Are synthetic mesh mid-urethral slings (MUS) for treatment of stress urinary incontinence a risk factor for autoimmune diseases?
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Introduction
The use of polypropylene mesh in surgery for stress urinary incontinence has become increasingly controversial in recent years. Some women have experienced serious adverse effects after mesh surgery. There have also been reports of autoimmune diseases and symptoms of persistent fatigue. We did a retrospective cohort study to compare subsequent admissions with autoimmune disease or Fibromyalgia or Myalgic Encephalomyelitis (ME) between women who had mesh and non-mesh surgeries during 2006-2013 in England.

Methods
Hospital Episodes Statistics records were used to identify all women who had a first mesh (retropubic or transobturator sling) or non-mesh (colposuspension or non-mesh sling) incontinence surgical procedure with the NHS in England during 2006-2013. Inpatient admission records up to 31st March 2019 were analysed to compare risk of subsequent admission with an autoimmune disease or Fibromyalgia or ME between treatment groups. A Fine & Gray’s subhazards model was used to compare in hazard up to 10 years postoperatively, accounting for the competing risk of death and patient characteristics. As the analysis cohort comprised all patients who had a record of these procedures done with the NHS, no formal sample size calculation was done.

Results
The cumulative incidence of autoimmune diseases at 10 years follow up was 8% for the 88,947 women who had mesh surgery and 9% for the 3,389 women who had non-mesh surgery. We found weak evidence that non-mesh surgery was associated with higher hazard of autoimmune diseases (hazard ratio: 1.12, 95% CI: 0.99, 1.27).

Conclusions
We did not find evidence that use of polypropylene mesh in surgery for SUI was associated with increased risk of autoimmune diseases. Further research evaluating subsequent attendances at rheumatology outpatient clinics would be valuable to confirm there is no increased risk.

Patient experience of Virtual Urogynaecology Services during Covid-19 pandemic
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Introduction
In response to the coronavirus pandemic all Urogynaecology clinic appointments were converted to virtual consultations (VCs). This provided an opportunity to evaluate patient experience, in a future where VCs are set to become increasingly mainstream. We aimed to establish the patient perspective of this service and identify which patient groups may benefit most from moving to a virtual system. The null hypothesis was that patients have the same experience with virtual consultation as with face-to-face.

Methods
In this registered service evaluation (CEU Project reference 9919), postal questionnaires were sent to patients who had VC appointments in May-June 2020 at a tertiary urogynaecology centre. Clinical outcome data were obtained from electronic patient records. The survey combined 3 validated tools: QQ-10, Patient Enablement Index and NHS Friends and Family Test (FFT). Qualitative and quantitative data were analysed. Our sample size was based on a power calculation for a VC RCT in this unit (number needed: 121 in intervention group)[1].

Results
308 women were contacted. 165 responded (54%). 86% patients described their experience of VC as ‘Very good’ or ‘Good’ (NHS FFT). Positive themes identified included convenience, thoroughness and feeling at ease. QQ-10 results demonstrated a Value score of 77 (0-100) and a Burden score of 17 (maximum value score 100, highest achievable burden score 0). 72% patients ‘Strongly’ or ‘Mostly agree’ to repeat VC. 22% patients were discharged, 72% required follow-up and 37% needed face-to-face consultation. Post-operative patients and those with lower urinary tract symptoms benefited most from VC, whereas a large proportion of prolapse patients require face-to-face consultation.

Conclusions
We report the largest qualitative and quantitative study of patient experience of VC in Urogynaecology. VC is convenient, acceptable and efficacious for conducting patient care in preselected groups. VC can also support patients in communicating with health professionals regarding intimate symptoms.

