Outcomes after surgical treatment for heavy menstural bleeding in England and Wales: evidence from a national audit

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Abstract

Objective To examine patient-reported outcomes & quality-of-life after treatment for heavy menstural bleeding (HMB).

Method Women aged 18–60 years newly referred to a gynecology outpatient department for HMB were eligible for the National HMB Audit (2010–2014). Baseline questionnaires were completed at the first outpatient visit (before consultations); follow-up questionnaires were posted one year after the first visit. Of the 15,325 women included at baseline, 8,517 (56%) returned the follow-up questionnaire and 8,493 (>99%) could be linked to the administrative hospital data ("the cohort"). The outcomes were mean symptom severity & condition-specific health-related quality-of-life scores one year after women’s first outpatient visit ("at follow up"). Quality-of-life scores could range from 0 (poorest) to 100 (best quality, HRQoL). Symptom severity scores could range from 0 (least severe) to 100 (most severe). The exposure was treatment type from the administrative hospital data: 'no surgery', 'endometrial ablation' (EA), 'hysterectomy' & 'other' (myomectomy/uterine artery embolisation). We fitted multivariable linear regression models to estimate mean severity & quality-of-life scores by treatment, adjusting for sociodemographic & HMB-related characteristics, and stratified by HMB-related pathology (HMB alone, fibroids/polyps (without endometriosis) & endometriosis (with/without polyps/fibroids)).

Result 3,316 women (39%) had received surgical treatment one year after their first outpatient clinic visit for HMB (EA: 1936 (23%), hysterectomy: 1201 (14%), nonsurgical/no treatment: 5177 (61%)). Overall, women reported less severe symptoms & better quality-of-life at follow up than baseline (baseline score: severity 60.5, HRQoL 36.1; mean change: severity score –30.4; HRQoL score 34.3). Women who had surgery (EA/hysterectomy/"other") reported more severe symptoms & worse quality-of-life at baseline, & less severe symptoms & better quality-of-life at follow up than those who did not have surgery (mean severity/HRQoL score 11–16 points larger for women who had EA/hysterectomy than those who had no surgery). Differences of 5 points are considered clinically important in trials. For women with HMB-related pathology, hysterectomy was the treatment associated with the least severe symptoms and best quality-of-life at follow up (mean severity/HRQoL score 22 points larger for women with fibroids/endometriosis than for no surgical treatment).

Conclusion We observed that surgery is the most beneficial treatment for quality-of-life. Surgery should be available as a first-line treatment where women do not want pharmacological treatment. Early referral and treatment for women with severe symptoms may result in more appropriate, timely treatment: referral pathways may need to be improved.

1102 Results of a prospective, multicenter study evaluating impact of a wireless implantable tibial nerve stimulator at 3 years in subjects with overactive bladder symptoms (OAB)

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Objective To determine the three year performance of a novel implantable tibial neurostimulation device (the BlueWind Medical RENOVA iStim System) in patients with refractory overactive bladder (OAB) symptoms. Impact of OAB symptoms, quality of life and safety profile was assessed.

Design and methods This was a 36 month multicentre prospective long-term extension study following an initial 6 month pilot study. Patients with refractory dry or wet OAB symptoms were recruited. Patients with clinically predominant stress urinary incontinence, large vaginal prolapse or those with neurological disease were excluded. The wireless peripheral neurostimulator device (BlueWind Medical Ltd.) was implanted using local anaesthesia on the posterior tibial nerve unless general anaesthesia was clinically indicated. The implant electrically stimulates the tibial nerve when activated using a wireless wearable external control unit (ECU). The efficacy and safety of the device were assessed using a 3 day bladder diary, QOL questionnaire (OAB-q) as well as clinical examination up to 36-months. The data were analysed by both per-protocol (PP) and intent to treat (ITT) population.

Result Following a pilot study of 36 patients, 20 were re-enrolled for this extended 3-year, follow-up study. At 6 months post activation of the device, 71% experienced clinical improvement. At 36 months 75% of the patients demonstrated treatment success with improvement in their OAB symptoms (defined as ≥50% reduction in urgent voids or leaks or normalisation of voids) in the ITT group. Clinical success was analysed separately for patients with Wet OAB. In PP population 58% and 75% of the wet OAB patients

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showed >50% reduction in the average number of leaks and large leaks at 3 years, respectively. In ITT population 50% and 80% of the wet OAB patients showed >50% reduction in the average number of leaks and large leaks, respectively. At 6 months 75% of the patients demonstrated >10 points improvement in their quality of life score defined as meaningful important difference (MID), this was sustained in 70% of patients at 36 months. No serious or other adverse events were reported during the extension study.

Conclusion This first long-term study of the BlueWind Medical RENOVA iStim system demonstrates safety, as well as a sustained improvement in OAB symptoms and quality of life. A larger study is required with a multicentre, prospective study [OASIS study] planned for later this year.

1797
Long term comparative study of Burch colposuspension versus mid urethral sling for surgical management of stress urinary incontinence
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Background Many surgical procedures are available for women with stress urinary incontinence (SUI), although few long-term comparative trials have been conducted to provide basis for treatment recommendations.

Design Longitudinal comparative study of women with predominant SUI and urodynamic stress incontinence who had surgery for SUI in form of Burch colposuspension or synthetic mid-urethral sling (MUS) from January 2000 to June 2018 in a tertiary referral centre in Australia.

Methods Longitudinal follow up by chart review and one-time phone follow up from an electronic database. The primary outcomes were success of index surgery in terms of validated patient reported measures and retreatment for the condition. Postoperative overactive bladder (OAB), voiding dysfunction, adverse events and overall satisfaction rates were also assessed.

This abstract presents the interim results of our continuing study.

Results Median follow up: 142 months (81% success rate) (P = NS). More earlier admissions/self-catheterisation for voiding difficulty in Burch group (14% versus 6%) but long-term voiding dysfunction symptoms are similar in both group (21% and 24%) --This could be influence of advancing age of cohort, 24% patients in MUS group have OAB on long term follow up versus 11% in Burch group (P = 0.04), <1% patient had vaginal sling exposure following MUS.

