Quality of Life and Symptom Assessment in Routine Urogynaecological Practice
Workshop 37
Tuesday 24 August 2010, 14:00 – 17:00

Time	Time	Topic	Speaker
14:00	14:10	Welcome, Introduction and objectives	Philip Toozs Hobson
14:10	14:35	Principles of psychometrics, acceptability & utility of questionnaires; The virtual urogynaecology clinic	Stephen Radley
14:35	15:00	Questionnaires as clinical tools;The assessment of patients with prolapse, incontinence & sexual dysfunction in practice	Swati Jha
15:00	15:25	Questionnaires as outcomes measures in urogynaecology ; Measuring outcome following intervention for prolapse & incontinence	Fiona Reid
15:25	15:40	Coffee break	
15:40	16:05	Patient oriented goals; What do we mean by success?	Dudley Robinson
16:05	16:30	Using questionnaires in a Urogynaecology MDT; Electronic bladder diaries	Philip Toozs Hobson
16:30	16:55	Panel discussion / Q&A / Case studies	All
16:55	17:00	Round up and conclusions	Philip Toozs Hobson

Aims of course/workshop

1. To understand the principles of psychometrics: Instrument design, development, validation & terminology used in this field.
2. To examine differences between patient centred outcomes, objective measurement of QoL & other conventional methods used in health care.
3. To understand the practical & ethical issues surrounding HR QoLmeasurement in day-to-day practice, including the feasibility, clinical utility & impact of using questionnaires & electronic interviewing as well as issues surrounding the storage, interpretation & data protection.
4. To explore the potential applications of questionnaires in urogynaecology, including, psychological profiling, on-line assessment, virtual clinics, long-term monitoring and self-help. *Insert broad aims of workshop here*

Educational Objectives

1. To learn the principles of QoL design & validation & psychometric testing (validity, reliability & responsiveness). The ICI, King's, BFLUTS, e-PAQ instruments are reviewed as well as generic QoL tools (SF-36 & SF-12).
2. To understand different aspects of QoL including respondent burden, clinical utility, feasibility, data protection & assessing impact on patient care
3. To discuss the role of differing outcome measures such as Patient related outcomes (PROM's), health screening, clinical assessment, electronic interviewing, audit, service

evaluation, cost effectiveness, impact, cost, data protection & data handling, internet & web-based interviewing. Patient consent, ethical issues relating to use of data for non-clinical purposes (service evaluation, audit & clinical governance).
4. To understand the wider applications in pelvic floor medicine, including psychological profiling of patients, virtual clinics, self-assessment & self-help, ethical, medico-legal & practical issues of such developments will be addressed. Data on using electronic bladder diaries will also be presented. Ample panel discussuion time is included.

Principles of Psychometrics

Stephen Radley

Talk 1

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Measuring HRQoL in practice

2 distinct applications:

(1) Evaluation of outcome
- Research, audit & Service evaluation
- Governance, appraisal & revalidation

(2) Assessment of patients
- Diagnosis & monitoring
- Symptom assessment & analysis
- Communication, standardisation & documentation

What is a questionnaire?

- Often referred to as instruments / tools
- Elicit information through written responses
- Developed from the social sciences
- Structured format

Traditional evaluation of medical care

- Clinical measures of outcome
  - Mortality and morbidity (e.g. complication) rates
  - Laboratory and radiological tests
  - Case note data
- 'Physical' criteria – easy to measure
- Focus on 'quantity' of life rather than 'quality'

Key characteristics of any test or measure… (e.g. Urodynamics)

Sensitivity: false –ve (Poor for OAB)

Specificity: false +ve (Poor for OAB & Voiding)

Reliability: stability (Poor for detrusor function)

Validity: robustness & relevance (Not valid for prolapse)

Acceptability: utility & feasibility (Discomfort, fear, UTI)

Cost: value (Manpower, equipment, time & delay)

Reasons for change

- Recognition that perspectives of health and illness not purely dependent on observable physical parameters
- Diagnosis & monitoring of most conditions demands accurate measure of symptoms

Health

"A state of complete physical mental and social well being and not merely the absence of disease or infirmity"

(World Health Organisation 1954)

Problems with objective judgements

- Judgments by clinicians often based on intuition and personal experience

  (Jenkinson, 1997)

- Show variations and low levels of agreement amongst doctors

  (Wigton, 1988)

What are the problems with the clinical interview?

Information obtained can be unreliable

Assessments patients make about their health differ to reports made by clinician (Fitzpatrick, 1994)

Estimates of HRQoL only reliable if given by the patient (Woodend et al 1997, Present et al 1993, Slevin et al 1988)

Barriers to disclosure

- Information is of a sensitive and personal nature
  - particularly relevant in urogynae: taboo embarrassing nature of symptoms
- Power relationship between the patient and doctor prevents full disclosure of information
  - the 'halo' effect.

Benefits of questionnaires

- Evaluate a patient's well-being / outcome of treatment in a more systematic way
- Can provide information on the physical, mental and social well-being of the patient
- Can remove some of the embarrassment from the clinical interview

Types of questionnaire

- Generic: Can be used for any disease / condition
  - SF-36, Nottingham Health Profile
- Disease / condition - specific: Designed to measure health status for the disease for which they have been developed. Items should reflect patient's experience of illness with that disease or condition
  - Kings Health Questionnaire (KHQ), ICI-Q, ePAQ

What makes a good questionnaire for practice?

- Clinically useful
- Developed using good methodology

3 stages

- Item generation
- Item reduction / scale generation
- Psychometric testing

What makes a questionnaire clinically useful?

