AN INTERNATIONAL UROGYNECOLOGICAL ASSOCIATION (IUGA)/ INTERNATIONAL CONTINENCE SOCIETY (ICS) JOINT REPORT ON THE TERMINOLOGY FOR REPORTING OUTCOMES OF SURGICAL PROCEDURES FOR PELVIC ORGAN PROLAPSE

Version 17

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Abstract

Introduction and hypothesis. A formal terminology has yet to be developed for reporting the outcomes for surgery for pelvic organ prolapse.

Methods This report on the above terminology combines the input of members of the Terminology and Standardisations Committees of 2 International Organisations, the International Continence Society (ICS) and the International Urogynecology Association (IUGA) and a joint Working Group on this topic, assisted by many expert external referees. An extensive process involved 17 versions and 6 collations prior to open to review on both IUGA and ICS websites to allow members 6 weeks to submit comments and recommendations which have enabled appropriate revisions.

Results. A terminology report to standardise reporting of outcomes from pelvic organ prolapse has been developed. The report concentrates on the definitions of outcome in primary and repeat surgery. In addition emphasis is made regarding patient reported outcomes which will enable researchers to report on the clinically meaningful results of surgery.

Conclusions A consensus based method for standardising terminology for reporting outcome measures of prolapse surgery has been developed as an aid to clinicians working in this area of research.

Key Words

Terminology, outcomes, surgical procedures, pelvic organ prolapsed, female pelvic floor dysfunction.

Preface

The aim of this report is to present a standardised terminology for the definitions of surgery and propose a structure for reporting the outcomes of surgical procedures for pelvic organ prolapse (POP). The document does not define success and failure, but outlines the structure that is recommended for reporting outcomes of surgical trials involving POP. The report includes patient-reported, subjective and objective outcomes and should be used in conjunction with the IUGA/ICS reports on the terminology for female pelvic floor

dysfunction, and the classification of the complications related to the insertion of prostheses and grafts and native tissue[1,2,3].

The first aim is to standardise the terminology used in this classification.

The word outcome is defined in the Oxford English dictionary[4] as [N] the way a thing turns out; a consequence: *it is the outcome of the vote that counts*

Introduction

Whilst recommendations for reporting outcomes of surgery for stress urinary incontinence have been reported[5,6], few exist for surgery of pelvic organ prolapse (POP).

The first attempt to quantify re-operation rates in women undergoing prolapse surgery was by Olsen et al[7]. This paper assessed both incontinence and prolapse surgery and the lifetime risk of requiring surgery was 11% with 29% requiring further surgery. If prolapse surgery alone was considered the lifetime risk was 6.7%. The definition of repeat surgery was any operation for prolapse or urinary incontinence following an index procedure, often some years previously. Whilst this paper is still commonly quoted, the failure to adjust for both time and variation in operative site, reduces the usefulness of the conclusions and might be misleading with regards to the true failure rate of POP surgery. This observation is borne out, when the same cohort was reviewed 10 years later with the authors[8] quoting a 17% re-operation rate. On further analysis of same compartment recurrence i.e. repeat anterior repair, the re-operation rate was significantly lower at 4.6%[9].

More recently several investigators have looked specifically at the issue of site specific recurrence with re-operation rates ranging from 2.8-9.7%[10,11,12]

In 2001 Weber et al[13] reported a 58 to 70% failure rate for anterior colporraphy. This study has been subject to further analysis as the definitions of objective success and failure were based on POPQ changes of small magnitude. It has been shown that when more clinically relevant criteria for success are used (i.e. anatomic recurrence beyond the hymen, symptomatic recurrence and re-operation), that outcome is considerably better with only 10% of subjects developing anatomic recurrence beyond the hymen, 5% developing symptomatic recurrence and re-operations less than 1% (at 23 months follow-up)[14].

A recent article looking at vault suspension suggested that re-operation rates after POP surgery which includes suspension of the apex are 1.3 to 3.9% at 17 to 32 months depending upon the type of vault suspension[15]. These data become more useful in terms of site and timescales.

The lack of subjective/patient-reported outcome measures in many studies was highlighted in a systematic review on mesh repairs commissioned by the National Institute for Clinical Excellence (NICE)[16] in the UK[17]. As a consequence of this and the uncertainty following further consideration of the Olsen and Weber[7,13] data, there is clearly a need for standardisation of outcome measures for pelvic organ prolapse surgery .

New Definitions

It is understood that there is close interaction among all three commonly defined compartments (apical/ vault, anterior and posterior) when discussing pelvic organ support or prolapse. However, for ease of use the definitions are limited to ‘primary’ or ‘recurrence at specific sites’ defined as apical/vault, anterior and posterior.

