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Original Article**Ultrasound-based endometriosis staging system (UBESS): validation study to predict complexity of laparoscopic surgery.**

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ABSTRACT

Study Objective: To validate the preoperative ultrasound-based endometriosis staging system (UBESS) for predicting the correct Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the Australasian Gynaecological Endoscopy and Surgery (AGES) Society's level of laparoscopic skill level required for endometriosis surgery.

Design: Multi-center retrospective cohort study (Canadian Task Force II-2)

Setting: A tertiary teaching hospital and a private gynecological clinic

Patients: 155 women presenting with chronic pelvic pain and/or a history of endometriosis

Interventions: Women underwent detailed specialized transvaginal ultrasound (TVS) in a tertiary referral unit to diagnose and stage endometriosis using the three stages of UBESS. The UBESS was correlated to RANZCOG/AGES laparoscopic skill levels. The UBESS classifications were correlated as such: UBESS I to predict RANZCOG/AGES surgical skill levels 1/2, UBESS II to predict RANZCOG/AGES skill levels 3/4 and UBESS III to predict RANZCOG/AGES skill level 6.

Main Results: The accuracy, sensitivity, specificity, positive and negative predictive values and positive and negative likelihood ratios of the UBESS I to predict the RANZCOG/AGES surgical skill levels 1/2 were: 99.4%, 98.9%, 100%, 100%, 98.5%, inf and .011; those of UBESS II to predict surgical skill levels 3/4 were: 98.1%, 96.8%, 98.4%, 93.8%, 99.2%, 60 and .033; and those for UBESS III to predict surgical skill level 6 were: 98.7%, 97.2%, 99.2%, 97.2%, 99.2%, 115.7 and 0.028, respectively. The rate of correctly predicting the exact level of skills needed was 98.1%, and Cohen's kappa statistic for the agreement between UBESS prediction and levels of training required at surgery is 0.97, indicating almost perfect agreement.

Conclusions: The UBESS can be utilized to predict the level of complexity of laparoscopic surgery for endometriosis based on the RANZCOG/AGES skills levels for laparoscopy. It now needs to be externally validated in multiple centers with various surgical skill level classification systems to assess the general applicability.

Keywords: laparoscopy, endometriosis, preoperative staging, transvaginal ultrasound

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INTRODUCTION

The World Endometriosis Society defines endometriosis as an inflammatory disease process, characterized by lesions of endometrial-like tissue outside the uterus, which are associated with various forms of pelvic pain and/or infertility ⁽¹⁾. Currently, the gold standard for the diagnosis of endometriosis is laparoscopy ⁽²⁾. At this time there is no widely used triaging tool allowing surgeons to determine severity of disease before operating. Increasing severity of disease may require advanced surgical skill and/or a multidisciplinary approach. Inadequate surgical skill may result in multiple surgeries for women with severe disease, which in turn yields greater healthcare costs and potentially additional risks and patient morbidity.

The ultrasound-based endometriosis staging system (UBESS) was designed to preoperatively stage endometriosis using transvaginal ultrasound (TVS). It has previously been shown to have an overall accuracy of 84.9% to predict the complexity of laparoscopic surgery in women with endometriosis when applied to the Royal College of Obstetricians and Gynaecologists' (RCOG) levels of laparoscopic surgery ⁽³⁾.

The aim of this study was to validate the performance of the UBESS to predict the complexity of laparoscopic surgery as determined by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the Australasian Gynaecological Endoscopy and Surgery (AGES) Society's levels of laparoscopic skill.

METHODS

STUDY DESIGN

The study was a multi-center retrospective cohort study of women referred to two specialist tertiary centers between August 2013 and April 2016. An Excel database was created using data collected from patients referred to these sites for chronic pelvic pain. For the purpose of this study, chronic pelvic pain was defined as lower abdominal or pelvic pain lasting for longer than six months, following either a continuous or intermittent course and not necessarily related to menstruation or sexual intercourse^(4, 5). Our research group has previously correlated the UBESS to the RCOG laparoscopic skill levels⁽³⁾. Accordingly, reference may be made to this previous publication for the original description of the study method.