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Hysterectomy or Hysteropexy? Long term follow-up from a randomised controlled trial.
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Introduction
In the UK Vaginal hysterectomy (VH) with apical suspension is the preferred surgical procedure for the treatment of uterine prolapse [1]. Yet many women would prefer avoid hysterectomy, potentially explaining the increasing use of uterine sparing alternatives [2, 3]. Laparoscopic mesh sacrohysteropexy (LSH), one such alternative, appears to have a risk of both mesh associated complications and reoperation for recurrent apical prolapse in the medium term[4]. To date, there are limited data from randomised studies, and that which exists is limited in the length of follow-up. The aim of this study was to compare vaginal hysterectomy and laparoscopic mesh sacrohysteropexy for the treatment of uterine prolapse.

Methods
This was a randomised controlled trial of VH and LSH for the treatment of symptomatic uterine prolapse, for which the 1-year outcomes have previously been reported [5]. We utilised the prespecified primary outcome of reoperation for apical prolapse. Secondary outcomes included PGI-I in prolapse symptoms, the ICIQ-VS, ICIQ- FLUTS and PISO-12 questionnaires, patient reported mesh complications and POP-Q. Follow-up was undertaken at a minimum of seven years postoperatively. Chi-squared test was used to compare dichotomous outcomes, Mann-Whitney U test was used to compare questionnaire scores and Kaplan-Meier survival analysis for the primary outcome was undertaken.

Results
101 women were randomised and there was no significant differences in the baseline characteristics of each group. At an average of 100 months post operatively (range 84-119 months), 62 women attended for follow-up. The risk of reoperation for apical prolapse was 17.2% following VH and 6.1% following LSH (relative risk 0.34, 95% CI 0.07 – 1.68, p = 0.17), with Kaplan-Meier survivorship over time shown in Figure 1. The incidence of any reoperation for prolapse is shown in Table 1. Laparoscopic sacrohysteropexy was associated with a statistically significant higher apical suspension (POP-Q point C -5 vs. -4.25, p = 0.02) and longer total vaginal length (9cm vs. 6cm, p<0.001). There was no difference in the change in ICIQ-VS scores between the two groups (ICIQ- VS change -22 vs. -25, p = 0.59). The ICIQ-FLUTS scores at follow up was no difference in the change in ICIQ-VS scores between the two groups (ICIQ-FLUTS change 4.25, p = 0.02) and longer total vaginal length (9cm vs. 6cm, p<0.001). There were no differences in the change in ICIQ-VS scores between the two groups (ICIQ-VS change -22 vs. -25, p = 0.59). The ICIQ-FLUTS scores at follow up were similar in both groups (9.5 and 9.4, p = 0.97), with no difference in either the filling, voiding or incontinence sub-scales. The percentage of patients reporting PGI-I in prolapse symptoms as ‘very much better’ and ‘much better’ was 86% after VH and 76% after LSH (p = 0.29).

None reported mesh removal, mesh erosion or chronic pain attributed to the mesh.

Conclusions
There may be potential advantages to LSH that include a low risk of apical reoperation, optimal anatomical apical support, and increased total vaginal length, consistently reported data. Larger trials are needed for precise estimates to inform practice, however, our data will contribute to any future meta-analyses.

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Episiotomy with operative vaginal delivery and the prevention of obstetric anal sphincter injury (OASI): A systematic review and meta-analysis
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Introduction
OASI complicates approximately 6% of vaginal deliveries [1]. This risk is increased with operative vaginal deliveries (OVD), particularly forceps [2]. However, there is conflicting evidence supporting the use of mediolateral episiotomy (MLE) with OVD. The objective of this study was to assess whether MLE affected OASI risk in OVD.

Methods
Electronic searches were performed in OVID Medline, Embase and Cochrane Library. Randomised (RCT) and prospective observational studies investigating the risk of OASI in OVD with/without MLE were eligible for inclusion (PROSPERO number: CRD420201965799). Pooled odds ratios (OR) were calculated using Revman 5.3. Risk of bias was assessed using the Cochrane RoB2 and ROBINS-I tool.

