0
38.7	Spine surgeons	2 (8.00)	3 (12.00)	10 (40.00)	10 (40.00)	0
	All surgeons	2 (1.57)	3 (2.36)	52 (40.94)	68 (53.54)	2 (1.57)
366.7	Spine surgeons	0	0	0	7 (28.00)	18 (72.00)
	All surgeons	0	0	0	12 (9.45)	115 (90.55)

Abbreviation: VIBe Scale, Validated Intraoperative Bleeding Scale.

severity. Likewise, the distribution of responses to the 10 videos common to the pooled surgical specialists and the spine specialists is shown in Table 4 and demonstrates consistent scoring and use of the scale's full range. The inter- and intraobserver coefficients for the individual spine specialties and their integration with the pooled surgical specialists are shown in Table 5.

DISCUSSION

In this study, we demonstrate that the Intraoperative Bleeding Severity Scale is a valid tool for assessing bleeding severity in spinal surgery. Although training differences exist between the specialties, neurological and orthopedic spine surgeons showed appreciable and acceptable interobserver agreement in scoring bleeding; additionally, both showed excellent intraobserver agreement in their ability to reliably assess bleeding grade. Furthermore, the results for spine surgeons were consistent with results obtained with the previous surgical specialists. This was evidenced by the appreciable interobserver agreement and excellent intraobserver agreement when pooled with the previous participants. Spine surgeons selected grades within the scale consistent with the known bleeding rate and utilized the entire response range reflecting their encounters with a variety of bleeding rates that occur during spinal surgeries. With further study, such rates may be assigned to represent bleeding types classically experienced by spine surgeons. Such types could include bleeding associated with muscle/soft tissue exposure, epidural bleeding, posterior element osteotomies (eg, laminectomy and posterior column osteotomies), pedicle hole preparation, vertebral body exposure (eg, osteotomy and corpectomy), pelvic bone penetration (eg, pelvic screw preparation and bone graft harvest), and paraspinal vessel bleeding (eg, segmental vessels, azygous, vena cava, and aorta). Additionally, the surgeons agreed that the scale was an objective and relevant tool for evaluating hemostatic agents in clinical studies and a valuable communication tool. These findings establish the VIBe Scale as a reliable and consistent tool across surgical specialties to build labeling claims, standardize inclusion and exclusion criteria, and evaluate surgical bleeding.

Table 5. Interobserver and intraobserver agreement for the spine specialists and pooled surgical specialist samples.

Specialty	Kendall's *W*	Agreement Status
Interobserver agreement		
Orthopedic	0.79	Acceptable
Neurological	0.88	Appreciable
Combined spine	0.80	Appreciable
Combined all	0.88	Appreciable
Intraobserver agreement		
Orthopedic	0.91	Excellent
Neurological	0.95	Excellent
Combined spine	0.92	Excellent
Combined all	0.96	Excellent

Spine surgeons participating in the study reported that >40% of their caseload is conducted in a minimally invasive fashion. Magnification and perception of bleeding are likely to be different in minimally invasive surgery and may limit the ability of the scale to generalize between open and minimally invasive surgeries. Despite this, 84% of respondents here suggested that the scale could be used as-is, or with modifications, for minimally invasive surgery. Further investigation is warranted to determine whether surgeons provide similar responses when presented with scenarios reflecting minimally invasive surgeries.

The development of clinical tools to assess surgery-associated outcomes, including bleeding, is an active area with numerous approaches.[24–27] For the VIBe Scale, videos depicting bleeding of known rates in a porcine model were used. Visual estimation of blood loss by surgeons and anesthesiologists is known to be inaccurate.[28,29] Despite this, the present results demonstrate replicable assessment of surgical bleeding grade within the VIBe Scale and confirm the established clinical utility of the scale, as 100% of the involved surgeons indicated that the scale was useful and relevant for assessing hemostasis in clinical studies. A notable advantage to this approach is the simplicity of the training, aided by the online tool and lack of investment in equipment or demands on the institution for use.

As part of a cross-functional team, the surgeon must communicate effectively to ensure high-quality treatment outcomes.[30] Unsurprisingly, given the negative impacts of bleeding on mortality and morbidity, one component of this communication is between the surgeon and anesthesiologist to control mean arterial pressure, maintain vital organ perfusion, and minimize blood loss.[2,4–7,31] Here, spine surgeons reported that the VIBe Scale could serve as a cross-functional communication tool to discuss intraoperative bleeding. Implementation of the VIBe Scale to discuss bleeding would not only allow surgeons to communicate about bleeding with diverse stakeholders in an objective fashion, but also improve surgical efficiency by allowing selection of appropriate hemostatic agents for expected bleeding, ultimately reducing intraoperative and postoperative bleeding complications. Furthermore, this could facilitate the development of consistent clinical algorithms for selection of hemostatic agents. This approach would also enable the team to strategize around the dynamics of bleeding and how best to mitigate loss during the surgical process. Use of simple clinical tools for such discussions may have outsized effects. For instance, implementation of a safety checklist prior to surgery has been repeatedly demonstrated to reduce surgical complications and mortality.[32,33] Furthermore, standardization of communication between all stakeholders (surgeons, anesthesiologists, supply chain, blood bank, and innovators of adjunctive hemostatic products) regarding blood loss may contribute to advances in blood management. Finally, the present study was in part funded by a corporation whose portfolio includes hemostatic agents. Although specific hemostatic agents were neither mentioned in this manuscript nor presented to the surgeons evaluating the videos, this may imbue the results with potential bias. Therefore, although other studies have been conducted in similar fashion,[21,34] future validation by an independent third party may be warranted.

CONCLUSION

The findings of the present study provide further evidence for the validity of the VIBe Scale by establishing its utility in spine surgery. The scale has been validated among a variety of surgical specialties and can provide a robust platform for consistent communication between stakeholders. Employing the Intraoperative Bleeding Severity Scale in clinical studies will generate relevant labeling claims and reduce complications that may arise through the choice of inappropriate hemostatic agents. Additionally, preoperative use of this scale may support proactive hemostasis strategies and the meticulous control of bleeding required for increasingly complex surgical procedures.

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