Vaginal prolapse repair using mesh

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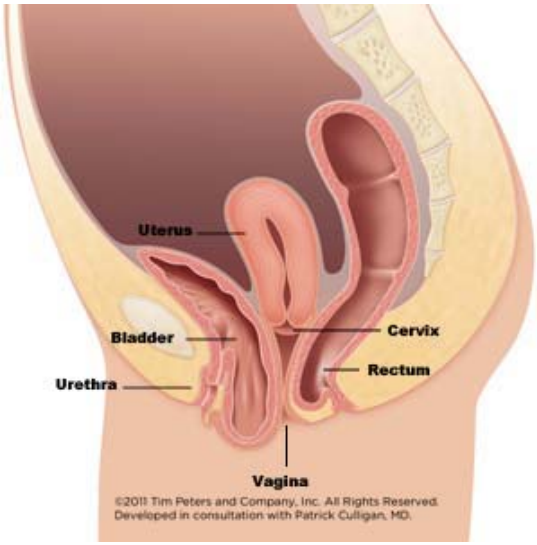
BACKGROUND


Uterus
Bladder
Urethra
Cervix
Rectum
Vagina
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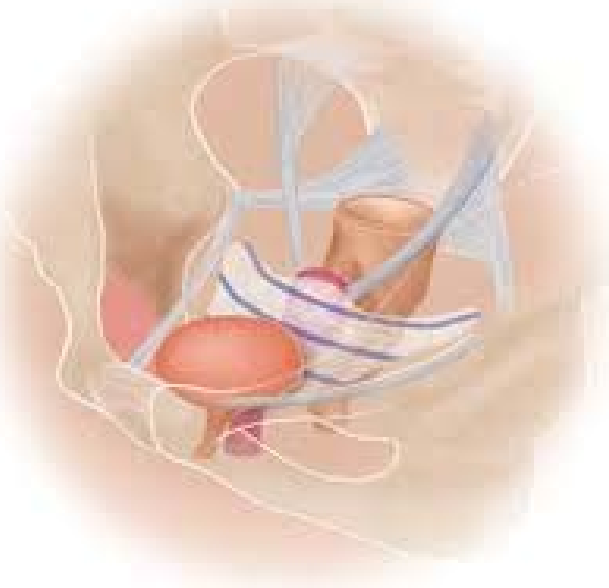
Developed in consultation with Patrick Culligan, MD.



The ‘mesh mess’

- 2002 - Mesh products for vaginal prolapse approved by the FDA
- October 2008 - Statement by the FDA reporting *rare* mesh-specific complications such as erosion, and limited evidence of benefit over native tissue repair (objective vs subjective). Caution urged.
- July 2011 - Further statement by the FDA reporting mesh-specific complications are *NOT rare*, again with limited evidence of any benefit. 522 studies sanctioned. Extreme caution urged.
- February 2012 – UGSA database established
- July 2012 – Several mesh products withdrawn from market (i.e. Prolift) after thousands of lawsuits filed by patients
- 2013 RANZCOG College Statement released with guidelines for consent, training, patient selection, and audit.

THE NATIONAL WOMEN'S VAGINAL MESH AUDIT

Our aims

- To retrospectively audit our outcomes for trans-vaginally implanted mesh, for the repair of pelvic organ prolapse, from 1 Jan 2005 to 31 Dec 2013
- To compare our mesh outcomes and complication rates to those reported in international literature
- And thereby to help direct/determine the future of vaginal mesh use at Auckland City Hospital

Methods

- 1177 potential cases coded as having had a “vaginal repair” between 1/1/05 and 31/12/13
- Operating theatre notes reviewed for all 1177 cases
- 196 surgical encounters identified as meeting inclusion criteria, having had a mesh placed transvaginally for the repair of pelvic organ prolapse
- Clinical records for eligible cases were comprehensively reviewed, and all relevant information transcribed onto a proforma. Two databases used – UGSA, and a local Excel file for information of interest that is not recorded on UGSA
- Databases merged and statistical analysis performed
- All patients who had mesh complications were ‘coded’ according to the IUGA/ICS complications classification calculator released in 2011. All four Urogynaecologists agreed on the coding given for each patient.
- Each patient could have more than one complication