The tertiary referral centers were the Advanced Endosurgery Unit at Nepean Hospital and OMNI Gynaecological Care in Sydney, Australia. Women who presented with chronic pelvic pain underwent TVS and gel sonovaginography (gel SVG)⁽³⁾. This was performed by one of three technicians in accordance with the 5-domain TVS protocol approach⁽⁶⁾. The primary sonologist was an expert in the field, with extensive experience in diagnosing deep endometriosis (DE)⁽³⁾. The primary sonologist also supervised the remaining two gynecological ultrasound fellows involved in this study. Informed consent was gained from the participants in this study, as required by the tertiary institutions' ethics approval protocols.

Inclusion criteria for the UBESS study were women of reproductive age, history of chronic pelvic pain and/or history of endometriosis as well as women who had consented for laparoscopy for endometriosis at the time of TVS consultation. Exclusion criteria for UBESS were women with malignancy, adnexal lesions other than endometrioma, pregnancy and menopause⁽³⁾.

The Excel database collated: medical history, sonographic and laparoscopic surgical data.

The sonographic data included specific phenotypic markers indicating potential endometriosis

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⁽³⁾. These were elicited using a uniform protocol for TVS procedures across both sites ⁽⁶⁾. Each participant was also apportioned a UBESS score at the time of preoperative ultrasound. The laparoscopic surgical data, which was later used to determine the RANZCOG/AGES laparoscopic skill level required for each procedure, was recorded at the conclusion of each patient's surgery. Each surgery was assigned a RANZCOG/AGES laparoscopic skill level of 1 –6 based on the findings and description of the attending surgeon, including the laparoscopic findings, level of difficulty and surgical techniques required ⁽³⁾. The RANZCOG/AGES skill level was decided by one of the gynecological ultrasound fellows, BG.

ETHICS APPROVAL

Ethical approval was awarded by the Nepean Blue Mountains Local Health District Human Research and Ethics Committee as an amendment to the ethics approved for the previous study comparing the UBESS to RCOG skill levels (HREC project number 16/08).

5-DOMAIN TVS EXAMINATION

Transvaginal ultrasound and gel SVG examination were performed in an outpatient setting. Equipment used included 7.5 MHz transvaginal probe (LOGIQ-e -1, General Electric Zipf, Austria or Medison X8, V20 or XG, Samsung Medison, Seoul, South Korea) ⁽³⁾. The 5-domain ultrasound-based approach was used for the TVS examination of each woman being investigated for endometriosis ^(3, 6). The domain-based TVS assessment began after informed consent was obtained. The 5 domains as described by Menakaya *et al.* ⁽⁶⁾ consist of: (1) routine assessment of the uterus and adnexa, (2) tenderness-guided assessment, (3) an assessment of pouch of Douglas (POD) status, ovarian and organ mobility, (4) an assessment for non-bowel DE of the anterior, lateral and posterior pelvic compartments and (5) an assessment of the anterior wall of the rectum and rectosigmoid ⁽⁶⁾.

ULTRASOUND-BASED ENDOMETRIOSIS STAGING SYSTEM

Sonographic data with gold standard laparoscopic outcomes collected during a previous TVS based study of women with suspected endometriosis was used to develop the UBESS⁽³⁾. The UBESS consists of three stages based upon histological phenotype of endometriosis, anatomical location and markers of local invasiveness⁽⁸⁾. Figure 1 outlines the UBESS classifications. Women in this study were assigned UBESS I, II or III at the time of TVS examination. The UBESS classification for each woman was recorded in the Excel spreadsheet at the time of TVS assessment.

SURGICAL INTERVENTION

There were seven surgeons involved with the study. Amongst these were minimally invasive gynecological surgeons (specialists who completed a formal fellowship in minimally invasive gynecological surgery) and general gynecological surgeons⁽³⁾. All surgical intervention was performed within 6 months of TVS examination and surgeons were blinded to each patient's individual UBESS score. The pelvic and abdominal cavities were methodically inspected to note any pre-existing pathology just prior to surgery⁽³⁾. An Excel database was then used to record all surgical data. Endometriosis was diagnosed in the patient if any of the following were satisfied: visualization of complete POD obliteration, sub-peritoneal disease confirmed with histological analysis of a resected nodule, or sub-peritoneal nodule not biopsied but visualized and palpated in a patient with otherwise proven endometriosis^(3, 9). Patients who were deemed to have more severe endometriosis with bowel involvement prior to surgery underwent preoperative colorectal consulting to discuss surgical risk^(3, 6).