Conclusion This is one of the largest comparative studies with substantial follow up comparing Burch and MUS showing that in the long term, patient reported success is equally high for both. More women have OAB symptoms when index surgery is MUS. Long term voiding dysfunction rates are similar.

1207
Sling the mesh? – a 6-month impact analysis of the suspension of vaginal mesh for stress urinary incontinence
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Objective To assess the impact of the suspension of the use of vaginal mesh on the management of patients with SUI. Vaginal mesh procedures for SUI have increasingly been associated with graft erosion, wound granulation, chronic pain and dyspareunia, with affected women lobbying regulatory bodies for discontinuation of these procedures. In July 2018, the UK Independent Medicines and Medical Devices Safety Review announced a pause on the use of surgical mesh for the treatment of SUI, until conditions to mitigate the risks of injury are met – the surgeon must be appropriately trained, undertake the procedure regularly, register each procedure on a patient-identifiable database, report any complications to the MHRA, and specialist centres must be accredited. The review is expected to conclude in March 2019 but how are urogynaecologists managing SUI now? What is the impact on patients and clinicians?

Design A questionnaire: (1) When did your unit stop using the TVT? (2) How did this change the service? (3) What alternatives are available in your unit? (4) What are the challenges? (5) Any complaints as a result of this change in practice? (6) Any problems as a result of this change? (7) If given the choice, would you prefer TVT as the first-choice surgical intervention?

Methods In January 2019, urogynaecology consultants across the UK and O&G trainees in the East of England completed the questionnaire. They were contacted by telephone, email or in person.

Results 16 hospitals responded, 15 in England and 1 in Wales. 14 stopped using vaginal mesh immediately – 1 tertiary hospital and the Welsh hospital continued, using MDTs, patient decision-making tools and extensive informed consent processes. 100% reported more patients attending clinic for reassurance/to discuss symptoms they attributed to their mesh. 80% offered peri-urethral

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bulking, 25% offered autologous slings, 75% offered open abdominal colposuspension (42% had experienced consultants training others). One offered longer trials of physiotherapy and three refer all surgical patients to other hospitals. 100% reported delayed surgical treatment, caused by referral to tertiary units, retraining of urogynaecologists and patients lingering on waiting lists until the suspension is lifted.

**Conclusion** Suspension of vaginal mesh created a dilemma for patients and urogynaecologists. Most relied on TVT/TOT and have lost expertise in alternatives. There is a delay in treatment, with many choosing conservative measures, retraining or waiting out the suspension. Urogynaecologists are committed to providing surgical options, although this will require stricter conditions in future.

1919
Transcutaneous tibial nerve stimulation to treat urgency urinary incontinence in older women: 12-month follow up of randomised trial

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**Objective** This study aimed to evaluate the efficacy and safety of transcutaneous tibial nerve stimulation (TTNS) for urge urinary incontinence (UUI) in women older than 60 years.

**Design** 106 women older than 60 years were randomised to perform Kegel exercises and bladder retraining isolated or associated with TTNS.

**Methods** TTNS was performed using a transcutaneous electrical nerve stimulation (TENS) machine program with the continuous mode, 10 Hz, 200 ms, 10 to 50 mA, according to hallux mobilisation, 30 minutes sessions, once a week for a 12-week period. Patients were evaluated initially, 4 weeks after the last session and each 3 months per 12 months through: global subjective satisfaction, 3-day bladder diary and International Consultation on Incontinence Questionnaire – Short Form. Kings Health Questionnaire was applied pretreatment and 4 weeks after the last session. Statistical analysis was performed using SPSS V17.0. Patients that initially were satisfied with TTNS and during the follow up presented worsening symptoms were invited for a 3 weeks booster during the 12 months’ follow up.

**Result** 101 women completed the 12-week protocol. There were no significant differences pretreatment between study groups. Subjective global satisfaction in the TTNS group was 66.7% (34) versus 32.0% (16) in the control group ($p < 0.001$). TTNS showed statistically significant improvement in QoL and UUI parameters when compared with the control group. 30 patients were satisfied after the 12-week protocol (34 TTNS group and 16 in the control group) and were followed-up. A total of 48 patients completed the 12-month follow up (32 TTNS group and 16 in the control group). 81.2% (25) of the patients that were initially satisfied with TTNS were satisfied at the end of 12 months. Among the patients who had responded to the initial therapy of the control group, 37.5% were still satisfied at the end of 12 months. The 3-week TTNS re-treatment booster over the 12-month follow up was performed by 59.4% (19) of the patients. No adverse events related to TTNS were reported.

**Conclusion** The results indicate that TTNS can be an effective and safe treatment for urgency urinary incontinence in elderly.

2082
Can transperineal ultrasound improve the diagnosis of obstetric anal sphincter injuries?

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**Objective** Obstetric anal sphincter injuries (OASIS) are often missed at the time of delivery and the rates of missed OASIS range from 12–87%. Missed OASIS at the time of delivery increases the risk of anal incontinence and up to one-third of women develop such symptoms. All maternity units in the UK have ready access to ultrasound and with an appropriate three dimensional (3D) probe transperineal ultrasound (TPUS) can be performed. Our aim was to evaluate whether 3D TPUS improves the detection of OASIS immediately after delivery.

**Design** Prospective observational study (Ethics approved).

**Methods** A prospective study of women undergoing their first vaginal delivery. Perineal trauma was initially assessed by the accoucher and women were then re-examined by a trained research fellow. All women had a 3D TPUS performed immediately after delivery to look for anal sphincter defects. A power calculation was undertaken and determined 216 women would be required.

**Results** 274 women were invited and 264 (95%) women agreed to participate. Two hundred and twenty six (86%) delivered vaginally. Twenty one (9.3%) sustained OASIS. 6 (29%) of these tears were missed by the accoucher which were picked up when women were re-examined by the trained research fellow. Five (24%) of the OASIS occurred in deliveries conducted by doctors who missed 2 (12.5%) cases. TPUS identified 19/21 (90.5%) anal sphincter defects vs 15/21 (71%) anal sphincter defects identified clinically by the accoucher ($p = 0.12$). In addition, TPUS identified 2 (9.6%) external anal sphincter defects that were not seen clinically. For TPUS the sensitivity was 90.5% for the detection of any anal sphincter defect and the specificity was 99%.