Our cases

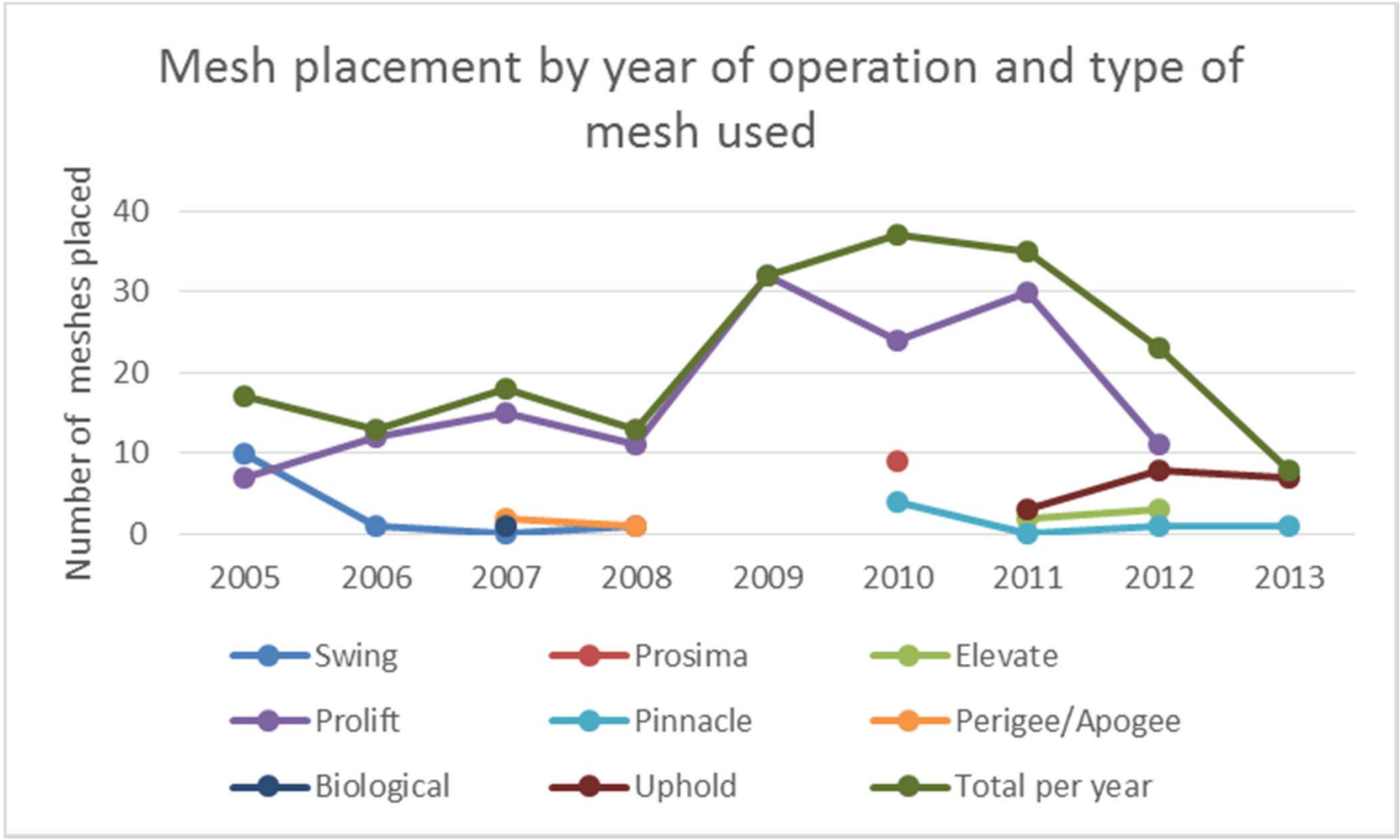
- 196 surgical encounters, from 192 individuals, which involved trans-vaginal placement of mesh for vaginal prolapse

