

W2, 15 October 2012 09:00 - 10:30

Start	End	Торіс	Speakers
09:00	09:05	Setting the scene – Electronic interviewing.	Matthew Parsons
09:05	09:25	Development of the electronic bladder diary	Matthew Parsons
09:25	09:35	Discussion	All
09:35	09:55	E-PAQ and quality of life assessment	Philip Toozs-Hobson
09:55	10:05	Discussion	All
10:05	10:20	'Virtual Assessment'	Matthew Parsons
			Philip Toozs-Hobson
10:20	10:30	Discussion	All

Aims of course/workshop

We would like to impart the lessons we have learned from implementing an electronic bladder diary service, and an electronic quality of life measure, in our busy UK urogynaecology centre. Advantages and disadvantages of computerised, electronic interviewing

Patient preference

Ability to calculate clinically useful measurements that are not feasible to calculate manually

Methods of administering tools to minimize patient errors and maximize compliance

Bladder diary patterns in different clinical conditions

Educational Objectives

It is generally accepted that a 3-day bladder diary should be completed as part of the assessment of LUTS; it is also accepted that quality of life measures are the best way of assessing the impact of symptoms, and measuring success after treatment.

Both of these measures are easy to complete, yet have tended to remain in the research arena and have not completely made the transition to everyday clinical practice. Having been part of the group (Bladder Diary Research Team) that developed an electronic bladder diary, and been an early adopter and regional centre for ePAQ, we have positively undertaken these forms of electronic assessment in our routine service, and would like to share our insights and the lessons we have learned.

Setting the Scene -Electronic Interviewing



Matthew Parsons MD MRCOG Consultant Obstetrician and Gynaecologist Birmingham Women's Hospital Honorary Senior Lecturer / Senior Academy Teacher University of Birmingham



Declaration

Bladder Diary Research Team

- LifeTech Grant to Professor Cardozo
 \$30,000 2003-4 (research fellow)
- Hotel and conference expenses
 - ICS Christchurch, NZ
 - AUA Atlanta, Georgia
 - Investigator meeting, Houston and Chicago
 - ICS Beijing, China
- Intellectual/practical support for MD thesis and ongoing research projects
- UroDiary system and site support from LifeTech/Genesis Medical
- Astellas, Pfizer

Electronic and Computer Assisted Interviewing

History taking

- One of the first skills we learn
- Remains one of the fundamental core skills
- Some do it well, some do not!
- Individuals performance varies • Mine varies with my mood!!

Prone to inaccuracy and error

- Unstructured format
- Doctor patient relationship
- Variations exist between
 - Healthcare professionals
 - Carer and patient
 - Across specialties

Coulter et al. 1994; Slevin et al. 1988

Quality of Life Assessment

Validated questionnaires

- Assess QoL impairment
 Urinary (or other) disorders
- Best and most reliable method of assessing impact of urinary symptoms Kelleher et al. 1997.

Structure

- Most very similar
- Domains; examining aspects of health
- Variable (and often copious) amounts of paper
 - Completion
 - Processing
 - Analysis

Radley et al.2006

Computer Interviewing

'Breaking the data bottle-neck' (Coddington and King)

• Allergy

- Slack et al. 1966
- Medical and psychiatric clinics
- Paediatric clinic

Coddington and King. 1972; Grossman et al. 1971

• Utility, patient preference, superior data quality with a PDA

Tiplady (AstraZeneca). 1997

Computerised Systems in Clinical Settings

Does it work?

 Test-retest (in rheumatoid arthritis) as high as the paper versions

Greenwood et al. 2006

- Diagnostic interview schedule (DIS) in psychiatry; computer vs trained layperson
 - Kappa 0.51 = other studies
 - Authors concluded against using DIS, not the computer!

Patient Acceptability

- No longer to complete
- 64% preferred computer (33% no preference)
- Ease of use (even computer naïve)
- 98% rated the touch screen very or quite easy; 96% willing to use in future

Greenwood et al. 2006

- EPAQ completed in <20 minutes for 90%
- 93% helpful; 94% relevant
- 8% too complicated; 2% upsetting

Radley; 2004

Cost

SF36

- Fixed, variable, and total cost/survey • Facsimile scanning/scoring vs touch screen Lofland et al. 2000
- Low intensity (250-1000/yr) fax<touch screen
- High intensity (>1500/yr) touch screen<fax
- Equality at around 1250 tests/yr

Conclusion

- Electronic interviewing has a long, strong track record in research
- Signs look good for use as a clinical tool
- Evidence of cost effectiveness, and acceptability

Electronic QoL Assessment

Philip Toozs-Hobson Birmingham Women's Hospital

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

Traditional evaluation of medical care

- Clinical measures of outcome
 - Mortality and morbidity (e.g. complication) rates
 - Laboratory and radiological tests
 Case note data
 - 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

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 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

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).