As our understanding of how these various compartments interact improves, the definitions of 'primary prolapse surgery/different site' and 'repeat surgery/same site' will evolve.

The nomenclature is proposed as standardised terminology for surgical trials and audit.

Primary surgery for POP is the first procedure required for the treatment of POP in any compartment

Further surgery[a] This gives a global figure for the number of subsequent procedures the patient undergoes directly or indirectly relating to the primary surgery. This is subdivided into:

a. Primary prolapse surgery/different site. A prolapse procedure in a new site/compartment following previous surgery in a different compartment (e.g. anterior repair following previous posterior repair).

b. Repeat surgery: is a repeat operation for prolapse arising from the same site.

Where combinations of procedures arise, e.g. new anterior repair plus further posterior repair these should be reported separately i.e. repeat posterior repair and primary anterior repair.

c. Surgery for Complications: e.g. mesh exposure or extrusion or pain or patient compromise e.g. haemorrhage (see complications section)

d. Surgery for non-prolapse related conditions e.g. subsequent surgery for stress urinary incontinence or faecal incontinence.

[a] Further surgery should not be interpreted as a measure or failure as the definitions of success and failure will be defined within the context of the individual study

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143 Reporting Outcomes

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145 One of the major difficulties in reporting the results of prolapse surgery is that, unlike most
146 other surgeries, there is a range of outcomes which are not reported in a consistent
147 manner; this makes assessment of procedures difficult.

148 The International Consultation on Incontinence (ICI) has already suggested that POP and
149 Urinary Incontinence surgery should report subjective, objective and quality of life
150 outcomes5. The importance of this is that there are then a number of measures that can
151 be used to generate useful information to benchmark practice for and against a particular
152 procedure and also inform patients about potential outcomes.

153

154 In terms of clinical research studies, entry criteria, design, methodology, power and absence
155 of bias assessment are important in allowing the reader to assess the reliability of the
156 findings with regards to changing practice. There are already accepted standards for study
157 design and reporting of RCT's including (but not limited to) the CONSORT[b] guidelines[18],
158 Moose[19] and STARD[20]. Researchers should quote which standard they adopt and reference
159 accordingly.

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[b] CONSORT requires detailed information provided by authors to reviewers. This is not always possible because many authors fail to provide complete descriptions of critical information. The frustration of trying to accurately evaluate systematic reviews and meta-analyses has led to a new instrument named PRISMA, which stands for 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses'. The aim of the PRISMA statement is to give authors an evidence-based minimum set of items to improve the reporting of systematic reviews and meta-analyses in POP issues.
PRISMA statement. Available at: http://www.prisma-statement. org/.

Until now few studies have provided data on patients' pre-operative goals and expectations [21,22,23,24]. These might have significant advantages over objective measures of outcome. With this in mind goals should be reported using SMART criteria[25]. This acronym stands for:-

Specific	e.g. defining goal (for POP, absence of bulge)
Measureable	e.g. validated symptom scale (e.g. POP-SS or ICIQ-VS or EPAQ) or objective measure e.g. POPQ
Appropriate	e.g. relevant to improving patient lifestyle
Realistic	e.g. achievable by treatment
Timely	e.g. at six months/2 years

So examples for POP surgery would be:-

(i) The absence of bother from a vaginal bulge as defined using the EPAQ score at 2 years. This is specific in absence of a bulge, measurable in terms of a binary question, appropriate as relevant to the surgery, realistic as a surgical outcome and timely at 2 years

(ii) Physical objective: Resumed exercise as defined by resuming low impact excercise without recurrence of bothersome/limiting symptoms by 6 months. Likewise this is specific in terms of defined outcome (resumed exercise), again measurable with a binary question, appropriate and realistic with a timeline.

(iii) Resumption of normal bowel movements as defined by ability to evacuate without digitation maintained at 2 years post surgery. Again this is a specific target ability to

evacuate bowels without digitation, which is realistic and appropriate and measureable with a binary question or bowel questionnaire with an appropriate timeline

Outcomes

The following data should be reported following surgical treatment of pelvic organ prolapse.

1. Perioperative data: Blood loss (mls) and or haemoglobin change, operating time, inpatient stay, return to usual activities of daily living, complications (see below).

2. Patient reported outcomes: The primary reported outcome would be the absence of a bulge, e.g. as determined from a validated symptom scale.
3. Satisfaction: Using qualitative measures such as a patient defined measure or a validated instrument
4. Quality of life Using an appropriately validated questionnaire for the population being studied. (see ICI and ICIQ)[26]
5. Objective outcomes (e.g. POPQ or simplified POPQ)[27,28,29]
    a. These should be tabulated with percentages achieving each level to again allow studies to compare results as definitions of success will vary from study to study.

