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

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Abstract

Introduction We assessed 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.

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 ($\beta = −0.013; P = 0.918$).

Conclusions 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.

Keywords Anterior repair · Colporrhaphy · Core outcome sets · Cystocele · Outcomes · Outcome measures

Introduction

The most common type of pelvic organ prolapse (PO) is anterior-compartment prolapse. Hendrix et al. demonstrated in a group of 16,616 postmenopausal women a prevalence of anterior-compartment prolapse of 34%, and this was much higher than the rates of apical- or posterior-compartment prolapse [1]. The aetiology of pelvic organ prolapse (POP) is complex and associated with various factors such as age, menopausal status and childbirth-related pelvic floor trauma [2, 3]. Possible surgical interventions include biological-graft, mesh and native tissue repair [4, 5]. The development of new surgical interventions is urgently required, and potential surgical
interventions require robust evaluation. Selecting appropriate efficacy and safety outcomes is a crucial step in designing randomised trials. Outcomes collected and reported in randomised trials should be relevant to a broad range of stakeholders, including women with anterior-compartment prolapse, healthcare professionals and researchers. For example, resolution of bladder symptoms is an important outcome for all stakeholders; however, it is not commonly reported across trials. Even when outcomes have been consistently reported, secondary research methods, including pair-wise meta-analysis, may be limited by the use of different definitions and measurement instruments [6, 7]. A core outcome set should help address these issues. The first stage in core outcome-set development is to evaluate outcome and outcome-measure reporting across published trials. Therefore, we systematically evaluated outcome and outcome-measure reporting in published randomised trials evaluating surgical interventions for anterior-compartment prolapse. In addition, we assessed the relationships between outcome reporting quality with other important variables, including year of publication, impact factor and methodological quality.

Materials and methods

This systematic review is part of a wider project of the International Collaboration for Harmonising Outcomes, Research and Standards in Urogynaecology and Women’s Health (CHORUS) (i-chorus.org) and was registered with the Core Outcome Measures in Effectiveness Trials (COMET) initiative database, registration number 981, and with the International Prospective Register of Systematic Reviews (PROSPERO), registration identification CRD42017062456. We searched bibliographical databases comprising the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE and MEDLINE from inception to September 2017. The search strategy used several MeSH terms, including bladder prolapse, cystocele and POP. Randomised trials evaluating surgical interventions for anterior-compartment prolapse were eligible. We included trials evaluating the surgical management of anterior prolapse as a unicompartmental prolapse procedure, as well as trials in which anterior repair was undertaken in addition to other surgical interventions. Non-randomised studies, observational studies and case reports were excluded.

Two researchers (CD and AE) independently screened the titles and abstracts of electronically retrieved articles. The articles potentially eligible for inclusion were retrieved in full text to assess eligibility, and reference lists were independently reviewed. Any discrepancies between the researchers were resolved by review of a third senior researcher (SKD). Two researchers (CD and AE) independently extracted the study characteristics, including year of publication, journal topicality (subspecialist, general obstetrics and gynaecology or general medicine), journal’s impact factor and commercial funding (yes/no). The journal’s impact factor was determined using InCites Journal Citation Reports (Clarivate Analytics, Thomson Reuters, New York, NY, USA). Funding status was identified by reviewing the article text and included the

