Laparoscopic entry techniques: clinical guideline, national survey, and medicolegal ramifications

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Abstract

safe laparoscopic entry through a systematic literature search and evidence-based medicine appraisal, to determine surgeon preferences for laparoscopic entry in the United Kingdom, and to appraise the medicolegal ramifications of complications arising from laparoscopic entry. *Methods* A systematic literature search of MEDLINE and EMBASE (1996–2007) was performed as well as a national surgeon survey by questionnaire (May–December 2006). *Results* Laparoscopic entry criteria involving 10 steps were established based on the systematic literature search and evidence-based critical appraisal. The national survey had 226 respondents, with the majority aware of the Middlesbrough consensus or Royal College of Obstetricians and Gynaecologists [RCOG]-sourced guidance. There was

Background This study aimed to establish criteria for

Conclusions Despite widespread awareness of laparoscopic entry guidelines, there remains considerable variation in the techniques adopted in clinical practice. Unless practice concurs with recommended guidance, women undergoing laparoscopy will be exposed to increased unnecessary

considerable variation in preferred laparoscopic entry

techniques. Currently, there is clear judicial guidance on the medicolegal stance toward laparoscopic entry-related

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complications.

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operative risk. Laparoscopic entry-related injury in an uncomplicated woman is considered negligent practice according to UK legal case law.

Keywords Laparoscopic entry · Guidelines · Laparoscopy · Pneumoperitoneum · Artificial · Surgical procedures · Minimally invasive · Intraoperative complications

Although complications associated with laparoscopic surgery fortunately are rare, a significant proportion of these occur at the time of laparoscopic abdominal wall entry [1–26]. Metaanalyses and large multicenter studies have provided pooled risks of vascular and bowel injury at the time of laparoscopic entry as 0.2 per 1,000 and 0.4 per 1,000, respectively [1, 19, 27–38]. Such complications may incur serious morbidity and mortality, which are compounded if such injuries are not detected at the time of original surgery, particularly in the case of bowel injury [1, 5, 39–47].

Two laparoscopic entry methods are used principally in gynecology and general surgery:

- 1. Closed entry laparoscopy with creation of a pneumoperitoneum at the umbilicus (or Palmer's point).
- 2. Open (Hasson) laparoscopy [48–50].

Other techniques, used less frequently and with limited supporting evidence [6] are direct entry [51–59], optical access trocars [60–70], and radially expanding trocars [71–76].

According to current evidence, based mainly on observational studies, no one laparoscopic entry method has demonstrated clear superiority over another. This has led to wide variation among clinicians as to which entry method should be recommended [6, 77, 78]. It has been suggested

that open (Hasson) entry is superior to closed entry techniques because vascular injury is less likely to occur [28, 32, 49, 50, 57, 77, 79–89], although this viewpoint has been challenged [28].

There is significant variation in laparoscopic entry practice in the United Kingdom [90–93] and at international locations [27, 94, 95]. In an attempt to minimize the risks of laparoscopy and unify clinical practice, a number of international bodies (International Middlesbrough Consensus [96], RCOG [draft version only] [97], SOGC [78], RANZ-COG [98], EAES [99], Society of American Gastrointestinal Endoscopic Surgeons [SAGES] [100], the French Society of Endoscopic Gynecology [101], the Netherlands [102] and individual experts [103–105]) have recommended specific "safe laparoscopic entry" principles. In fact, several small studies [106–108] have shown that adoption of a recommended technique [78, 96] can reduce the incidence of laparoscopic entry-related complications.

We aimed to evaluate the status of gynecologic laparoscopic entry in the United Kingdom, bearing in mind that litigated cases normally consider both what should be (published recommendations) and what is (questionnaire enquiries) occurring in clinical practice. To achieve this, we planned to establish evidence-based criteria for safe laparoscopic entry through a systematic literature search and critical appraisal of the literature, to identify what laparoscopic entry techniques are used currently in the United Kingdom, and to explore any factors that may influence the preference for a particular technique. This was determined through a United Kingdom-wide questionnaire survey. The current judicial viewpoint on laparoscopic entry injuries was identified from the published literature.

