The Management of Urinary Incontinence in the Post Mesh Era
‘out with the old, in with the new”

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Disclosures

- Conflict of interest:

Speaking engagements and honoraria

  - Pfizer
  - GSK
  - Astellas

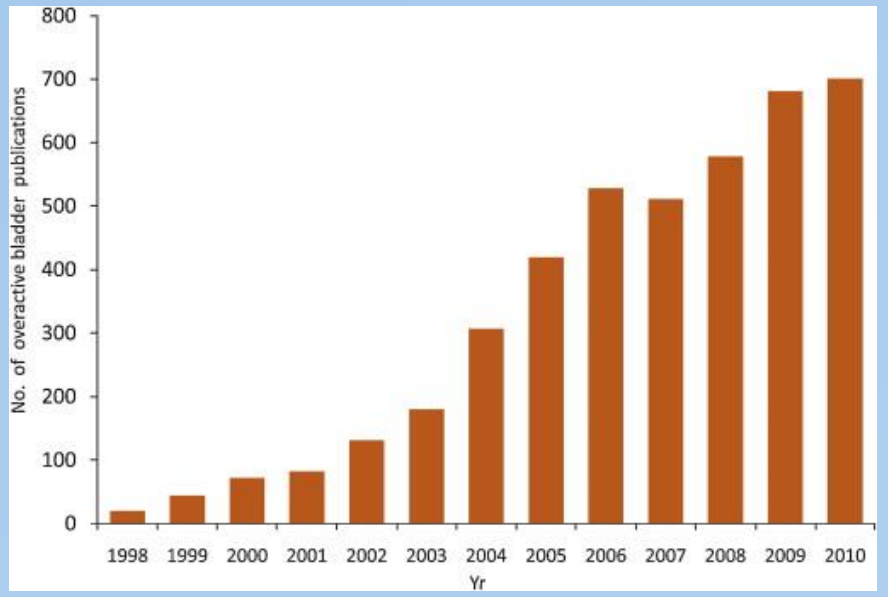
Regional advisory board: Astellas and Olympus

DOH/Public Health Commissioning: Chelmsford City Council

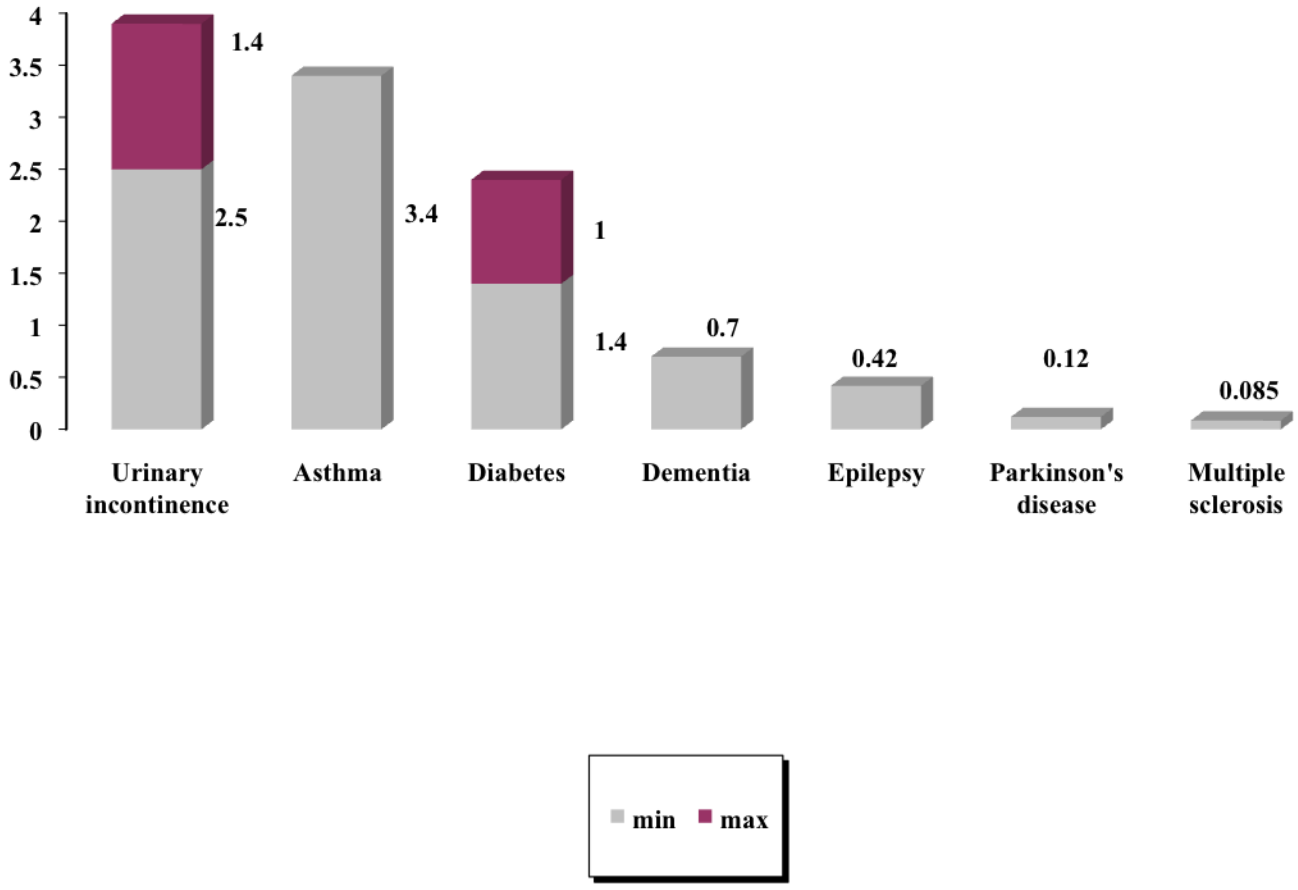
Overview

- Review the assessment of bladder problems (SUI,UUI,Total)
- Red flags to watch out for
- Definitions of various types of urinary incontinence (UI)
- Management in the primary care setting
- NICE guidelines and requirements for secondary care providers
- The Mesh crisis
- Significant changes in Mx (pathways, counselling, procedures)
- "out with the old, in with the new”

Are benign bladder complaints important?