**Conclusion** 9% of women sustained OASIS. 30% of OASIS were missed by the healthcare professionals. TPUS did not improve the detection of OASIS. Therefore training accouchers to perform an accurate rectal and vaginal examination with adequate light needs to be emphasised.
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1826 Impact of a multi-centre quality improvement project to reduce the incidence of obstetric anal sphincter injury (OASI) in the UK: a stepped-wedge cluster randomised trial
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Objective To evaluate the impact of a quality improvement intervention on OASI rates in 16 maternity units across England, Scotland and Wales.

Design The intervention was a ‘care bundle’ including four elements (provision of antenatal information to women, manual perineal protection, episiotomy when clinically indicated and perineal examination following childbirth), supported with a skills development module and an awareness campaign. The study had a stepped-wedge cluster randomised trial design. The intervention was sequentially rolled out starting from January 2017 in four regions, each comprising of four maternity units of various sizes and types. A new region was initiated approximately every three months and the first three months of the intervention was considered as a ‘transition period’, when the care bundle was launched at the units and the local clinical champions cascaded the training and educational materials to their colleagues.

Methods Data for births from October 2016 to April 2018 were extracted from local electronic maternity information systems for 15 units and from administrative data for one unit. All singleton, live, vaginal births were included in the study. Births at home/in transit, water births and births during the transition period were excluded. The multi-level logistic regression to estimate the impact of the intervention on OASI rate adjusted for secular time trends and risk factors for OASI (age, ethnicity, BMI, parity, birthweight, mode of delivery), and included a random effect to account for clustering at the unit level.

Results 55 060 births were included in the study (median age 30 years, interquartile range 26–34 years; 46% primiparous; 79% spontaneous vaginal and 21% instrumental births; 25% with episiotomy). The OASI rate was 3.3% in the pre-intervention period, and 3.0% in the post-intervention period (adjusted OR 0.79 (0.65–0.97), P = 0.003). OASI rates declined for spontaneous vaginal births (2.6% to 2.2%, adjusted OR 0.66 (0.60–0.71), P < 0.001), but there was no change for instrumental births (7.6% for forceps in both periods, 2.7% to 2.6% for vacuum). There were no secular trends in OASI rates in the study period and no change in the overall mode of birth (including caesarean section) or episiotomy rate distributions in pre- and post-intervention periods.

Conclusion A stepwise roll-out and routine clinical data were used to evaluate the effectiveness of a multi-centre quality improvement initiative. Implementation of a care bundle, alongside a skill development training and an awareness campaign improved obstetric outcomes. The project highlighted a general need and interest to better manage perineal care.

1141 Macropaste and Bulkamid – experience of bladder neck injections over 8 years
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Objective Primary outcome was to compare the success of Bladder Neck Injection (BNIs) according to the agent used.

Design Retrospective case series of women undergoing BNIs for SUI in this tertiary unit.

Methods Patients having BNI from October 2010 to October 2018 (n = 173) identified from the departmental audit databases. Trakcare electronic notes were reviewed. Diagnosis with either clinical assessment or with cystometric findings was recorded. Patients were invited for an initial treatment. Those who had not noticed sufficient improvement were offered a further ‘top-up’ (within 6 months from first). Primary outcome was patient reported improvement outcomes on a four-point scale: ‘cured’, ‘improved’, ‘no change’, ‘worse’ as used on the BSUG audit database. Treatment ‘success’ was defined as ‘cured’ or ‘improved’. Statistical analysis was performed using Paired and Unpaired t-tests.

Results There has been four-fold rise in the number of procedures performed since 2010, with an average of 11 cases yearly between 2010 and 2016, increasing to 48 yearly in 2017 and 2018. Macropaste was the main agent from 2010-2015, with Bulkamid, introduced 2016. Patients having Macropaste were slightly older (63 years versus 57 years, P = 0.018*). There was no significant difference in Mid-urethral Closure Pressures (Bulkamid 49 cmH2O versus Macropaste 42 cmH2O, P = 0.270). 89% (n = 154) of procedures were performed under Local Anaesthesia (LA). Mean average time for follow up for this study was 35 months for all BNI procedures. Complete follow-up data were obtained on 114 patients.

Primary Outcome: Overall success for this follow-up period was 69%. Initial success rate following first BNI was higher with Macropaste at 72% (n = 57) than 65% with Bulkamid (n = 57). Secondary outcomes: Significant mean average reductions were seen in ICIQ-SF completed pre and post-BNI questionnaires; 6.8 (n = 13), P = 0.001*.

• Top-up rates were similar; n = 8 (14%) Macropaste versus n = 9 (15.8%) with Bulkamid.

• 32 patients representing with recurrent SUI proceeded to a further treatment course. These were nearly twice as likely following Macropaste (n = 21/57, 36.8%) than Bulkamid (n = 11/57, 19.3%). Mean time to 2nd treatment course was injection 15 months (range 7-37) and 9 months (range 1-11) respectively.

Conclusion The number of women opting for BNI has increased substantially over the last 2 years. Although initial success rates with Macropaste were slightly higher and may be due to the learning curve for introduction of a new technique with
analysed using RevMan software.

Secondary outcomes were patient-reported and objective success. Data were collected by the authors from the National Health Service (England) using a database of women with SUI and OAB. The primary outcomes were: 1) patient-reported success; 2) objective success; 3) patient-reported success and objective success; 4) patient-reported success and objective success (N = 1077 women) were included in the meta-analysis: comparison of urodynamics versus clinical assessment only showed no evidence of significant difference in the patient-reported and objective success (P = 0.520, RR:0.91, 95% CI 0.69–1.21 and P = 0.470, RR:0.87, 95% CI 0.59–1.28 respectively). Eight RCTs were identified for surgical management of SUI of which five (n = 1077 women) were included in the meta-analysis: there was no evidence of significant difference in patient-reported success (P = 0.710, RR:0.98, 95% CI 0.88–1.09) and objective success (P = 0.930, RR:1.00, 95% CI 0.94–1.06) between the two arms. No RCTs were identified for the invasive management of OAB. Assessment of risk of bias using Jadad score highlighted the poor quality of the current evidence in this field.