- Easy to use in clinical practice
  Quick and easy to administer and analyse (electronic methods)
- Detects changes if they exist
- Cost effective
- Meaningful clinical scales

Key characteristics of a test…

(e.g. Urodynamics)

Sensitivity (false -ve) Poor for OAB

Specificity (false +ve) Poor for OAB & Voiding

Reliability (stability) Poor for detrusor function

Validity (robustness & relevance) Prolapse

Acceptability (utility & feasibility) Discomfort,UTI

Cost (value) Manpower, equipment, patient time

Basic principles of psychometrics

- Reliable
- Valid
- Sensitive to change or 'responsive': i.e. will detect changes in health status if they exist!

(Kline 1986, Nunnally 1978).

Validity

The extent to which a questionnaire is measuring what it should be measuring

Responsiveness

The ability of health status measures to detect and describe changes in patients' health status over time and whether these changes are clinically relevant

(Kazis et al 1989).

Responsiveness

The ability of a measure to detect and describe clinically relevant changes in health over time

Does it discriminate between those who change a lot and those who change a little?

Can it identify factors associated with good outcome?

Can it be used to determine differences in treatment effects between different groups in clinical trials?

To what extent do the changes measured by questionnaire matter to the patient?

Utility

Is the instrument of value in clinical practice?

Can patients & clinicians use it?

How does it impact on patient care?

How much does it cost to administer?

Can it be used in different settings?

Pelvic floor disorders

Urinary

Bowel

Vaginal

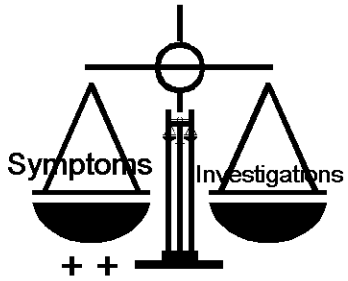
Sexual

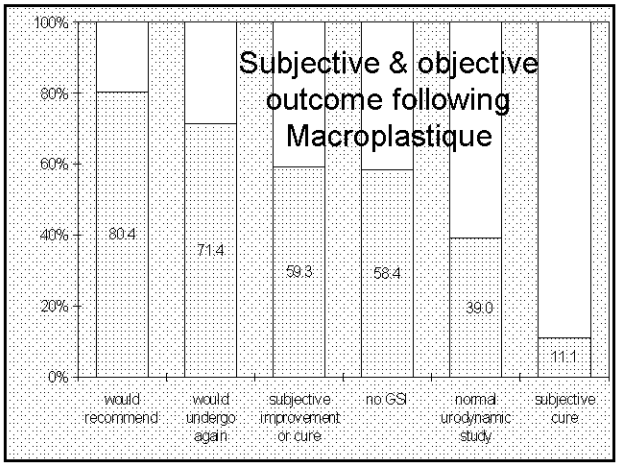
Patient assessment

History + Examination = clinical

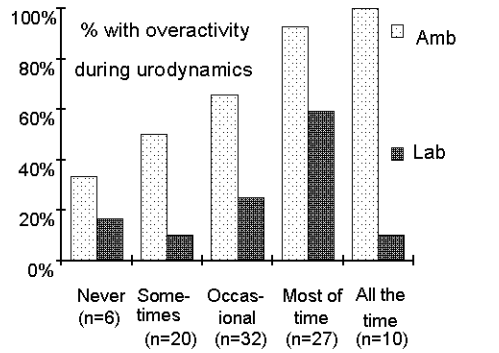
Therapeutic trials, Laboratory investigations

The assessment of incontinence in women





"Does urine leak before you can make it to the toilet?"



Diagnosis of incontinence

History + Examination = clinical diagnosis

Supplemented by…

Simple tests & observations

Therapeutic trials

Laboratory investigations

Perception of symptoms is more important to individuals than any clinical or urodynamic diagnosis

Measures of incontinence

(***all*** have reliability issues)

Clinical measures – Symptoms, Quality of life

Physical findings – Examination, Urinalysis

Investigations – Urodynamics, Ultrasound

'An unreliable witness'

Correlation between the symptom of urgency and demonstrable detrusor overactivity during conventional urodynamics is poor

Agreement

68% of cases of stress incontinence

51% of cases of detrusor instability

Jarvis et al. 1980

Development of ePAQ scales

- Factor Analysis
  - Urinary, Vaginal, Bowel & Sexual Dimensions
  - 14 clinically meaningful scales
- Secondary Factor Analysis
  - Urinary, Vaginal, Bowel & Sexual Dimensions
  - 19 clinically meaningful scales

e-PAQ Bowel dimension domains & items

IBS
- Pain pre-defacation
- Regularity
- Variability of stools
- Mucous or slime
- Bloating

Constipation
- Normal stool consistency
- Laxative use
- Hard stools

Evacuation
- Incomplete evacuation
- Straining
- Painful evacuation
- Perineal splinting
- Anal digitation
- Inability to evacuate

Continence
- Liquid stool incontinence
- Solid stool incontinence
- Flatus incontinence
- Insensible incontinence
- Urgency
- Urgency faecal incontinence
- Inability to defer

Quality of life
- Overall impact
- Physical activities impact
- Social activities impact

ePAQ reliability

- Internal consistency reliability = self-consistent
  - Scores > 0.7 usually indicate that scale items are measuring related constructs

  Version 1 = 13/14 ePAQ scales > 0.7

  Version 2 = 19/19 ePAQ scales > 0.7

- Test-retest reliability = the same scores should be obtained at re-testing given that there has been no change

  - 126 women (62%) completed the e-PAQ a 2nd time 3-6 days later

Construct validity:

We hypothesised that:

- Lower mean scores would be obtained in each domain from data from women in primary care (indicating better health)

  ✓ (P<0.05)

- Range of recorded symptoms and proportion of women recording maximal symptoms would be less for each domain in primary care

  ✓(P<0.05)

Patient satisfaction data

QQ-10

245 women following ePAQ completion

Agreement or disagreement with related statements about ePAQ…

'Please circle the answer that best fits your opinion about the questionnaire that you have just completed'

Additional comments…

Helped express my problems enormously

Helped focus on urgent and relevant problem

Helped me express my symptoms

Made me realise the extent of my problem

Helped talk at ease about my problems

It was really easy to use

Good, enjoyable, easy and quick!