OUR RESULTS: AN OVERVIEW

POPULATION DEMOGRAPHICS		
DHB of origin		
	ADHB	65%
	Other DHB's	35%
Ethnicity		
	NZ European	68%
	Other European	10%
	Maori	4%
	Other	18%
NZ Deprivation Index (median)		6
Age at operation (years)		64
BMI		
	18.5-24.9	29%
	25.0-29.9	38%
	> 30	32%
Smoking status		
	Current	9%
	Past/Never	91%
Parity (average)		3
Menopausal		
	Pre	6%
	Post	89%

OPERATION AND FOLLOWUP		
Surgeon		
	1	58%
	2	21%
	3	11%
	4	4%
	Other	5%
Anaesthetic Type		
	GA	93%
	GA + regional	2%
	Regional	5%
Antibiotic prophylaxis		
	Given	97%
	Not given	3%
Prolapse surgery (any compartment)		
	Primary repair	58%
	Re-do	42%
Estimated blood loss		
	0-299 mL	86%
	300-499mL	10%
	> 500mL	3%
Length of hospital stay (median/days)		3
Time to first outpatient visit (median/weeks)		9
Duration of outpatient follow up (median/months)		6.5

Trends in the use of mesh



COMPLICATIONS

Classifying complications (IUGA/ICS)

- Category
  - Vaginal complications – erosion, shrinkage, prominence
  - Bladder/urinary tract
  - Bowel
  - Skin, musculoskeletal
  - Systemic i.e. bleeding complications
- Time frame
  - Within 48 hours of surgery
  - 48 hours to 2 months
  - 2 to 12 months
  - More than 12 months after surgery
- Site of complication

Other outcome measures reported in literature

- New stress urinary incontinence
- New dyspareunia
- New chronic pelvic pain

Complications coding according to the ICS/IUGA

Of 192 patients, there were….