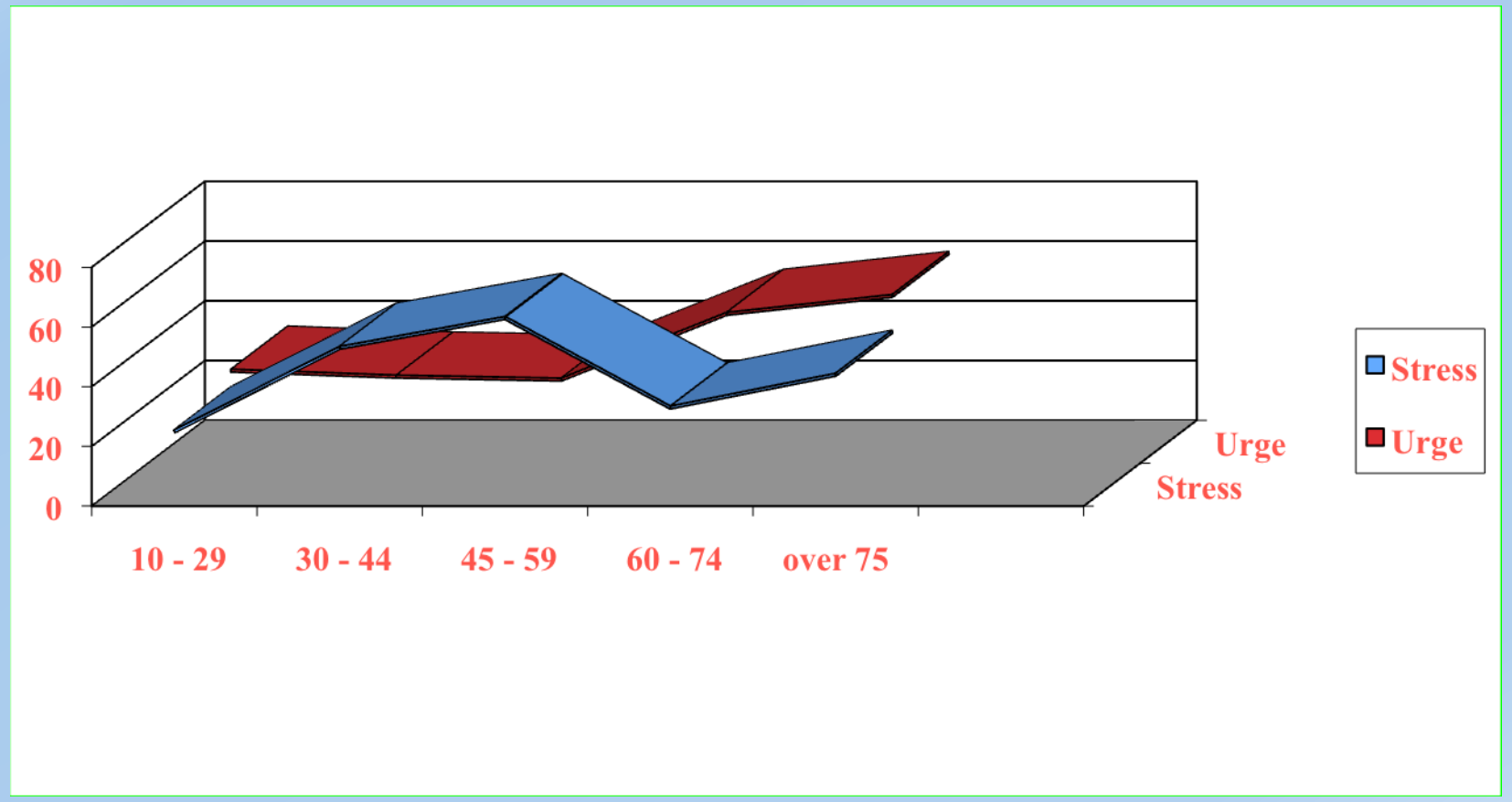


Prevalence of common diseases in the UK



The Continence Foundation. 2000

Type of incontinence related to age



Millard R BJU 1985 57 98-9

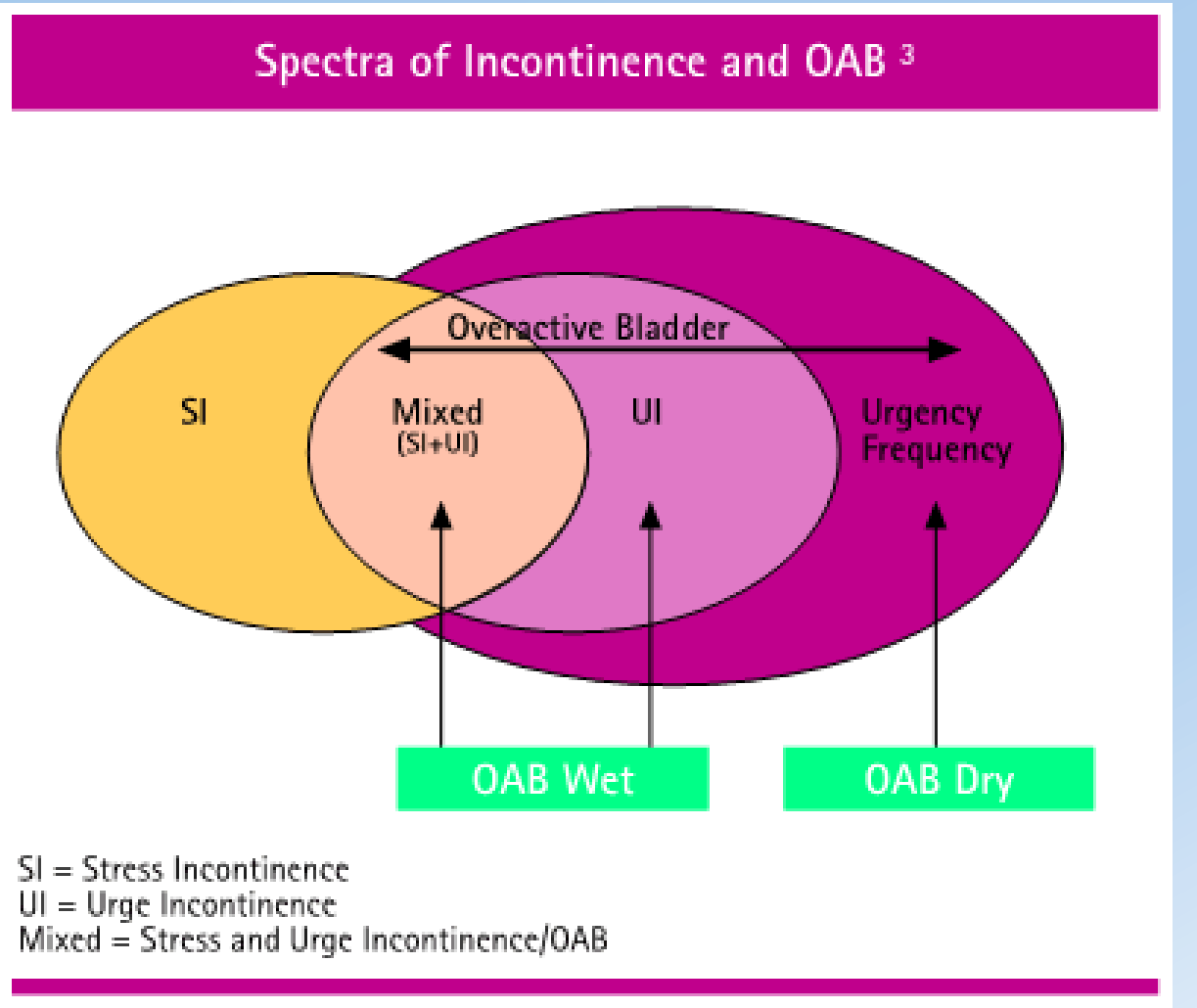
Impact of UI

- 60% avoid going away from home
- 50% feel odd or different from others
- 45% avoid public transport
- 50% avoid sexual activity for fear of incontinence
  - Norton et al, BMJ 1988

- Incontinence is second to dementia as an initiating factor for admission to residential/care homes
  - Thom et al, Age and Ageing 1997

Assessment of Bladder symptoms
History

- Incontinence of urine ?
- What type of incontinence ?
  - Constant (adult, child)
  - *SUI*
  - *UUI*
  - *Mixed*
    - Functional
    - Overflow etc
- Impact on quality of life?



Assessment of Bladder symptoms

- **Constant drip**
- **Pain: abdominal /perineal**
- **Heamaturia**
- **Pneumaturia**
- **Recurrent/persistent infection**

- **Neurological symptoms**

Assessment of UI
Examination

- Abdomen:
  - ? Tenderness
  - Palpable bladder
  - Scars
- Perineal inspection
  - Atrophy
  - Urethral mucosa prolapse
- **Vaginal examination**
  - **Adnexal mass**
  - ? **Pelvic mass**
  - Pelvic organ prolapse
  - SUI
  - Pelvic floor muscle strength

Minimum investigations

- Urine dipstick/MSU
- Voiding diary
- Post void residual volume

Frequency volume charts

- 72 *consecutive* hours
- Basic patterns:
  - Normal voided volume, increased frequency: increased fluid intake, DI, DM
  - Reduced fixed volumes, day and night: intravesical pathology (interstitial cystitis or CIS)
  - Reduced variable volume, day and night: detrusor overactivity
  - Normal early morning void, reduced variable day volumes: psychosomatic.

Time	Day 1		Day 2		Day 3	
	IN	OUT	IN	OUT	IN	OUT
0700	[illegible]	75				75
0800	150		150	80	150	
0900		100		100		100
1000	150		150		150	
1100		90				90
1200		100		100		
1300	150		150		150	100
1400		75				
1500		50		75		100
1600						
1700		100		100		80
1800	150		150		150	
1900		105		105		
2000		70		70		100
2100						
2200	200	100	200	100	200	80
2300		50		50		
2400	50	110	50		50	110
0100						
0200		75		80		75
0300				50		
0400		70				70
0500				100		
0600		100				100
TOTAL		1270		1010		1080

When you go to the toilet, measure the urine you pass in a jug (in mls if possible). Record it in the box next to the nearest hour.

When you go to bed, put a line in the chart at the right time. This helps us to see how many times you get up at night

Time	Date 21/9			Date 22/9			Date 23/9			Date 24/9			Date 25/9		
	1			2			3			4			5		
AM	In	Out		In	Out		In	Out		In	Out	AM	In	Out	
1						1	500	270		100	400	1			
2						2	~~300~~	300		50	350	2		400	
3						3		200 170			575	3			
4						4					250	4		200	
5						5		400		500	150	5		210	
6						6		360		500	360	6			
7						7	1000	240			260	7		220	
8						8	600	300 400		700	250	8	600	140	
9						9		300			350	9	300		
10						10		260			260	10		300	
11						11	300	180			230	11		230	
12						12		280		600		12	600	135	
PM						PM						PM		~~330~~	
9.30 1	500	320	11.10	1000	320	1					200	1		230	
10.15 2		270	11.59		220	2		300		350	240	2	300	160	
11.30 3		220	1248		250	3	600	250		500		3		210	
12.38 4		311	1.52		400	4	300	260				4	100		
2.10 5		150	3.0		170	5	250	280		500	230	5			
3.15 6	500	120	3.51		270	6	440	250 200			185	6	500	120	
4.45 7		300	5.02		320	7	440	350		800	260	7		160	
5.35 8		260	6.40		240	8	440	260			320	8	500	140	
6.40 9		270	7.00	1200	260	9	300	200 100		350		9		180 ~~210~~	
7.40 10	1000	400	8.00			10	300				260	10	500	100	
8 10 11		200				12	500	250			260	11		350	
9.00 12		350									320	12		270	
Total	In	Out		In	Out		In	Out		In	Out		In	Out	

If you are unable to complete the whole chart, please try to complete at least three days.