It was good fun

Good idea, well done!

Thank You

References www.epaq-online.co.uk

ePAQ-PF: Tests of data quality
International Urogynaecology Journal, 2008

Electronic interviewing in urogynaecology;
Concept development & psychometric testing of ePAQ-PF
BJOG 2006

Development & psychometric testing of a symptom index for pelvic organ prolapse
J Obs & Gyn 2005

Measuring quality of life in urogynaecology
BJOG 2004

Development and validation of a questionnaire for the assessment of bowel and lower urinary tract symptoms in women
BJOG 2002

Questionnaires as clinical tools

Swati Jha

Talk 2

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Responsiveness

Essential property of any health-related quality of life (HRQoL) measure. Refers to an instrument's ability to detect change over time

Outcomes: Why

- Health is a *dynamic* experience
- Takes into account the subjective experience of patients
- A multidimensional concept encompassing physical, social and psychological aspects associated with a disease

Which outcomes?

- Clinician assessment
- Patient perception
- Investigations
- Functional

Perception of results of colposuspension

- Subjective improvement 72%
- Recommend to friend 68%
- Surgeon satisfaction 85 %
- Surgeon would offer same treatment 94%
  - Black N et al, BMJ 1998; 315: 1493-8

Outcome: How

- Baseline measurements
- Measurements following intervention
  - What time interval?
  - Are repeat measurements necessary?
- Responsiveness of tool
- Ease of documentation
- Time, cost & acceptability of process

Traditional evaluation of outcome of medical care

- Clinical measures of outcome
  - mortality and morbidity, eg complication rates
  - laboratory and radiological tests
  - case note data
- Physical criteria
- Focus on *quantity* of life rather than *quality*

Measuring outcome…

- Physical measurements
  - Subjective (I'm dry) / Objective (POP-Q)
- Continuation of treatment
- Cost
- QoL measurements
  - Subjective (I'm better) / Objective (Questionnaire)
  - Generic (SF-36) / Condition specific (ICI-Q)

Urogynaecological Disorders

- Chronic rather than acute
- Rarely life threatening
- Taboo, embarrassing, inconveniencing
- Health and illness not corelated to physical signs

Need to evaluate…

Patients, Service, Treatments, Clinicians

Outcome: adherence to treatment

- Failure to attend therapy appointments
- Failure to take medication
- Expensive and wasteful

Adherence to treatment

- Marker of tolerability and efficacy of intervention
- Marker of other healthcare needs
  - Correlation between *decreased* antimuscarinic use and *increased* health care service use

Balkrishnan R et al J Urol 2006;175:1067-71

Discontinuation of treatment
(surrogate marker of outcome)

- Comparison of tolerability of solifenacin and extended release tolterodine (STAR trial)

Chapple CR et al Eur Urol 2006;49:187-8

- Long term treatment with darifenacin for overactive bladder

Haab F et al BJU International 2006;98:1025-32

Problems with clinical judgements

Assessments patients make about their health differ to reports made by clinicians

Menstrual symptoms classed as severe by the patient, rated as moderate by the doctor (Coulter 1994)

Estimates of HRQoL only reliable if given by the patient (Woodend 1997, Present 1993, Slevin 1988)

Information is of a sensitive and personal nature (particularly in urogynaecology)

Relationship between the patient and doctor prevents full disclosure of information

Aims of health status measurement

- Multidimensional: encompassing physical, social and psychological aspects
- Evaluates the impact of disease and associated treatments from the patient's perspective
- Measures this systematically using standardised questionnaires and interview schedules

Why is the measurement of health status or HRQoL important?

- Takes into account the subjective experience of patients
- A multidimensional concept encompassing physical, social and psychological aspects associated with a disease
- Health is a *dynamic* experience

Generic measurement tools

- Designed to measure a range of health problems
- In theory, can be used to measure health status for *any* illness
- Data are available on normal populations

Short Form 36 (SF 36)
Nottingham Health Profile (NHP)

Limitations of generic measures

- Too broad
- Not sensitive enough to measure changes in specific conditions (incontinence)

Condition specific measurement tools

- Designed to measure health status *only* for the condition for which they have been developed
- Items should reflect patient's experience of illness with that disease or condition

ICI
Kings Health Questionnaire (KHQ)
ePAQ

What makes a good HRQoL questionnaire?