Results
Of the 1265 studies found, eight were used for meta-analysis (n=7525 women). Six studies reported outcomes in nulliparous women (n=6282) and two studies pooled nulliparous and multiparous women together (n=1243). Overall, MLE significantly reduced the risk of OASI with OVD (OR 0.27 [95% CI 0.24-0.30]). MLE was more protective against OASI with forceps deliveries (OR 0.08 [95% CI 0.06-0.10]) compared to ventouse deliveries (OR 0.35 [95% CI 0.30-0.40]). The anticipated absolute risk reduction was 20.5% equating to a number needed to treat of 5 women to prevent one OASI. Evidence quality was evaluated using the GRADE toolbox (Table 1).

Conclusions
This meta-analysis of mostly nulliparous women showed that MLE can reduce the risk of OASI and should be considered in OVDs. As there is only one RCT, which was not adequately powered, this information will be useful in aiding clinical decision making and counselling in the antenatal period and during labour.

Outcome | Relative effect (95% CI) | Anticipated absolute effects (95% CI) | Difference | Certainty
--- | --- | --- | --- | ---
Instrumental | OR 0.27 (0.24 to 0.30) | 31.5% | 11.5% (10 to 12.1) | 20.5% fewer (21.6 fewer to 19.4 fewer)

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Sexual function in BPS/IC – A Systematic Review and Meta-analysis of the Literature
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Introduction
Bladder Pain Syndrome/Interstitial Cystitis (BPS/IC) can adversely affect physical, mental and sexual health. The aim of the systematic review is to compare sexual function in patients with BPS/IC and healthy controls and to examine whether treatment of BPS/IC improves sexual function.

Methods
A literature search was conducted using pre-defined Keywords. The HADS platform was used to search Embase, Medline and other databases. The PRISMA statement was used for reporting. Studies comparing sexual function in BPS/IC patients to healthy controls or to the same patients before/after treatment were included. Where appropriate, data was pooled in a meta-analysis using a random effect model and where different tools were used, the Standardised Mean Difference (SMD) was used for comparison.

Results
Out of 376 studies initially identified, 22 studies met the criteria and were included in the systematic review. 9 of these reported enough data to be further included in the meta-analysis. Five studies compared sexual function in BPS/IC cases to healthy controls. All studies found that sexual function was worse in BPS/IC cases compared to controls using the FSFI. Pooled data from 4 studies showed that the mean difference was 6.64 (CI 2.66, 10.62) in total FSFI scores between the cases and control groups, p=0.001. Further analysis also showed better sexual function in the FSFI subdomains in healthy controls.

Four studies compared sexual function in BPS/IC patients before treatment to after treatment. Pooled data from 3 studies showed an overall improvement in sexual function following intravesical treatment: SMD= 0.69 (CI 0.23, 1.14), p=0.009. Further meta-analysis showed improvement in the following subdomains: desire, arousal, orgasm, satisfaction, pain and lubrication.

Conclusions
Our review suggests that sexual function is worse in BPS/IC patients compared to the general population, but that it improves with BPS/IC treatment.

Pregnancy and Female Sexual Function
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Introduction
Female sexual function remains an under investigated and neglected topic in medical research. Studies have found a strong association between female sexual dysfunction (FSD) and decreased physical, emotional and overall life satisfaction. Although FSD and the impact it has on quality of life is becoming increasingly recognised, the effect of pregnancy on FSD is relatively under-researched.

Methods
Based on a significance level of 5% and a study power of 80% a power calculation was performed using an assumed 20% loss to follow up rate. 85 primiparous women with singleton pregnancies were recruited at their 26.55 was used to diagnose FSD.

Results
There was an overall decrease in total FSFI scores across the three trimesters, from a median full-scale score of 27.5 in the first trimester, to 24.7 in the second and 21.4 in the third trimester. There was a very significant decrease in all scores (the full scale score and the six domains- desire, lubrication, arousal, orgasm, satisfaction and pain), from the first trimester to the third trimester with each outcome (p<0.0001). There were 30 women with FDS in the first trimester,50 in the second and 68 in the third (p<0.05).