BED

out BED

TIME

3,171

Time	Day 1		Day 2		Day 3	
	IN	OUT	IN	OUT	IN	OUT
0700		300		350		275
0800	150	100	150		150	100
0900		50		100		50
1000	200	25	200	75	200	25
1100		50		50		50
1200			150	50	150	
1300	150	200		25		100
1400		50		50	150	75
1500		50		50		50
1600	200	75	200	25	200	
1700				25		
1800						150
1900		200	150			75
2000	150	75		150	150	50
2100				75		
2200		150				50
2300	150	75		75	150	50
2400			150			
0100						
0200						
0300						
0400						
0500						
0600						
TOTAL	1000	1400	1000	1100	1150	1200

Definitions

Urinary Incontinence (UI)

A condition in which involuntary loss of urine is a social or hygienic problem *and is objectively demonstrated*

vs

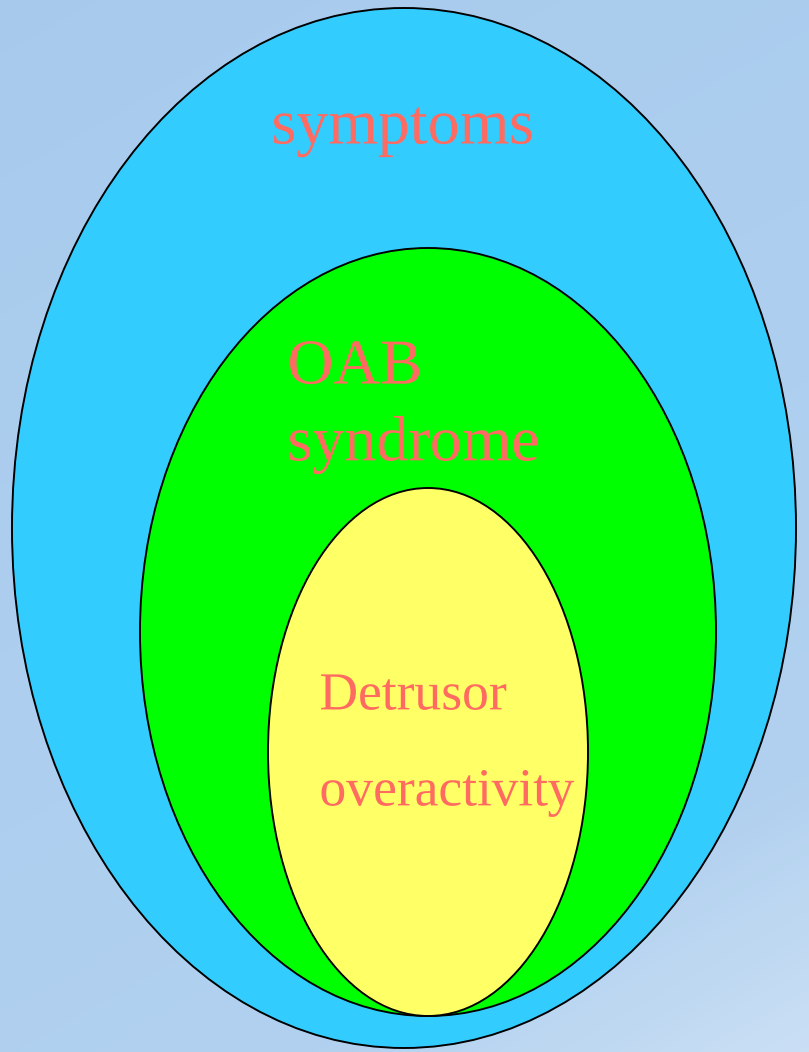
Hyperhidrosis or Excessive Vaginal Discharge

Definition of Overactive Bladder

urgency with or without urge incontinence, usually associated with frequency and nocturia

Overactive bladder

- Symptoms
- Condition / syndrome
- Urodynamic diagnosis



Definition of Stress Urinary Incontinence

the complaint of any involuntary loss of urine on effort or physical exertion (e.g sporting activities) or on sneezing or coughing”

Initial management of UI

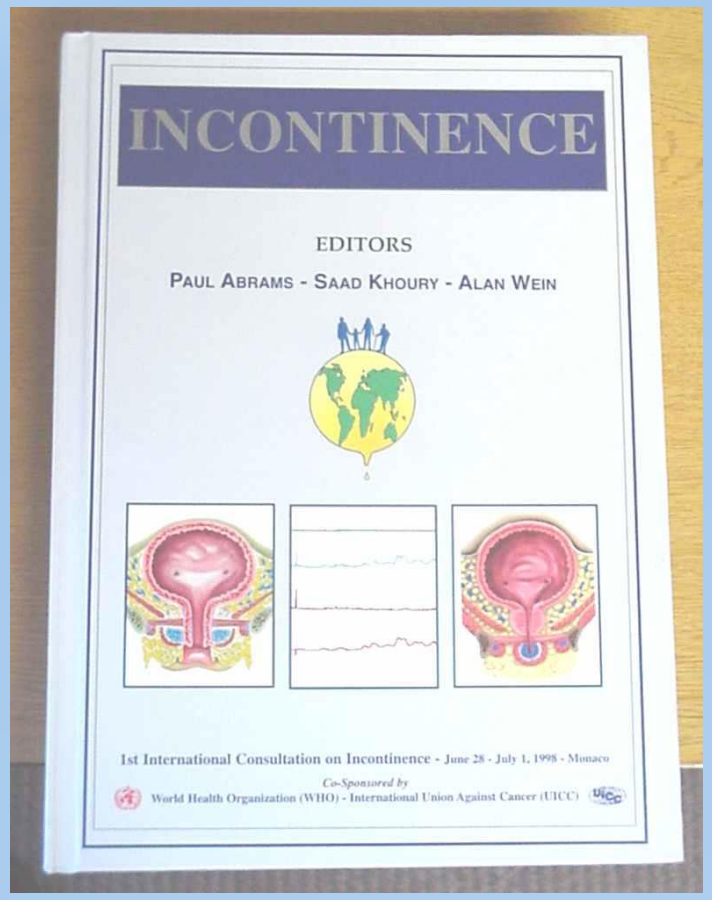
Stress Urinary Incontinence

Conservative management

Primary Care

- Lifestyle changes (fluid type and volume)
- Pelvic floor muscle training
    - 3 months
    - Supervised
    - Biofeedback
    - Vaginal cones
- Weight loss
- Medication: HRT topical

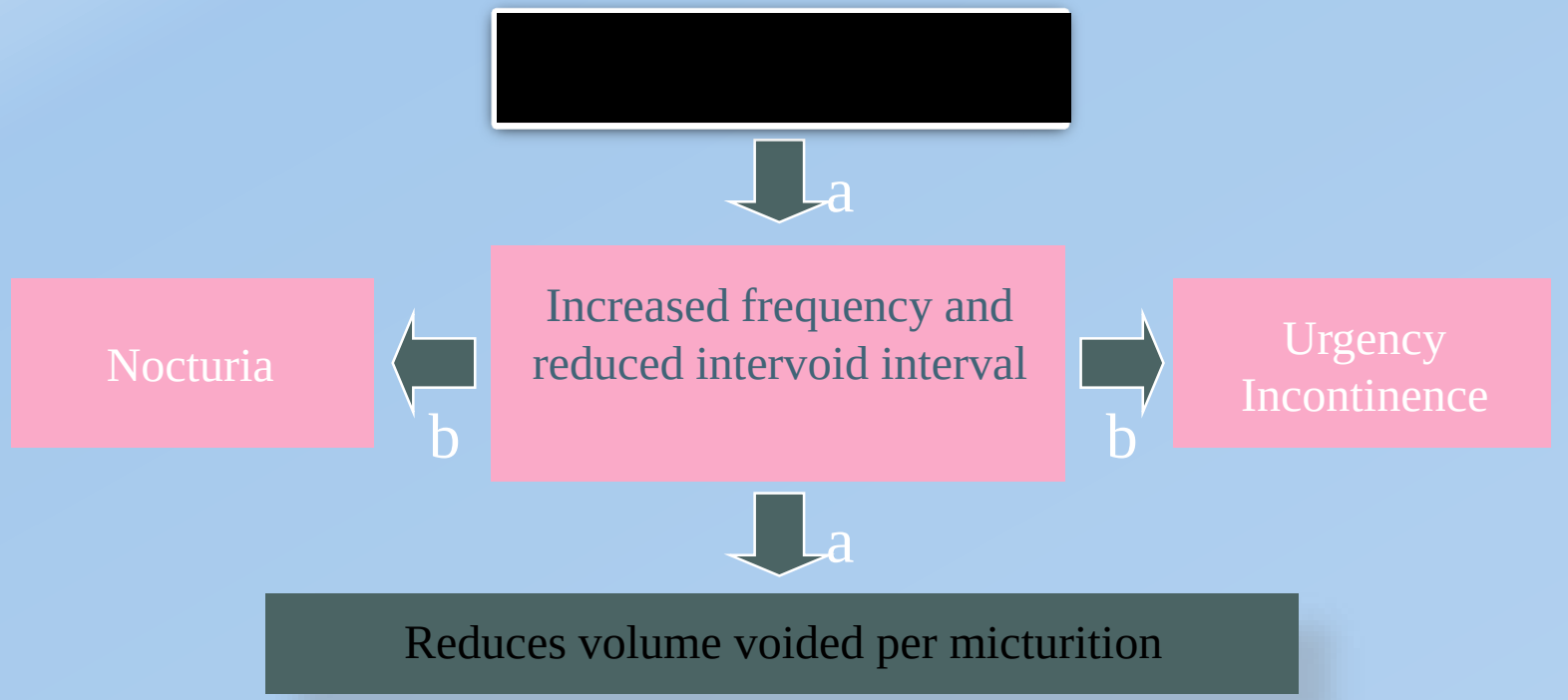
Bladder training and PFMT



- Grade A recommendations from WHO, European Ass of Urology guidelines level 1 evidence, NICE.

Initial management of OAB/UUI

Urgency is regarded as a driver for other symptoms[1]



a = Proven direct effect

b = Effect correlated with Urgency but inconsistent due to multifactorial aetiology of the symptom

1. Adapted from Chapple CR et al. BJU Int 2005;95:335-40

Toilet mapping!