Conclusion There is no robust evidence that routine urodynamic investigations prior to surgical management of SUI and nonsurgical management of UI lead to better treatment outcomes compared to clinical assessment only. There were no RCTs evaluating routine urodynamics prior to invasive treatments of OAB. This review highlights the poor quality of the current evidence and the need for well-designed clinical trials to evaluate the clinical and cost-effectiveness of routine urodynamic investigations prior to surgical management of SUI and OAB.

### Abstracts

**Do preoperative urodynamics lead to better outcomes in management of urinary incontinence in women: a linked systematic review and meta-analysis**

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**Background** Urinary incontinence (UI) is a common and distressing condition that has a profound impact on a woman’s physical and psychosocial wellbeing. Urodynamics is an invasive test to evaluate the neuromuscular function of the urinary bladder. There is a lack of robust evidence to demonstrate improved patients’ outcome following treatment based on urodynamic assessment as compared to clinical assessment only.

**Objective** To assess the current evidence for clinical and cost-effectiveness of routine invasive urodynamic investigations, as compared to clinical assessment only, prior to nonsurgical and surgical treatments for women with stress urinary incontinence (SUI) and overactive bladder (OAB).

**Methods** Three literature searches were performed using MEDLINE, EMBASE, Cochrane Register of Clinical Trials, CINAHL and trial registries with no language restrictions (last updated on the 18th January 2019). We included randomised controlled trials (RCTs) comparing ‘urodynamics’ versus ‘clinical assessment only’ prior to: 1) nonsurgical treatment for UI, 2a) surgical treatment for SUI and 2b) invasive treatment for OAB, with meta-analyses conducted separately for each group. Primary outcomes were patient-reported and objective success. Secondary outcomes were adverse events, impact on women’s quality of life, sexual function and health economic measures. Data were analysed using RevMan software.

**Results** Four RCTs were identified for nonsurgical management of UI of which two (n = 150 women) were included in the meta-analysis: comparison of urodynamics versus clinical assessment only showed no evidence of significant difference in the patient-reported and objective success (P = 0.520, RR:0.91, 95% CI 0.69–1.21 and P = 0.470, RR:0.87, 95% CI 0.59–1.28 respectively). Eight RCTs were identified for surgical management of SUI of which five (n = 1077 women) were included in the meta-analysis: there was no evidence of significant difference in patient-reported success (P = 0.710, RR:0.98, 95% CI 0.88–1.09) and objective success (P = 0.930, RR:1.00, 95% CI 0.94–1.06) between the two arms. No RCTs were identified for the invasive management of OAB. Assessment of risk of bias using Jadad score highlighted the poor quality of the current evidence in this field.

**Conclusion** There is no robust evidence that routine urodynamic investigations prior to surgical management of SUI and nonsurgical management of UI lead to better treatment outcomes compared to clinical assessment only. There were no RCTs evaluating routine urodynamics prior to invasive treatments of OAB. This review highlights the poor quality of the current evidence and the need for well-designed clinical trials to evaluate the clinical and cost-effectiveness of routine urodynamic investigations prior to surgical management of SUI and OAB.
2530  
Outcomes and outcome measures in apical prolapse surgery: a systematic review of variations and a call to develop core outcome sets  
Lourenco, T; Pergialiotis, V; Durnea, C; Elfituri, A; Haddad, J; Betschart, C; Falconi, G; Doumouchtsis, S

Abstracts

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Outcomes and outcome measures in apical prolapse surgery: a systematic review of variations and a call to develop core outcome sets  
Lourenco, T; Pergialiotis, V; Durnea, C; Elfituri, A; Haddad, J; Betschart, C; Falconi, G; Doumouchtsis, S

Objective To evaluate the associations between mode of delivery and incidence of obstetric anal sphincter injuries (OASIs) at vaginal delivery (VD) in subsequent pregnancy.  
Design Retrospective case series of a tertiary level maternity unit. Data were extracted from 74 184 maternity records and logged on to a database. We included parous women without a previous perineal trauma following different modes of delivery and a control primiparous group.  
Methods 16 year retrospective case series, between 1999 and 2015, looking at first and second pregnancies. Inclusion criteria were met by 21 535 participants, of which 1229 sustained OASIs. Three previous modes of delivery including failed operative vaginal delivery (FOVD) and second stage emergency caesarean section (EmCS); elective Caesarean section (ELCS) and vaginal delivery maintaining an intact perineum (VD) were compared with a control primiparous group. This was done using multivariate regression analysis controlling for previously identified statistically significant co-variables including maternal age, ethnicity, BMI, epidural use, fetal weight, fetal sex and modes of delivery.  
Results The incidence of OASIs was 17.3% at first vaginal delivery after prior FOVD, 12.9% after previous ELCS and 0.6% after prior VD maintaining an intact perineum, compared with 6% in the control primiparous group of women. Multivariate regression analysis demonstrated prior FOVD was associated with a 2.8-fold increase risk of OASIS (odds ratio (OR): 2.8; 95% confidence interval: 1.35–5.78) and prior ELCS with a 2.1-fold increase (OR: 2.106; 95% CI: 1.27–3.48). Prior VD, maintaining an intact perineum, was found to be protective (OR: 0.09; 95% CI: 0.04–0.17), when compared to primiparous women.  
Conclusion A previous FOVD+EmCS and ELCS are associated with significantly increased OASIS rates in subsequent vaginal delivery, while a previous VD with intact perineum was protective.  