Conclusions
For primiparous women pregnancy appears to have a negative impact on sexual function with 86.1% of women being classified as suffering from FSD in the third trimester. The importance of sexual function in overall quality of life is well known and so it is important that the changes experienced by women and their partners are discussed by doctors with their patients.

A Systematic Review of English Language Patient-Reported Outcome Measures for Use in Urogynaecology and Female Pelvic Medicine
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Introduction
Patient-reported outcome measures (PROMs) are widely used in clinical practice and research in urogynaecology. There is no consensus on which PROMs should be used and no review identifying all available tools and comparing the psychometric properties of these.

Methods
Systematic review following PRISMA guidelines. Studies where women had been administered an English language PROM which assessed pelvic floor symptomatology and psychometric properties had been reported were included. Ovid Medline, AMED, CINAHL, Cochrane Collaboration, EMBASE and Web of Science databases were searched from January 1966 to August 2020.

Results
6003 studies were screened, 312 manuscripts were reviewed in full with 148 studies included. 85 PROMs assessing pelvic floor symptoms in a urogynaecology population were identified. 43 PROMs assessed lower urinary tract symptoms in 95 studies, four PROMs assessed vaginal symptoms in seven studies, 20 PROMs assessed bowel symptoms in 27 studies and three PROMs assessed sexual symptoms in seven studies. 15 PROMs assessed two or more of these symptom areas in 60 studies. The PROMs with the best available psychometric evidence within these five symptom areas were (urinary symptoms) the incontinence quality of life questionnaire (I-QOL aka ICIQ-Ulqo) and International Consultation on Incontinence Questionnaire (ICIQ-UI-SF), (bowel symptoms) the Accidental Bowel Leakage Evaluation (ABLE) questionnaire and the International Consultation on Incontinence Bowel questionnaire (ICIQ-B), (vaginal symptoms) the Pelvic Organ Prolapse Symptom Score (POPSS), (sexual symptoms) the Pelvic organ prolapse- urinary Incontinence Sexual Function Questionnaire- IUGA revised (PISQ-IR) and (comprehensive PROMs) the Australian Pelvic Floor Questionnaire and the Electronic Personal Assessment Questionnaire-Pelvic floor (ePAQ-PF).

Conclusions
Multiple PROMs with robust psychometric properties are available within urogynaecology, but many of the tools used in clinical practice or research do not have robust psychometric properties. Formal recommendations of which English-language PROMs to use within clinical practice and research in urogynaecology are now required.

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Comprehensive systematic review of patient reported outcome measures (PROMs) used in women with pelvic organ prolapse (POP)

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Introduction

Comprehensive systematic reviews analysing the various PROMs are essential in order to provide clinicians evidence-based recommendations in the selection of the most suitable PROM for a particular condition. However, given the large number of measures available, it is unclear which PROMs are suitable for use in research or clinical practice. Objective: To systematically assess the measurement properties of PROMs for women with POP.

Methods

A systematic review of studies evaluating the measurement properties of PROMs in adults with POP was conducted. MEDLINE, EMBASE, PsycINFO and CINAHL were systematically searched from inception. The COSMIN-based Standards for the selection of health Measurement Instruments (COSMIN) checklist was used to appraise the methodological quality of the selected studies following the full-text review. Data on the study population, questionnaire characteristics and measurement properties was extracted. Finally, a narrative synthesis of the extracted data was undertaken.

Results

After removal of the duplicates, 1318 abstracts were screened. For complete text review based on the title and/or abstract, 75 articles were reviewed in detail and of these, 45 articles were excluded. A total number of 30 articles which robustly evaluated a total of 12 PROMS used in women with POP were included. Three PROMs that qualified for full evaluation were PFID-SF 20, POP SS and ePAQ-PF and are the instruments that were considered to have adequate or sufficient content validity.

(Tables 1)

Conclusions

The PFID-SF 20, POP SS and ePAQ-PF have demonstrated sufficient evidence to be recommended for use in clinical and research settings in order to capture maximum information from the patient.