![Fig. 1 Study search and inclusion](image-url)
| Author             | Study year | Journal                                         | Impact factor | Journal type | Jadad score | MOME NT score | Study size | Commercial funding | Validated questionnaire use | Intervention group 1       | Intervention group 2 | Intervention group 3 | Intervention group 4       |
|--------------------|------------|-------------------------------------------------|---------------|--------------|-------------|---------------|------------|-------------------|---------------------------|---------------------------|------------------|----------------------|---------------------------|
| Altman et al.      | 2011       | New England Journal of Medicine                 | 29.1          | G            | 4           | 5             | 389        | Yes               | Yes                       | Anterior colporrhaphy        | Transvaginal mesh repair |
| Antosh et al.      | 2013       | Obstetrics and Gynaecology                      | 4.78          | S            | 3           | 6             | 60         | No                | Yes                       | Use of dilators post prolapse surgery | Non-use of dilators post prolapse surgery |
| Ballard et al.     | 2014       | International Urogynecology Journal             | 2.17          | G            | 5           | 5             | 150        | No                | Yes                       | Preop. bowel preparation   | Preop. non bowel preparation |
| Benson et al.      | 1996       | American Journal of Obstetrics and Gynaecology  | –             | S            | 3           | 3             | 80         | No                | No                        | Pelvic surgery for prolapse   | Abdominal surgery          |
| Borstad et al.     | 2009       | International Urogynecology Journal             | 2.84          | SS           | 3           | 4             | 184        | No                | No                        | Anterior colporrhaphy TVT    | Anterior colporrhaphy + TVT staged procedure |
| Bray et al.        | 2017       | European Journal of Obstetrics & Gynaecology and Reproductive Biology | N/A           | G            | 3           | 5             | 60         | No                | N/A                       | Suprapubic catheter          | Immediate removal of catheter |
| Carey et al.       | 2009       | British Journal of Obstetrics and Gynaecology   | 4.64          | S            | 3           | 5             | 139        | Yes               | Yes                       | Conventional vaginal repair  | Mesh vaginal repair         |
| Choe et al.        | 2000       | Journal of Urology                              | 2.64          | SS           | 2           | 3             | 40         | No                | Yes                       | Antilogous vaginal wall slings | Micromesh                     |
| Colombo et al.     | 2000       | British Journal of Obstetrics and Gynaecology   | 4.64          | S            | 3           | 3             | 71         | No                | No                        | Anterior colporrhaphy        | Burch colposuspension       |
| da Silveira et al. | 2014       | International Urogynecology Journal             | 2.17          | SS           | 3           | 5             | 184        | Yes               | Yes                       | Native tissue repair        | Synthetic mesh repair       |
| Dahlgren et al.    | 2011       | Acta Obstetricia et Gynaecologica Scandinavica  | 2.2           | S            | 3           | 3             | 135        | No                | Yes                       | Conventional colporrhaphy    | Porcine skin graft          |
| Delroy et al.      | 2013       | International Urogynecology Journal             | 2.45          | SS           | 5           | 6             | 79         | Yes               | Yes                       | Anterior colporrhaphy        | Transvaginal mesh repair    |
| Dias et al.        | 2016       |                                                 | 2.48          | SS           | 5           | 6             | 88         | No                | Yes                       |                           |                               |
| Author                        | Study year | Journal                                      | Impact factor | Journal type | Jadad score | MOME NT score | Commercial funding | Validated questionnaire use | Intervention group 1                      | Intervention group 2                      | Intervention group 3                      | Intervention group 4                      |
|------------------------------|------------|-----------------------------------------------|---------------|--------------|-------------|----------------|--------------------|---------------------------|------------------------------------------|------------------------------------------|------------------------------------------|------------------------------------------|
| de Tayrac et al.             | 2012       | Neurourology and Urodynamics                  | 2.53          | SS           | 3           | 5             | 147                | No                        | Yes                       | Anterior colporrhaphy                  | Transvaginal mesh repair                 | Anterior colporrhaphy                  | Transvaginal mesh repair                 |
| Ek et al.                    | 2012       | International Urogynecology Journal          | 2.53          | SS           | 2           | 4             | 99                 | No                        | Yes                       | Anterior trocar-guided transvaginal mesh repair | Anterior colporrhaphy                  | Trocar guided transvaginal mesh repair  | Trocar guided transvaginal mesh repair  |
| Ek et al.                    | 2010       | Neurourology and Urodynamics                  | 3.01          | SS           | 5           | 4             | 50                 | No                        | N/A                       | Anterior colporrhaphy                  | Transvaginal mesh repair                 | Anterior colporrhaphy                  | Transvaginal mesh repair                 |
| El-Nazer et al.              | 2012       | American Journal of Obstetrics and Gynaecology | 1.56          | S            | 5           | 5             | 44                 | No                        | Yes                       | Anterior colporrhaphy                  | Conventional anterior colporrhaphy       | Partially absorbable mesh               | Partially absorbable mesh               |
| Farthmann et al.             | 2013       | International Urogynecology Journal          | 2.45          | SS           | 3           | 3             | 200                | Yes                       | Yes                      | Conventional anterior colporrhaphy       | Partially absorbable mesh               | SIS graft                                | SIS graft                                |
| Feldner et al.               | 2010       | International Urogynecology Journal          | 2.66          | SS           | 5           | 5             | 56                 | Yes                       | Yes                      | Anterior colporrhaphy                  | SIS graft                                | Traditional colporrhaphy                | Traditional colporrhaphy                |
| Feldner et al.               | 2012       | Clinical Science                             | 5.87          | G            | 5           | 4             | 56                 | No                        | Yes                       | Small intestine submucosa graft         | 24-h catheterisation and vaginal tampon | 3-h catheterisation and vaginal tampon  | 3-h catheterisation and vaginal tampon  |
| Galvind et al.               | 2007       | Acta Obstetricia et Gynecologica Scandinavica | 1.94          | G            | 3           | 2             | 136                | No                        | N/A                       | Anterior colporrhaphy                  | Colporrhaphy and fascial patch           | Colporrhaphy and fascial patch           | Colporrhaphy and fascial patch           |