OAB: management

Conservative management

Primary Care

- Lifestyle changes (fluid type and volume)
- Pelvic floor muscle training
    - 3 months
    - Supervised
    - Biofeedback
    - Vaginal cones
- Weight loss
- Medication: HRT topical

Risk factors for OAB

- Smoking (1.44 RR) Dollos BJUI 2003
- Obesity Dollos BJUI 2003
- Carbonated drinks Dollos BJUI 2003
- Tea/Coffee

Caffeine and OAB

- 3,7-dihydro-1, 3, 7-trimethyl-1H-purine-2,6-dione
  - block adenosine effects on A_{2A} and A_{1} receptors
  - inhibits cyclic nucleotide breakdown via inhibition of phosphodiesterase
  - blocks $GABA_{A}$ receptors
  - mobilizes intracellular calcium depots

Q_{max} and Q_{ave} were significantly increased in the caffeine group*

FD=first desire to void, ND=normal desire to void, SD=strong desire to void, MCC=maximal cystometric capacity decreased in caffeine group **P≤0.05**

Effect of caffeine on bladder function in patients with overactive bladder symptoms

Lohsiriwat Supatra, Hirunsai Muthita, Chaiyaprasithi Bansithi

Year : 2011 | Volume: 3 | Issue Number: 1 | Page: 14-18

‘I only drink green tea’

- Assam Black Tea - 86 mg
- Bai Mu Dan / China White Tea - 75 mg
- Chinese Ti Kuan Yin Oolong - 37 mg
- Darjeeling Autumnal (Darjeeling White Tea - 56 mg
- Indian Green Tea - 59 mg
- Kenyan Green Tea - 58 mg
- Ceylon Black Tea - 58 mg

- Drip Brewed Arabica Coffee (6 oz) - 80-130 mg
- Drip Brewed Robusta Coffee (6 oz) - 140-200 mg
- Drip Brewed Passiona Excelsa/Arabica Low-Caffeine Coffee Blend (6 fl oz) - 40-60 mg
- Instant Coffee (8 oz) - 27-173 mg (often around 65 to 90 mg)

Pharmacotherapy

- *Oral*

Imipramine: 25 - 50 mg nocte
Propiverine
Anticholinergics

B3 Agonists
Desmopressin: 100 - 200 ug nocte

- Intravesical
    - Botox/Dysport

Anticholinergics

- Anticholinergic agents are currently the first-line therapy for OAB

- They exhibit their primary action by inhibiting involuntary detrusor muscle contractions (at the level of the efferent pathway), but identification of muscarinic receptors in the urothelium/suburothelium suggests that they may also affect the afferent sensory pathway

- No head-to-head trials of these agents have assessed efficacy and side effects. The available literature suggests that these agents are clinically similar and that none appears to offer a major distinct advantage over the others.

Management of OAB in the elderly patient

- Studies with both Solifenacin and Fesoterodine have demonstrated that large proportion of elderly patients require higher doses for optimal eficacy
    - Wagg et al 2006, Kraus et al 2010
- Older patients suffer more adverse events from therapy but are more adherent to their therapy
    - Wagg et al 2006

Research

Original Investigation

Cumulative Use of Strong Anticholinergics and Incident Dementia
A Prospective Cohort Study

Shelly L. Gray, PharmD, MS; Melissa L. Anderson, MS; Sascha Dublin, MD, PhD; Joseph T. Hanlon, PharmD, MS; Rebecca Hubbard, PhD; Rod Walker, MS; Onchee Yu, MS; Paul K. Crane, MD, MPH; Eric B. Larson, MD, MPH

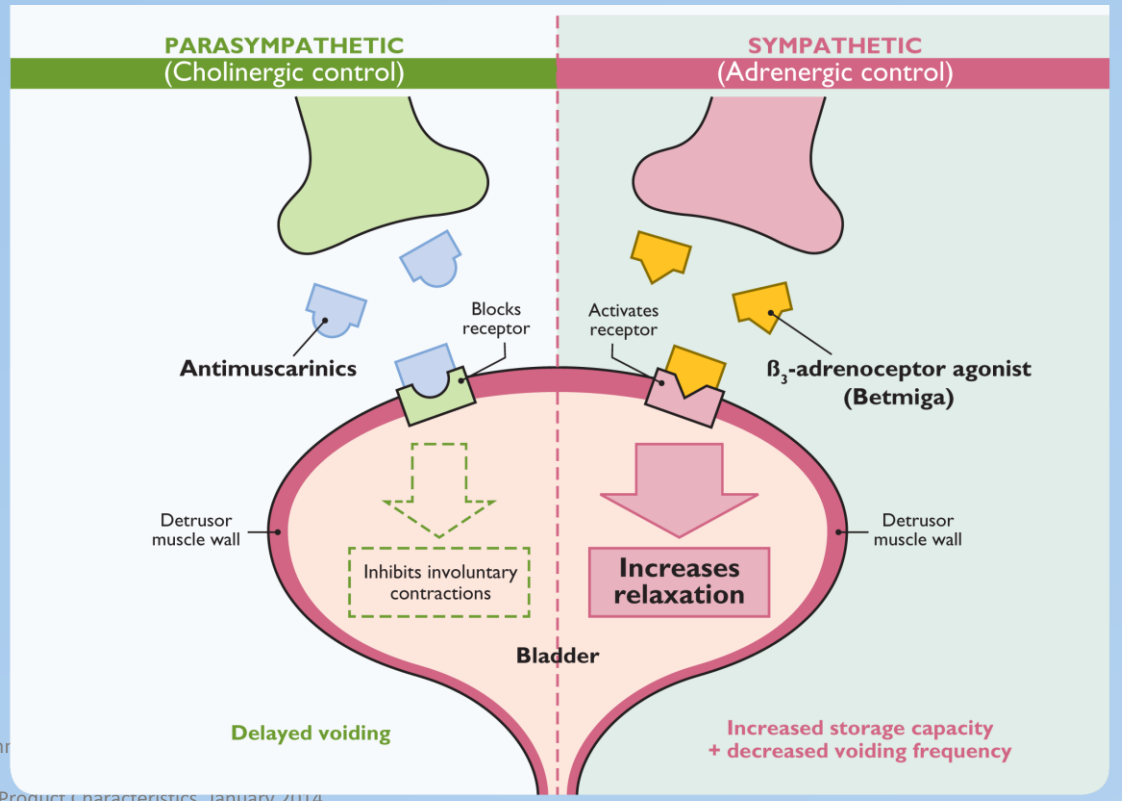
DESIGN, SETTING, AND PARTICIPANTS Prospective population-based cohort study using data from the Adult Changes in Thought study in Group Health, an integrated health care delivery system in Seattle, Washington. We included 3434 participants 65 years or older with no dementia at study entry. Initial recruitment occurred from 1994 through 1996 and from 2000 through 2003. Beginning in 2004, continuous replacement for deaths occurred. All participants were followed up every 2 years. Data through September 30, 2012, were included in these analyses.

CONCLUSIONS AND RELEVANCE Higher cumulative anticholinergic use is associated with an increased risk for dementia. Efforts to increase awareness among health care professionals and older adults about this potential medication-related risk are important to minimize anticholinergic use over time.

JAMA Intern Med. doi:10.1001/jamainternmed.2014.7663
Published online January 26, 2015.

Mirabegron is a treatment for OAB that works differently to antimuscarinics[1,2]

Mode of action of OAB treatments[1,3]



Adapted from Betmiga Sumr

1. Betmiga Summary of Product Characteristics, January 2014.
2. Gras J. *Drugs of Today* 2012;**48**(1):25-32.
3. Chu F, Dmochowski R. *Am J Med* 2006;**119**(3A):3S–8S.

Date of preparation: March 2014. BET13018UK(1)

Urinary incontinence

The management of urinary incontinence in women

Issued: September 2013 last modified: January 2015

NICE clinical guideline 171

guidance.nice.org.uk/cg171

1.8.4 The MDT for urinary incontinence should include:

- a urogynaecologist
- a urologist with a sub-specialist interest in female urology

- a specialist nurse
- a specialist physiotherapist
- a colorectal surgeon with a sub-specialist interest in functional bowel problems, for women with coexisting bowel problems
- a member of the care of the elderly team and/or occupational therapist, for women with functional impairment. **[new 2013]**

The multidisciplinary team (MDT)

- Offer invasive therapy for OAB and/or SUI symptoms only after an MDT review. **[new 2013]**

Urinary incontinence in women

Issued: January 2015

NICE quality standard 77

guidance.nice.org.uk/qs77

Quality statement 7: Multidisciplinary team review before surgery or invasive treatment

Quality statement

Women with overactive bladder or stress urinary incontinence symptoms have a multidisciplinary team review before they are offered surgery or other invasive treatment.

Rationale

Surgery or other invasive treatment should only be considered if conservative management and pharmacological treatment have been unsuccessful. Multidisciplinary team review can ensure that all other possible treatments have been considered before surgery and other invasive treatments. The whole team approach can also help the decision of whether invasive treatment is suitable for the woman.