Methods

Establishing criteria for safe laparoscopic entry

Electronic searches of MEDLINE (Ovid version 1996–December 2007) and EMBASE (Ovid version 1996–December 2007) were performed using relevant combinations of medical subject headings (laparoscopy, gynecologic surgical procedures, intraoperative complications, postoperative complications, pneumoperitoneum, artificial, malpractice, risk assessment, legal liability, judicial role, jurisprudence) and text words. International guidelines were identified by interrogating specialized electronic repositories (e.g., national guideline clearinghouse, national electronic library for health, Organising Medical Networked Information [OMNI], Turning Research into Practice [TRIP] database, E guidelines, and Geneva Foundation for Medical Education and Research [GFMER] databases) and by searching national Collegiate (e.g. Royal College of

Obstetricians and Gynaecologists [RCOG], American College of Obstetricians and Gynecologists [ACOG], Royal Australian and New Zealand College of Obstetricians and Gynaecologists [RANZCOG], Society of Obstetricians and Gynaecologists of Canada [SOGC] and specialist international laparoscopy organization (e.g., American Association of Gynecologic Laparoscopists [AAGL], Society of Laparoendoscopic Surgeons [SLS], International Society for Gynecologic Endoscopy [ISGE], British Society of Gynaecological Endoscopy [BSGE], SAGES, European Association for Endoscopic Surgery [EAES], Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (part of Royal Australasian College of Surgeons) [ASERNIP-S]) Web sites. The literature was critically appraised according to established evidence-based criteria (see Appendix and Scottish Intercollegiate Guidelines Network [SIGN] recommendations [109, 110]) to generate a list of key steps necessary for safe laparoscopic entry. For each step, we denoted a level of evidence and grade of recommendation and discussed their derivation from the supporting literature.

Questionnaire survey

The questionnaire, developed in collaboration with the BSGE, recorded

- Clinician grade and method of entry into the uncomplicated woman or high-risk woman (defined as any woman with previous suprapubic or midline laparotomy and very thin or obese women)
- The angle of entry for the Veress needle and primary trocar
- The criteria used to test for correct placement of the Veress needle
- Adequacy of carbon dioxide (CO₂) pneumoperitoneum before primary trocar insertion
- Whether the clinician routinely inspected the abdomen for laparoscopic injury at the beginning or end of the laparoscopy procedure
- Whether the clinician had experienced (personally or through witnessing) any laparoscopic entry-related bowel or vascular injury
- Awareness of the Middlesbrough Consensus
- RCOG-sourced information on recommended laparoscopic entry practice.

In contrast to previous questionnaire studies, we aimed to compare practice among trainee grades and consultant specialists. The study population consisted of three groups:

1. Registered BSGE members May 2006. The questionnaire and a prepaid postage reply envelope were



- included in the BSGE May 2006 quarterly newsletter sent to all 180 registered BSGE members.
- Specialist registrar trainees. The questionnaire was distributed to all trainees who attended regional study days at Birmingham Women's Hospital, UK.
- 3. Attendees at the joint RCOG/BSGE conference held Friday, December 8, 2006, at the Royal College of Obstetricians and Gynaecologists, London, UK, at which a questionnaire through an electronic audience participation format was used. Audience members responded through handheld devices, and instantaneous feedback on the entire audience was electronically displayed after each question.

Results

Evidence-based criteria for safe laparoscopic entry

The original systematic literature review identified 276 primary studies relating to laparoscopic techniques and

complications, 21 secondary studies (13 metaanalyses and 8 clinical guidelines), and 12 citations relating to medicolegal aspects of laparoscopy entry-related complications. A further 17 relevant citations were identified through the bibliography of primary and secondary (clinical guidelines, reviews) studies. Through a process of critical literature appraisal, 10-step evidence-based criteria for safe closed umbilical laparoscopic entry were constructed (Table 1). The level of evidence justifying each step is outlined in the following sections.

Suitability criteria (step 1)

Women who are extremely thin [111–113], obese [114–117], or known to have abdominal adhesions are at increased risk for laparoscopic entry-related injury at the umbilical entry point. The estimated risks for umbilical and/or anterior abdominal wall adhesions are 0–5% for women with no prior laparoscopic surgery, 20–30% for those with a previous suprapubic laparotomy, and 50–65% for those with a previous midline laparotomy [118–138].