Outcome reporting in randomised controlled trials on the pharmacological management of idiopathic overactive bladder in women: A systematic review and proposal for interim core outcome sets.

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Introduction

Overactive bladder (OAB) syndrome is common with a potentially significant impact on quality of life (QoL). Systematic reviews on randomised controlled trials (RCTs) have recommended “better reporting of the definition of cure and a standardised approach to subjective assessment”. At present no comparison of socio-economic factors or QoL have been made between anticholinergics and other medications. Is it therefore clear that current evidence is inadequate and methodological limitations in RCT affect their comparability.

Methods

To compare the selection and reporting of core outcomes (COS) and outcome measures (COMS) across RCTs on pharmacological therapy for women with idiopathic OAB. RCTs were identified using EMBASE, Medline and COCHRANE. Full text articles from 1919-current, written in English, including only women were selected. COS and COMS were extracted, as were interventions, sample size, journal type, commercial funding. Methodological and outcome reporting quality were evaluated using JADAD and MOMENT scores.

Results

Thirty-eight studies were identified, including 18,316 women. Sixty-nine outcomes were reported, using 62 different outcome measures. The most commonly reported outcome domains were efficacy (86.8%), safety (73.7%) and QoL (60.5%). The most commonly reported outcome in each domain was urgency incontinence episodes (UIE) (52.6%), change in validated questionnaire scores (36.8%) and anti-muscarinic related side effects (76.3%). There was not statistically significant association between journal type (P=0.224) or commercial funding (P=0.111) and quality of outcome reporting.

Conclusions

The development of COS and COMS sets may address variations in the selection and reporting of COS and COMS and lead to higher quality evidence and better patient care. We propose the use of most frequently reported COS and COMS as interim sets. The main domains we recommend are efficacy, safety and QoL, with outcomes: UIE, urgency episodes and nocturia episodes for efficacy; anti-muscarinic adverse events, other adverse events and discontinuation rates for safety; and changes in questionnaire scores for QoL.

Prospective service evaluation and patient satisfaction of virtual specialist-led clinic in Urogynaecology in a tertiary centre

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Introduction

COVID-19 pandemic has led to drastic changes in the healthcare provision and overnight changes were introduced by the NHS with large-scale implementation of telemedicine. It aimed to minimise the unnecessary exposure to the healthcare personnel and the patients, while providing safe and effective care to the patients during the pandemic. Telemedicine is not a new concept and traditionally, it has been used in primary care, triaging services and nurse-helplines for a long time where it has proven beneficial (1.2). Our aim was to evaluate the feasibility, acceptability, patients’ convenience and satisfaction of Urogynaecology telephone clinical care in our unit during the COVID-19 pandemic.

Methods

A telephone survey of the patients conducted between 27/04/2020 and 12/05/2020. We asked closed and open-ended questions. Patients’ satisfaction evaluated using both 5-point Likert scale and 10-point visual analogue scale (VAS). We used descriptive statistics to analyse quantitative data and inductive thematic analysis for free-text comments.

Results

101/109 (93%) participants completed the survey. Median consultation duration:16minutes, median patient age:60years, with 51% having ≥1 comorbidity. 33% were new and 13% tertiary referral cases. For face-to-face appointments, patients travelled median distance of 28miles, with 99% requiring means of transport and 30% time off-work. 97% were happy/very happy with telephone consultation, with 90% scoring 8-10 on VAS. Patients considered telephone clinics convenient as it avoided travel, parking charges, long waits at hospital and need to organise childcare. Major limitations were loss of non-verbal cues, difficulties
encountered by patients with hearing or memory problems, language barrier or where an examination was required.

**Conclusions**

Urogynaecology telephone clinics were feasible, acceptable and convenient with high level of patients’ satisfaction during the current COVID-19 pandemic. We recommend a combination of face to face and virtual appointments as the way forward in the recovery stage. Robust studies are required to evaluate the feasibility of integrating telemedicine into routine Urogynaecology practice in the future.

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