- Psychometrically sound
- Clinically useful
- Detects changes if they exist
- Easy to use in clinical practice
- Quick and easy to administer and analyse (electronic methods)
- Cost effective

The cost of measuring outcome

- Patient and clinician time
- Hospital costs
- Printing, completing, analysing, storing and comparing data

Commercial studies: approximately £1000 per patient

Psychometric properties

- Reliability
- Validity
- Responsiveness

Change in symptoms after TVT in different age groups using ePAQ

- Linear regression found greater pre-op symptom severity associated with greater improvement post-op
- The age at which TVT performed did not significantly influence outcome
- Age and preoperative symptoms did not influence postoperative OAB and VD scores

Mean pre and post op SUI scores in < 50 and >50 year old women undergoing TVT (N = 50)

Age	Pre-op (Mean score)	Post-op (Mean score)
< 50	54	7
> 50	65	12

Mean pre and post op QoL scores in < 50 and >50 year old women undergoing TVT (N = 50)

Age	Pre-op (Mean score)	Post-op (Mean score)
< 50	65	7
> 50	64	9

Summary

The measurement of outcome in individual patients is increasingly required for …

Service evaluation
Audit
Appraisal & revalidation
Clinical governance
Research

… ***but*** needs to be meaningful, accurate, practical & affordable

Responsiveness and Outcomes

Fiona Reid

Talk 4

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WHY?

- To demonstrate that an operation is feasible, safe and effective
- To compare one operation with another
- To identify reasons for failure
- To inform health economic choices

WHY?

- To inform patient choice
- Appraisal
  - To audit practice
  - To compare surgeons
  - To ensure patient satisfaction

Medical History

OUTCOME	AT DISCHARGE
Cured	15
Improved	4
Failed	1
Lost	-
Total	20

Kelly, H. and W. Dumm (1914). Surg Gynec Obstet: 444-450.

Inadequacy of the medical history.

"The cause of one failure was not known because the patient stated she was greatly improved when seen in our follow-up clinic"

BUT……

"when seen later outside the hospital said she still leaked, and will not return."

Marshall, V., A. Marchetti, et al. (1949). SurgGynec Obstet 88: 509-518.

Bias of Clinical History

	Retrospective chart review (% of patients)	Questionnaire based study (% of patients)
Cure	72	47

Sirls et al 1995 J Urol (154) 5

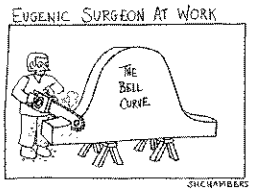
Discordant Outcomes

- Urodynamics after surgery.
- Women complaining of persistent incontinence
- 25% urodynamics no leakage.

Bates, C. and S. Stanton (1973). Surg Gynec Obstet 136: 17-22.

Is the patient wrong?

"Some were unduly worried by amounts of leakage too small to be seen on cystography and which most patients would tolerate without complaint."



HOW?

- Patients' observations (symptoms/history)
- Quantification of symptoms (e.g. urine loss pad test / urodynamics)
- Physicians observations (anatomical and functional)
- Quality of life
- Socio-economic data

ICS Recommendations 1998. Mattiasson, A et al. Neurourol Urodyn 17: 249

The cost of measuring outcome

- Patient and clinician time
- Hospital costs
- Printing, completing, analysing, storing and comparing data

Commercial studies: approximately £1000 per patient

Medical History

OUTCOME	DISCHARGE	FOLLOW UP (1-12 YEARS)
Cured	15	4
Total	20	16

Kelly, H. and W. Dumm (1914). Surg Gynec Obstet: 444-450.

Why Questionnaires?

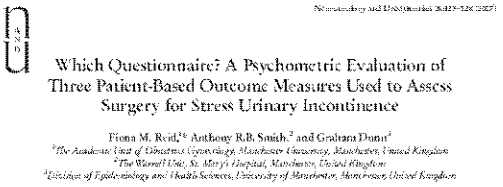
- Patients perceptions
- Psychometric valid
- Feasibility
  - Long term follow up

Types of PRO

- Disease Specific- Nocturia-ICIQ
- Population Specific e.g MEASA
- Dimension Specific e.g pain
- Generic- SF36
- Individulised- SeiQoL
- Utility mesaures- EuroQoL

Ideal

- Good psychometric properties
  - Reliable over time period
  - Valid
  - Responsive
  - Interpretable



Which Questionnaire? A Psychometric Evaluation of Three Patient-Based Outcome Measures Used to Assess Surgery for Stress Urinary Incontinence

Fiona M. Reid,[1*] Anthony R.B. Smith,[2] and Graham Dunn[3]

[1]The Academic Unit of Obstetrics Gynecology, Manchester Maternity, Manchester, United Kingdom
[2]The Manuel Unit, St. Mary's Hospital, Manchester, United Kingdom
[3]Division of Epidemiology and Health Sciences, University of Manchester, Manchester, United Kingdom

Results

- SSI /SII
  - Best Psychometric properties
- KHQ
  - Ceiling & Floor effects
  - 56% Incontinence Impact
- BFULTS
  - Sex function poor psychometric properties

Conclusion

- Psychometric properties vary depending on population
- Content is important
- **What is the question?**

What to measure

- Global Impression
- Quality of life
- Symptoms

Patient Global Impression (PGI)

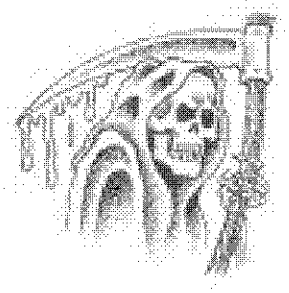
Table I. Patient Global Impression of Improvement (PGI-I) Scale

Check the one number that best describes how your urinary tract condition is now, compared with how it was before you began taking medication in this study.