Quality measures

Structure

Invasive management and surgery for benign bladder conditions

Surgical intervention for OAB/UUI

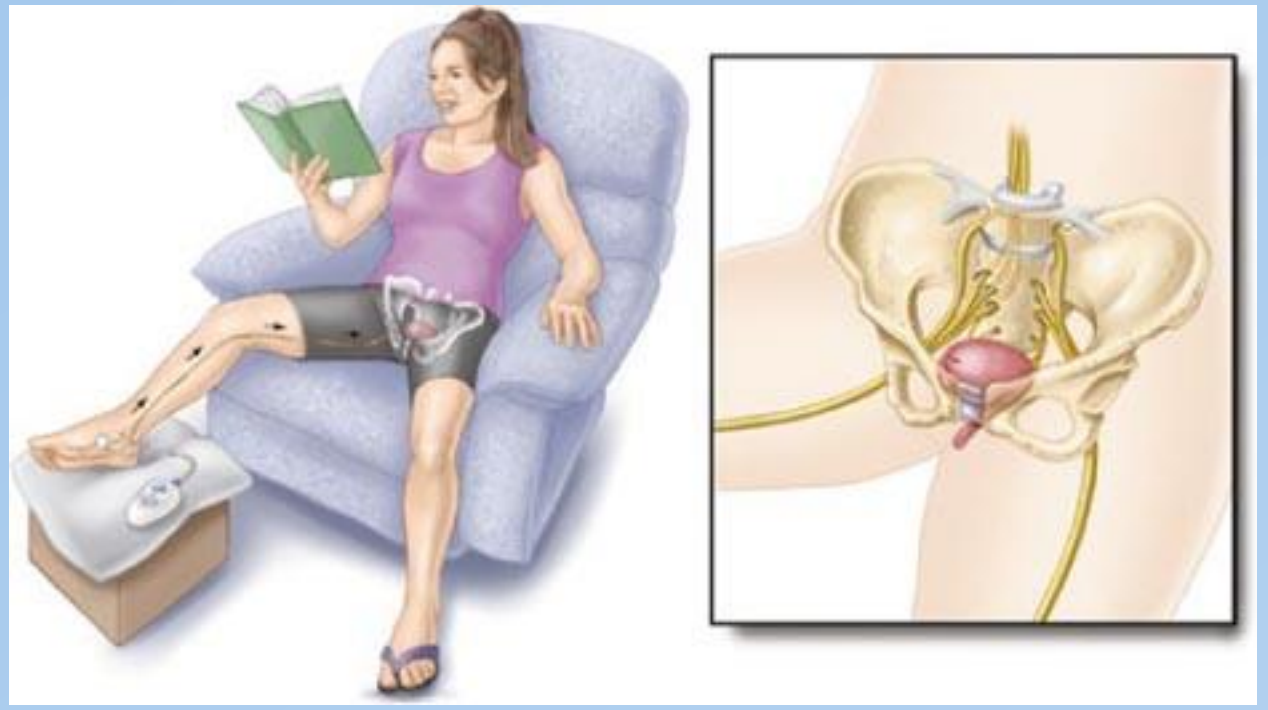
Indications

- Significant symptoms
- Failed conservative & drug therapy
- Realistic expectations

Procedures

- Cystodistension
- Botulinum toxin injections
- PTNS
- Autoaugmentation
- Clam cystoplasty
- Ileal conduit

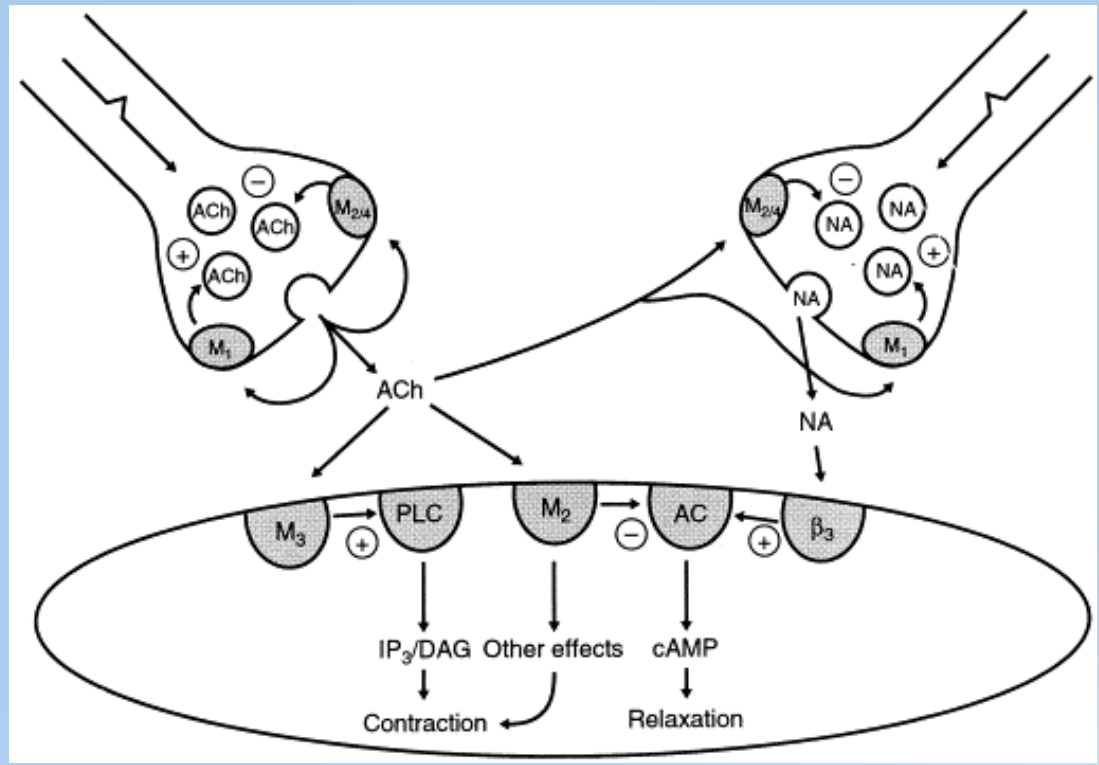
Tibial nerve stimulation (neuromodulation/SNS)



12 treatments, one per week, and each session takes about 30 minutes.

BOTULINUM TOXIN

- ISC
- Recurrent UTI’s
- Non curative



Surgical Intervention for Stress Urinary Incontinence

- Surgical options
  - Periurethral bulking
  - Mid urethral slings
    - Autologous: rectus or tensor fascia lata
    - Synthetic TVT-R (retropubic) vs TVT-O (transobturator)
    - Adjustable
    - Minislings
  - Colposuspension
  - Artificial urinary sphincter

Primary surgical intervention

Mid urethral tape is the new standard; as effective as colposuspension with less morbidity

- TVT-R/TVT-O 85% satisfaction rate; 66% dry rate
- TVT-R longer follow-up data, slightly better dry rate, but riskier
- TVT-O comparable outcomes, safer
- Adjustable slings: no better
- Minislings: little data; inferior results.

Independent

NEW MESH HORROR

For years, we've exposed how mesh implants used to treat women incontinent after childbirth have left many in agony. Now we reveal BOWEL patients are victims, too

Tragedy: Lucinda Methuen-Campbell took her own life after suffering dreadful pain

Daily Mail CAMPAIGN

HELP THE WOMEN MAIMED BY THE MESH

By LOIS ROGERS

HOW I will ever get over this, I just don't know,' says Philip Chatfield. 'If I hear a loud scream, it takes me straight back: sometimes it went on for half an hour without stopping.

'She was in agony. I just didn't know what to do. She tried so hard to live with it but, in the end, she just gave up.'

Philip, 59, a sculptor from the Gower Peninsula in remote South Wales, is describing the final years of his former partner, Lucinda Methuen-Campbell, the mother of their son, Angus, who is now 19.

Lucinda, 58, committed suicide earlier this year. She was one of more than 100 patients to have complained of crippling pain after they received implantable surgical mesh to treat bowel problems.

The material used is the same as the controversial gynaecological mesh used to repair post-childbirth incontinence. In some women treated for incontinence, this material has fragmented and 'migrated', leaving many in permanent, agonising pain.

Some have suffered such severe nerve damage that they cannot walk and rely on wheelchairs.

Following a long campaign by Good Health, the use of the vaginal mesh is now the subject of a government inquiry, but no date has yet been given for its conclusion.

But now, there are concerns about the mesh used in rectal surgery (rectopexy), with up to 100 patients given the mesh by a Bristol surgeon, Anthony Dixon, embarking on legal action — against Mr Dixon himself, as well as Southmead Hospital in Bristol where he worked for the NHS, and the Spire Bristol Hospital, where he practised privately.

Most are patients who developed constipation and extreme pain in mid-life, which subsequently turned out to be the symptom of a prolapsed bowel.

Lucinda was a private patient of Mr Dixon. 'She developed a bowel problem in 2013 and said she was in terrible pain,' recalls Philip.

'She found Mr Dixon on the internet and went to see him as a private patient in December of that year. He said he knew exactly what was wrong and seemed pretty gung-ho about fixing it.'

She had the first operation to put in the mesh early in 2014 — 'but it didn't work', says Philip. 'She was literally screaming in agony. She had two more operations, but neither of them worked, either.'

PHILIP continues: 'Although she and I had split up in 2001, when Angus was two, I felt I had to move back in to help her.

'I had no idea I was going to be there trying to help her for the next four-and-a-half years.

'I slept downstairs, but I could always hear her crying out. I couldn't work. I spent all my time trying to do practical things to help her.'

Lucinda, who also had a daughter, Poppy, 35, from an earlier relationship, lived in a village outside Swansea, South Wales, and had been a much-loved classroom assistant at a local primary school.

'I was the person who found her,' says Philip. 'The shock and trauma are very hard to cope with.

'To try so hard for so long to help someone, and all for nothing, is very hard to bear.'

Like Lucinda, Sam Van Der Heijden, 58, a former NHS administrator from Bexhill-on-Sea, East Sussex, who has three adult children, found her way to Mr Dixon as a private patient, following an internet search in 2011. 'He came up as a pioneering surgeon for bowel problems,' she says. 'He told me I needed a rectopexy. Mr Dixon told me the bowel was going to be pulled up and stapled with titanium tacks to the base of my spine.

'I was so pleased something was being done. I didn't question whether it would work.'

But she says she's been left in agonising pain, which has affected her marriage and her ability to work. She has since undergone further surgery to remove the embedded mesh, which has caused permanent nerve damage. 'This has ruined the past eight years of my life,' she adds.

Another of Mr Dixon's patients, Ian Waterfield, 56, a former chef from Huddersfield, is one of the first men to report life-limiting damage caused by mesh surgery.

A sports enthusiast who travelled the world swimming, skiing and attending music festivals, he developed digestive problems in mid-life, with bouts of projectile vomiting and severe constipation that began 14 years ago.

Despite several spells in hospital, his symptoms were repeatedly dismissed as irritable bowel syndrome — until 2009, when he was diagnosed with a prolapsed bowel. He was referred to Mr Dixon through the NHS and underwent the mesh repair operation in 2010.

But the procedure did not work and led to repeated operations and the removal of a section of his bowel.