6. Further surgery

a. As per definitions above

7. Economic evaluation/cost analysis. See below.

8. Complications Complications specifically related to mesh and native tissue should be reported as per the IUGA/ICS classification of complications directly related to the insertion of prostheses and grafts and native tissue in female pelvic floor surgery [2].

Patient reported outcomes (Subjective outcomes).

- The primary outcome should be subjective and would usually be the absence of a bulge. This can be regarded as a 'subjective cure[30] . This can be recorded as part of a symptom scale up to date details of validated questionnaires can be found on the ICI website.

  To make this fit with the SMART criteria this should be defined at a specific time interval and classified on a 7-point Likert scale (much better, slightly better, no change, slightly worse, much worse) e.g. the patient global impression of improvement (PGI-I)[31] (see below).

- Satisfaction.

  The patient global impression of improvement (PGI-I)[31] should be reported as a 7 - point scale.

  Qualitative assessment. This could include the acronym EGGS[32] or an assessment of goal achievement. Again these should be SMART. The number of pre-specified goals

should be recorded and the number achieved post-operatively also reported for responsiveness and reliability of goal achievement[21].

- Secondary outcomes should include an assessment of the following:

  Other symptoms known to be associated with prolapse e.g.

  Backache

  LUTS e.g. overactive bladder, stress urinary incontinence (either pre-existing or de-novo), voiding difficulty.

  Bowel dysfunction e.g. obstructed defecation, feeling of incomplete emptying, constipation and digitation.

  Sexual dysfunction e.g. dyspareunia, loss of libido, abstinence due to prolapse symptoms, change in sexual satisfaction.

  De novo/new onset symptoms e.g. LUTS, sexual dysfunction, pain, bowel dysfunction.

Objective outcomes. These should include pre- and post-operative assessment with a timeline for changes. The recommended method of the ICS and IUGA is the POP-Q[33] or simplified POP-Q[29].

Authors should report the site of the leading edge of the prolapse in a table form giving the percentages of patients achieving different points. This will then allow comparison of objective results between studies[c]. Alternatively, the Weber et al classification[34] can be used.

Quality of Life. Appropriate and fully validated quality of life instruments should be used such to cover prolapse, urinary, bowel and sexual function[26]. New questionnaires can be included when they have demonstrated good psychometric properties (i.e. validity, reliability and responsiveness) in women with pelvic organ prolapse

Timelines for Further Surgery

This should be described using the classification above and described chronologically as below. Readers should note these timescales are different to those in the mesh complications report (1) i.e.

Very early (up to 3 months)

Early (up to one year)

Intermediate (12-36 months)

Late (3-5 years)

Very late (greater than 5 years)

[c] With the advent of electronic publishing authors may be able to include several tables outlining this over and above the details included in any paper publication

Cost Analysis

Despite considerable cost, a sparsity of cost-effectiveness data exist on prolapse surgery. Investigators are encouraged to include economic analyses in their studies whenever possible.

Economic evaluation techniques provide systematic ways to compare the costs and consequences of clinical and other health sector interventions. Cost-utility analysis (CUA)—a form of cost-effectiveness analysis (CEA)—is by far the most commonly-used and requires one to quantify the effects of interventions on morbidity and mortality. In a CUA, benefits are measured in physical units (e.g., quality-adjusted life-years (QALYs) and costs are monetized to create a ratio of costs to consequences (e.g., "cost per QALY saved"). QALY's are usually calculated through a validated general quality of life outcome such as SF-36 or EQ-5D or by other measures of utility like the standard gamble or time-trade off technique . These ratios enable one to compare competing interventions on the basis of the cost at which they create improvements in health-related quality-of-life. CUA is particularly useful when two interventions create different health and longevity profiles (e.g., Drug A results in superior clinical results and also greater costs than Drug B). If it is known that the health consequences of two interventions are clinically equivalent in QoL outcomes, a cost-minimisation analysis (CMA) as performed above is an appropriate analytical approach.

Economic analyses should attempt to quantify both direct and indirect costs. Direct medical costs should include personnel costs/time (physician, nurse, technician), diagnostic and laboratory tests, hospital costs, treatment costs (drugs, operating room time, etc.), treatment of side effects, and outpatient visits. Indirect costs are often more difficult to quantify but should include e.g. loss of productivity, time lost from work, loss of service to family and community, and premature mortality. In economic evaluations, it is important to consider the

perspective of the evaluation, as the perspective (e.g., patients, hospital, third-party payer, government, society) will have significant influence on which costs should be included in the analysis.