CORRELATION OF UBESS WITH SURGICAL DATA AND RANZCOG/AGES SURGICAL SKILL LEVELS 1 - 6

Women then went on to have the laparoscopy, during which the severity of disease was recorded. Each surgery was assigned a RANZCOG/AGES laparoscopic skill level of 1–6 (Figure 2)⁽¹⁰⁾. Levels of surgical complexity were assigned based on the recorded findings at

laparoscopy and surgical techniques undertaken⁽³⁾. Surgeons were blinded to the UBESS classification during and after surgery when documenting the case. The notes were then used to allocate a RANZCOG/AGES surgical skill level. The ability of the UBESS to predict surgical complexity was then assessed by retrospectively correlating the two sets of data⁽³⁾. The correlation of UBESS was as follows: UBESS I to predict RANZCOG/AGES skill levels 1 and 2, UBESS II to predict RANZCOG/AGES skill levels 3 and 4 and UBESS III to predict RANZCOG/AGES skill level 6 (Figure 1). Skill level 5 was not included as it pertains to myomectomy and hysterectomy, not endometriosis surgery.

STATISTICAL ANALYSIS

The parameters of accuracy, sensitivity, specificity, positive predictive value, negative predictive value and likelihood ratios with confidence intervals were used to determine the ability of the UBESS to predict the RANZCOG/AGES levels of laparoscopic complexity⁽³⁾. The Cohen's kappa statistic was also used to determine the level of agreement. Diagnostic performance rested upon the ability of UBESS I to predict RANCOG/AGES skill level 1/ 2, UBESS II to predict RANZCOG/AGES skill level 3/4 and UBESS III to predict RANZCOG/AGES skill level 6. Normality tests have been used for the continuous variables and p-values were obtained from t-tests or Wilcoxon rank sum tests for the difference between two group of patients whenever appropriate (i.e. for variables that do not follow normal distributions, non-parametric Wilcoxon rank sum tests will be used instead of t-tests). In this study, the only variables that are normally distributed are age, age of menarche and age of diagnosis of endometriosis. Wilcoxon rank sum tests was used for all the other variables.

RESULTS

A total of 155 women were included in the final analysis. The mean and standard deviation were 32.7 +/- 8.6 for age, 12.7+/-1.9 for age of menarche, 25.7 +/- 8.4 for age at diagnosis of endometriosis. From the clinical history, 88 (58%) patients have parity of 1 or more, 38

(28.8%) have history of miscarriage(s), and 4 (3.1%) have previous history of ectopic pregnancy.

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PERFORMANCE OF UBESS IN PREDICTING LEVEL OF COMPLEXITY FOR LAPAROSCOPIC SURGERY FOR ENDOMETRIOSIS

The overall accuracy of the UBESS in predicting the RANZCOG/AGES laparoscopic skill level was 98.1%. There was almost perfect agreement between the UBESS and the levels of laparoscopic skill needed at time of surgery with a Cohen's kappa statistic of 0.97. Accuracy, sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio for each UBESS can be found in Table 1. The UBESS was able to predict all RANZCOG/AGES laparoscopic skill levels with an accuracy greater than 98%. The UBESS classification I was the most accurate to predict RANZCOG/AGES skill levels 1/2 (Tables 1 and 2).

DISCUSSION

The UBESS has performed well with an overall accuracy of 98.1% when predicting the RANZCOG/AGES laparoscopic skill levels. The Cohen's kappa of 0.97 for the agreement between UBESS and prediction of laparoscopic levels of training required at surgery indicated almost perfect agreement. The UBESS I performed best with an accuracy of 99.4%; this was followed by an accuracy of 98.7% for UBESS III and 98.1% for UBESS II.