'I have been a complete wreck ever since,' he says. 'I don't have a life, I have an existence.

'I can't work and my relationship broke down because of this. I am in constant pain — it's like bits of broken glass sticking into me.

'Some nights, I don't bother going to bed. I only sleep for five minutes at a time.'

Sohier Elneil, a London-based gynaecologist who specialises in repairing injuries linked to implanted surgical mesh, has become a vociferous campaigner against its use for women with incontinence.

She believes rectopexy is now unravelling as a potential problem area, too.

'In the past year, I have done repairs on 15 of Mr Dixon's patients,' she says.

'There is a problem with the material itself — disintegrating and moving around inside people's bodies — and with the technique being used to insert it.'

According to lawyer Madeleine Pinschof, of Thompsons Solicitors, who is representing 61 of Mr Dixon's patients, the complaints about Mr Dixon 'are mostly about whether the operations were appropriate in the first place'. She says some of the complaints relate to surgery that was performed up to ten years ago.

Last August, restrictions were placed on Mr Dixon's practice by the General Medical Council, preventing him from carrying out bowel repair surgery.

Chris Burton, the medical director of North Bristol NHS Trust, which operates Southmead Hospital, would not tell Good Health when Mr Dixon had stopped treating patients at the hospital.

He said: '[Mr Dixon] is not currently providing any clinical services to patients at our hospital.

'We would like to reassure patients that we are taking this very seriously and our investigations are continuing.

'It would be inappropriate for us to comment on specific details while our investigations are ongoing.'

Dr Jean-Jacques de Gorter, medical director of the Spire Group, said it had suspended Mr Dixon's practising privileges pending the investigation.

As the Mail has reported, last Friday, an inquest into Lucinda Methuen-Campbell's death concluded she had taken her own life because of intractable pain.

LUCINDA'S family say she had experienced mental health problems — which worsened after the death of her own mother in 2013 — before she saw Mr Dixon.

Her sister, Catherine, 53, a mother-of-four who lives in Lewes, East Sussex, says: 'We can't say if she killed herself because of the mesh. Mr Dixon should never have touched her, but he wasn't to know she was mentally ill because she saw him as a private patient and her GP would not have told him.'

Details of patients' complaints were put to Mr Dixon by Good Health through the Medical Protection Society, a doctors' insurance company which is co-ordinating his defence.

He declined to comment, citing patient confidentiality.

A spokesman for NHS Resolution, which deals with litigation by patients, said it is currently negotiating a group 'protocol' to cover the various types of compensation claims against Mr Dixon, but he said as more claimants are continuing to come forward, the process is 'ongoing'.

■ *FOR confidential support in the UK, call the Samaritans on 116 123 or visit a local Samaritans branch — see samaritans.org for details.*

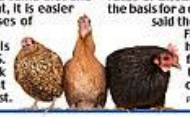
BIRDS OF A FEATHER

THE amazing things birds could teach us about human health. This week: Diagnosing cancer

THE chicken is the only animal that spontaneously develops ovarian cancer and up to 30 per cent of egg-laying hens develop the disease.

Because all birds can have the same diet and live in an identical environment, it is easier to investigate biological causes of disease than in women.

Now, researchers at Illinois and Rush universities in the U.S. are using chickens to look for markers in the blood that could help create a cancer test.



Diet may also have an impact, according to research on chickens published in the journal Gynecologic Oncology, which showed that chickens fed flaxseed had increased survival rates from ovarian cancer.

They also had less severe disease and lower rates of disease spread — which may provide the basis for a clinical trial of flaxseed in women, said the researchers.

Flaxseed contains omega-3, which has been shown to block the formation of tumours, such as those that can develop in the colon, breast, skin and lungs.

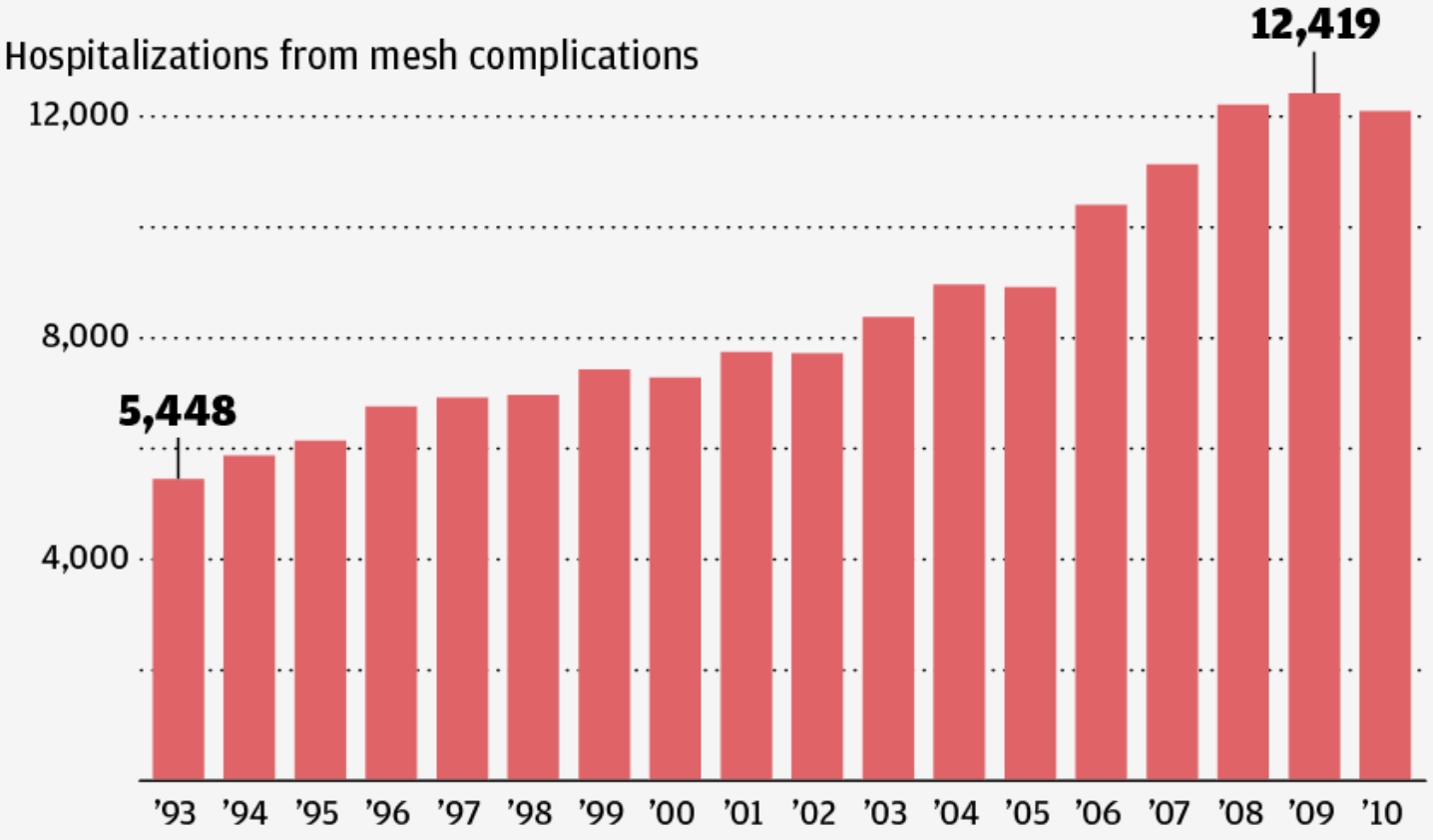
Picture: ALAMY

Mid urethral tapes complications

- Injury to urinary tract
- Intermittent self catheterization: short term 1:5, long term <1%
- Groin pain (TVT-O); bowel injury (TVT-R)
- *De novo OAB 16%*
- *Dysparunia 5%*
- *Tape extrusion; 7% in the long term. (Synthetic tapes <40 yrs with caution)*

