Grading the complexity of endoscopic procedures: results of an ASGE working party

CME

Peter B. Cotton, MD, FRCS, FRCP, Glenn Eisen, MD, MPH, Joseph Romagnuolo, MD, MScEpid, FRCPC, John Vargo, MD, MPH, Todd Baron, MD, Paul Tarnasky, MD, Steve Schutz, MD, Brian Jacobson, MD, MPH, Chris Bott, BS, Bret Petersen, MD

Charleston, South Carolina; Portland, Oregon; Cleveland, Ohio; Rochester, Minnesota; Dallas, Texas; Boise, Idaho; Boston, Massachusetts, USA

Background: Working parties of the American Society for Gastrointestinal Endoscopy (ASGE) Quality Committee recently published a proposed new lexicon for adverse events and a separate extensive review of risk factors. The complexity of procedures also affects outcomes.

Objective: To establish a system for grading the complexity of endoscopic procedures.

Design: Voting on levels 1 (easiest) to 4 (most difficult) on a list of possible procedures and contexts.

Setting: Community and academic gastroenterologists in the United States, Canada, and Britain.

Main Outcome Measurements: Median scores of votes cast.

Results: Consensus list of levels 1 through 4 contexts and procedures.

Limitations: Eminence rather than evidence based.

Conclusions: A consensus list was developed for comments and testing to complement the proposed lexicons for adverse events and risk factors. (Gastrointest Endosc 2011;73:868-74.)

A working party of the American Society for Gastrointestinal Endoscopy (ASGE) recently published a lexicon for defining and classifying adverse events and their severity.[1] This should facilitate the important task of standardizing the reporting of "complication rates." However, the authors recognized that some endoscopic procedures are more difficult and risky than others. As a result, reports of rates of adverse events cannot be interpreted or compared meaningfully unless the complexity spectrum of the procedures is known. Thus, a perforation rate for a series of upper endoscopies is uninterpretable unless it is known how many esophageal strictures were managed. Likewise, the pancreatitis rate after ERCP is markedly influenced by the precise clinical context, indication, and interventions performed or attempted. Recording the complexity spectrum of an endoscopic series would allow rates of adverse events and procedural success to be presented in a meaningful way so that endoscopists performing more complex procedures do not appear to be more dangerous and/or less successful than their less adventurous peers.

Schutz and Abbott[2] first addressed the complexity issue for ERCP and suggested a 5-point scale for "difficulty," which has been used extensively in a simplified form.[3] Use of that scale in an analysis of data from 7 different centers confirmed that technical success rates were much higher in level 1 ERCP procedures.[4] Raganath et al[5] drew similar

Abbreviation: ASGE, American Society for Gastrointestinal Endoscopy.

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Current affiliations: Medical University of South Carolina (P.B.C., J.R., C.B.), Charleston, South Carolina, Oregon Health Sciences University (G.E.), Portland, Oregon, Cleveland Clinic Foundation (J.V.), Cleveland, Ohio, Mayo Clinic (T.B., B.P.), Rochester, Minnesota, Digestive Health Associates of Texas (P.T.), Dallas, Texas, Boise Digestive Health Clinic (S.S.), Boise, Idaho, Boston University Medical Center (B.J.), Boston, Massachusetts, USA.

Reprint requests: Peter B. Cotton, MD, FRCP, FRCS, Digestive Disease Center, Medical University of South Carolina, 25 Courtenay, ART 7100A, MSC 290, Charleston, SC 29425-2900.

If you would like to chat with an author of this article, you may contact Dr. Cotton at cottonp@musc.edu.

conclusions with a slightly different ERCP scale. These studies were not large enough to look at correlations with rates of adverse events.

No one has attempted to develop equivalent scales for upper endoscopy, colonoscopy, or EUS. For this reason, a subset of the authors of the adverse events working party set out to develop a broad classification of procedural complexity.

Take-home Message

- For quality measurement and enhancement it must be possible to document the outcomes of procedures in a structured manner.
- Until now there has been no complexity scale covering all major procedures. This working party of ASGE canvassed opinion and proposes such a scale for comment and testing alongside the other two lexicons.