| Gandhi et al.                | 2005       | American Journal of Obstetrics and Gynaecology | 4             | S            | 3           | 5             | 154                | No                        | No                       | Anterior colporrhaphy                  | Spontaneous postop. micturition          | Micturition after bladder refill         | Micturition after bladder refill         |
| Geller et al.                | 2011       | British Journal of Obstetrics and Gynaecology | 4.34          | S            | 3           | 4             | 50                 | No                        | N/A                       | Spontaneous postop. micturition          | Micturition after bladder refill         | Mesh repair                             | Mesh repair                             |
| Glazener et al.              | 2017       | The Lancet                                   | N/A           | G            | 3           | 6             | 1352               | No                        | Yes                       | Standard repair                       | Mesh repair                             | Biological graft                        | Biological graft                        |
| Glazener et al.              | 2017       | Health Technology Assessment                 | N/A           | G            | 4           | 6             | 3087               | No                        | Yes                       | Standard repair                       | Mesh repair                             | Biological graft                        | Biological graft                        |
| Guerette et al.              | 2009       |                                               | 4.69          | S            | 4           | 4             | 94                 | Yes                       | Yes                       | Anterior repair                       |                                      |                                      |                                      |
| Author | Study year | Journal | Impact factor | Journal type | Jadad score | MOME score | Study size | Commercial funding | Validated questionnaire use | Intervention group 1 | Intervention group 2 | Intervention group 3 | Intervention group 4 |
|--------|------------|---------|---------------|--------------|-------------|------------|------------|-------------------|------------------------|-------------------|----------------------|----------------------|---------------------|
| Gupta et al. | 2014 | South African Journal of Obstetrics & Gynaecology | 0.23 | S | 3 | 4 | 106 | No | N/A | Anterior repair | Anterior repair + porcine graft mesh |
| Hakvoort | 2004 | British Journal of Obstetrics and Gynaecology | 4.75 | S | 2 | 3 | 100 | No | N/A | 4-day catheterisation | 1-day catheterisation |
| Henn et al. | 2016 | International Urogynecology Journal | 1.83 | SS | 5 | 6 | 80 | No | N/A | Vaginal vasoconstrictor infiltration | Vaginal saline infiltration |
| Hiltunen et al. | 2007 | Obstetrics and Gynaecology | 4.45 | G | 3 | 4 | 202 | No | No | Anterior colporrhaphy | Transvaginal mesh repair |
| Nieminen et al. | 2010 | American Journal of Obstetrics and Gynaecology | 4.98 | G | 3 | 4 | 202 | No | No | Anterior colporrhaphy | Transvaginal mesh repair |
| Nieminen et al. | 2008 | International Urogynecology Journal | 2.51 | SS | 3 | 2 | 202 | No | No | Anterior colporrhaphy | Transvaginal mesh repair |
| Huang et al. | 2010 | International Urogynecology Journal | 2.66 | SS | 3 | 3 | 90 | No | N/A | Removal of catheter on day 2 postop. | Removal of catheter on day 3 postop. |
| Hviid et al. | 2010 | International Urogynecology Journal | 2.66 | SS | 3 | 3 | 61 | No | Yes | Conventional anterior repair | Anterior repair + porcine skin collagen implants |
| Iglesia et al. | 2010 | Obstetrics and Gynaecology | 4.98 | S | 5 | 6 | 65 | No | Yes | Conventional colporrhaphy or uterosacral ligament suspension | Vaginal colpopexy with mesh |
| Kamilya et al. | 2010 | Journal of Obstetrics and Gynaecology Research | 1.13 | S | 3 | 6 | 200 | No | N/A | Catheter removal day 4 postop. | Catheter removal day 1 postop. |
| Khalil et al. | 2016 | Journal of Clinical Anaesthesia | 1.64 | S | 5 | 5 | 57 | No | No | General anaesthesia | General anaesthesia + |
| Author            | Study year | Journal                               | Impact factor | Journal type | Jadad score | MOME score | Study size | Commercial funding | Validated questionnaire use | Intervention group 1                                      | Intervention group 2                                      | Intervention group 3                                      | Intervention group 4                                      |
|-------------------|------------|---------------------------------------|---------------|--------------|-------------|------------|------------|---------------------|----------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|
| Kringle et al.    | 2010       | International Urogynecology Journal    | 2.66          | SS           | 3           | 5          | 232        | No                  | N/A                        | Intraurethral catheterisation                             | Suprapubic catheterisation 24 h                          | Suprapubic catheterisation 96 h                           | Suprapubic catheterisation 96 h                           |
| Lambin et al.     | 2013       | International Urogynecology Journal    | 2.45          | SS           | 3           | 5          | 68         | No                  | Yes                       | Anterior colporrhaphy with vaginal colposuspension        | Transvaginal mesh repair                                 | Anterior colporrhaphy                                     | Anterior colporrhaphy                                     |
| Lazzeri et al.    | 2007       | Journal of Urology                    | 4.27          | S            | 3           | 5          | 47         | No                  | Yes                       | Abdominal prolapse repair NO Burch colposuspension       | Abdominal prolapse repair NO Burch colposuspension       | Abdominal prolapse repair NO Burch colposuspension       | Abdominal prolapse repair NO Burch colposuspension       |
| Lindholm et al.   | 1985       | International Journal of Gynaecology   | N/A           | S            | 4           | 3          | 20         | No                  | N/A                        | Phenoxethylamine use                                      | Control                                                  | Control                                                  | Control                                                  |
| Mahuvrata et al.  | 2011       | Journal of Obstetrics and Gynaecology  | 0.75          | G            | 5           | 5          | 66         | No                  | Yes                       | Mesh repair                                              | PDS                                                      | Vicryl                                                   | Other laxatives postoperative                             |
| McNanley et al.   | 2012       | Female Pelvic Medicine & Reconstructive Surgery | 0.42          | SS           | 3           | 6          | 60         | No                  | Yes                       | Docusate sodium laxative postoperative                   | Other laxatives postoperative                             | Other laxatives postoperative                             | Other laxatives postoperative                             |
| Menefee et al.    | 2011       | Obstetrics and Gynaecology             | 5.34          | S            | 5           | 6          | 99         | Yes                 | No                        | Anterior colporrhaphy plication                          | Mesh repair                                              | Mesh repair                                              | Mesh repair                                              |