Table 1 Evidence-based criteria for safe laparoscopic entry: 10 steps

Step	Intervention	Level of evidence and grade of recommendation (see Appendix)	Supporting references
1	Suitability criteria: consider alternative entry (e.g., Palmer's point or open [Hasson] technique) for patients with risk factors such as previous abdominal surgery, obesity, extremely thin physique, or known abdominal adhesions	2++, B	Adhesion risks: [118–138]
2	Safety criteria: patient should be lying flat with an empty bladder; palpation should be used for the abdominal aorta, any masses; and the Veress needle should be checked for spring action and gas patency	4, GPP	
3	Incision: 10-mm vertical intraumbilical incision starting deep inside the umbilicus pit and extending caudally	4, GPP	
4	Insertion of the Veress needle: at the deep umbilical pit, 90° to the skin, with or without stabilizing or elevating the umbilical sheath/fascia or anterior abdominal wall, and in a controlled manner with insertion of less than 2 cm of the Veress needletip	2+, C (indirect evidence from knowledge of abdominal anatomy)	[51, 111–113, 145–149]
5	No movement of the Veress needle after insertion to avoid converting a possible needlepoint injury into a large complex tear	4, GPP	
6	Safety abdominal pressure check of Veress placement: most reliably achieved by using a Veress IAP of less than 10 mmHg	2+, C	[108, 150–152]
7	Safety abdominal pressure check for primary trocar: the IAP should be 25 mmHg to achieve the maximum safe distance between the anterior abdominal wall and the underlying abdominal contents	2+, C	[108, 153–157]
8	Vertical primary trocar insertion: inserted in a controlled two-handed screwing manner vertically at 90° to the skin, with only the tip of the trocar inserted through the abdominal wall	2+, C >	[111–113, 145–147]
9	Injury check: an initial 360° laparoscopic check for intraperitoneal organ injury is performed	4, GPP	
10	No epigastric for secondary trocar(s) insertion: inserted under direct vision in a controlled two-handed manner at 90° to the skin, avoiding inferior epigastric vessels	2+, C (indirect evidence from knowledge of abdominal anatomy)	[158–162]

GPP, good practice points; IAP, intraabdominal pressure

Note: The acronym, SCIIN (suitability, criteria, incision, insertion, no movement) SAVE (safety abdominal Veress), SAVING (safety, abdominal pressure [trocar], vertical trocar, injury check, no epigastrics) is suggested for the 10 steps



Prospective observational studies suggest that the risk of laparoscopic entry-related injury may be considerably reduced by the use of an alternative entry (e.g., left upper-quadrant Palmer's point or open Hasson technique) for women with such risk factors. However, the actual relative risk reduction is not quantified because the studies have no comparator. Left upper-quadrant Palmer's laparoscopic entry also could be considered if there has been failure to achieve pneumoperitoneum at the umbilicus. Notably, limited evidence shows that testing for reduced (<1 cm) visceral slide (ultrasound-visualized movement of the underlying bowel or omentum) may be helpful in detecting subumbilical adhesions, thereby allowing consideration of an alternative laparoscopic entry strategy [139–144].

Supine patient positioning, safety checks, and umbilical incision (steps 2 and 3)

Reliable data on appropriate patient positioning and on location and type of umbilical incision were not identified. Consequently, we suggest that the patient be laid flat at the commencement of laparoscopy to avoid the theoretical risk of the "pelvic" bowel being displaced toward the umbilicus, thereby exposing the bowel to entry-related injury. On a similar stance, adoption of an alternative entry technique is advisable if a prominent abdominal aorta pulsation is identified in close proximity to the undersurface of the umbilicus. Current consensus among clinicians is for a 10-mm vertical intraumbilical incision extending caudally.

Controlled vertical (90°) Veress needle entry (steps 4 and 5)

No comparative studies have assessed the optimum angle of Veress needle entry. However, fusion of the parietal peritoneum and linea alba at the pit of the umbilicus logically dictates that a vertical (90° to the horizontal abdomen) Veress insertion represents the shortest skin-toperitoneum anatomic distance to enable direct peritoneal entry. According to computed tomography (CT) abdominal mapping [111, 112, 145] and actual laparoscopy [113, 146, 147], this skin-to-peritoneum distance at the umbilical pit is consistently no greater than 2 cm, irrespective of abdominal obesity. Nevertheless, it is suggested that the Veress angle of entry should vary (45° in nonobese women and 90° in obese women) because CT abdominal imaging [112]) and visualization at laparoscopy [113] have shown that the location of the underlying aortic bifurcation (which may be prone to Veress injury) tends to be directly under the umbilicus in nonobese women or 2-3 cm caudal to the umbilicus in obese women. The umbilicus pit (and underlying parietal peritoneum) also may be stabilized or successfully elevated away (either by grasping of the lower abdominal wall or by application of tissue forceps/towel clips within 2 cm of the umbilicus) from underlying abdominal viscera during Veress insertion [51, 147–149]. However, a reasonable summary of the indirect evidence stated is that traversing the abdomen's thinnest portion by controlled 90° vertical entry, with Veress needle tip insertion no greater than 2 cm and selective umbilical stabilization/elevation, is likely to be the safest route of Veress insertion for the vast majority of women, regardless of any caudal displacement of their umbilicus.