DEFINING COMPLEXITY

Any procedure can turn out to be difficult technically (eg, cannulation in a diverticulum at ERCP or colonoscopy with multiple loops). However, these challenges are somewhat subjective and may reflect levels of expertise rather than generic and reproducible issues. Our goal was to focus primarily on those circumstances in which difficulty is predictable before the procedure starts (eg, performing ERCP in a patient with known Billroth II anatomy, EGD for the treatment of malignant esophageal obstruc-

TABLE 1. Upper endoscopy and small bowel

					Vote							
					1		2		3		4	
	Voters	Median	Mean	SD	No.	%	No.	%	No.	%	No.	%
Diagnostic EGD, with or without biopsy/cytology	74	1	1.00	0.00	74	100.0	0	0.0	0	0.0	0	0.0
Gastric polypectomy (stalked <1 cm)	76	2	1.67	0.55	28	36.8	45	59.2	3	3.9	0	0.0
APC vascular lesions	71	2	1.77	0.51	19	26.8	49	69.0	3	4.2	0	0.0
Dilation benign esophageal stricture	76	2	1.82	0.48	17	22.4	56	73.7	3	3.9	0	0.0
Gastric polypectomy (stalked 1-2 cm)	75	2	1.99	0.65	15	20.0	47	62.7	12	16.0	1	1.3
Nutritional support (catheter placement, PEG)	76	2	2.04	0.60	12	15.8	49	64.5	15	19.7	0	0.0
Foreign body removal	76	2	2.29	0.54	2	2.6	51	67.1	22	28.9	1	1.3
Push enteroscopy	74	2	2.32	0.74	6	8.1	44	59.5	18	24.3	6	8.1
Hemostasis	75	2	2.33	0.62	4	5.3	44	58.7	25	33.3	2	2.7
Dilation malignant esophageal stricture	75	2	2.43	0.60	2	2.7	41	54.7	30	40.0	2	2.7
Gastric polypectomy (stalked > 2 cm)	72	3	2.54	0.84	7	9.7	28	38.9	28	38.9	9	12.5
Esophageal stent	74	3	2.59	0.74	5	6.8	26	35.1	37	50.0	6	8.1
Endoscopically assisted achalasia dilation	71	3	2.76	0.73	3	4.2	20	28.2	39	54.9	9	12.7
Dilation malignant duodenal stricture	71	3	2.92	0.69	2	2.8	14	19.7	43	60.6	12	16.9
Device-assisted enteroscopy (eg, balloon)	59	3	3.14	0.68	1	1.7	7	11.9	34	57.6	17	28.8
Tumor and Barrett's ablation	62	3	3.19	0.67	0	0.0	9	14.5	32	51.6	21	33.9
Duodenal stent	72	3	3.24	0.68	1	1.4	7	9.7	38	52.8	26	36.1
Resect sessile lesions, EMR/ESD	67	4	3.43	0.76	1	1.5	8	11.9	19	28.4	39	58.2
Percutaneous endoscopic jejunostomy	74	4	3.62	0.66	1	1.4	4	5.4	17	23.0	52	70.3
Cricopharyngeal myotomy	52	4	3.81	0.53	1	1.9	0	0.0	7	13.5	44	84.6
Add 1 level for items below?						% Yes		% No				
Previous failed/incomplete procedure outside	74		1.14	0.34	64	86.5	10	13.5				
Emergency cases outside of normal hours	74		1.28	0.45	53	71.6	21	28.4				
Age <3 y	55		1.35	0.58	38	69.1	16	29.1				

Items with majority agreement are highlighted.
APC, Argon plasma coagulation; *ESD*, endoscopic submucosal dissection.

TABLE 2. Colonoscopy

					Vote							
					1		2		3		4	
	Voters	Median	Mean	SD	No.	%	No.	%	#	%	#	%
Diagnostic, sampling, tattooing	73	1	1.11	0.31	65	89.0	8	11.0	0	0.0	0	0.0
Colonoscopy via colostomy	76	1	1.55	0.66	39	51.3	34	44.7	1	1.3	2	2.6
Stalked polypectomy <1 cm	75	2	1.53	0.53	36	48.0	38	50.7	1	1.3	0	0.0
APC in mid or left colon	74	2	1.86	0.56	16	21.6	53	71.6	4	5.4	1	1.4
Stalked polypectomy 1-2 cm	75	2	1.92	0.63	17	22.7	48	64.0	9	12.0	1	1.3
Decompression tube	72	2	2.14	0.81	15	20.8	36	50.0	17	23.6	4	5.6
Banding varices and hemorrhoids	65	2	2.18	0.66	7	10.8	41	63.1	15	23.1	2	3.1
APC in the right colon	73	2	2.33	0.62	4	5.5	43	58.9	24	32.9	2	2.7
Active hemostasis	76	2	2.36	0.74	8	10.5	37	48.7	27	35.5	4	5.3
Stalked polypectomy >2 cm	75	3	2.57	0.76	5	6.7	29	38.7	34	45.3	7	9.3
Stricture dilation	72	3	2.58	0.60	1	1.4	31	43.1	37	51.4	3	4.2
Colonic stent rectum/sigmoid	68	3	2.66	0.70	4	5.9	20	29.4	39	57.4	5	7.4
Colonic stent above sigmoid	65	3	3.09	0.70	1	1.5	10	15.4	36	55.4	18	27.7
EMR and ESD	65	4	3.52	0.62	0	0.0	4	6.2	23	35.4	38	58.5
Percutaneous endoscopic colostomy	69	4	3.84	0.44	0	0.0	2	2.9	7	10.1	60	87.0
Add one level for items below?						% Yes		% No				
Previous incomplete procedure outside	73		1.11	0.31	65	89.0	8	11.0				
Age <3 y	55		1.29	0.46	39	70.9	16	29.1				
Emergency case outside of normal hours	73		1.33	0.47	49	67.1	24	32.9				