| Meschia et al.    | 2003       | American Journal of Obstetrics and Gynaecology | 2.96          | S            | 3           | 5          | 50         | No                  | No                        | Endopelvic fascia plication                              | TVT + Anterior repair                                    | TVT + Anterior repair                                    | TVT + Anterior repair                                    |
| Minassian et al.  | 2014       | Neurology and Urodynamics              | 2.71          | SS           | 3           | 5          | 70         | No                  | Yes                       | Conventional anterior colporrhaphy 24 h                  | Abdominal paravaginal defect repair                      | Abdominal paravaginal defect repair                      | Abdominal paravaginal defect repair                      |
| Miranda et al.    | 2011       | Journal of Obstetrics and Gynaecology Canada | 1.42          | S            | 5           | 2          | 22         | No                  | N/A                       | Anterior colporrhaphy with polyglactin 910 mesh          | Anterior colporrhaphy without plication of pubovesical fascia | Anterior colporrhaphy without plication of pubovesical fascia | Anterior colporrhaphy without plication of pubovesical fascia |
| Natale et al.     | 2009       |                                     | 2.84          | SS           | 3           | 5          | 190        | No                  | Yes                       | Anterior colporrhaphy 24 h                               | Synthetic mesh                                           | Synthetic mesh                                           | Synthetic mesh                                           |
| Author                  | Study year | Journal                                           | Impact factor | Journal type | Jadad score | MOMEN score | Study size | Commercial funding | Validated questionnaire use | Intervention group 1                      | Intervention group 2                     | Intervention group 3                      | Intervention group 4                      |
|------------------------|------------|---------------------------------------------------|---------------|--------------|-------------|--------------|------------|---------------------|------------------------------------------|-------------------------------------------|-------------------------------------------|-------------------------------------------|-------------------------------------------|
| Park et al.⁴           | 2013       | International Urogynecology Journal               | 2.45          | SS           | 3           | 5            | 92         | No                  | Yes                                      | Anterior repair + TVT                     | TVT                                       |                                           |                                           |
| Pauls et al.⁴          | 2015       | American Journal of Obstetrics and Gynaecology    | 5.23          | S            | 5           | 5            | 74         | No                  | Yes                                      | Dexamethasone prior to surgery            | Placebo                                  |                                           |                                           |
| Ploeger et al.²         | 2015       | International Urogynecology Journal               | 1.83          | SS           | 3           | 6            | 91         | Yes                 | Yes                                      | Prolapse surgery                         | Prolapse surgery + TVT                    |                                           |                                           |
| Qatawneh et al.²        | 2013       | Gynaecological Surgery                            | 0.46          | S            | 3           | 5            | 116        | No                  | No                                       | Native tissue repair                     | Mesh repair                              |                                           |                                           |
| Quadri et al.⁴         | 2000       | International Urogynecology Journal               | 1.15          | SS           | 3           | 3            | 45         | No                  | N/A                                      | Use of PGE-2                             | Control                                  |                                           |                                           |
| Robert et al.⁴         | 2014       | Obstetrics and Gynaecology                        | 4.76          | S            | 5           | 4            | 57         | Yes                 | Yes                                      | Anterior colporrhaphy                    | Transvaginal mesh repair                 |                                           |                                           |
| Rudnicki et al.⁴       | 2013       | British Journal of Obstetrics and Gynaecology     | 2.9           | G            | 3           | 5            | 160        | No                  | Yes                                      | Anterior colporrhaphy                    | Transvaginal mesh repair                 |                                           |                                           |
| Rudnicki et al.⁴       | 2015       | British Journal of Obstetrics and Gynaecology     | 2.9           | G            | 3           | 3            | 138        | No                  | Yes                                      | Anterior colporrhaphy                    | Transvaginal mesh repair                 |                                           |                                           |
| Sand et al.⁴           | 2001       | American Journal of Obstetrics and Gynaecology    | 2.72          | S            | 3           | 4            | 161        | No                  | N/A                                      | Conventional anterior colporrhaphy       | Use of mesh                              |                                           |                                           |
| Schierlitz et al.       | 2013       | International Urogynecology Journal               | 2.45          | SS           | 3           | 5            | 80         | No                  | Yes                                      | Conventional pelvic repair               | Conventional pelvic repair + TVT          |                                           |                                           |
| Segal et al.³           | 2006       | International Urogynecology Journal               | 2.38          | SS           | 3           | 5            | 40         | No                  | No                                       | Local anaesthesia                        | General anaesthesia                      |                                           |                                           |
| Sivasilioglu et al.⁴   | 2007       | International Urogynecology Journal               | 2.79          | SS           | 3           | 2            | 90         | No                  | Yes                                      | Anterior colporrhaphy                    | Transvaginal mesh repair                 |                                           |                                           |
| Stekkinger et al.       | 2011       | International Urogynecology Journal               | 1.74          | G            | 3           | 5            | 126        | No                  | N/A                                      | Trans urethral catheter                   | S/pubic catheter                        |                                           |                                           |
Table 1 (continued)