2690  
A systematic review of outcome and outcome-measure reporting in randomised trials evaluating surgical interventions for anterior-compartment vaginal prolapse: a call to action to develop a core outcome set  
Durnea, C; Pergialiotis, V; Duffy, J; Bergstrom, L; Elfituri, A; Doumouchtsis, S

Objective To assess outcome and outcome-measure reporting in randomised controlled trials evaluating surgical interventions for anterior-compartment vaginal prolapse and explored the
relationships between outcome reporting quality with journal impact factor, year of publication, and methodological quality. **Design** Systematic review of 80 Randomised Controlled Trials (RCT) meeting the inclusion criteria out of 2482 studies identified. **Methods** We searched the bibliographical databases from inception to October 2017. Two researchers independently selected studies and assessed study characteristics, methodological quality ( Jadad criteria; range 1–5), and outcome reporting quality Management of Otitis Media with Effusion in Cleft Palate (MOMENT) criteria; range 1–6], and extracted relevant data. We used a multivariate linear regression to assess associations between outcome reporting quality and other variables. **Results** Eighty publications reporting data from 10 924 participants were included. Seventeen different surgical interventions were evaluated. One hundred different outcomes and 112 outcome measures were reported. Outcomes were inconsistently reported across trials; for example, 43 trials reported anatomical treatment success rates (12 outcome measures), 25 trials reported quality of life (15 outcome measures) and eight trials reported postoperative pain (seven outcome measures). Multivariate linear regression demonstrated a relationship between outcome reporting quality with methodological quality \( (\beta = 0.412; P = 0.018) \). No relationship was demonstrated between outcome reporting quality with impact factor \( (\beta = 0.078; P = 0.306) \), year of publication \( (\beta = 0.149; P = 0.295) \), study size \( (\beta = 0.008; P = 0.961) \) and commercial funding \( (\beta = -0.013; P = 0.918) \). **Conclusion** Anterior-compartment vaginal prolapse trials report many different outcomes and outcome measures and often neglect to report important safety outcomes. Developing, disseminating and implementing a core outcome set will help address these issues.

2778 What shape is your bladder in? Trans-abdominal ultrasound assessment of bladder shape in the detection of involuntary detrusor activity **Buchanan, C1; Gray, T1; Li, W2; Philips, L2; Abdi, S1; Campbell, P1; Farkas, A1; Radley, S1**

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**Objective** We hypothesised that bladder shape changes detected using trans-abdominal ultrasound (TA-USS) could provide a noninvasive and useful measure of involuntary detrusor activity. **Design** This pilot study aimed to evaluate TA-USS assessment of bladder shape changes during physiological-filling and urodynamics to develop methods for detecting and quantifying shape changes during involuntary detrusor activity. The initial study included healthy volunteers as well as symptomatic patients subjected to physiological filling of the bladder to compare and contrast bladder shape at set intervals. This study was then extended to allow TA-USS at the time of urodynamics in symptomatic patients to allow comparison with urodynamic results and determine if TA-USS is a potential less-invasive alternative for detecting and diagnosing detrusor overactivity. **Methods** IRAS approval was obtained (Project ID:173975). 20 healthy volunteers and 17 women with overactive bladder (OAB) symptoms who had previously undergone urodynamics, 8 of whom had detrusor overactivity, completed symptom questionnaires and three-day bladder diaries. Following voiding, participants drank 1000 ml water before undergoing serial TA-USS (transverse and longitudinal) at 30-minute intervals during physiological filling over 90-minutes and during episodes of urgency. In a further study, serial TA-USS images were captured during urodynamics in 22 women with OAB symptoms. Statistical analysis was with Mann–Whitney U test and binomial logistic regression. **Results** The transverse view of the bladder provided the most reliable plane to assess shape change. A sphericity index \( \left( \frac{\text{ratio}}{\text{ratio}} \right) \) derived from the ratio between maximum and minimum circumscribed ellipses, fitting entirely within and outside the bladder outline, offered the most reliable and reproducible measurement system. Of participants undergoing TA-USS during urodynamics, 12 had detrusor-overactivity and ten remained acontractile. There were significant differences in sphericity between detrusor-overactivity and acontractile groups \( (P < 0.001) \). Binomial logistic regression discriminated between detrusor-overactivity and acontractile bladders based on a model including volume and sphericity-index derived from patients scanned during urodynamics. When applied to the physiological-filling study groups, this model identified involuntary detrusor activity in six women with OAB symptoms. **Conclusion** Bladder shape changes detected during physiological-filling and urodynamics have provided baseline data for evaluating TA-USS as a potential diagnostic tool. Initial findings suggest this imaging modality may be of value in the assessment of detrusor function and warrants further research including refining measurement techniques and evaluating different patient groups.

2091 Intrapartum risk factors for levator ani muscle avulsion **Wong, KW1; Thakar, R2; Sultan, A2; Andrews, V1**

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**Objective** Levator ani muscle (LAM) avulsions are a risk factor for pelvic organ prolapse (POP), and occur in 15–35% of women following their first vaginal delivery. We aimed to determine intrapartum risk factors for LAM avulsions diagnosed by three dimensional transperineal ultrasound (3D TPUS). **Design** Prospective observational study. **Methods** A prospective study of women undergoing their first vaginal delivery. 3D TPUS was performed to look for LAM avulsion at 10–12 weeks following a vaginal birth. Demographic and obstetric variables were investigated for their association with LAM avulsion including: age, body mass index, ethnicity, gestational age, epidural analgesia, first and second stage duration,
mode of delivery, types of perineal trauma, use of mediolateral episiotomy, birthweight and fetal head position at the time of delivery.

**Results** 264/274 (95%) women agreed to participate, 226 (86%) women delivered vaginally, 195/226 (86%) women returned for follow up. One TPUUS was not suitable for analysis. 49 (25%) women had LAM avulsion after vaginal birth. Forceps delivery and mediolateral episiotomy were identified as risk factors. The incidence of LAM avulsion was significantly higher after forceps delivery: 22/49 (45%) vs 24/145 (17%) who did not sustain LAM avulsion $(P = 0.001)$. Women were seven-fold more likely to sustain LAM avulsion following forceps delivery 22/49 (45%) when compared with women who were delivered by ventouse 3/49 (6%). For mediolateral episiotomies, 28/49 (57%) women had LAM avulsion following an episiotomy and 57/145 (40%) women had intact LAM following an episiotomy $(P = 0.03)$. Multivariate analysis showed that only forceps delivery was an independent risk factor for LAM avulsion $(P = 0.004)$.

**Conclusion** 25% of women sustained LAM avulsion following their first vaginal delivery particularly after a forceps delivery. Training should therefore focus on minimising the use of forceps when an assisted vaginal delivery is undertaken and obstetricians should be made aware of the pelvic floor effects of forceps delivery.

**Abstracts**

**2129 Is there a role for transperineal ultrasound imaging of the anal sphincter immediately after primary repair of third degree tears?**

**Wong, KW1; Thakar, R2; Sultan, A2; Andrews, V1**

1University Hospital Lewisham, London, UK; 2Croydon University Hospital, London, UK

**Objective** To assess whether three dimensional transperineal ultrasound (3D TPUS) is useful in assessing anal sphincter integrity immediately following primary repair of obstetric anal sphincter injuries (OASIS).