This study's results suggest the UBESS allows for accurate triaging of women to the appropriately trained surgeon. For example, a RANZCOG/AGES skill level 2 surgeon who may only want to operate on women with UBESS I classification will be reassured that UBESS I has a sensitivity of 98.9% and specificity of 100% for their skill level. The UBESS III category has a sensitivity of 97.2% and a specificity of 99.2% for identifying patients requiring a surgeon with the most advanced skill. When minimally invasive surgeons assess patients with UBESS III classification, they can be confident there is a higher disease burden that is within their scope of practice. In addition to further supporting literature that demonstrates the ability of TVS to predict DE^(11, 12), we believe this study shows that the

UBESS has the potential to reduce the number of patients who experience a traditional two-step laparoscopic approach. Ideally, patients are operated on by a surgeon with the necessary skill to treat their level of disease during their first, and potentially, only surgery.

Khong *et al.* demonstrated that women with POD obliteration are three times more likely to have bowel DE ⁽¹³⁾. Twenty three of 30 women were found to have POD obliteration and were classified as UBESS III (Table 3). Although the UBESS does not specifically utilize POD obliteration as a feature to stratify patients into the three categories, we believe the high prevalence of POD obliteration in RANZCOG/AGES level 6 cases and the association with bowel DE justifies consultation by a minimally invasive surgeon. Further, this should ideally take place in a center capable of colorectal intervention. This sonographic finding may allow for more advanced and rigorous counselling regarding complete surgical resection of disease.

One strength of this study is that surgeons were blinded to the patient's apportioned UBESS classification, diminishing bias in their surgical notes which were used to allocate RANZCOG/AGES surgical skill level. However, the researcher (BG) responsible for assigning a RANZCOG/AGES level was also part of UBESS classification assignment. Though we do not believe the study results are confounded by bias, we must acknowledge that this is a possibility. In future studies, it would be prudent to ensure that observers are blinded to patient data and previous classifications.

The grouping of RANZCOG/AGES surgical skill levels could be considered a weakness; levels 1 and 2 were grouped as were levels 3 and 4. In particular, grouping levels 3/4 and equating them to UBESS II may challenge generalist gynecologists, who are expected to exhibit competency for level 3 skills, but not level 4, and family physicians in the referral process. If a patient with UBESS II classification is referred to a surgeon with RANZCOG/AGES skill level 3, but the disease present at the time of surgery requires a surgeon of skill level 4, the patient may not experience optimal care. Conversely,

RANZCOG/AGES skill level 6 gynecologists will also occasionally encounter inappropriate referrals for patients who may be adequately managed by a generalist. This may have an impact on limited healthcare resources and consultation and surgical waitlists.

Another limitation of this study is that it assumes the availability of highly-skilled ultrasound operators. Like minimally invasive gynecological surgeons, operators with the skill to scan patients with suspected endometriosis and apportion a UBESS classification are not omnipresent. Therefore, this suggested model of care may be limited to tertiary care or academic centers, which then creates inequity in patient care. Ultimately, we need to increase awareness of advanced ultrasound techniques to diagnosis endometriosis, educate gynecologists, radiologists, sonologists, and sonographers already in practice, and introduce comprehensive training models in specialist training programs.

As mentioned above, a study comparing the UBESS and RCOG laparoscopic skill levels has been completed ⁽³⁾. The overall accuracy was 84.9%, compared with this study's overall accuracy of 98.1%. We hypothesize this discrepancy in accuracy is due to a difference in the respective Royal Colleges' skill level definitions and categorization. Though the findings of our study are promising for the utility of the UBESS, the specific generalizability of the UBESS to laparoscopic skill categories abroad requires external validation studies.

Lastly, endometriosis ultrasound is rapidly evolving, which may result in alterations or improvements to the UBESS model. Similarly, specialist training programs are advancing, whereby current graduating specialists have stronger laparoscopic skills than their predecessors. This may lead to modifications in RANZCOG/AGES surgical skill standards. Despite these possibilities, we feel strongly that at this time, this study adds to the literature and can guide both family physicians and all gynecologists in the management of patients with endometriosis.

CONCLUSIONS

The UBESS can be used to preoperatively determine severity of disease in women with endometriosis in Australia and New Zealand. It could also be used to triage women to surgeons exhibiting the appropriate surgical skill level required to best treat the disease. As such, patients would be more likely to undergo a single operation that includes adequate planning for surgical treatment and resection of their disease. It is now pertinent to externally validate the UBESS within Australia, New Zealand and beyond. The UBESS should be trialled across several units internationally to determine its general applicability. It is hoped that the UBESS will be successful in its ability to predict surgical skill levels across multiple centers, and in doing so go on to reduce the need for a two-step laparoscopic approach in the management of patients with endometriosis.