Safety test for correct Veress placement using an intraabdominal pressure of 10 mmHg or less (step 6)

A variety of safety tests for correct intraperitoneal placement of the Veress needle are used in clinical practice including double-click, aspiration, and hanging-drop tests. Prospective studies of women undergoing laparoscopy have shown that a Veress intraabdominal pressure (IAP) of 10 mmHg or less reliably indicates correct Veress placement at umbilical [108, 150, 151] and Palmer's point entry [152] locations. The Veress IAP pressure correlates positively with the weight and body mass index (BMI) and negatively with the parity of women [151].

Controlled vertical (90°) primary trocar insertion at 25 mmHg IAP (steps 7, 8, and 9)

Prospective observational studies have shown that higher intraabdominal CO2 insufflated pressures achieve greater anterior abdominal wall splinting and intraabdominal CO₂ gas bubble space [108, 153-155]. An IAP of 25 mmHg has been shown to achieve a maximum safe distance between the anterior abdominal wall and underlying abdominal contents without compromising cardiorespiratory function [156, 157]. A two-handed, screwing manner-controlled vertical (90°) entry of only the primary trocar tip uses the safe CO2 bubble depth afforded through an IAP of 25 mmHg and is highly unlikely to injure underlying vessels according to actual laparoscopy [113, 146, 147] and abdominal vasculature CT mapping studies [111, 112, 145]. Although there is no direct supporting evidence, an initial check for bowel and vascular injury immediately after primary trocar insertion is recommended to avoid missing this complication and exposing the women to serious morbidity.

Controlled insertion of secondary trocars under direct vision (step 10)

Epigastric vessels can be identified reliably through a combination of direct visualization (vessels lie 1–2 cm lateral to the medial umbilical ligaments [obliterated]



umbilical arteries]), transillumination, and external anatomic landmarks [158–162]. In most women, a useful and safe point of insertion is 2 cm from the anterior superior iliac crest along an imaginary line connecting the iliac crest to the umbilicus. Controlled insertion, at a 90° angle to the skin, using a two-handed screwing manner for the secondary trocar (analogous to that used for insertion of the primary trocar), should be observed under direct vision to ensure that no inadvertent injury of abdominal organs occurs.

Questionnaire survey

There was a 62% (n = 112) response rate for the postal questionnaire and 100% response rates for the SpR registrars (n = 82) and attendees (n = 32) at the RCOG/BSGE meeting. Analysis of all 226 total respondents was performed.

Entry technique for uncomplicated versus high-risk women

The vast majority of surgeons would use a closed umbilical laparoscopic entry for uncomplicated women and a Hasson or Palmer's point entry for women with a previous midline laparotomy (Table 2). However, there was inconsistency in the selection of entry technique for women with previous suprapubic laparotomy or obesity and for those who were extremely thin (Table 2).

Veress and primary trocar entry

Only 18% of surgeons would use the recommended 90°/ 90° Veress and primary trocar entry method (Table 3).

Safety checks performed to ensure correct Veress placement and those used before primary trocar insertion are depicted in Tables 4 and 5 respectively. The proportion of respondents aware of evidence-based guidance or possessing previous experience of laparoscopic injury is depicted in Table 6.

Medicolegal ramifications

The civil standard of law is used in UK medicolegal litigation. This means the claimant (woman patient) has the responsibility to prove it more likely than not (>51% probability) that the injury she incurred arose through a negligently performed surgical technique rather than a nonnegligently performed procedure by the defendant (surgeon).

Laparoscopic entry-related complications have contributed significantly to medical litigation in gynecologic surgery [26, 40, 41, 163–170]. Until recently, there was inconsistency in the judicial viewpoint in the awarding of negligent or nonnegligent verdicts. However, the case of Palmer v Cardiff and Vale NHS Trust [171] has now set judicial guidance in this area. The court ruled that the likelihood of laparoscopically related bowel injury occurring in an uncomplicated case if there has been good surgical technique is highly unlikely. If there is no alternative plausible nonnegligent explanation for the complication, then the defendant is liable, in compliance with the legal maxim res ipsa loquitir ("the thing speaks for itself"). This overruled the defendant's viewpoint that injury is a recognized complication of laparoscopy and that its occurrence is therefore not proof of negligence per se.