1. Very much better
2. Much better
3. A little better
4. No change
5. A little worse
6. Much worse
7. Very much worse

Yalcin & Bump AJOG 2003 189 (1)

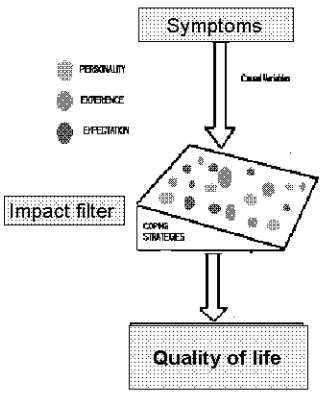
Pre-operative Counselling



Standard of care

Limitations PGI

- No detail



Content

- Comprehensive
  - Symptoms
  - Impact
  - Quality of life
  - Global impression score
- One instrument for all patients

Problems

- Incomplete Data
  - Missing
  - Illegible
  - Incorrect printing
- Cost
  - Data entry
  - Distribution
  - Printing
- Burden due to length

E Questionnaires

- Missing Data
- Anonymity
- Branching

• However

- Technophobia
- Cost & Availability
  - PFDI , ePAQ-PF

Int Urogynecol J (2008) 19:1531–1539
DOI 10.1007/s00192-008-0651-6

ORIGINAL ARTICLE

Paper versus web-based administration of the Pelvic Floor Distress Inventory 20 and Pelvic Floor Impact Questionnaire 7

Victoria L. Handa · Matthew D. Barber · Stephen B. Young · Michael P. Aronson · Abraham Morse · Geoffrey W. Cundiff

Received: 29 November 2007 / Accepted: 25 April 2008 / Published online: 17 May 2008
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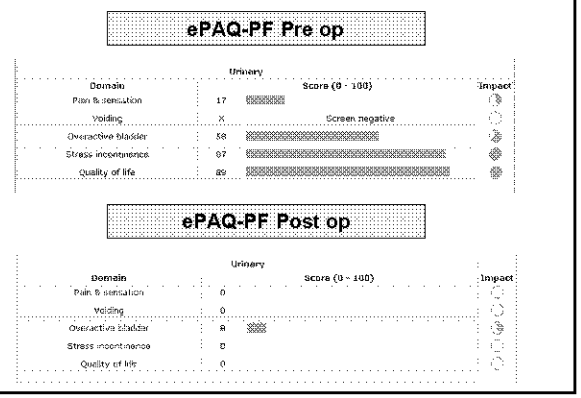
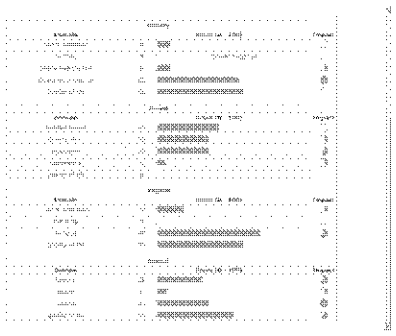
PFDI & PFIQ

- 93% used internet before
- 22% prefer PBQ
- Prefer eQ significantly younger (40 v 60)
  - BUT
- 35% declined to participate

PFDI & PFIQ

- 2.8% missing items on PBQ
- BUT
- 21% subjects a missing item PBQ





Interpretabilty

- Statistical changes
- Clinical changes
- Multiple tools

Conclusions :Outcomes

- Symptoms
- Impact
- Quality of life
- Global impression of change

- Electronic questionnaires allow branching
- One instrument for all occasions

PRO industry

- IS-QoL
  - www.isoqol.org
- Cochrane
  - www.cochrane-pro-mg.org
- ICI-Q
  - www.iciq.net

Patient oriented goals; What do we mean by success?

Dudley Robinson

Talk 4

Workshop 37

Success is...

At 4 years	not wetting your pants
At 10 years	having friends
At 17 years	having a driving licence
At 20 years	having sex
At 40 years	having money
At 60 years	having sex
At 70 years	having a driving licence
At 80 years	having friends
At 84 years	not wetting your pants

Introduction

'restoration to health or good condition'

Oxford English Dictionary

Introduction

'When I operate on patients with stress incontinence almost all are cured; you know what I mean?'

Jerry Blaivas, 1997

'Cure'

- **Subjective cure**
  Improvement in lower urinary tract symptoms
- **Objective cure**
  Repeat lower urinary tract investigation
- **Quality of life evaluation**
  Disease specific QoL questionnaires
- **Patient orientated outcome measures**
  Patient orientated goals

Assessment of Cure

- **Incontinence is multidimensional**
- **Outcome assessment should include different measures**

International Continence Society
Urodynamics Society
American Urological Association
WHO International Consultation on Incontinence

Assessment of Cure

- **Assessment measures may include:**
  Patient symptoms
  Quantification of symptoms
  Objective measurements
  QoL measurements
  Socio-economic evaluations
- **No single outcome measure is appropriate in all cases**

Assessment of Cure

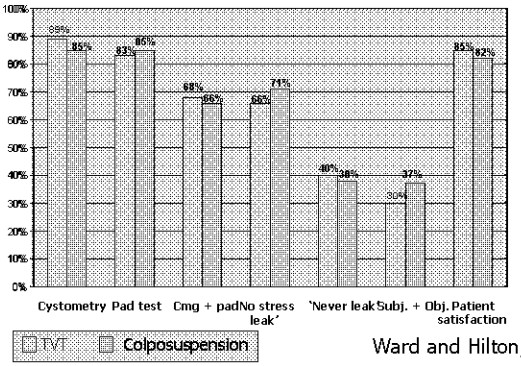
National Institutes of Health (NIH) Criteria

- **Resolution of the symptom**
- **Resolution of the sign**
- **Absence of new urinary symptoms**
  Frequency urgency urge incontinence
- **Absence of new concomitant symptoms**
  sexual function bowel function prolapse