**Design** Prospective observational study.

**Methods** Women undergoing their first vaginal delivery who sustained OASIS were invited to participate. 3D TPUS was performed immediately after primary repair of OASIS to look for sustained OASIS were invited to participate. 3D TPUS was performed immediately after primary repair.

**Results** 274 women were invited and 264 (95%) women agreed to participate. 226 (86%) had a vaginal delivery, 21 (8%) sustained OASIS of whom 20 (95%) came for follow up. 8 (40%) had a 3a tear and 12 (60%) a 3b tear. 8/20 (40%) women had residual external anal sphincter (EAS) defects identified by TPUS immediately after repair. Of these eight women, two (25%) sustained a 3a tear and six (75%) a 3b tear. There was no significant difference in the likelihood of having residual EAS defects immediately after repair between subjects with a Grade 3a or a Grade 3b tear $(P = 0.37)$. Of these eight defects 6 (75%) remained at follow up at 12 weeks. No new defects were seen at follow up at 12 weeks among the twelve women where there was no defect seen immediately following primary repair.

**Conclusion** Women who had no defect detected following primary repair of OASIS, this finding persisted at 12 weeks postpartum. Of those with a defect on TPUUS immediately after repair this was confirmed in 75% of cases at 12 weeks. This suggests that persistent sphincter defects reflect inadequate primary repair and therefore more focused training is required.

**2913 Clinical competence in performing and recognising a mediolateral episiotomy of protective angle and length: a systematic review**

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James Cook University, Townsville, Australia

**Objective** It is assumed that all doctors and midwives understand and apply evidence-based principles in performing episiotomies in their everyday practice. However, remarkable discrepancies between even the most reputable literature sources in defining and describing the technique of performing mediolateral episiotomy (MLE) suggest that there is much ambiguity and confusion for both researchers and clinicians alike.

**Design** The systematic review protocol was written prior to starting the review and registered in the international prospective register of systematic reviews (PROSPERO/ID CRD42017070523) last updated on December 15, 2017. The review is reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.

**Methods** A database search was performed using: Medline, CINAHL, Scopus, Informit, the Cochrane Library and PubMed from database inception to 17 September 2017, with a final search on 10 February 2017. Studies were included if they examined clinicians’ competency in performing an ‘ideal’ or ‘correct’ mediolateral episiotomy, as well as those studies that compared the performance of different professional roles. Studies usually defined an ‘ideal’ incision as one that met the criteria of an acceptable angle of incision from the midline, starting incision point distance from the midline and in terms of the length of the incision created.

**Results** While many of the studies included in this review were not of high quality (author self-assessment) and had their own study criteria for a MLE, the literature suggests clinicians are generally unable to perform or simulate episiotomies within such standards. Overall, most of the literature reported doctors were performing more ‘ideal’, lateral and longer incisions compared to midwives; however, there were studies that found the opposite, showing statistically significant results in favour of midwives performing more protective episiotomies. There was no association between clinicians’ participation in formal training courses and their ability to perform the ‘ideal’ incision, though...
one study did find an increased number of episiotomies performed under supervision improved clinicians competency. **Conclusion** The obvious lack of understanding around defining and performing MLE for clinicians of various professional roles suggests the need to produce a uniform set of guidelines, and to develop a universal, low-cost approach for teaching and performing the MLE technique in any clinical environment around the world.

1784
**Innovative treatment of uterovaginal prolapse with autologous membrane from platelet rich plasma**
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**Objective** To present our experience of uterovaginal prolapse repair augmented with autologous platelet rich plasma (PRP) membrane.

**Design** Prospective cohort study of women who underwent primary or secondary uterovaginal prolapse surgery augmented with autologous PRP membrane. Women were enrolled into the study at FBW Gynaecology Plus, a private practice in Adelaide, Australia during August 2018 to January 2019. In Australia, vaginal mesh and biological implants have been withdrawn from the market. Therefore, autologous membrane was used to enhance the vaginal repair.

**Methods** Women who were consented for pelvic organ prolapse surgery were recruited to this study for PRP membrane augmentation of vaginal repair at the time of surgery. PRP kit was used to create autologous membrane, which required sequential centrifugation. The PRP membrane was sutured onto endopelvic fascia after site-specific vaginal repair. Follow up was planned at 6 weeks, 6 months, and 12 months. Patient assessment included Pelvic organ prolapse quantification (POPQ), degree of vaginal atrophy, and Australia Pelvic Floor Questionnaire (APFQ).

**Results** There have been 20 cases of PRP membrane augmented vaginal repairs. Baseline characteristics was compared to follow up. Results of the study and video of the autologous membrane will be presented at the conference.

**Conclusion** PRP membrane appears to be a feasible treatment to supplement symptomatic uterovaginal prolapse, especially in recurrent pelvic floor repair. Further research and longer follow up is required.

121
**How to manage complex vesicovaginal fistulae?**
**Sachdev, PS**

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**Introduction** Vesicovaginal fistulae can have devastating impact on quality life of the women affected. Successful closure of complex fistulae remains challenging. We describe procedures used for repairing complex vesicovaginal fistulae in addition to simple layered closure that improves surgical outcomes.

**Objective** To describe the procedures used in addition to simple layered closure to improve surgical outcomes in complex vesicovaginal fistula.

**Methods** A descriptive study of 280 patients with complex fistulae was carried out between June 2007 to June 2018 at Liaquat University Hospital and Isra University hospital Hyderabad Pakistan. Additional procedures such as placement of grafts, insertion of ureteric catheters, diversion of fibrotic bands in the vagina/episiotomy cut, use of fibromuscular slings and modification of suturing technique were used in addition to simple layered closure to improve our results.

**Results** During study period 280 with complex fistulae underwent repair. In addition to simple layered closure, which was used in all patients, grafts (Mauritius, omental, peritoneal) were used in 108 (60%) of patients. Ureteric catheter were inserted in 154 (55%) of patients. Fibromuscular sling (bulbococcyeous muscles) in 8 (2.8%) patients, diversion of fibrotic vaginal drains/episiotomy in 11 (3.9%) patients, bifurcation of cervix in 17 (6%) patients and elongation of urethra in 8 (2.8%) patients. 28 (10%) patients were lost to follow up. Of the rest, at three months 201 had no urinary continence.