Items with majority agreement are highlighted.
APC, Argon plasma coagulation; *ESD*, endoscopic submucosal dissection.

tion, colonoscopy with mucosal resection). A scale of predicted or expected difficulty would be useful for advising patients about the chance of technical success and also to help endoscopists to decide which cases to attempt and which perhaps to refer elsewhere. It could also be used for structuring phases in training and stages of credentialing. To be meaningful and usable, such a scale would then best focus on the clinical contexts (eg, management of malignant dysphagia, hematemesis, pancreatitis) rather than the specific likely maneuvers (eg, stent, sphincterotomy, clipping).

It is also legitimate to take into consideration certain anatomical or pathological challenges that may become apparent during procedures (eg, finding a >2-cm sessile polyp at colonoscopy or pancreas divisum during ERCP) because these do require additional technical skill. Some of these may be known beforehand through previous imaging or indeed referral after a previous procedure performed elsewhere.

Our concept of complexity embraces more than simple technical difficulty. It includes some elements of clinical difficulty and/or perceived risk. In general, procedures that are more challenging technically are also more risky, but there are obvious exceptions. For example, performing ERCP, with or without sphincterotomy, for suspected sphincter dysfunction, is technically simple, but is also clinically challenging and certainly risky and requires a careful informed approach. The same applies to dilation procedures in malignant esophageal strictures. Conversely, performing ERCP after gastric bypass is a technical tour de force, but is only associated with a slightly increased risk. Overall, our complexity scale is intended to arm the endoscopist (and the informed patient) with knowledge of the level of training, expertise, and care needed to approach a particular patient.

There are also circumstances that may increase the challenge and affect the complexity of given procedures, such as when they are done outside of normal working hours, in