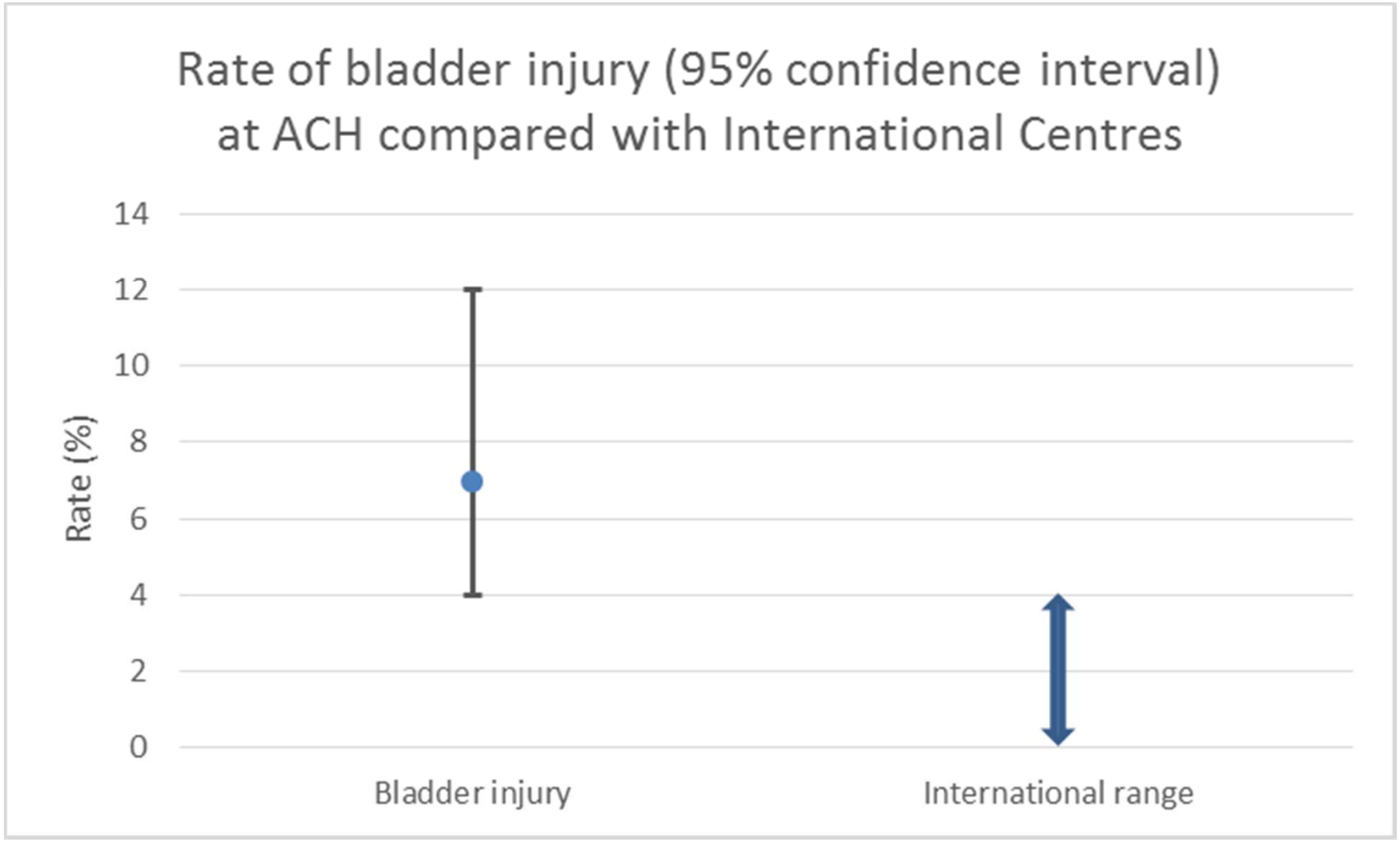
- 42 patients who had any complication identified and coded (22 percent)
- 31 patients who had any vaginal mesh complication (16 percent)
- 15 patients who had mesh erosion through vaginal skin (8 percent)
- 1 patient who had a mesh erosion into bladder (< 1 percent)
- 11 of 16 patients (69 percent) with erosion returned to theatre for treatment