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 retesting given that there has been no change

 $-\,$ 126 women (62%) completed the e-PAQ a 2^{nd} 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)

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!

e-PAQ					
There are 4 sections to this questionnaire 1. Bladder & urinary symptoms 2. Bowel symptoms 3. Vaginal symptoms and prolapse 4. Sex life If you do not understand or want help with a question, press the button which looks like this:					
	HELP				
< BACK			NEXT >		





S4 Thinking about the last 4 weeks							
Does urine leak when you have sexual intercourse?							
Not relevant	Never	Occasionally	Most of the time	All of the time			
BACK	?		X	NEXT ►			







		Bowel		
Any problems	Positive	Duration	1 - 5 years	
Constipation	01			
Duration	012345			
Evacuation probs	Neg	Duration		
Incontinence	Positive	Duration	1 - 5 years	
Frequency	2 / day	Impact	0123	
Consistency	Sloppy			
Regularity	Fairly irregular	Impact	0123	
Stool variability	Moderate	Impact	0023	
Mucous or slime	0123	Impact		
Bloating	0123	Impact		
Stool liquid	0123	Impact	0123	
Laxative use	Never			
Stool hard	0123	Impact	0123	
Incomplete evac	0123	Impact	0123	
Straining evac	0123	Impact		
Painful evac	0023	Impact		
Evac duration	< 5 min			
Perineal splinting	0123	Impact		
Anal digitation	0123	Impact		
Unable to evac	0123	Impact		
Reduced sensation	0023	Impact	0123	
Liquid stool inco	0123	Impact	0(12(3)	
Flatus inco	0123	Impact	0123	
Solid stool inco	0123	Impact		
Inco no reason	0023	Impact		
Urgency	0123	Impact	0123	
Urge inco	0123	Impact	0123	
Able to defer	Occasionally	Impact	0123	
Pad use	2 - 3 / day			
QOL Overall impact	0(12)3			



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	litinary				Urinary		
Dornein	(inter)	Score (0 - 100)	Insect	Domain		Score (0 - 100)	impa
Pain & sensation	17			Pain	×	Screen negative	
Voiding	X	Screen recative		Voiding	×	Screen negative	0
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Perineal Trauma Clinic	Urinery			
	Domain		Score (0 - 100)	Impact
	Pain & sensation	0		0
	Voiding	0		0
30 year old	Overactive bladder	8		0
A	Stress incontinence	0		0
Asian woman	Quality of life	0		0
		E	lowel	
	Domain		Score (0 - 100)	Impact
20 / 40 weeks pregnant	Irritable bowel	7		0
	Constipation	×	Screen negative	0
	Evacuation	×	Screen negative	0
	Continence	33		0
	Quality of life	22		
		v	aginal	
	Domain		Score (0 - 100)	Impact
	Pain & sensation	×	Screen negative	0
	Capacity	×	Screen negative	0
	Prolapse	×	Screen negative	0
	Quality of life	×	Screen negative	
		s	exual	
	Domain		Score (0 - 100)	Impact
	Urinary	0		0
	Bowel	0		0
	Vaginal	X	Screen negative	0
	Quality of life	0		0

	Urinary			
	Domain		Score (0 - 100)	Impact
	Pain	22		0
	Voiding		Screen negative	0
	Overactive bladder	67		
80 year old	Stress incontinence	53		
	Quality of life	33		
		Boy	iel	
	Domain		Score (0 - 100)	Impact
New Referral	Irritable bowel	7		0
New Herena	Constipation	22		0
	Evacuation	14		0
	Continence	19		
	Quality of life	0		
Urinary Incontinence	Vaginal			
	Domain		Score (0 - 100)	Impact
	Pain & sensation	0		0
	Capacity	-	Screen negative	0
epag-online	Prolapse	17		0
-le el composition de la composition de	Quality of life	11		
		Sex	al	
	Domain		Score (0 - 100)	Impact
	Uninary	•	Screen negative	0
	Bowel	-	Screen negative	0
	Vaginal	-	Screen negative	0
	Dyspareunia	•	Screen negative	0
	General sex life		Screen negative	0

(Electronic) **Bladder Diaries**



Matthew Parsons Consultant, Department of Urogynaecology **Birmingham Women's Hospital**







Symptoms or Urodynamics? Do we need both?