TABLE 3. ERCP

					Vote							
					1		2		3		4	
	Voters	Median	Mean	SD	No.	%	No.	%	No.	%	No.	%
Deep cannulation main papilla, duct of interest	62	1	1.31	0.67	49	79.0	8	12.9	4	6.5	1	1.6
Brush cytology	66	1	1.36	0.52	43	65.2	22	33.3	1	1.5	0	0.0
Biliary stent extraction/exchange	66	1.5	1.53	0.56	33	50.0	31	47.0	2	3.0	0	0.0
Stents for bile leaks	65	2	1.62	0.63	30	46.2	30	46.2	5	7.7	0	0.0
Biliary stones <10 mm, extraction	66	2	1.67	0.56	25	37.9	38	57.6	3	4.5	0	0.0
Stents for extrahepatic tumors	64	2	1.92	0.60	14	21.9	41	64.1	9	14.1	0	0.0
Prophylactic pancreatic stents	61	2	1.93	0.63	14	23.0	37	60.7	10	16.4	0	0.0
Benign biliary stricture treatment, subhilar	65	2	2.05	0.57	9	13.8	44	67.7	12	18.5	0	0.0
Remove pancreatic stones, mobile and <5 mm	54	3	2.57	0.77	4	7.4	20	37.0	25	46.3	5	9.3
Biliary stones >10 mm, extraction	66	3	2.62	0.55	1	1.5	24	36.4	40	60.6	1	1.5
Management of acute or recurrent pancreatitis	57	3	2.67	0.66	0	0.0	25	43.9	26	45.6	6	10.5
Extraction of internally migrated biliary stent	64	3	2.73	0.67	1	1.6	22	34.4	34	53.1	7	10.9
Suspected SOD (with or without manometry)	52	3	2.83	0.81	3	5.8	13	25.0	26	50.0	10	19.2
Minor papilla cannulation (in divisum)	57	3	3.04	0.76	0	0.0	15	26.3	25	43.9	17	29.8
Management of pancreatic strictures	55	3	3.05	0.62	0	0.0	9	16.4	34	61.8	12	21.8
Treat benign biliary stricture, hilar, and above	66	3	3.14	0.65	1	1.5	7	10.6	40	60.6	18	27.3
Intraductal imaging, biopsy, FNA	52	3	3.15	0.78	1	1.9	9	17.3	23	44.2	19	36.5
Hilar tumors	66	3	3.20	0.68	1	1.5	7	10.6	36	54.5	22	33.3
Minor papilla therapy	55	3	3.31	0.74	0	0.0	9	16.4	20	36.4	26	47.3
Intrahepatic stones	65	3	3.35	0.67	0	0.0	7	10.8	28	43.1	30	46.2
Extract internally migrated pancreatic stent	58	3.5	3.43	0.65	1	1.7	2	3.4	26	44.8	29	50.0
Remove pancreatic stones, fixed or >5 mm	52	4	3.44	0.70	0	0.0	6	11.5	17	32.7	29	55.8
Intraductal image-guided therapy, EHL, PDT	46	4	3.50	0.69	0	0.0	5	10.9	13	28.3	28	60.9
Ampullectomy	58	4	3.55	0.60	0	0.0	3	5.2	20	34.5	35	60.3
Pseudocyst drainage, necrosectomy	53	4	3.68	0.51	0	0.0	1	1.9	15	28.3	37	69.8
Whipple/Roux-en-Y or bariatric surgery	58	4	3.97	0.18	0	0.0	0	0.0	2	3.4	56	96.6
Add 1 level for items below?						% Yes		% No				
Patient has Billroth II anatomy	62		1.08	0.27	57	91.9	5	8.1				
Previous failed/incomplete procedure outside	60		1.08	0.28	55	91.7	5	8.3				
Age <3 y	45		1.33	0.60	32	71.1	12	26.7				
Emergency case outside of normal hours	61		1.41	0.50	36	59.0	25	41.0				

Items with majority agreement are highlighted.
SOD, Sphincter of Oddi dysfunction; *EHL*, electrohydraulic lithotripsy; *PDT*, photodynamic therapy.

very young children, in patients with surgically altered anatomy, and when the procedure has been unsuccessful before.

METHODS

We made comprehensive lists of specific endoscopic techniques, clinical contexts in which they are used, and some anatomical/pathological challenges that may be encountered during their use. These were sent to the 17 members of the ASGE Adverse Events Working Party to review. Their comments resulted in a final list, with a total of 20 items for EGD, 13 for EUS, 26 for ERCP, and 15 for colonoscopy. The resulting voting sheet was distributed to the 10 members of the ASGE Quality Committee, the 7

TABLE 4. EUS

					Vote							
					1		2		3		4	
	Voters	Median	Mean	SD	No.	%	No.	%	No.	%	No.	%
Diagnostic upper or lower, no FNA	38	1	1.13	0.41	34	89.5	3	7.9	1	2.6	0	0.0
Diagnostic pancreatobiliary, no FNA	38	2	1.84	0.72	13	34.2	18	47.4	7	18.4	0	0.0
FNA of gut wall or contiguous stricture	37	2	2.24	0.68	3	8.1	24	64.9	8	21.6	2	5.4
Diagnostic requiring dilation, no FNA	36	2	2.25	0.69	5	13.9	17	47.2	14	38.9	0	0.0
Celiac plexus blockade	38	2	2.42	0.83	3	7.9	21	55.3	9	23.7	5	13.2
Inject tumor therapy	35	3	2.71	0.86	2	5.7	13	37.1	13	37.1	7	20.0
Pseudocyst aspiration/drainage	37	3	2.73	0.87	1	2.7	17	45.9	10	27.0	9	24.3
FNA distant/noncontiguous stricture*	37	3	2.76	0.64	1	2.7	10	27.0	23	62.2	3	8.1
Cholangiopancreatography, diagnostic	37	3	2.89	0.84	1	2.7	12	32.4	14	37.8	10	27.0
Fiducial placement	27	3	3.04	0.71	0	0.0	6	22.2	14	51.9	7	25.9
EUS with EMR	34	3	3.09	0.67	0	0.0	6	17.6	19	55.9	9	26.5
Pseudocyst enterostomy	36	4	3.50	0.70	0	0.0	4	11.1	10	27.8	22	61.1
Cholangiopancreatography with therapy	36	4	3.69	0.62	0	0.0	3	8.3	5	13.9	28	77.8
Add 1 level for items below?						% Yes		% No				
Surgically altered anatomy	40		1.15	0.36	34	85.0	6	15.0				
Previous incomplete procedure	38		1.18	0.39	31	81.6	7	18.4				
Age <3 y	29		1.34	0.48	19	65.5	10	34.5				
Emergency case outside of normal hours	38		1.53	0.51	18	47.4	20	52.6				