Table 2 Laparoscopic entry technique for uncomplicated versus high-risk women^a

Veress entry technique	Uncomplicated	High-risk women					
	women n (%)	Women with previous suprapubic laparotomy <i>n</i> (%)	Women with previous midline laparotomy $n\ (\%)$	Women with obesity n (%)	Women who are extremely thin <i>n</i> (%)		
Closed umb	213 (94)	193 (85)	37 (16)	179 (79)	189 (84)		
Open (Hasson)	5 (2)	14 (6)	49 (22)	13 (6)	15 (7)		
Palmer's point	1 (<1)	8 (4)	102 (45)	4 (2)	2 (<1)		
Suprapubic point	3 (1)	1 (<1)	4 (2)	9 (4)	6 (3)		
Direct entry	3 (1)	2 (<1)	0	3 (1)	2 (<1)		
Transvaginal culdoscopy	1 (<1)	1 (<1)	1 (<1)	1 (<1)	1 (<1)		
Closed umb or suprapubic	0	0	1 (<1)	4 (2)	1 (<1)		
Hasson or Palmer's	0	3 (1)	23 (10)	0	1 (<1)		
Closed umb or Palmer's	0	2 (<1)	5 (2)	0	4 (2)		
Closed umb or Hasson or Palmer's	0	0	3 (1)	1 (<1)	0		
Closed umb or Hasson	0	2 (<1)	1 (<1)	9 (4)	6 (3)		

umb, umbilical

^a Direct entry would be gasless direct primary trocar abdominal entry and would not use a Veress needle



Table 3 Frequency of angle of entry for Veress needle and primary trocar

	Angle of primary trocar entry n (%)					Total (n)
	90°	60°	45°	30°	Z-angle ^b	
Angle of Veress needle entry						
90°	40 (18)	28 (12)	24 (11)	1	1	94
60°	6	34 (15)	9	0	2	51
45°	1	11	57 (25)	1	3	73
30°	0	1	1	0	0	2
Not used ^a	3	1	1	1	0	6
Total	50	75	92	3	6	226

a Veress needle angle not determined because practitioner prefers to use either the Hasson or direct entry method for insertion of the primary trocar

Note: The five most frequent Veress and primary trocar combinations are shaded in grey with bold type

Table 4 Safety checks performed to ensure correct Veress placement^a

SpR, Specialist Registrar
^a Pressure refers to
preinsufflation intraabdominal
pressure recorded as lower than
8 mmHg. Two Veress clicks
refers to the audible or tactile
impression of two Veress clicks
at abdominal insertion. Saline
aspiration refers to the four-
component saline aspiration,
injection, aspiration, drop test
commonly known as Palmer's
test

Table 5 Safety checks performed before primary trocar insertion^a

Tests	SpR (n = 63)	1–3 SpR $(n = 41)$	1-5 Consultant $(n = 122)$	Total count <i>n</i> (%)
Pressure & saline aspiration & two Veress clicks	14	11	28	53 (23)
Pressure & saline aspiration	13	11	24	48 (21)
Saline aspiration	20	6	10	36 (16)
Pressure & two Veress clicks	6	5	21	32 (14)
Pressure	3	4	14	21 (9)
Saline aspiration & two Veress clicks	6	1	4	11 (5)
Pressure & freely moving Veress & two Veress clicks	0	0	7	7 (3)
Two Veress clicks	1	1	3	5 (2)
Freely moving Veress & two Veress clicks	0	1	2	3 (1)
Pressure and freely moving Veress	0	0	3	3 (1)
Freely moving Veress	0	0	2	2 (<1)
Veress not used	0	1	4	5 (2)

Tests	SpR 1-3	SpR 4–5	Consultant	Total count n (%)
IAP 25 mmHg	29	22	48	99 (44)
Distension and IAP 25 mmHg	20	6	14	40 (18)
Distension and IAP 12-15 mmHg	4	0	21	25 (11)
Distension	2	4	13	19 (8)
IAP 12–15 mmHg	4	4	8	16 (7)
Distension >3 1 CO ₂ , IAP 12–15 mmHg	1	3	6	10 (4)
Distension >3 1 CO ₂ , IAP 25 mmHg	2	2	6	10 (4)
Distension >3 1 CO ₂	0	0	5	5 (2)
CO ₂ >3 1	1	0	1	2 (<1)

IAP, intraabdominal pressure

^a Distension refers to clinical abdominal wall distension

The judicial guidance accepted that given a woman without risk factors and a surgeon following a safe technique (i.e., correct insertion of the Veress needle, its position checked, insufflation of the peritoneal cavity to 25 mmHg, and

controlled insertion of the primary trocar with penetration of the cavity by just the trocar tip), the risk of injury is highly improbable. Thus the occurrence of any injury under these circumstances would imply a negligent technique.