Weber 2001

Humpty Dumpty

TVT/Colposuspension Study



Ward and Hilton, 2000

TVT/Colposuspension Study

- Negative CMG, Negative Pad test
  TVT: 66% Colposuspension: 57%
- Subjective Outcome (BFLUTS)
  TVT: 59% Colposuspension: 53%
- Subjective Outcome: No leakage ever
  TVT: 36% Colposuspension: 28%
- Subjective and Objective Outcome
  TVT: 26% Colposuspension: 26%
- NIH Outcome Criteria
  TVT: 9% Colposuspension: 6%

Hilton 2002

Assessing Outcome: Patient Outcome Measures

Patient Expectations

- Prospective questionnaire based study
- 100 consecutive women recruited from tertiary referral urodynamic clinic

Complete cure of all bladder symptoms	17%
A good improvement in bladder symptoms	43%
Being able to cope better so your life is affected less	13%
Any improvement in bladder symptoms	10%

Robinson et al, 2003

Cure: Acceptability of Symptoms

	Yes	Probably	No
Never ever leaking no matter what you do	63%	22%	13%
Occasional small leak on cough/sneeze	22%	43%	33%
Occasional small leak on strenuous exercise	29%	42%	27%
Occasional large leak on cough/sneeze	8%	9%	78%
Frequent small leaks on cough/sneeze	14%	22%	61%
A sudden urge or need to pass water (no leak)	26%	34%	40%
Occasionally leaking before reaching toilet	15%	32%	52%
Having to pass water very often during the day	26%	39%	3%
Having to get up once at night to pass water	36%	37%	24%
Having to get up twice or more at night	15%	21%	63%
Occasionally having to wear panty liners	20%	38%	38%
Occasionally having to wear pads	12%	24%	61%
Having to wear pads most of the time	9%	5%	85%
Leaking during sexual intercourse	7%	79%	9%

Acceptability of Treatment

	Yes	No
Pelvic floor exercises for 6 months	60%	26%
Pelvic floor exercises for life	41%	44%
Regular drugs for life	14%	69%
Drugs to take as needed	51%	32%
Major operation (85% cure; 2% risk of catheterising)	23%	57%
Minor operation (85% cure; 2% risk of catheterising)	38%	43%
Clinic procedure (60% improvement; no long term risk)	57%	24%
Long term catheter	3%	79%
Learning to self catheterise	11%	73%

Robinson et al, 2003

Cure: Results

- No correlation between quality of life score and acceptability of symptoms (r=-0.031; p=0.756)
- No correlation between quality of life scoring and acceptability of treatment (r=0.127; p=0.245)
- Sub group analysis by urodynamic diagnosis and duration of symptoms did not alter these findings

Assessing Outcome: Quality of Life

QoL: Clinician or Patient

- To investigate the relationship between physician assessed QoL and patient completed QoL
- 79 women with urinary symptoms.
- All completed UDI-6
- Following interview blinded physician completed UDI-6 on the basis of their impression of QoL
- Poor concordance between groups (45% - 68%)
- Physicians underestimated bother 25%-37% of the time

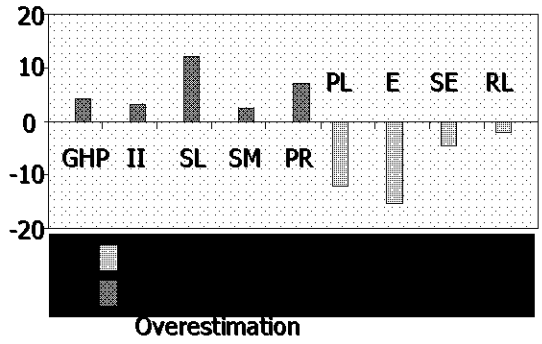
Rodriguez et al, 2003

KHQ: Clinician or Patient

- To investigate the relationship between physician assessed KHQ and patient completed KHQ
- 75 women with urinary symptoms
- All completed KHQ
- Following detailed interview blinded physician completed KHQ on the basis of their impression of QoL
- Physicians tended to underestimate bother
- Poor concordance between groups

Srikrishna et al, 2006

KHQ: Clinician or Patient

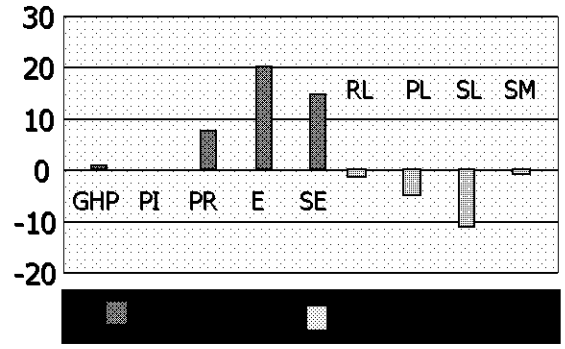


pQoL: Clinician or Patient

- To investigate the relationship between physician assessed pQoL and patient completed pQoL
- 25 women with symptoms of urogenital prolapse
- All completed pQoL questionnaire
- Following detailed interview blinded physician completed pQoL on the basis of their impression of QoL
- Physicians tended to underestimate bother
- Poor concordance between groups

Srikrishna et al, 2006

pQoL: Clinician or Patient



Assessing Outcome: Patient Centred Goals

Patient-Centred goals

- No 'gold standard' outcome measures
- Investigation into patient's perspective of success
- 33 women having surgery for pelvic floor dysfunction
- Pre-operative questionnaire listing upto 5 goals
  - Urinary/bowel symptoms
  - General/other health
  - Improving activity
  - Social relationships/self-image
  - Physical appearance
- Follow-up questionnaires at 6 and 12 weeks