| Author            | Study year | Journal                                      | Impact factor | Journal type | Jadad score | MOMEN T score | Study size | Commercial funding | Intervention group 1 | Intervention group 2 | Intervention group 3 | Intervention group 4 |
|-------------------|------------|----------------------------------------------|---------------|--------------|-------------|---------------|------------|---------------------|----------------------|----------------------|----------------------|----------------------|
| Tamanini et al.   | 2012       | Gynecologic and Obstetric investigation      | 1.24          | G            | 4           | 5             | 100        | No                  | Anterior colporrhaphy | Transvaginal mesh repair |
|                   |            | International Braz J J Urol: official journal of the Brazilian Society of Urology |               |              |             |               |            |                     |                      |                      |                      |                      |
| Tamanini et al.   | 2012       | Gynecologic and Obstetric investigation      | 1.24          | G            | 4           | 5             | 100        | No                  | Anterior colporrhaphy | Transvaginal mesh repair |
|                   |            | International Braz J J Urol: official journal of the Brazilian Society of Urology |               |              |             |               |            |                     |                      |                      |                      |                      |
| Tamanini et al.   | 2014       | Journal of Urology                           | 4.68          | S            | 4           | 5             | 92         | No                  | Anterior colporrhaphy | Transvaginal mesh repair |
|                   |            |                                             |               |              |             |               |            |                     |                      |                      |                      |                      |
| Tantanasis et al. | 2008       | Acta Obstetricia et Gynecologica Scandinavica | 1.72          | S            | 2           | 2             | 50         | No                  | Anterior colporrhaphy | Bladder base tape repair |
| Thiagamoorthy et al. | 2013    | International Urogynecology Journal         | 2.45          | SS           | 5           | 6             | 190        | N/A                 | Use of postop. vaginal pack | No use of postop. vaginal pack |
| Tincello et al.   | 2009       | British Journal of Obstetrics and Gynaecology | 4.18          | S            | 3           | 4             | 31         | No                  | Colposuspension + anterior repair | TVT + Anterior repair |
| Turgal et al.     | 2013       | European Journal of Obstetrics & Gynaecology and Reproductive Biology | 2.4           | G            | 3           | 2             | 40         | No                  | Anterior colporrhaphy | Transvaginal mesh repair |
| Van et al.        | 2011       | International Urogynecology Journal         | 2.39          | SS           | 3           | 5             | 179        | N/A                 | 1-day suprapubic catheterisation | 3-day suprapubic catheterisation |
| Vollebregt et al. | 2011       | British Journal of Obstetrics and Gynaecology | 2.96          | S            | 5           | 6             | 125        | No                  | Anterior colporrhaphy | Transvaginal mesh repair |
|                   |            |                                             |               |              |             |               |            |                     |                      |                      |                      |                      |
|                   |            |                                             |               |              |             |               |            |                     |                      |                      |                      |                      |
| Author                  | Study year | Journal                                      | Impact factor | Journal type | Jadad score | MOME NT score | Study size | Commercial funding | Validated questionnaire use | Intervention group 1                                                                 | Intervention group 2                                      | Intervention group 3                                      | Intervention group 4                                                                 |
|------------------------|------------|----------------------------------------------|---------------|--------------|-------------|---------------|------------|-------------------|-------------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Vollebregt et al.      | 2001       | American Journal of Obstetrics and Gynaecology | 2.72          | G            | 2           | 3             | 114        | No                | No                           | Unilateral anterior colporrhaphy                                                          | Anterior colporrhaphy                                        | Transvaginal mesh repair                                                                    |
| Weber et al.           | 2011       | American Journal of Obstetrics and Gynaecology | 5.34          | G            | 4           | 4             | 114        | No                | No                           | Unilateral anterior colporrhaphy                                                          | Anterior colporrhaphy                                        | Transvaginal mesh repair                                                                    |
| Chmielewski et al.     | 2011       | International Urogynaecology Journal          | 2.39          | SS           | 3           | 6             | 246        | No                | N/A                          | Postop. catheterisation for 2 days                                                        | Postop. catheterisation for 5 days                                                                          | Transvaginal mesh repair                                                                    |
| Weemhoff et al.        | 2016       | Female Pelvic Medicine & Reconstructive Surgery | 1.49          | SS           | 4           | 5             | 93         | No                | Yes                          | Use of postop. vaginal pack                                                              | No use of postop. vaginal pack                                                                           | Transvaginal mesh repair                                                                    |
| Withagen et al.        | 2011       | Obstetrics and Gynaecology                    | 5.34          | S            | 5           | 6             | 194        | No                | Yes                          | Conventional colporrhaphy                                                               | Transvaginal mesh repair                                                                    |
| Milani et al.          | 2011       | Journal of Sexual Medicine                    | 3.67          | SS           | 3           | 6             | 59         | No                | Yes                          | Conventional colporrhaphy                                                               | Trocar-guided Mesh                                                                                       |
| Yuk et al.             | 2012       | Minimally Invasive Gynaecology                | 2.1           | S            | 3           | 3             | 87         | No                | N/A                          | 2-point mesh                                                                        | 4-point mesh                                                                                           |