 $^{^{\}rm b}$ Z-angle system corresponds to initial shallow angle <30°, then a steeper angle >60°

Table 6 Awareness of evidence-based guidance and previous experience of laparoscopic injury

	SpR 1–3 $(n = 63)$	SpR 4–5 $(n = 41)$	Consultant ^a $(n = 122)$	Total $(n = 226) n (\%)$
Awareness of Middlesbrough consensus				
Yes	27	22	100	149 (66)
No	36	19	22	77 (34)
Awareness of RCOG guidance				
Yes	55	33	90	78 (79)
No	8	8	32	48 (21)
Previous experience of laparoscopic inju	ıry			
Yes, bowel injury	14	13	57	84 (37)
Yes, vascular injury	7	4	7	18 (8)
Yes, both vascular and bowel injury	4	5	32	41 (18)
No	38	19	26	83 (37)
Routine inspection of the abdomen				
Yes	48	38	110	196 (87)
No	15	3	12	30 (13)

RCOG, Royal College of Obstetricians and Gynaecologists

Discussion

On the basis of our systematic literature search and critical appraisal of the published literature and available guidelines, we constructed a 10-step evidence-based guideline for safe closed laparoscopic entry. Our findings are analogous to the original 11 safety steps of Semm and Semm [105]. However, we have updated these steps in line with current evidence-based literature and have ascribed the level of evidence to each step supported by the literature citation or citations for that step. We believe that these 10 steps represent the current most up-to-date evidence enabling clinicians to practice safe closed laparoscopic entry.

Our national questionnaire study showed considerable heterogeneity in laparoscopic entry practice despite widespread awareness of the Middlesbrough Consensus or RCOG-sourced guidance. The inconsistency, inherent throughout every step of the laparoscopic entry procedure, has been identified by previous UK-based surveys [90–93]. Fundamentally, there was a failure to appreciate risk factors that would justify a change in entry technique as well as failure to adopt the correct safety checks after Veress insertion and before primary trocar insertion. Even if there were authoritative guidance on safe laparoscopic entry technique, it is unclear how many practitioners actually would change their clinical practice accordingly. However, an Australian-based questionnaire study suggests that this would be supported by the majority of minimally invasive surgeons [94].

We acknowledge that our sample size was limited and that we surveyed a highly selected group. It is reassuring that we have shown no real differences between trainees and specialists. However, it is of great concern that even in the "expert" specialist group, entry technique varies widely. It is possible that a survey of general gynecologists may identify an even wider and more alarming variation in practice.

We strongly believe that safe laparoscopic entry guidance, such as the 10 steps shown in Table 1, should be disseminated widely. However, we accept that following such guidance would not necessarily negate the risk of laparoscopic entry-related injury, nor would it protect the clinician against any ruling of negligence should a complication occur. We believe that written guidance should be reinforced through simulated training [172, 173], structured formal assessment, and consistent clinical direction by specialists. Unless practice concurs with recommended guidance, women undergoing laparoscopy will be exposed to increased unnecessary operative risk.

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Appendix. Scottish Intercollegiate Guidelines Network (SIGN) grading system

Levels of evidence

- 1++ High-quality metaanalyses, systematic reviews of RCTs or RCTs with a very low risk of bias
- 1+ Well-conducted metaanalyses, systematic reviews of RCTs or RCTs with a low risk of bias
- Metaanalyses, systematic reviews of RCTs or RCTs with a high risk of bias



^a Consultant category includes 4 staff grades, 5 associate specialists and 113 consultants

Appendix continued

Levels of evidence

- 2++ High-quality systematic reviews of case-control or cohort studies
 - High-quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
- 2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
- 2- Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
- 3 Nonanalytic studies (e.g., case reports, case series)
- 4 Expert opinion

Grades of recommendation

- A At least one metaanalysis, systematic review, or RCT rated as 1++ and directly applicable to the target population, or a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
- B A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+
- C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++
- D Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+
- GPP Good practice points: recommended best practice based on the clinical experience of the guideline development group

RCT, randomized clinical trial

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