Complications of surgery

These need to be classified as intra-operative, post operative and generic.

Intra-operative

- Visceral injury (bladder/bowel)
- Nerve injury
- Unscheduled additional procedure (eg oopherectomy at vaginal hysterectomy for whatever reason e.g. haemorrhage)
- haemorrhage

Post operative

- Urinary retention
- De novo urinary incontinence
- Fistula
- Haematoma
- Dyspareunia
- Urinary tract infection
- Constipation/bowel dysfunction

- Pelvic infection/abscess
- Pain
- Sinus
- Haemorrhage
- DVT/ PE

Generic

The Dindo classification[35], consists of 4 severity grades of complications. This has been modified to include a fifth category [36]

The Clavien-Dindo Complication Classification:

Grade I: requires no treatment

Grade II: requires drug therapy

Grade III: requires a procedure or intervention (a: in local; b: general anesthesia)

Grade IV: IC/ICU organ or system dysfunction (a: single organ; b: multi-organ dysfunction)

Grade V: death

Major complications should be recorded and include:

- Haemorrhage requiring blood transfusion
- Return to theatre/Operating room within 72 hours of surgery, return to hospital within 30 days for procedure related event, return to theatre within 30 days for procedure related event.

- Severe infection requiring prolonged admission or additional intravenous antibiotics

- Long- term complications causing disruption to quality of life and/or impairment of normal physical or mental functioning

Pain is classified separately and dealt with in a separate report for the classification of prostheses (mesh, implants, tapes) complications[2] . As in the native tissue classification[3] there is a categorical description of complications with a numerical value referring to the description and an alphabetical classification describing symptoms. This classification has a C value for category, T for time and S for site. Additional information on pain may include permanent or temporary and severity as measured by impact on quality of life (which may be descriptive or QoL based) and treatment required (e.g. simple oral analgesia, compound analgesia, opiates, referral and management by pain team)

DISCUSSION

New surgical procedures for POP reconstructive surgery have evolved dramatically over the last 15 years suggesting that the perceived dissatisfaction with conventional/traditional surgery as expressed by White[37] at the turn of the twentieth century persists. This

perception is based on clinical experience and reports of anatomical failure and re-operation[7,13]. As the interpretations of these findings have been questioned by more recent studies, there is an urgent need for a standardised method of reporting surgical outcomes so that appropriate success and failure rates can be reported.

This document has been borne from the recognition that contemporary practice lacks sufficient reproducible evidence to help clinicians translate findings into clinical practice and enable patients to be aware of likely outcomes.

The assessment of prolapse surgery has been subject to a number of limitations. Firstly and perhaps most importantly is the quality of studies with most being case series with very few properly constructed (and powered) RCT's. As a result the quality of the available evidence is lacking. The emphasis then lies within systematic reviews and meta-analyses which may be less robust due to the lack of good quality data.

It can be argued that new procedures have been introduced despite a lack of evidence of poor outcomes from traditional/conventional surgery. Such procedures are often introduced in a less regulated manner than for new drug therapies[38] .

This report sets out to provide a framework through which researchers and clinicians can standardise reporting and allow results to become more transferable.

History has taught us that surgical complications (particularly in the case of implants) may be long term and researchers should be encouraged to revisit early (e.g. 1 year) results and include long term data of 5-10 years.

The Austrian and Finnish experiences with mid-urethral slings e.g. TVT have demonstrated that in addition to properly constructed prospective trials that there is a moral and ethical responsibility for users of advanced techniques such as those employing implants, to contribute to clinical governance and audit through local, regional or national databases.

Summary of recommendations for POP surgical outcomes

In all surgical t*rials of POP surgery authors should report*:

Methods, CONSORT and type of surgery (primary or further using the agreed definitions). The table below also outlines what should be reported in audit of clinical practice and surgical trials. In addition researchers should give a commitment in the original trial design and at publication of early results, to publish longer term data at a minimum of 5 years.

	Clinical	Research
Type of surgery	R	R
Primary outcome including patient satisfaction	R	R
Secondary outcomes	O	R
Timelines	O	R
Cost analysis	N	R
Complications Commitment to longer term follow up	R O	R R
cost analysis	O	O

R= Routine O=optional N=not required

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415 This has been through 18 versions and 6 collations prior to open to review on both IUGA
416 and ICS websites to allow members 4 weeks to submit comments and recommendations
417 which have enabled appropriate revisions.

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