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Appendix

Table 1. Analysis of UBESS to predict RANZCOG/AGES surgical skill level

UBESS	RANZCOG/AGES surgical skill level	Prevalence (%) (95% CI)	Accuracy (%) (95% CI)	Sensitivity (%) (95% CI)	Specificity (%) (CI 95%)	PPV (%) (CI 95%)	NPV (%) (CI 95%)	LR+ (CI 95%)	LR- (CI 95%)
UBESS I	1/2	56.8, (48.6,64.7)	99.4, (96.5, 100)	98.9, (93.8, 100)	100, (92.1, 100)	100, (93.8, 100)	98.5, (92.1, 100)	N/A	0.011, (0.002, 0.08)
UBESS II	3/4	20, (14, 27.2)	98.1, (94.4, 99.6)	96.8, (83.3, 99.9)	98.4, (94.3, 99.8)	93.8, (79.2, 99.2)	99.2, (95.6, 100)	60, (15.2, 237.6)	0.033, (0.005, 0.225)
UBESS III	6	23.2, (16.8, 30.7)	98.7, (95.4, 99.8)	97.2, (85.5, 99.9)	99.2, (95.4, 100)	97.2, (85.5, 99.9)	99.2, (95.4, 100)	115.7, (16.4, 815.2)	0.028, (0.004, 0.194)

Table 1 (n=155)

Legend: UBESS = Ultrasound Based Endometriosis Staging System; RANZCOG = Royal Australian and New Zealand Obstetricians and Gynaecologists; AGES = Australasian Gynaecological Endoscopy and Surgery Society; CI = Confidence Interval; PPV = Positive predictive value; NPV = Negative predictive value; LR+ = Likelihood ratio (positive); LR- = Likelihood ratio (negative)

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Table 2. Performance of UBESS in predicting RANZCOG/AGES surgical skill level

UBESS	RANZCOG/AGES surgical skill level		
	1/2	3/4	6
I	87	0	0
II	1	30	1
III	0	1	35

Overall accuracy: 98.1%
Cohen's kappa: 0.97

Table 2 (n=155)

Legend: UBESS = ultrasound-based endometriosis staging system; RANZCOG= Royal Australian and New Zealand College of Obstetricians and Gynecologists; AGES=Australasian Gynaecological Endoscopy and Surgery Society

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Table 3. Prevalence of ultrasound findings in the RANZCOG/AGES surgical skill level categories

	Number of cases (n)	Prevalence (%)	Number of missing (n)	Number of cases in RANZCOG / AGES 1/2 (n)	Prevalence in RANZCOG / AGES 1/2 (%)	Number of cases in RANZCOG / AGES 3/4 (n)	Prevalence in RANZCOG / AGES 3/4 (%)	Number of cases in RANZCOG / AGES 6 (n)	Prevalence in RANZCOG / AGES 6 (%)	P Fisher	Chi Squared
Posterior compartment DE											
POD obliteration	30	19.4	0	3	3.4	4	12.9	23	63.9	<.001	<.001
Rectocervical nodule	27	17.4	0	0	0.0	1	3.2	26	72.2	<.001	<.001
Rectosigmoid nodule	34	21.9	0	0	0.0	1	3.2	33	91.7	<.001	<.001
Rectovaginal nodule	1	0.6	0	0	0.0	1	3.2	0	0.0	.200	.134
Vagina nodule	1	0.6	0	0	0.0	1	3.2	0	0.0	.200	.134
Bowel infiltration	27	17.4	0	0	0.0	1	3.2	26	72.2	<.001	<.001
Ovarian fixation											
Ovary fixed, any side	57	37.7	3	12	14.0	18	58.1	27	79.4	<.001	<.001
Left ovary fixed	43	28.5	3	10	11.6	11	35.5	22	64.7	<.001	<.001
Right ovary fixed	38	24.8	2	3	3.4	13	43.3	22	62.9	<.001	<.001
Ovarian cysts, all types											
Left ovary	46	29.7	0	19	21.6	11	35.5	16	44.4	.028	.030
Right ovary	48	31.2	1	20	22.7	9	30.0	19	52.8	.005	.005
Ovarian endometrioma											
Left ovarian endometrioma	18	11.6	0	0	0.0	8	25.8	10	27.8	.000	.000
Right ovarian endometrioma	22	14.3	1	0	0.0	7	23.3	15	41.7	<.001	<.001