**Conclusion** Repair of complex vesicovaginal fistula is a challenging endeavour but better surgical outcomes can be achieved by using different techniques in addition to basic surgical principles.

2793
**Ease of use and accuracy of a perineal measuring device (Episiometer) to ensure correct angle and length of a mediolateral episiotomy: a mixed-methods study**

**Van Der Lugt, B**1; **Harvey, N**1; **Woolley, T**1; **Gupta, S**1; **Inania, M**2; **van Santen, B**1; **Ananthram, H**1; **Rane, A**1

1James Cook University, Townsville, Australia; 2Balaji Hospital, Jodhpur, India; 3Caboolture Hospital, Caboolture, Australia

**Introduction** To guide clinicians in performing mediolateral episiotomies (MLEs) at 60-degrees, a new clinical innovation called the ‘Episiometer’ was developed. The aim of this study was to assess the usability and accuracy of the Episiometer in guiding clinicians to perform a safe episiotomy in both low- and high-resource settings.

**Design** A prospective, multi-site Phase-I clinical trial was conducted between January 2017 and July 2018, involving three international study sites: Australia; Papua New Guinea; and India. The study design was mixed-methods, incorporating an explanatory sequential design using surveys, clinician interviews and patient chart review to determine the usability and accuracy of the Episiometer. The patient chart review and results of this are discussed in an accompanying article.
Abstracts

**Methods** The ‘Episiometer’ is the clinical innovation designed to attain an episiotomy cutting angle of 60-degrees. The instrument is designed to assist clinicians to make an accurate and consistent episiotomy cutting angle within a ‘safe’ green zone between 45–60 degrees and length of at least 4 cm. The instrument also improves the visibility of the 60-degree line to clinicians, and provides an exact measurement for length (located on the 60-degree angle line). Clinicians from all three sites were recruited to provide feedback and measurements of incisions performed using the Episiometer (n = 135) following attendance at a minimum of at least one training session with site coordinators. Twenty of these clinicians were then recruited randomly from the sample who responded in the surveys and interviewed face-to-face. Patients were followed up 6-weeks postpartum to monitor potential complications (n = 120).

**Results** Overall, the Episiometer was well received by clinicians – particularly by more junior staff members who were significantly more likely to report the Episiometer as being beneficial in guiding a safe MLE compared to their more senior counterparts (P = 0.003 and P = 0.011, respectively). In addition, 89% of incisions (107/120) were within the ‘safe zone’ between 45-60 degrees, and 40% (48/120) were made at exactly 60-degrees. No patient had any degree of perineal tear at follow up.

**Conclusion** The Episiometer is a well-received clinical innovation in both high-resource and lower resource settings. When used as directed, the Episiometer produces an accurate and safe incision, and reduces variation in clinicians’ performance of episiotomy.

**1224**

**Prospective study of pain scores and patient satisfaction during and after vaginal prolapse repairs under local anaesthetic**

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**Objectives** (1) To evaluate the perioperative and postoperative pain scores for vaginal prolapse repair under local anaesthetic. (2) To look at the overall patient satisfaction with the procedure.

**Design** A prospective cohort study to reduce recall bias.

**Methods** October 2017 to August 2018, 20 women were identified who had day-case vaginal prolapse repairs under local anaesthetic. Two questionnaires were devised, one given to patients on the day of surgery and the other to be filled out on day 7. Using a visual analogue scale (VAS), women were asked to record their pain scores: 1) during administration of the local anaesthetic, 2) during the procedure, 3) immediately after the operation, 4) 1 week post operation. This was followed by a qualitative assessment of patient satisfaction with the procedure.

**Results** All 20 women agreed to fill out the questionnaire on the day of surgery and 17 women returned the second questionnaire via post 1 week later (85% response rate). Of the 20 women, 11 (55%) had an anterior repair, 8 (40%) had a posterior repair and 1 (5%) had both. VAS for pain are accepted as: 0–4 = no pain, 0.5–4.4 = mild pain/discomfort, 4.5–7.4 = moderate pain and 7.5–10 = severe pain. No pain or mild pain/discomfort was recorded in 95% of patients during administration of local anaesthetic, 100% during the procedure, 100% immediately after the procedure and 100% 1 week after the procedure. Looking at patient satisfaction, 100% of patients felt happy with their procedure regarding pain, 100% of patients reported they would have another local anaesthetic vaginal repair if required and 100% said they would recommend local anaesthetic vaginal repair to a friend. Most comments were positive, sighting professionalism and lack of pain, the few negative comments were around embarrassment during the procedure.

**Conclusion** Overall, the acceptability to patients of performing vaginal prolapse surgery under local anaesthetic has been demonstrated. Patients benefit from the removal of risks associated with general/regional anaesthetic, a reduction in adverse effects such as postoperative nausea and vomiting, and in general have a shorter hospital stay. The technique offers significant financial savings for the hospital with reduced length of stay and increased use of day case lists.

**1320**

**Predicting patient preference for mode of delivery following obstetric anal sphincter injury**

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**Introduction** Patients who sustain an obstetric anal sphincter injury (OASI) have the opportunity to select an elective caesarean section over a vaginal delivery in subsequent pregnancies. It remains unclear whether there are identifiable factors that predict expectant mothers’ choices.

**Objectives** The primary aim of our study was to explore factors which may predict patient preference for mode of delivery in subsequent pregnancy following an OASI.

**Design** Retrospective analysis.

**Methods** Data were retrospectively collected for patients attending a specialist OASIS clinic between July 2016 and February 2018. Information routinely collected in clinical practice was considered including mode of previous delivery, severity of OASI, combined with anal incontinence symptoms and endoanal ultrasound results. Logistic regression analysis was used to explore the relationship between these variables and the preferred mode of delivery.