Items with majority agreement are highlighted.
*Beyond the gut wall, mediastinum, or pancreas.

members of the ASGE Adverse Events Working Party who were not members of the Quality Committee, the 33 members of the Canadian Association of Gastroenterology Consensus Group on Quality/Safety indicators, and the 190 registered members of the ERCP Quality Network. Of the latter, 141 are in the United States, 30 in Britain, and 19 in other countries. They were encouraged to ask their clinical colleagues to participate. All were asked to score each item on a scale of 1 to 4, with 1 being the least complex. They were also asked to consider whether the level should be increased by 1 point (to a maximum of 4) by any of the following circumstances: age younger than 3 years, work outside of normal hours, altered anatomy, and previous failed attempt.

The data were thought to be best presented with descriptive statistics. Means and medians of the scores given by each participant for each context/intervention were calculated. Standard deviations were calculated to assess the variance of these responses. The most common rank given for a specific context/intervention was highlighted. Good agreement was defined as more than 50% of physicians agreeing with the most common rank.

RESULTS

Votes were received from 76 endoscopists, 60% of whom were in academic centers and 40% in private practice. Some did not score all of the items because not all endoscopists felt comfortable scoring procedures with which they were not familiar or of that they did not perform in adequate volume. Overall data are shown in Tables 1 through 4, with votes in more than 50% agreement highlighted in black and the few with less than 50% in gray. The procedures and contexts are segregated into 4 levels using the median scores. In almost all cases, ranking by the median scores corresponded to the highest number of votes in that rank. There were 2 exceptions in ERCP, ie, minor papilla therapy and intrahepatic stones. The 2 items with medians of 1.5 (biliary stent extraction) and 3.5 (intrahepatic stones) were ranked down and up,

TABLE 5. Proposed complexity levels

For all categories and contexts, increase 1 level (to a maximum of 4) for any procedure done outside of normal working hours, on a child younger than 3 years or procedure that had been unsuccessful before.
Upper endoscopy and small bowel
1. Diagnostic EGD, with or without biopsy/cytology
2. Dilation esophageal stricture
Treat vascular lesions, hemostasis
Gastric polypectomy, stalked <2 cm
Nutritional support (catheter placement, PEG)
Foreign body removal
Push enteroscopy
3. Gastric polypectomy (stalked >2 cm)
Esophageal stent
Dilation duodenal stricture
Duodenal stent
Tumor and Barrett's ablation
Endoscopically assisted achalasia dilation
Device-assisted enteroscopy (eg, balloon)
4. Percutaneous endoscopic jejunostomy
Resect sessile lesions (EMR/ESD)
Cricopharnygeal myotomy
Colonoscopy
1. Diagnostic (sampling, tattooing), colonoscopy via ostomy
2. Polypectomy, stalked <2 cm
Treat vascular lesions, hemostasis
Decompression tube
Banding varices and hemorrhoids
3. Polypectomy, stalked >2 cm
Stricture dilation
Colonic stent
4. Percutaneous endoscopic colostomy
Colonic EMR and ESD
ERCP
Increase 1 level (to a maximum of 4) when the patient has had Billroth II gastrectomy
1. Deep cannulation of duct of interest, main papilla, sampling
Biliary stent removal/exchange
2. Biliary stone extraction <10 mm
Treat biliary leaks
Treat extrahepatic benign and malignant strictures
Place prophylactic pancreatic stents
3. Biliary stone extraction >10 mm
Minor papilla cannulation in divisum, and therapy
Remove of internally migrated biliary stents
Intraductal imaging, biopsy, FNA
Manage of acute or recurrent pancreatitis
Treat pancreatic strictures
Remove pancreatic stones mobile and <5 mm
Treat hilar tumors
Treat benign biliary strictures, hilum and above
Manage suspected sphincter of Oddi dysfunction (with or without manometry)
4. Remove internally migrated pancreatic stents
Intraductal image-guided therapy (eg, photodynamic therapy, electrohydraulic lithotripsy)
Pancreatic stones impacted and/or >5 mm
Intrahepatic stones
Pseudocyst drainage, necrosectomy
Ampullectomy
ERCP after Whipple or Roux-en-Y bariatric surgery
EUS
1. Diagnostic upper or lower, no sampling (FNA)
2. Diagnostic pancreatobiliary, no FNA
Diagnostic requiring dilation, no FNA
FNA gut wall or contiguous structure (mediastinum, pancreas)
Celiac plexus blockade
3. FNA distant/noncontiguous structure
Inject tumor therapy
Fiducial placement
EUS with EMR
Pseudocyst aspiration/drainage
Cholangiopancreatography diagnostic
4. Pseudocyst enterostomy
Cholangiopancreatography with therapy (eg, stent, choledochoduodenostomy)