*SS* subspecialty (urogynaecology), *S* specialty (obs/gyn), *G* general, *TVT* tension free vaginal tape (retropubic tape), *PDS* polydioxanone

*a* Studies focused on surgical management of anterior repair solely, *b* original study, *c* secondary analysis
donation of equipment or other resources. Two researchers (CD and AE) independently assessed the methodological quality of included randomised trials using the modified Jadad criteria (score range 1–5) [8]. Studies were assessed as high quality when they achieved a score >4. Outcome reporting quality was assessed using the Management of Otitis Media with Effusion in Cleft Palate (MOMENT) criteria (score range 1–5) [9]. Studies were assessed as high quality when they achieved a score >4.

The non-parametric Spearman’s rank correlation coefficient (Spearman’s rho) was used to explore univariate associations between outcome reporting quality and impact factor during the year of publication, year of publication and methodological quality. Multivariate linear regression analysis using the Enter model was also undertaken to assess the combined association of quality of outcome reporting and journal type, impact factor during the year of publication, year of publication and methodological quality (independent variables) with outcome reporting (dependent variable). All tests were two-tailed. Statistical significance was set at 0.05, and analyses were conducted using the SPSS statistical software (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY, USA).

This study was reported with reference to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [6].

Results

In total, 2482 titles and abstracts were screened, and 231 potentially relevant studies were examined in detail (Fig. 1). Sixty-eight randomised trials, reporting data from 10,499 participants, met the inclusion criteria (Table 1) [5, 10–88]. Additionally, 12 randomised trials published long-term follow-up data [5, 22, 29, 39, 40, 64, 71, 72, 79, 81, 86, 87].

| Outcome domains                        | RCTs reporting on the domain | Outcomes reported | Outcome measures reported |
|----------------------------------------|-----------------------------|-------------------|--------------------------|
| Presence of symptoms posttreatment     | 50                          | 28                | 28                       |
| Prolapse treatment success rate        | 47                          | 3                 | 16                       |
| Perioperative complications and         | 46                          | 15                | 13                       |
| observations                           |                             |                   |                          |
| Quality of life and satisfaction with  | 40                          | 5                 | 25                       |
| treatment                               |                             |                   |                          |
| Treatment success evaluation           | 15                          | 11                | –                        |
| Postoperative catheterisation          | 10                          | 17                | 10                       |
| Pain                                   | 9                           | 4                 | 7                        |
| Mesh-related outcomes                  | 8                           | 3                 | –                        |

RCT randomised controlled trial

Trials were published between 1985 and 2017, with most being published in subspecialty journals (33/80; 41%). Trials were frequently published in journals with an impact factor <3 [median = 2.7; interquartile range (IQR) = 2.2–4.3] and were generally small (median = 93; IQR = 60–154). Ten trials (14%) declared commercial funding. The methodological quality and outcome reporting quality varied considerably between trials (Table 1). One hundred different outcomes were organised into 11 thematic domains. The three most commonly reported thematic domains were presence of symptoms posttreatment (50 trials, 28 outcomes; 28 outcome measures), prolapse treatment success rates (47 trials; 3 outcomes; 16 outcome measures) and perioperative complications (46 trials; 15 outcomes; 13 outcome measures) (Table 2). Commonly reported outcomes were anatomical prolapse stage (43 trials; 54%), commonly assessed using the Pelvic Organ Prolapse Quantification (POP-Q) instrument (35 trials; 81%), QoL (25 trials; 31%); and intra- and postoperative complications (23 trials; 29%). Patient-reported outcomes were infrequently reported; for example, a minority of trials reported prolapse symptoms (9 trials; 11%), urinary symptoms (11 trials; 14%) and sexual dysfunction (14 trials; 17%) (Table 3). Eleven trials (14%) reported patient satisfaction.

Forty-two randomised trials compared native tissue or biological graft versus mesh repair for anterior vaginal prolapse. Mesh-related complications were rarely reported: seven trials (9%) reported mesh erosion, six (7%) reported mesh shrinkage and a single trial (1%) reported the degree of morbidity associated with mesh. Only three trials (4%) evaluated cost effectiveness. One hundred and twelve different outcome measures were reported (Table 4). Forty-six questionnaires were used as measurement instruments, most of which were validated (45; 98%). Anterior prolapse symptoms were measured using the Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ-12) (13 trials; 16%), Urogenital Distress Inventory (UDI-6) (11 trials; 14%) and the Pelvic Floor Distress Inventory...
Table 3 Outcomes reported in 80 randomised controlled trials (RCTs) evaluating surgical management of anterior-compartment prolapse

| Outcomes                                                                 | Reporting studies |
|--------------------------------------------------------------------------|-------------------|
| Prolapse treatment success rate                                           |                   |
| Anatomical prolapse stage                                                | 43                |
| Composite anatomical/functional success rate                              | 3                 |
| Urethral mobility                                                         | 1                 |
| Perioperative complications and observations                             |                   |
| Complications intra-/postoperatively                                     | 23                |
| Postoperative hospital stay length                                        | 11                |
| Blood loss intraoperatively                                               | 6                 |
| Duration of operation                                                    | 6                 |
| Quality and time of recovery                                             | 4                 |
| Postoperative nausea and vomiting                                        | 3                 |
| Bleeding postoperatively (with/out vaginal pack use)                      | 2                 |
| Constipation preoperatively                                               | 2                 |
| Blood pressure                                                           | 2                 |
| Blood transfusion indicated                                               | 2                 |
| Heart rate change                                                        | 2                 |
| Consistency of bowel movement postoperatively                            | 1                 |
| Intra- and postoperative morbidity                                       | 1                 |
| Time to first postoperative bowel movement                               | 1                 |
| Time to mobilisation                                                     | 1                 |
| Pain                                                                     |                   |
| Postoperative pain                                                       | 8                 |
| Intraoperative requirement of analgesics                                  | 1                 |
| Total analgesic consumption                                              | 1                 |
| Pain level associated with first postoperative bowel movement            | 1                 |
| Postoperative catheterisation                                            |                   |
| Postoperative UTI                                                        | 5                 |
| Recatheterisation rates                                                  | 5                 |
| Postoperative catheterisation duration                                   | 4                 |
| First postvoid residual volume                                           | 4                 |
| Time to normal spontaneous voiding                                       | 2                 |
| Acute urinary retention                                                  | 1                 |
| Bacterial count in the urine                                             | 1                 |
| Catheter blockage                                                        | 1                 |
| Day of spontaneous voiding                                               | 1                 |
| Diagnostic accuracy of different voiding trial methods                   | 1                 |
| Mean residual urine volume pre- and postoperatively                      | 1                 |
| Prediction of voiding dysfunction lasting >7 days.                        | 1                 |
| Prolonged catheterisation                                                | 1                 |
| Pyelectasia                                                              | 1                 |
| Residual urine volume                                                    | 1                 |
| Urinary retention prevention with intravesically administered prostaglandin-E2 | 1              |
| Urinary retention rates                                                  | 1                 |
| Postoperative vaginal packing                                            |                   |
| Bleeding postoperatively (with/out vaginal pack use) (compared with menstrual average) | 1 |