Hullfish et al, 2002

Patient-Centred goals: Examples

- 'Able to play tennis again'
- 'Laughing with the kids without worrying'
- 'Not having to wear pads anymore'
- 'Being able to sit through a play or film'
- 'Less times up at night to the bathroom'
- 'Feeling better about my partner looking at me'
- 'Getting rid of that bulge in my vagina'

Patient-Centred goals

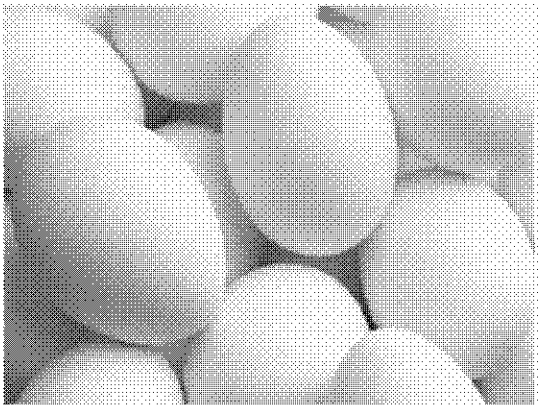
- Women reported a mean of 3.6 goals pre-op
  81.8% listed symptom relief
  66.7% listed at least one activity related goal
- 73.9% of goals met at 6 wks
- 84.9% of goals met at 12 wks
- At 6 wks most goals had been met for activity, symptoms, general health and appearance
- At 12 weeks goals relating to social roles, sexuality and self image were met

Hullfish et al, 2002

Patient Centred Goals

- One year follow-up following surgery
- Patient satisfaction rates at 1 year no different to 3 months following surgery
- Patient satisfaction and achievement of goals ($p<0.0005$)
- Objective cure of prolapse and satisfaction ($p=0.006$)
- Objective cure of incontinence not associated ($p=0.602$)
- Perception of surgical success positively associated;
  with achievement of goals ($p=0.013$)
  and satisfaction ($p<0.0005$)

Mahajan et al, 2004



EGGS

- **Expectations**
  Related to: Symptoms, treatment, health service
- **Goal Setting**
  Positive events that the patient expects to occur
- **Goal Achievement**
  Patient assessed and poorly related to objective measures
- **Satisfaction**
  Overall measure of the 'worth' of treatment

Brubaker and Shull, 2005

Patient-Centred goals

- Prospective longitudinal observational study
- Women recruited from tertiary referral UDA clinic
- Subjective and objective outcome measures
- Up to 5 pre-operative goals listed by: Patient and Surgeon
- 112 patients recruited followed over 24 months
- POP-Q assessment at 6 weeks and 24 months showed significant improvement ($p< 0.05$)
- Mean goal achievement at 24 months;
  Patients - 90% Surgeons - 90%

Srikrishna et al, 2009

Goal Achievement: 2 Years

99.5	94.1	93.1
96.3	91.5	91.6
92.1	86.4	92.4
91.1	83.1	89.5
86.8	76.8	89.3
85.2	74.1	88.7
67.9	69.5	82.7

Srikrishna et al, 2009

Assessing Outcome: Clinician Outcome Measures

Assessment of Outcome

- Prospective cohort study
- 18 hospitals in North Thames region
- Continence procedures performed

  85% surgeon satisfaction

  66% patients met expectations

  28% fully continent

Black et al, 1997; 1998

Assessment of Outcome

- Clinical outcome in Urogynaecology
- 91 patients, 25 nurses, 135 ICS members
- VAS to record importance of clinical outcomes
- Subjective improvement and improvement in QoL rated most highly
- Strong agreement between groups
- Subjective outcome and QoL should be primary outcome measures

Tincello and Alfirevic, 2002

Assessment of Outcome

- Prospective postal questionnaire study
- Members of ICS (UK) were identified from the ICS mailing list
- Structured questionnaire with covering letter and reply paid envelope
- All responses received within 12 weeks of the mailing date were included in the analysis
- 299 questionnaires were distributed

  156 were returned completed correctly

  Response rate 52.7%

Robinson et al, 2006

Clinician: Expectations of Treatment

Complete cure of all bladder symptoms	3.2%
A good improvement so they no longer interfere with your life	85.9%
Being able to cope better so your life is affected less	10.2%
Any improvement in your bladder symptoms no matter how small	0.6%

Clinician: Assessment of Outcome

	Research	Clinical
Subjective improvement in symptoms	7.7%	42.6%
Subjective improvement in QoL	8.3%	36.1%
Objective cure on urodynamic testing	1.9%	0.6%
Objective on pad testing	3.2%	1.3%
Subjective (QoL) and objective (UDS) cure	17.9%	4.5%
Subjective (QoL) and objective (pad test) cure	30.1%	11.6%
Subjective (QoL) and objective (UDS/pad test) cure	30.8%	3.2%

Robinson et al, 2006

How do we Manage Expectations?

- Realistic counselling regarding benefits and risks
- Discussion about
  - What the treatment will achieve
  - What the treatment won't achieve
- Exploration regarding why the patient is seeking treatment
- What are the goals of treatment?

Making expectations more realistic may improve success rates

What is success? – and who says so?