Linda Cardozo MD FRCOG

Department of Urogynaecology Kings College Hospital London



Aims of Investigations

- Make accurate diagnosis
- Verify / quantify incontinence
- Identify underlying pathology
- Monitor treatment
- Education / Research / Audit

Urgency and Frequency: Causes

- Urological
- Urinary tract infection Urethral syndrome
- Detrusor overactivity Bladder tumour Bladder calculus

- Gynaecological

 Cystocele
 Previous pelvic surgery Genital
- Urethritis
- Vulvovaginitis Urethral caruncle
- Upper motor neurone lesion Impaired renal function
- Congestive heart failure

- General Excessive intake Pregnancy

- Urethral diverticulum Small capacity bladder Interstitial cystitis Radiation cystitis / fibrosis Chronic residual
- Pelvic mass (Fibroids)
- Atrophy Herpes Warts •
- Diabetes mellitus Diabetes insipidus
- Anxiety Habit



Urgency and Frequency: Causes Urological • Detrusor overactivity

NICE

Bladder diaries should be used in the initial assessment of women with UI or OAB. Women should be encouraged to complete a minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days.

Bladder diaries are a reliable method of quantifying urinary frequency and incontinence episodes. The Guideline Development Group (GDG) concluded that a 3-day period allows variation in day-to-day activities to be captured while securing reasonable compliance. (See section 3.9 of the full quideline.)

Synonyms

- Bladder diary
- Frequency-volume chart
- Voiding diary

Main Uses

Fluid intake

- Compulsive or excessive fluid intake
- Diabetes mellitus

Inappropriate timing

- Normal fluid volumes consumed at the wrong time
- Nocturia

Main Uses

Excess of caffeine or alcohol

• Bladder irritants causing symptoms

Habits

- Learned or habitual frequency
- Semi-objectively assessed

Treatment

On the basis of the chart...

- Commence therapeutic intervention
- Behavioural modification
- Lifestyle adaptation
- Little delay
- gets people 'doing something'

Non-Completion

Factors

- Non-Caucasian race
- Prolapse as primary complaint
- Poor predictor of an absence of urinary symptoms

Heit M, Brubaker L. 1996





An Audit of Completion of a Bladder Diary Prior to Urodynamic Studies

Matthew Parsons, Andrea Dixon, Marva Thomas, Ramatu Sankoh, Linda Cardozo, John Bidmead, Dudley Robinson, James Balmforth Department of Urogynaecology King's College Hospital

London

Results					
21/6/04 - 16/7/04	LDC N (%)	JB N (%)	Combined		
Number of appointments sent	87	47	134		
DNA	12(13.7%)	7(14.9%)	19(14.18%)		
Self-cancelled	2(2.2%)	5(10.6%)	7(5.2%)		
King's-cancelled	1(1.1%)		1(0.7%)		
Test not done (on arrival)			1(0.7%)		
Information not recorded (attendance)			2(1.4%)		
Of those women attending (n=107)					
Received the bladder diary			68(63.5%)		
Received King's Health Questionnaire			40(37.3%)		
No written information received			2(1.8%)		
Receipt not recorded			11(10.2%)		
Of those women who received a diary (n=68	3)				
Completed the bladder diary			22(32%)		

Of the women sent an appointment for urodynamic studies (n=134)

- <u>16.4%</u> attended the one-stop urodynamics clinic with a completed bladder diary
- Negative impact on utilisation of NHS resources
- Detrimental to the quality of assessment of LUTS

Components of a diary

Instructions

- Culture and age specific instructions
 - Audit at KCH
 - Explanatory letter
 - Increased completion from 22% to 75.5%

Components of a diary

Diary

- Paper diary
- Cheap, easy to produce
- Easily and safely stored
- Fluid intake
- Timing and volume
- Urine passed
 Timing and volume
- Relevant symptoms
 - Incontinence

Bladder Diary

To have 'value'

- It must be completed correctly
- If length is great compliance will be poor
- Increased variability may compromise shorter diaries
- 3-day diary has become a 'standard'

Paper and Electronic Diaries

Problems with paper charts

- Manual calculation
- Time consuming
- Prone to miscalculation
- 'Eye-balled'

Paper and Electronic Diaries

Hand Held Computerised Diaries

- Developed to improve compliance
- Preferred by patients
 - Reflected problems
 - Motivation
 - Easier to remember

Rabin JM et al. 1993

• A computerised diary would incur considerable cost in most units

Intelligent Character Recognition

Character Recognition Software

- Advanced OCR system
- Allows hand writing to be learned by a computer during processing to improve accuracy and recognition levels
- Accurate recognition of Latin-script, typewritten text (OCR) is largely a solved problem

UroDiary™

- Analyses hand-written character entries on a paper diary
- Calculates 'results' which can be determined by the user
- Expresses results as a 'centile' result







Is manual calculation of urine production accurate?