Table 3 (continued)

| Outcomes                                                                 | Reporting studies |
|--------------------------------------------------------------------------|-------------------|
| Bleeding postoperatively (with/out vaginal pack use)                     | 1                 |
| Presence of vaginal haematoma                                            | 1                 |
| Presence of vaginal infection                                            | 1                 |
| Bother related to the pack                                               | 1                 |
| Presence of symptoms posttreatment                                       |                   |
| Sexual dysfunction symptoms                                              | 14                |
| Urinary symptoms                                                         | 11                |
| Prolapse symptoms postoperatively                                        | 9                 |
| Dyspareunia                                                              | 6                 |
| SUI postoperatively                                                      | 5                 |
| De novo SUI postoperatively                                              | 4                 |
| Change in urinary symptoms (any)                                         | 3                 |
| Prolapse symptoms severity                                               | 3                 |
| De novo urinary urgency                                                  | 2                 |
| Postoperative urinary symptoms                                           | 2                 |
| Urinary symptoms severity                                                | 2                 |
| Bowel symptoms                                                           | 2                 |
| Facal incontinence                                                       | 2                 |
| Postoperative bowel symptoms                                             | 2                 |
| Change in incontinence rates                                             | 1                 |
| De novo urinary symptoms                                                 | 1                 |
| De novo voiding difficulty                                               | 1                 |
| Urgency and urge urinary incontinence                                    | 1                 |
| Worsening urinary symptoms (any)                                         | 1                 |
| Obstructed defecation                                                    | 1                 |
| Back pain improvement                                                    | 1                 |
| Change in a pelvic symptom score                                         | 1                 |
| Change of vaginal symptoms                                               | 1                 |
| Symptomatic prolapse improvement                                         | 1                 |
| Time of prolapse recurrence                                              | 1                 |
| De novo dyspareunia                                                      | 1                 |
| Sexual function in partner                                               | 1                 |
| QoL and satisfaction with treatment                                      | 25                |
| QoL. and impact from symptoms evaluation                                 |                   |
| Patient satisfaction with treatment                                      | 11                |
| Surgeon satisfaction with operation                                      | 2                 |
| Patient acceptability of preoperative bowel preparation                  | 1                 |
| Surgeon—ease of procedure                                                | 1                 |
| Treatment success evaluation                                             |                   |
| Symptoms—presence posttreatment                                          | 5                 |
| Subjective cure rates                                                    | 3                 |
| Cure of SUI postoperatively                                              | 3                 |
| Reoperation rates                                                        | 3                 |
| Symptoms—bother change                                                  | 2                 |
| Retreatment success rates                                                | 1                 |
| Symptom improvement                                                      | 1                 |
| Functional recurrence                                                    | 1                 |
| Healing abnormalities                                                    | 1                 |
Table 3 (continued)

| Outcomes                                                                 | Reporting studies |
|--------------------------------------------------------------------------|-------------------|
| Need for subsequent anti-incontinence surgery                            | 1                 |
| Treatment of overactive bladder                                         | 1                 |
| Mesh-related outcomes                                                    |                   |
| Mesh erosion                                                             | 6                 |
| Mesh shrinkage                                                           | 2                 |
| Degree of morbidity in mesh vs. native tissue                           | 1                 |
| Cost/effectiveness                                                       |                   |
| Cost-effectiveness of treatment                                          | 2                 |
| Cost of procedure                                                        | 1                 |
| Recruitment feasibility                                                  |                   |
| Number of patients agreed to participate                                 | 1                 |
| Number of eligible patients                                              | 1                 |
| Physician acceptance and protocol                                        | 1                 |
| Rate of recruitment compliance                                           | 1                 |

UTI urinary tract infection, SUI stress urinary incontinence, QoL quality of life

(PFDI-20) (9 trials; 11%), QoL was measured using the Prolapse Quality of Life (P-QoL) (10 trials; 12%), Pelvic Floor Impact Questionnaire Short Form (PFIQ-7) (8 trials; 10%) and the Incontinence Impact Questionnaire Short Form (IIQ-7) (6 trials; 7%). Table 5 summarises our main findings, demonstrating the most frequently reported outcomes. It reveals the significant discrepancies in terms of outcome reporting.

We observed a moderate correlation between outcome reporting quality and year of publication in the univariate analysis ($r = 0.458; p < .001$) and study quality ($r = 0.409; p < .001$) (Table 6). The latter index significantly affected outcome reporting in the multivariate logistic regression ($\beta = 0.412; p = .018$).