MESH COMPLICATIONS

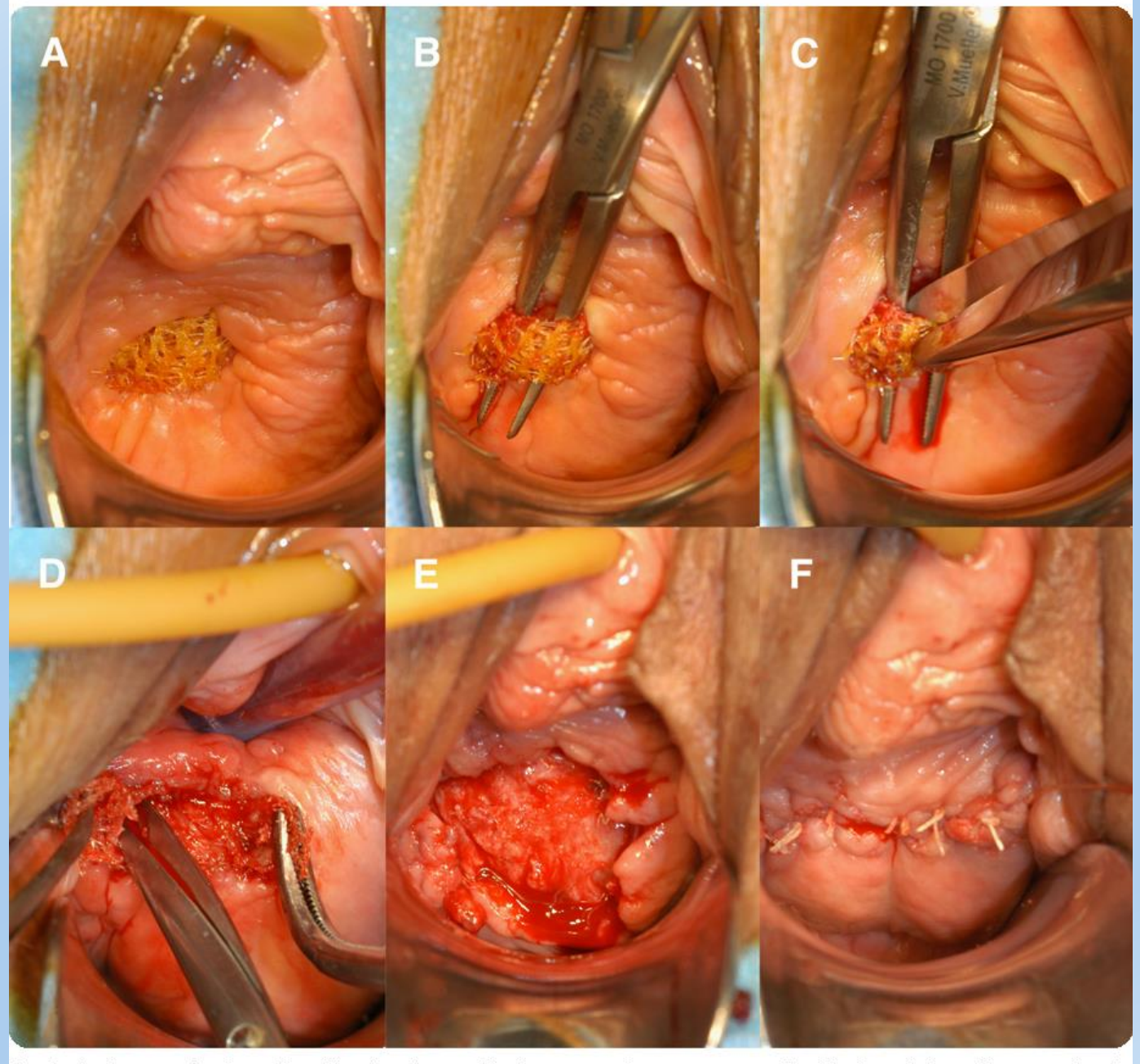
Hospitalizations due to vaginal mesh problems more than doubled from 1993 to 2010. Little medical evidence supported moving mesh from hernia repairs to women's pelvic organs. The FDA approved some vaginal mesh products based on their similarity to a product that had already been recalled for bad performance.

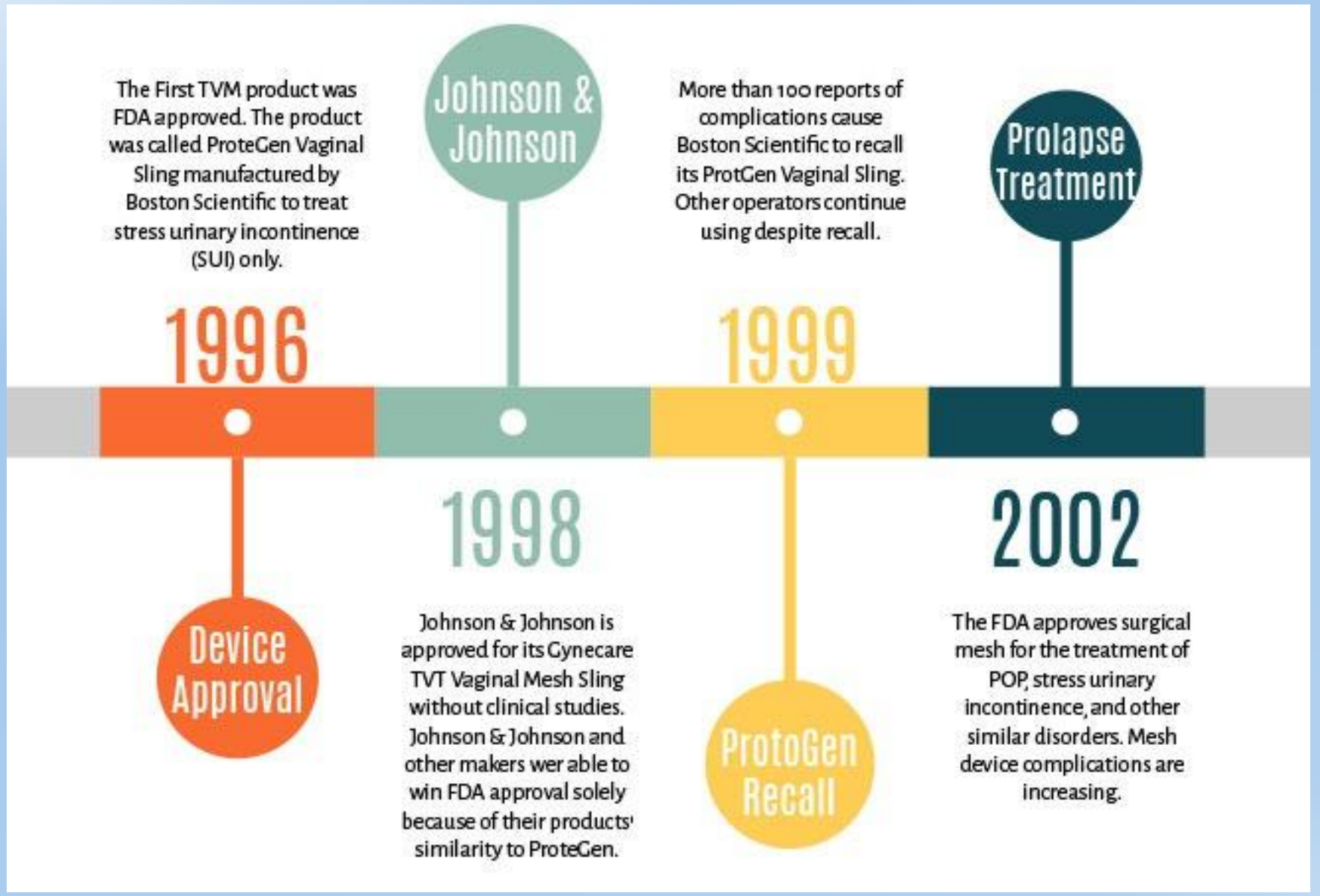


SOURCE: U.S. Health and Human Services Department

MCT

Surgical technique of mesh excision




1996
Device Approval
The First TVM product was FDA approved. The product was called ProteGen Vaginal Sling manufactured by Boston Scientific to treat stress urinary incontinence (SUI) only.
1998
Johnson & Johnson
Johnson & Johnson is approved for its Gynecare TVT Vaginal Mesh Sling without clinical studies. Johnson & Johnson and other makers wer able to win FDA approval solely because of their products' similarity to ProteGen.
1999
ProtoGen Recall
More than 100 reports of complications cause Boston Scientific to recall its ProtGen Vaginal Sling. Other operators continue using despite recall.
2002
Prolapse Treatment
The FDA approves surgical mesh for the treatment of POP, stress urinary incontinence, and other similar disorders. Mesh device complications are increasing.