Matthew Parsons, William Tissot, Linda Cardozo, Cindy Amundsen, Ananias Diokno On behalf of the Bladder Diary Research Team

International Continence Society

Definitions

- Night time after last void before going to bed, up to and including the first void after waking
- Day time after first morning void, up to and including last void prior to bed Am J Obstet Gynecol. 2002;187(1):116-26

Assumptions underlying ICS definition

- The first void of the day tends to occur at, or shortly after, wakeup.
- The last void of the day tends to occur at, or shortly before, bedtime

Results

Night volume

 14% of diaries show an overstatement of >/= 100mls in the 'ICS' diary

Night time production index

 12.6% of diaries show an overstatement by >/= 10% of the night 'proportion' in the 'ICS' diary

Paper and Electronic Diaries

Intelligent Character Recognition

Combines benefits

- Cheap and convenient paper diaries to patients
- Accurate and rapid calculation using a PC
- Popular with patients

Parsons M et al. 2005





Manual and electronic bladder diaries: performance and patient preference

Matthew Parsons, Maria Vella, Linda Cardozo On behalf of the Bladder Diary Research Team

Sponsor – LifeTech Inc, Houston, Texas

Method

Objective

 Compare handwriting recognition software with a manual paper diary in the assessment of a bladder diary

Demographics

- 50 asymptomatic women
- 3 days paper diary; 3 days electronic diary
 - Order by study number
 - Preferences questionnaire
 - Ethics approval
 - ✓ £50 honorarium
- Mean age 45.16 years (range 25-65)
- 37 white (74%), 11 black (22%), and 2 Asian (4%)

Results and Statistics

SPSS v12

- Janus V database(LifeTech) vs Casio handheld calculator
 Diary data compared with Pearson's correlation coefficient
- Input times compared with paired samples t test
- Mean calculation time

 3 min 46.37 sec (SD 1 min 4.7 sec) electronic diary
 6 min 2.83 sec (SD 2 min 7.02 sec) manual diary (p < 0.0001)

- 64% preferred the electronic diary
- 26% preferred the manual diary
- 10% no preference

Results					
Variable	Correlation coefficient	p value			
Intake	0.788	<0.0001			
24 hour volume	0.775	<0.0001			
Diurnal frequency	0.695	<0.0001			
24 hour frequency	0.658	<0.0001			
Mean voided volume	0.759	<0.0001			
Maximum voided volume	0.680	<0.0001			

Conclusion

- The electronic diary collects the same information from users as the manual paper diary
- It is more rapidly analysed and preferred by the majority
- The electronic diary is a potentially useful tool for the study of urinary symptoms

BDRT

Normal females study

- 161 asymptomatic women
- 19.6 81.8 years age range
- 4 independent study sites
- 3-day bladder diaries
- Ethics approval Amundsen CL, Parsons M et al. Neurourol Urodyn 2007



- Functional bladder capacity
 decreases with aging
 - increases with increasing V_{24}
- 24-hour frequency
 - increases with both aging and
 - increases with increasing $V_{\rm 24}.$

What about DO?

• 29 women

- King's College Hospital
- Duke Medical Centre, N Carolina
 no significant between-site differences
- Ethics
- Proven DO (no USI)
 - median age: 56.9 years; range: 28.7-80.2 years
- Age matched control group from reference population
 - median age: 56.9 years; range: 29.9-79.1 years
 - Amundsen CL, Parsons M, Cardozo L et al. J Urol 2006

What about DO?

- If we take a cut off of 10% of functional bladder capacity as being significant
- Correct diaries for V₂₄ rather than just age alone







2. patient with an unusually high V_{24}

Conclusion

Bladder Diaries

- Cheap
- Rapid
- Reliable and accurate
- Research tool
- Helpful as a clinical tool

Conclusions

- Helps in the initial management of women with LUTS
- Easy to administer
- Well received and tolerated

Conclusions

- Remains unable to 'diagnose' detrusor overactivity
- Correcting for age and fluid intake increases the utility of the diary by raising clinical suspicion of reduced bladder capacity

Aims of Investigations

- ***** Make accurate diagnosis
- ✓Verify / quantify incontinence
- \checkmark Identify underlying pathology
- \checkmark Monitor treatment
- \checkmark Education / Research / Audit



Notes Record your notes from the workshop here