**Discussion**

**Summary of main findings**

This study demonstrated considerable variation in outcome and outcome-measure reporting across published trials evaluating surgical interventions for anterior-compartment prolapse. Commonly reported outcomes included normalised anatomy, QoL and pain. Patient-reported outcomes were infrequently reported, and a minority of trials reported on patient satisfaction. Mesh-related complications, including erosion, shrinkage and morbidity, were rarely reported. Forty-five different questionnaires were used as measurement instruments; most were validated. Only a few trials considered cost effectiveness.
### Strengths and limitations

Strengths of our systematic review include originality, a rigorous search strategy and methodological robustness. To our
Table 5  Reported outcomes by by more than eight studies with greater than 93 participants (median value)

| Study              | Sample size (N) | Outcomes                                      |
|--------------------|-----------------|-----------------------------------------------|
|                    |                 | Anatomical prolapse stage | Quality of life and impact from symptoms | Complications intra-/postoperatively | Sexual dysfunction symptoms | Postoperative hospital stay length | Urinary symptoms | Patient satisfaction with treatment | Prolapse symptoms postoperatively | Postoperative pain |
| Glazener et al.    | 1352            | x | x | x | x | x | x |
| Altman et al.      | 389             | x | x | x | x |
| Wei et al.         | 337             | x | x |
| Weemhoff et al.    | 246             | x | x | x |
| Nieminen et al.    | 203             | x | x | x |
| Hiltunen et al.    | 202             | x | x | x |
| Farthmann et al.   | 200             | x | x | x | x |
| Kamilya et al.     | 200             | x | x |
| Withagen et al.    | 194             | x | x | x | x | x |
| Natale et al.      | 190             | x | x |
| Thiaagamoonthy et al. | 190         | x | x |
| da Silveira et al. | 184             | x | x | x |
| Borstad et al.     | 184             | x | x |
| Van et al.         | 179             | x | x |
| Sand et al.        | 161             | x | x | x |
| Rudnicki et al.    | 160             | x | x | x |
| Gandhi et al.      | 154             | x | x |
| Ballard et al.     | 150             | x | x | x | x |
| de Tayrac et al.   | 147             | x | x | x | x |
| Carey et al.       | 139             | x | x | x | x |
| Rudnicki et al.    | 138             | x | x | x | x |
| Dahlgren et al.    | 135             | x | x | x | x | x |
| Stekkinger et al.  | 126             | x | x | x |
| Vollebregt et al.  | 125             | x | x | x | x |
| Qatawneh et al.    | 116             | x | x | x | x | x |
| Weber et al.       | 114             | x | x |
| Chmielewski et al. | 114             | x | x |
| Gupta et al.       | 106             | x | x |
| Tamanini et al.    | 100             | x | x | x | x | x |
| Hakvoort           | 100             | x | x | x | x | x |
| Menefee et al.     | 99              | x | x | x | x | x |
| Ek et al.          | 99              | x | x | x | x | x |
knowledge, this systematic review is the first to evaluate outcomes and outcome measures in anterior-compartment prolapse trials. Study screening and selection and data extraction and assessment were conducted independently by two researchers to avoid bias. Our findings were based on outcome reporting in published randomised trials. The exclusion of observational studies may have potentially missed outcomes related to harm [89, 90] and selecting only trials reported in English may have introduced selection bias. The variation of interventions for correcting anterior prolapse may have caused variation in outcome and outcome-measure reporting.

**Interpretation**

Randomised trials require a substantial investment of resources. Variation in outcomes and outcome measures limits the ability of trials to be combined with meta-analyses, which contributes to inevitable research waste, as identified in various areas of women’s health, including childbirth trauma, endometriosis and pre-eclampsia [91–94]. This systematic review is the first step in the development of a minimum data set, which will be known as a core outcome set. It will be developed with reference to methods described by the COMET initiative, Core Outcomes in Women’s and Newborn Health (CROWN) initiative and other core-outcome-set development studies, including those on endometriosis, pre-eclampsia, termination of pregnancy, Twin-Twin Transfusion Syndrome and neonatal medicine [95–99].

CHORUS is aiming to work towards a standardisation of outcomes and outcome measures and subsequently establish a minimum of standards in research and clinical practice. Chorus working groups are currently evaluating reported outcomes in all areas of urogynaecology and have been registered with the COMET (registration number 981, http://www.comet-initiative.org/studies/details/981) and CROWN initiatives. Each working group has carefully considered the scope of its work [100], and CHORUS will replicate the

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**Table 5** (continued)

| Study | Sample size (N) | Outcomes | Study Sample size (N) | Outcomes | Study Sample size (N) |
|-------|----------------|----------|-----------------------|----------|-----------------------|
| Guerette et al. | 94 | x | | | |
| Westermann et al. | <93 | x | | | |
| Studies not included | | | | | |
| Total studies | 43 | 25 | 11 | 9 | 8 |

**Table 6** Univariate and multivariate correlation with outcome reporting quality

| Factor | Univariate | Multivariate |
|--------|------------|--------------|
|        | Spearman’s rho | P value | Beta | P value |
| Study quality (Jadad) | 0.409 | <0.001 | 0.412 | 0.018 |
| Journal IF | 0.053 | 0.643 | 0.078 | 0.306 |
| Year of publication | 0.458 | <0.001 | 0.149 | 0.295 |
| Study size | 0.215 | 0.051 | 0.008 | 0.961 |
| Journal type | – | – | 0.024 | 0.852 |
| Commercial funding | – | – | –0.013 | 0.918 |
| Validated questionnaire | – | – | 1.310 | 0.196 |

Bolded data statistically significant
success of other international initiatives that have standarised outcome selection, collection and reporting across preterm birth research [101].

In the absence of a core outcome, we recommend QoL (incorporating sexual function), postoperative complications, patient and physician satisfaction and postoperative prolapse, bladder and bowel symptoms be collected across all anterior prolapse trials.

Conclusion
Anterior-compartment 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.

Compliance with ethical standards

Conflicts of interest The authors report that they have no conflicts of interest.

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