Complication summary

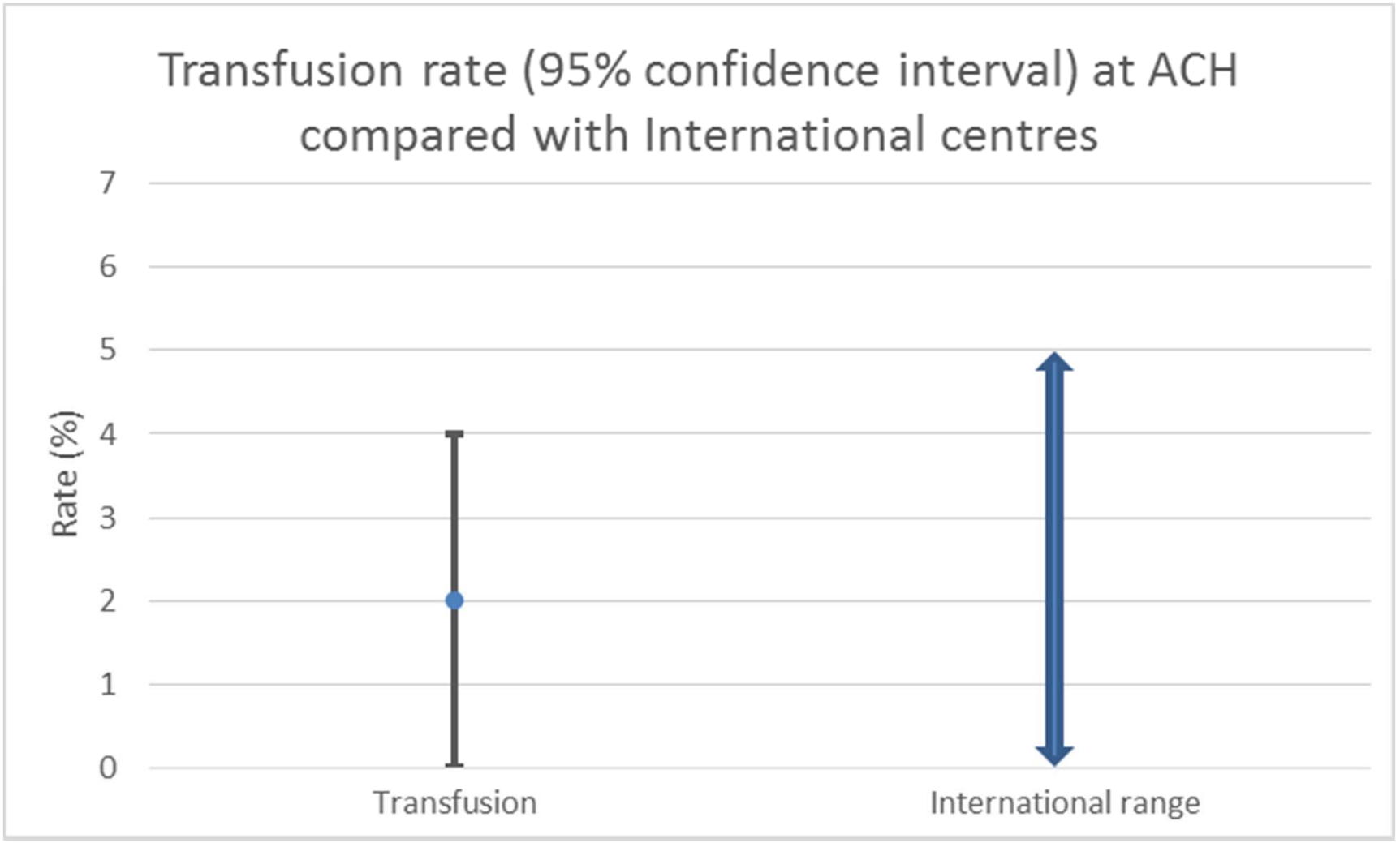
- Cystotomy or trocar injury to bladder = 7%
- Need for perioperative transfusion = 2%
- Mesh erosion = 8%
- De novo stress urinary incontinence = 8%