**Results** A total of 188 patients were identified of whom 153 had complete data for analysis. Approximately 30% (n = 45) of patients preferred to have a caesarean section in their subsequent pregnancy. Bivariate analysis revealed significant associations between choosing a caesarean section in subsequent pregnancy and individuals with major tears (P = 0.001), high anal incontinence scores (P = 0.001) and defects on endoanal ultrasound (P < 0.001). Logistic regression analysis showed statistically significant associations between Caucasian ethnicity (Odds Ratio (OR) 12.6, 95% CI 2.4–69.9) and endoanal ultrasound results (OR 2.3, 95% CI 1.7–3.2) with preference for caesarean section.
Conclusion Our data suggest that emphasis is placed by patients on endoanal ultrasound results when making their decision about mode of delivery in a subsequent pregnancy, suggesting a useful application of this tool. Ethnicity is a strong predictor of choice of delivery after OASI and may be potentially useful in forecasting maternity unit services.

1647
Rectus sheath fascial sling as a TVT-O in treatment of stress urinary incontinence

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Objective The aim of the study is to figure out the safety and efficacy of a novel surgeon tailored sling formed of a piece of autologous rectus fascia in its middle part and two arms of polypropylene mesh through the same surgical technique of TVT-O in order to decrease the incidence of erosions and reduce the cost in developing country.

Design This is a prospective cohort study aiming to decrease the incidence of erosions and reduce the cost in developing country.

Materials and methods Our study included 70 women diagnosed to have stress urinary incontinence using a cough stress test and urodynamic studies during the period from August 2016 to January 2018 at the Urology Department Cairo University Hospitals. The patients were treated with a hybrid sling formed of a central part of autologous rectus sheath (2 × 6 cm) and two arms of polypropylene mesh (2 × 10 cm) The Stress and Urgency Incontinence Quality of life Questionnaire (SUIQQ) and urodynamic variables were compared before and after surgery.

Results At 12 months of follow up, 85.7% of the patients were cured, 8.6% were improved and in 5.7% the procedure failed. The SUI, UUI and QoL indices were improved significantly. There were no significant differences before and after surgery in bladder capacity, compliance, flow rates. No cases of vaginal or urethral erosions were reported.

Conclusion The autologous nature of the mid urethral sling offers similar efficacy and much less chances of urethral and vaginal erosions compared to traditional synthetic slings and through a less invasive surgical technique compared to traditional pubourethral sling.

1837
Laparoscopic and sacrospinous hysteropexy: a 5-year retrospective review in a tertiary UK Hospital

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Objective To evaluate and compare the safety and efficacy of both uterus-sparing, apical support procedures available at Cambridge University Hospital Urogynaecology Unit.

Design Retrospective review of patients undergoing laparoscopic sacrohysteropexy and vaginal sacrospinous hysteropexy between January 2012 and September 2017. Both surgical procedures for apical prolapse treatment were offered in our unit from January 2012 and the 5 year interval was chosen to give the maximal average length of follow up.

Methods A search was performed for both procedures; vaginal sacrospinous hysteropexy (Q54.5) and laparoscopic sacrohysteropexy (Q54.5 & Y75.2) from January 2012–September 2017. Total population size: 89 patients. Notes were reviewed using our online medical record system which was introduced in 2015 and patient records predating this were retrieved from medical records in hardcopy. Five patient records were unavailable therefore a total of 84 notes were reviewed. Data collected included demographics, pre- and post-op Pelvic Organ Prolapse Quantification (POP-Q) measurements, vaginal symptoms (VS) scores, and Quality of Life (QoL) scores. Complications and prolapse recurrence rates were also recorded. The following were compared against quoted national rates for vaginal prolapse surgery: visceral injury (bladder, bowel): 7/1000, excessive blood loss requiring transfusion: 2/100.

Results 32 cases of vaginal sacrospinous hysteropexy and 52 laparoscopic sacrohysteropexy. Those undergoing vaginal surgery for apical prolapse were significantly more likely to have concomitant anterior and/or posterior colporrhaphy, 97% compared to 42%. Mean change to Point C in POP-Q was similar in both groups and both groups saw objective improvement. Post operative Quality of Life score for both groups was equal at 2. Infection rate and blood loss were greater in the vaginal surgery group. No patients required blood transfusion, compared to 2% quoted rate after vaginal hysterectomy. Up to 13% recurrence rate of pelvic organ prolapse (POP) at 6 months average follow up, however most not apical. There were no documented cases of uterine or cervical cancer diagnoses following these uterine preservation procedures.

Conclusion Following vaginal sacrospinous hysteropexy and laparoscopic sacrohysteropexy, QoL score and VS score were reduced by approximately 2/3rds, indicating improvement. With both uterus-preserving apical support procedures, the mean rate of symptomatic prolapse at 6 months follow up was 12%, lower than quoted after vaginal hysterectomy. In this study between 2012 and 2017 there were proportionately more laparoscopic cases. This is likely to change given current mesh concerns, and this study indicates the safety and efficacy of vaginal sacrospinous hysteropexy, a nonmesh alternative.
Appraisal of guidelines on the use of vaginal mesh implants for pelvic organ prolapse using the AGREE II instrument tool

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Abstract


Objective

The aim of this study was to systematically evaluate the quality of guidelines on vaginal mesh procedures for POP repair using the AGREE II instrument.

Design

Systematic review.

Methods

Literature searches were performed using Medline, PubMed, Web of Science and ScienceDirect databases from inception to November 2018. National and International associations were searched manually. The inclusion criteria were published national and international guidelines on the use of vaginal mesh for the vaginal prolapse management. Six appraisers independently scored each guideline using AGREE II Reporting Checklist.

Results

Five guidelines were included and appraised. The mean overall quality rating of the five guidelines was between 4.2 and 6.3 which suggests a high quality of the guidelines on the use of vaginal mesh in women with POP. Highest scores were noted in the domains related to Scope and Purpose and Clarity of Presentation, and the lowest in Applicability and Editorial Independence. The SOGC guideline was the one with the overall highest scores in individual domains and overall quality rating. Only three out of five guidelines included information about the process and methodology they followed and included the level of evidence of the recommendations.

Conclusion

The quality of the guidelines on the use of vaginal meshes for the treatment of POP is high but there is room for improvement especially in aspects of methodological development and stakeholder involvement. Tools as AGREE II are useful to validate the quality of the existing guidelines and can be used as a guidance tool, when national and international guidelines are in the process of development.