respectively, according to the majority vote. Several items that were separated in the voting lists (eg, different-sized polyps and stones) achieved the same rank in the voting and are thus combined in the final proposed list (Table 5).

There was a majority in favor of all of the proposed 1-level additions, except for EUS outside of normal hours, which is a very rare event.

DISCUSSION

This is the first attempt to provide rankings for the complexity of all major endoscopic procedures. We did not include capsule endoscopy, which is very simple to perform and virtually without risk. There will be additional endoscopic techniques in the future, eg, bariatric procedures, fundoplication, and full-thickness resections. Those are likely to justify fourth level rankings.

Our listings for ERCP differ substantially from those first proposed by Schutz and Abbott.[2] The scope of ERCP has expanded since their seminal paper, and many procedures that they ranked highly at grade 4 (out of 5), such as common duct stenting, are now routine and should be in the armamentarium of anyone offering ERCP services. Also, we concentrated on clinical contexts rather than individual techniques. There was also criticism of their inclusion of "precut biliary sphincterotomy" at their highest level (grade 5). It is not technically difficult and, as a result, is used too frequently instead of a proper cannulation technique, but it is risky. As explained in the Methods section, we attempted to provide a scale of complexity that combines technical difficulty and some element of perceived risk.

The other main factor that affects risk is the clinical status of the patient. Certain issues are obvious, such as sepsis, hemodynamic instability, and coagulopathy. Thus, it would be helpful to have a parallel risk scale, based on patient comorbidities. The only scale in common use is the American Society of Anesthesiologists grade, which correlates somewhat with the risk of cardiopulmonary events, but not with the risk for noncardiopulmonary events, such as perforation, bleeding, and pancreatitis.

A recent exhaustive review of the published literature on the risks of endoscopic procedures did not reveal a simple generic comorbidity scale that could be recommended.[6,7] The authors did develop a list of risk factors that should be documented, based on existing evidence of correlation with risk of specific events, and others that should be recorded in clinical trials designed to establish which metrics are important.

The chances of technical success in any procedure depend on the level of training and expertise, but these also probably affect risk. Thus, to complete the picture, it would be helpful to have some way to document the level of expertise of individual endoscopists; this is clearly difficult to define. However, the increasing use of benchmarking systems will allow endoscopists to know their rates of technical success and adverse events.[8,9]

Our proposed levels of complexity can be used in designing and monitoring training programs and for credentialing. In upper endoscopy, colonoscopy, and ERCP, level 2 should be the threshold for independent basic practice. It is not appropriate to offer colonoscopy without being able to remove most polyps, ERCP without competence in basic biliary therapeutics, or upper endoscopy without expertise in hemostasis. EUS, because of limited availability of physicians trained to level 2, is perhaps different, and there may be some endoscopists who practice at level 1, assuming that they select their cases appropriately. For all procedures, however, more training is required to achieve competence (and credentialing) in level 3 and 4 procedures.

Recommendations

The ASGE Working Party on Adverse Events recommended using the proposed new lexicon in large multiinstitutional prospective studies to test its validity and practicality.[1] We now suggest that these studies incorporate the complexity metrics that we developed and the risk factors already published.[6,7] The results of such studies should provide data with which to validate or adjust the metrics, with potential benefit for patients, teachers, and endoscopists, as well as credentialing and paying agencies. Eventually, combining validated scales for complexity, risk, and expertise will give individual endoscopists and patients a much better idea of the likely outcome in an individual case, ie, more truly informed consent.

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