- De novo dyspareunia = 7 women*
- Chronic pelvic pain = data not available

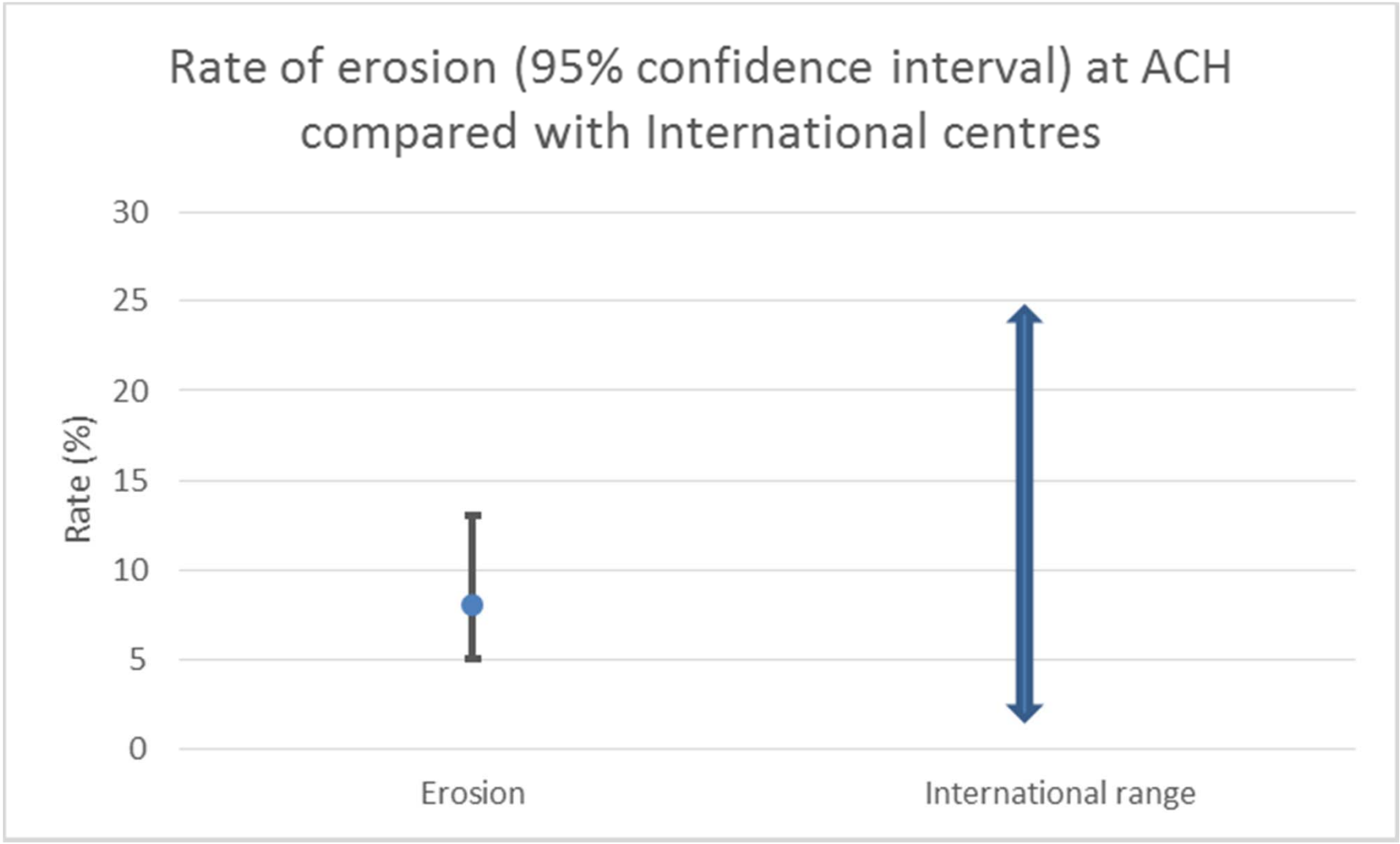
Bladder injury



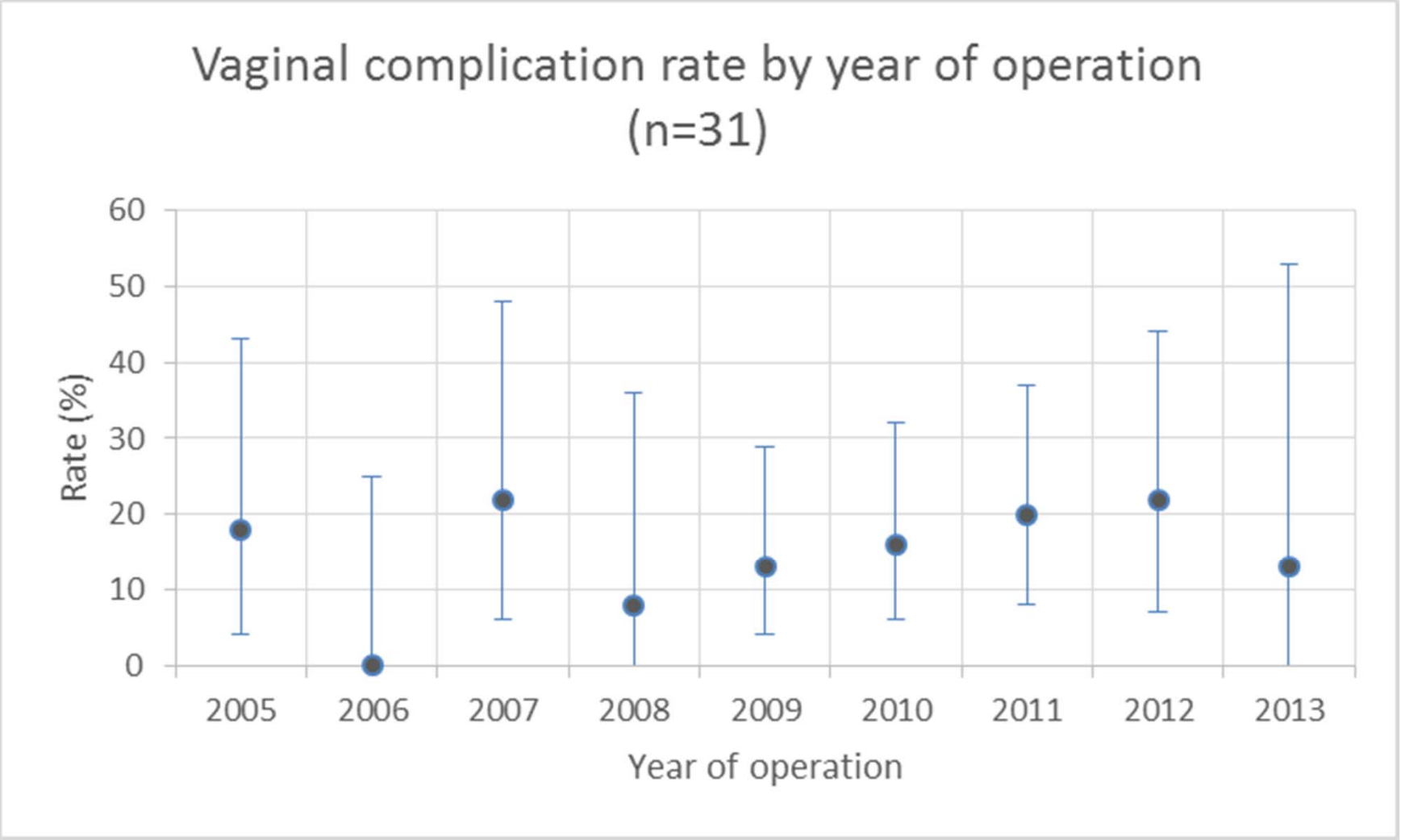
Perioperative transfusion



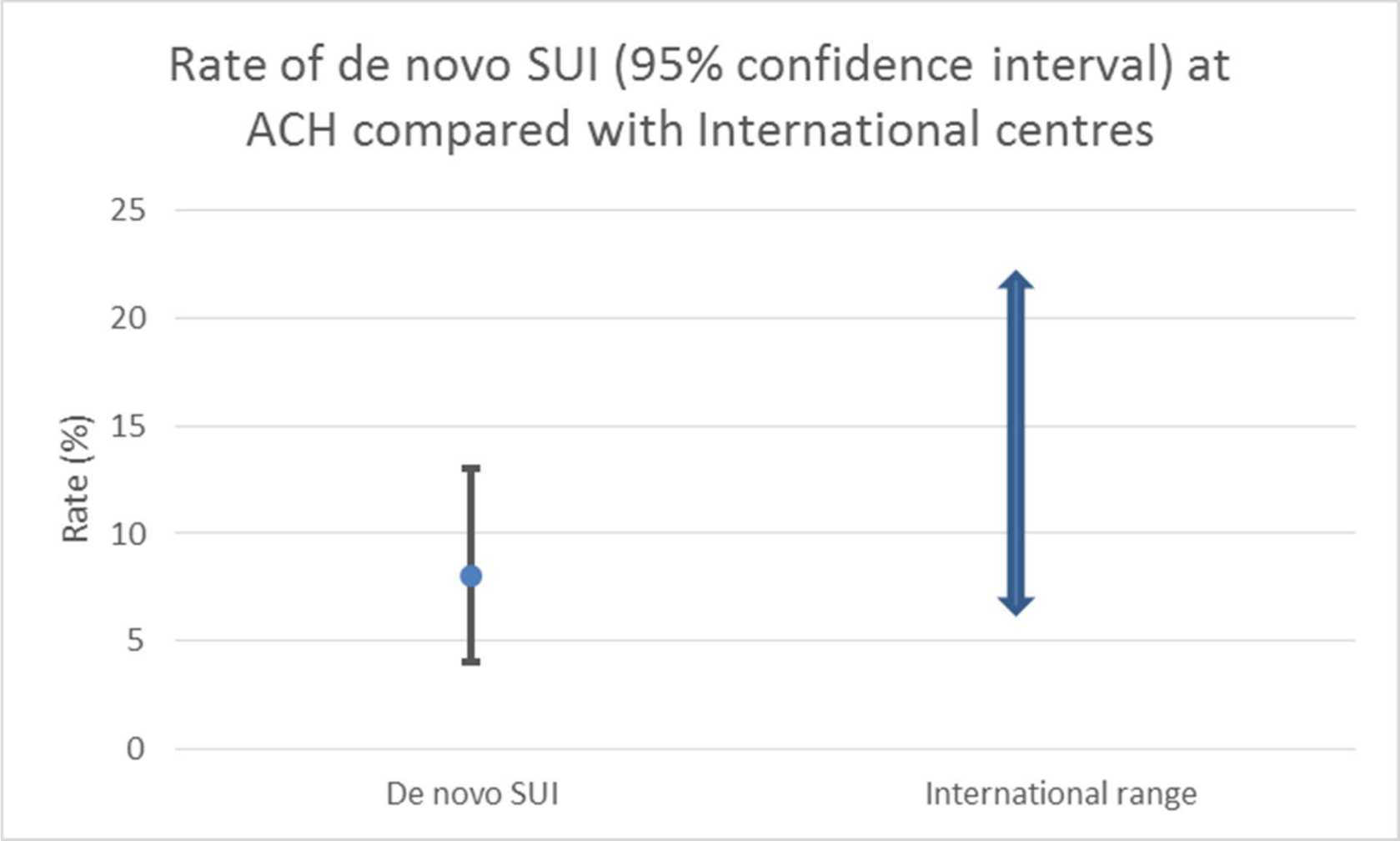
Mesh erosion



Vaginal complications over time



De novo SUI


Rate of de novo SUI (95% confidence interval) at ACH compared with International centres
Rate (%)
25
20
15
10
5
0
De novo SUI
International range

WHERE TO FROM HERE?

The future of mesh at ACH

- Significant change in practice with far fewer meshes now being placed
- Development of an Evidence Based scoring aide to determine in which patients the benefits of mesh are likely to outweigh the risks
- Practitioners to use UGSA database to record and review their individual practice and outcomes

Difficulties

- Large number of external referrals – not all perioperative information available
- Consistency of documentation, for example POP-Q score (stage of prolapse) absent for 7% of patients preoperatively
- Lack of validated tools to assess subjective outcomes for patients – ie sexuality, pelvic pain, urinary and prolapse symptoms, and overall satisfaction