Impact on management of patients with benign bladder conditions

Formal pathways

MDT

Reporting of outcome measures

Strong emphasis on conservative measures

Counselling

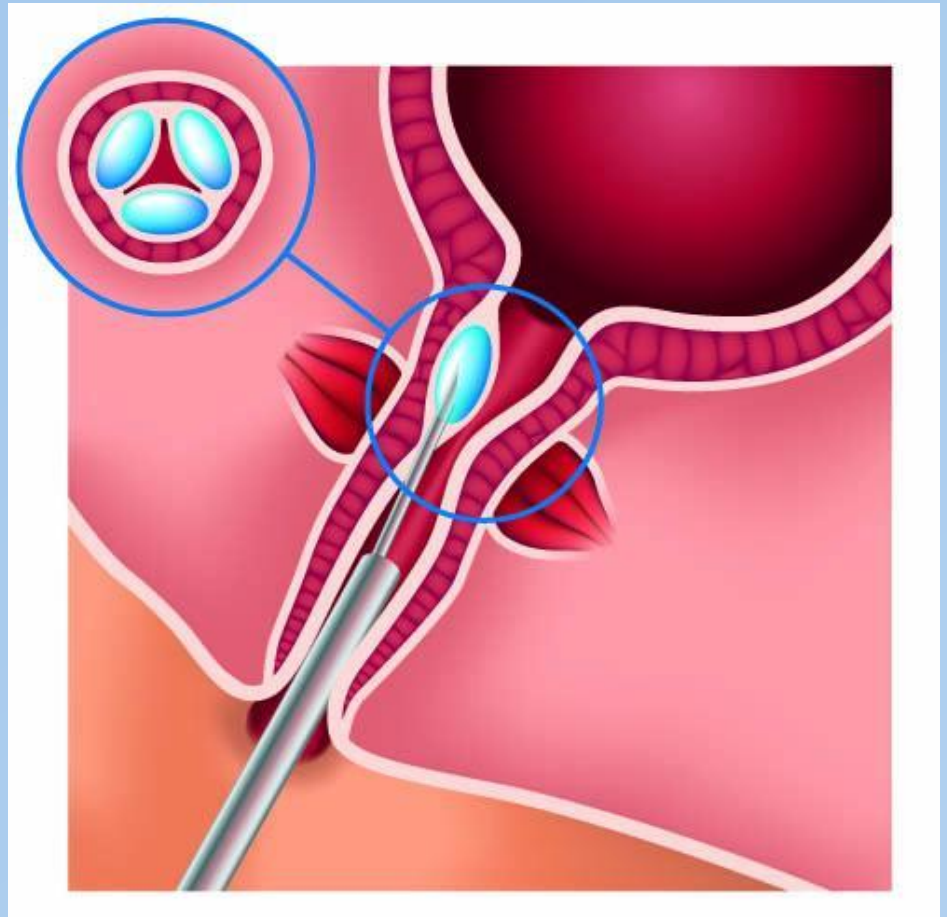
Shared decision making tools

Consent

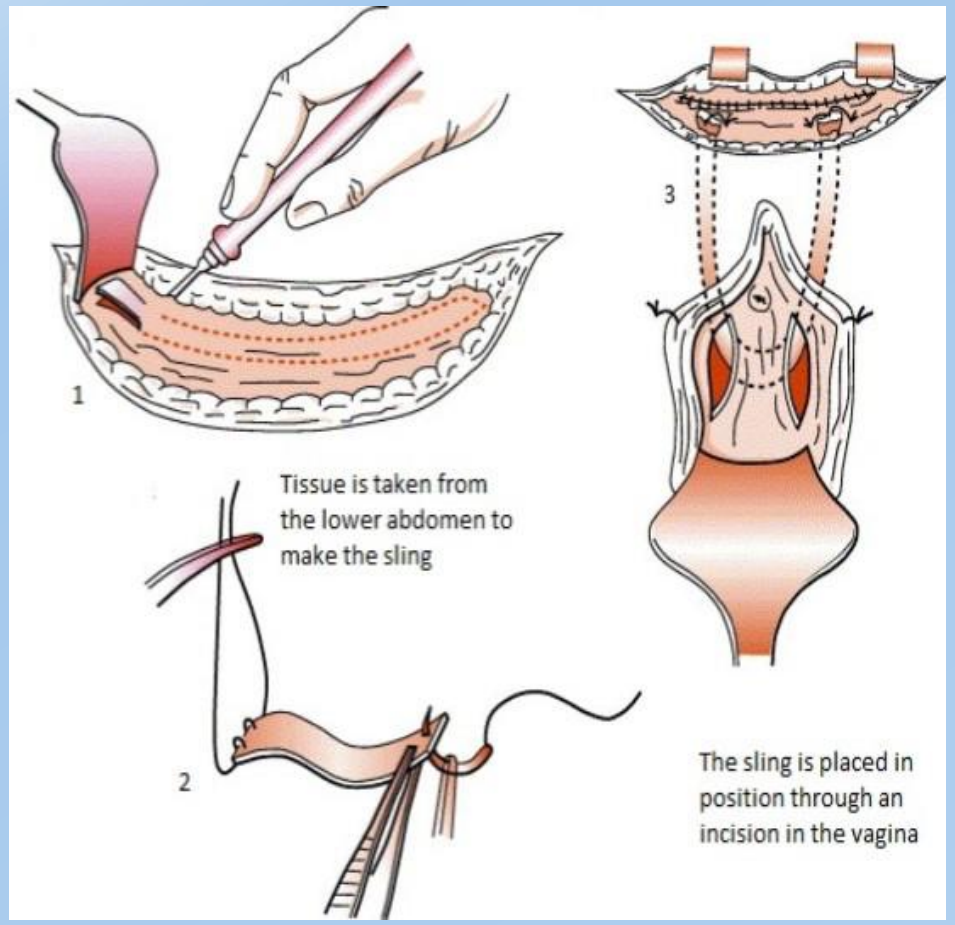
Cooling off period

Choice of procedures for SUI

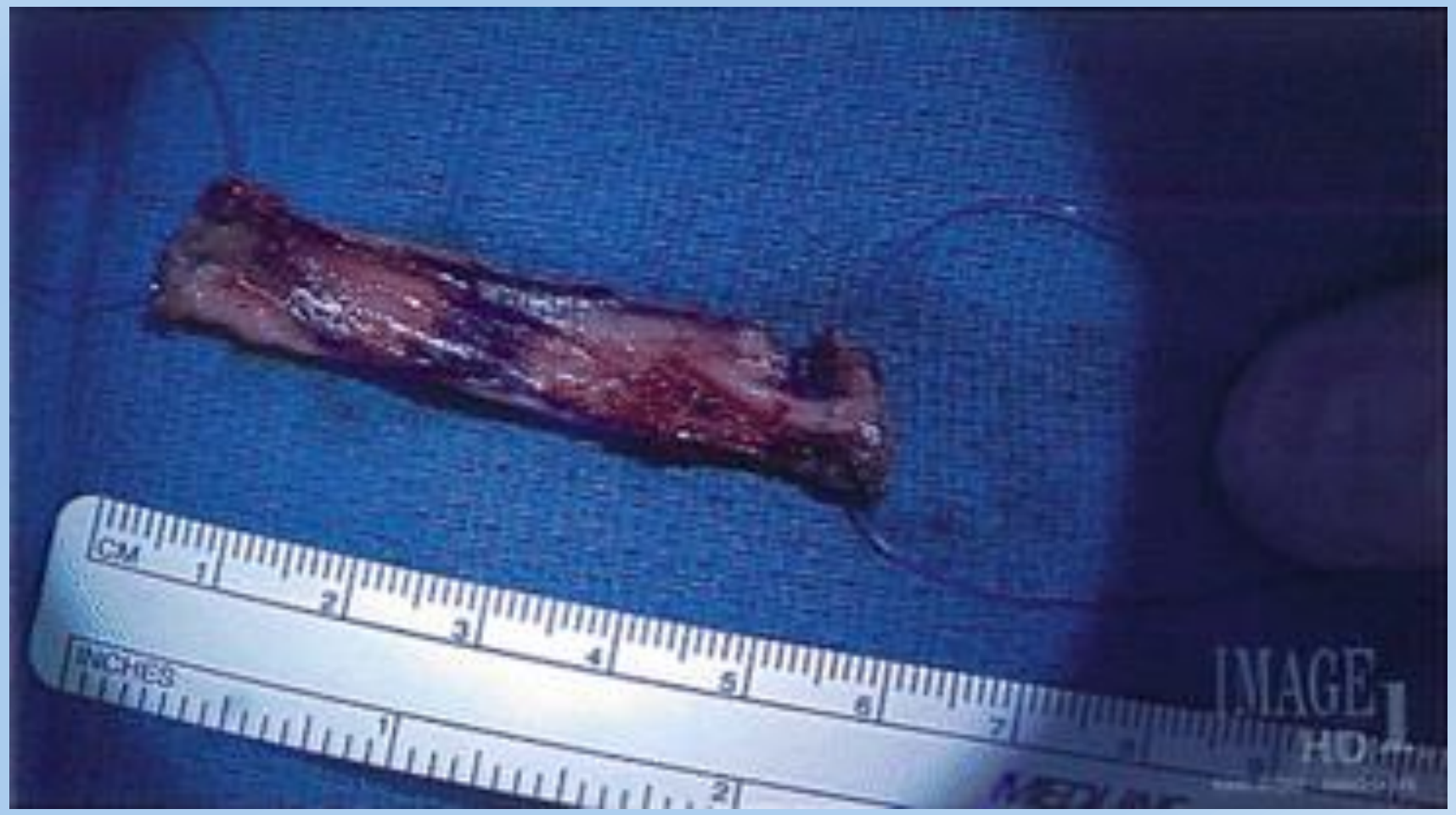
Periurethral bulking



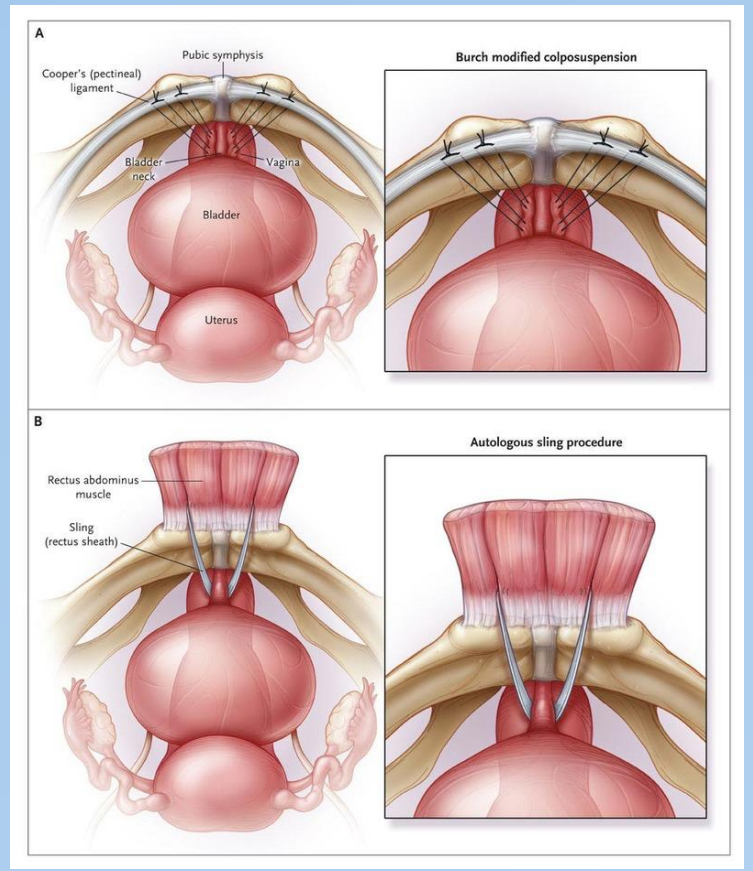
Autologous Pubovaginal Sling



- 90% satisfaction rate
- ISC up to 30%
- Scar pain
- 24-48 hours in patient stay
- Little risk of erosion


CM
1
2
3
4
5
6
7
INCHES
1
2
IMAGE

Colposuspension



Take home message

- Benign bladder conditions are very common
- Remember the red-flags and voiding diaries
- Manage empirically and conservatively in the first instance
- MDT
- Report outcomes
- Consent and mutual decision making tool
- Mesh is out!

  “out with the new, in with the old”

at least for the time being