Table 3

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Legend; RANZCOG = Royal Australian and New Zealand College of Obstetricians and Gynaecologists; AGES = Australasian Gynaecological Endoscopy and Surgery Society; POD = Pouch of Douglas

Figure 1. UBESS by ultrasound findings and predicted RANZCOG/AGES surgical skill level

UBESS	UBESS features demonstrable on advanced TVS	RANZCOG/AGES surgical skill level
I	Normal mobile ovaries, absent non-bowel and absent bowel DE, normal POD +/- SST	Level 1: negative laparoscopy or mild stage disease RANZCOG/AGES 1/2
II	Endometrioma +/- immobile ovaries +/- non-bowel DE +/- normal POD	Level 2: moderate stage disease RANZCOG/AGES 3/4
III	Bowel DE +/- immobile ovaries (endometriomas) +/- non-bowel DE +/- normal POD	Level 3: severe stage disease RANZCOG/AGES 6

Figure 1

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Legend: +/-=with or without; DE=deep endometriosis; POD=pouch of Douglas; SST=site-specific tenderness; TVS=transvaginal scan; SVG= sonovaginography; RANZCOG= Royal Australian and New Zealand College of Obstetricians and Gynaecologists; AGES = Australasian Gynaecological Endoscopy and Surgery Society

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Figure 2. RANZCOG/AGES surgical skill levels ⁽¹⁰⁾.

RANZCOG/AGES laparoscopic skill level	Complexity of laparoscopic procedure
1	The minimum requirement is the supervised performance of 40 or more diagnostic laparoscopic procedures before unsupervised operating. Such a level should be achieved during registrar training.
2	The minimum requirement is the supervised performance of 20 simple operative procedures such as tubal ligation, simple cyst aspiration, simple adhesiolysis, and/or ablation of minor stage (AFS I-II) endometriosis before performing unsupervised surgery. This level should also be achieved during registrar training.
3	Laparoscopic ovarian cystectomy and oophorectomy when there is normal anatomy. Laparoscopic salpingotomy or salpingectomy for the treatment of ectopic pregnancy. The College feels that all trainees who obtained their Fellowship should be able to perform to Level 3 laparoscopic surgery. Level 3 procedures would be initially carried out with the assistance of a recognized endoscopic surgeon within your training hospital until judged satisfactory. This may take anywhere from 10 to more than 50 procedures before appropriate skills have been developed. There will be a small group of gynaecological surgeons who may never learn the necessary skills to safely be able to perform gynaecological endoscopic surgical procedures.
4	Laparoscopically assisted vaginal hysterectomy (LAVH) and excisional surgery for AFS score level 3 endometriosis. Level 4 procedures should be carried out under supervision until it is recognized that training is judged to be satisfactory. This may take anywhere from 10 to more than 50 procedures before appropriate skills have been developed.

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5	This level is an advanced level. This includes total laparoscopic hysterectomy, laparoscopic Burch and laparoscopic myomectomy.
6	Procedures at this level are as follows: laparoscopic pelvic floor repair, AFS level 4 endometriosis surgery. This is excisional surgery and not ablation. Laparoscopic removal of residual ovaries with significant distortion of the anatomy. Laparoscopic oncological procedures such as laparoscopic pelvic lymph node and para-aortic lymph node dissection and radical hysterectomy. To perform level 5 and 6 surgery, as well as laparoscopic suturing, surgeons should have completed formal preceptorships or Fellowship training under the supervision of appropriately skilled laparoscopic surgeons.

Figure 2

Legend: RANZCOG= Royal Australian and New Zealand College of Obstetricians and Gynaecologists; AGES = Australasian

Gynaecological Endoscopy and Surgery Society.