- Clinician
  - Objective Outcomes
- Patient
  - Subjective Outcomes
  - Patient Goals
  - Patient Satisfaction
- Health service
  - Waiting Lists
  - Cost Effectiveness

Conclusion

- Causes of lower urinary tract dysfunction are multi-factorial
- Assessment should be multi-dimensional
- No single outcome measure is appropriate
- Objective outcome measures allow direct comparisons to be made in research setting
- May lack sensitivity to detect subjective measures of outcome
- Objective cure of incontinence does not always equate to 'cure'

Conclusion

- Subjective outcome measures and satisfaction may be more appropriate in the clinical setting
- May be more meaningful to patients
- Patient orientated goals allow a 'patient-clinician contract' to be established
- Achievement of goals may be used as an outcome measure clinically
- Cure may be best defined subjectively in the clinical setting

The great question which I have not been able to answer is –'What does a woman want?'

Sigmund Freud

The Role of the MDT

Philip Toozs-Hobson

Talk 5

IUGA/ICS workshop 37

Introduction

- Electronic bladder diaries
- MDT
- Resource management
- Minimum standards
- Electronic audit tools

Why do we have an MDT?

- Educational
- Supportive
- Clinical Dilemma's
- Allows a holistic approach
- Conveys information
- Utilisation of limited resources
- Meet and discuss issues with colleagues
- Just occasionally have a mistake corrected

Politics of MDT

- Or why you should do it…
  Clinical Governance
- Forms from MDT
  - Records all discussions out of notes
  - Available for Clinical director
  - Available for audit
- Evidence of questioning practice

Quality Assurance

- Traces reviewed
  - Quality
    - "dirty UDA"
    - botty wobble
    - line giggle
  - Diagnosis questioned
    - Whether there is DO
    - Review decisions

Answer a clinical dilemma

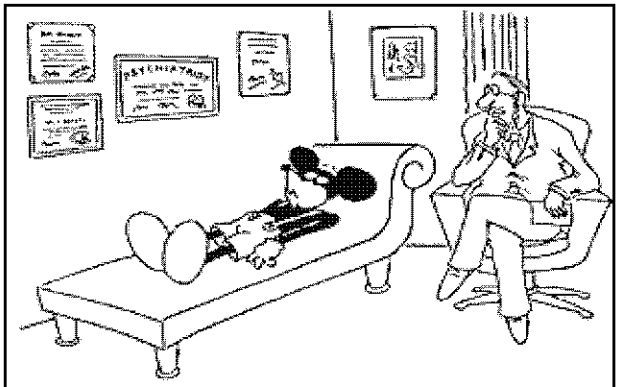
- How to manage voiding difficulties post TVT
  - 171 cases identified
  - 134 (78%) voided normally
  - 37 (22%) required longer catheterisation
  - 17 (10%) resolved within a week
  - 10 (6%) resolved within 6 months
  - 5 (3%) elected to continue with ISC
  - 5 (3%) elected to have tape cut
  - 1 SUI returned
- NNT calculated and additional failures

Holistic approach

- Research interest in psychological factors
- How can we improve on surgery?
- Previously had opportunity to work with Psychologist

Links between bladder and psyche

- In a cystometric experiment bladder pressure changes seen to vary with stressful and relaxing discussion topics
  Straub 1948
- High levels of **chronic depression** and **functional symptomatology** in patients with OAB who failed to respond to treatment Stone 1978
- **Same scores as psychiatric outpatients** in patients with bladder symptoms but normal urodynamics
  Norton 1990



"What lies at the root of all your problems in my opinion, is that you inhabit a fantasy world."

Effect of problems

Restriction on choice of activities and socialising

- Effect on exercise
- Relationships and sex
- Not mixing
- Working
- Going out in public
- Freedom
- Travelling and holidays
- Quality of life

Frequent concerns

- Awareness of toilets
- Urinary symptoms
- Smell
- Hygiene

Practical considerations

- Pads
- Carrying pants around
- Limitation on clothing choice
- Planning fluids and activities

"I wear a skirt in case I have to nip behind a bush"

The future & start of the condition

Age

Hope for the future

Expectations of treatment

General hope

General fear for the future

"I don't want to get like my mother which was desperate. It make me feel like an old woman. I know I am an old woman but I don't want to have old woman problems"

Uncertainty for the future

Theories of cause

- Physical
- Emotional

"I had a difficult birth which tore my insides, maybe that started it off"

Presentation

- Route of referral
- Trigger for presentation

"I was worried about what might happen if I did not do anything about it"

Psychological challenges

'just in case' pad wearer

Poor motivation/compliance despite successful treatment

Successful surgery with dissatisfied patient

Does treatment address the things which matter most?

Should management plans be individualised?

Do psychological issues need to be addressed directly ?

What should be done when conventional treatment leaves women dissatisfied?

Are there alternative treatments for urinary incontinence?

Hypnosis for OAB

68% had resolution or improvement

44% reverted to normal cystometry

Freeman 1982

Psychotherapy

Improvement in urgency, incontinence and nocturia

Macauley 1987

Self-Foot Reflexology

Frequency, situation score, vaginal contraction pressures, daily life discomfort

Kang 2004

Resource management

- Ambulatory UDA
  - Limited resource, 4 hour test, 2 max per week
- PTNS
  - 10-20 funded PA
- In patient bladder drill
- External referral
  - New opinion
  - When things not gone well
  - Other services eg SNS

What MDTs do we have?

- Twice weekly departmental
  - "working" MDT discusses cases as required
  - Reviews all video UDA
  - Reviews nurses UDA (where appropriate)
- Monthly with colorectal surgeon OASIS clinic
- 3 monthly joint Urology/community MDT
  - Teaching and cross referral
  - Includes presentations and speakers
- National

UKCS/BSUG requirements

- Audit
  - Identify topics
    - Voiding difficulties post tape
  - Requirement of NICE
- Requirement of UKCS certification
  - Raising standards
  - Avoids lone practioner
  - Protects staff and patients