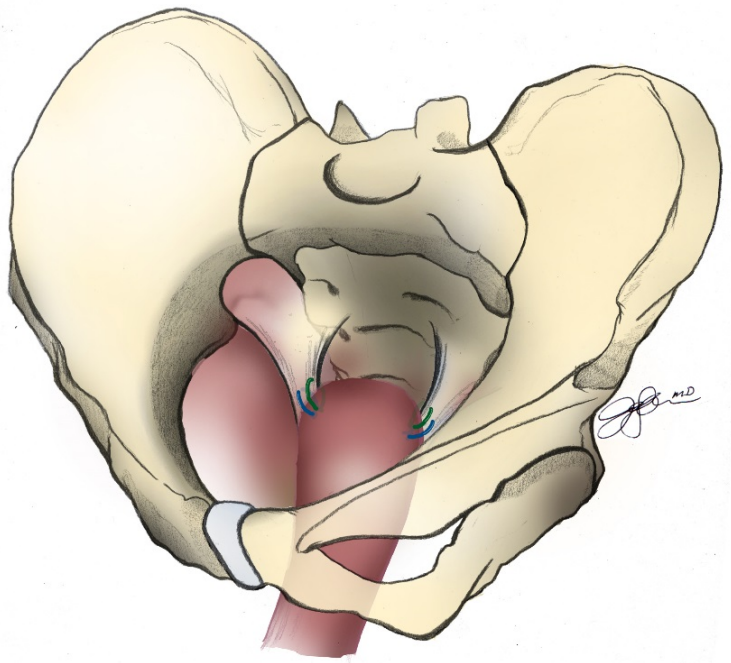
pelvic floor disorders Network

Eunice Kennedy Shriver National Institute of Child Health and Human Development

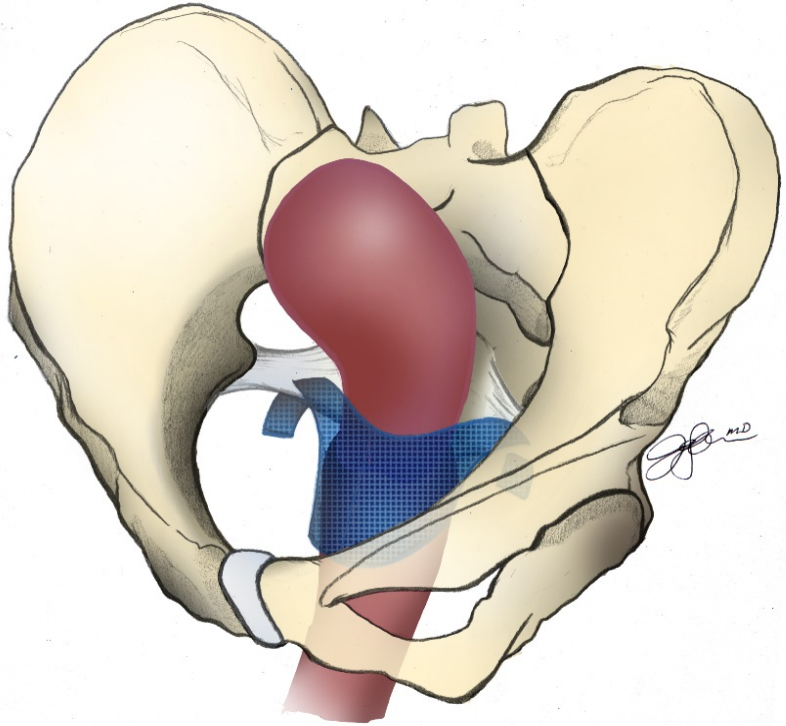


The SUPeR trial:

A Randomized Trial of Vaginal Hysterectomy versus Vaginal Mesh Hysteropexy for Uterovaginal Prolapse

Charles W. Nager, MD for the
Pelvic Floor Disorders Network

October 11, 2018



RTI INTERNATIONAL

Summary of Major Inclusion and Exclusion Criteria

Inclusion

- **Amenorrheic** for at least one year (all were postmenopausal)
- Symptomatic **prolapse beyond the hymen**
- **Uterine descent** into at least the **lower half of the vagina**

Exclusion

- **Uterine abnormalities** were excluded

Primary Outcome

The primary outcome of treatment failure was a composite measure in which failure could be **any** of the 3 following events:

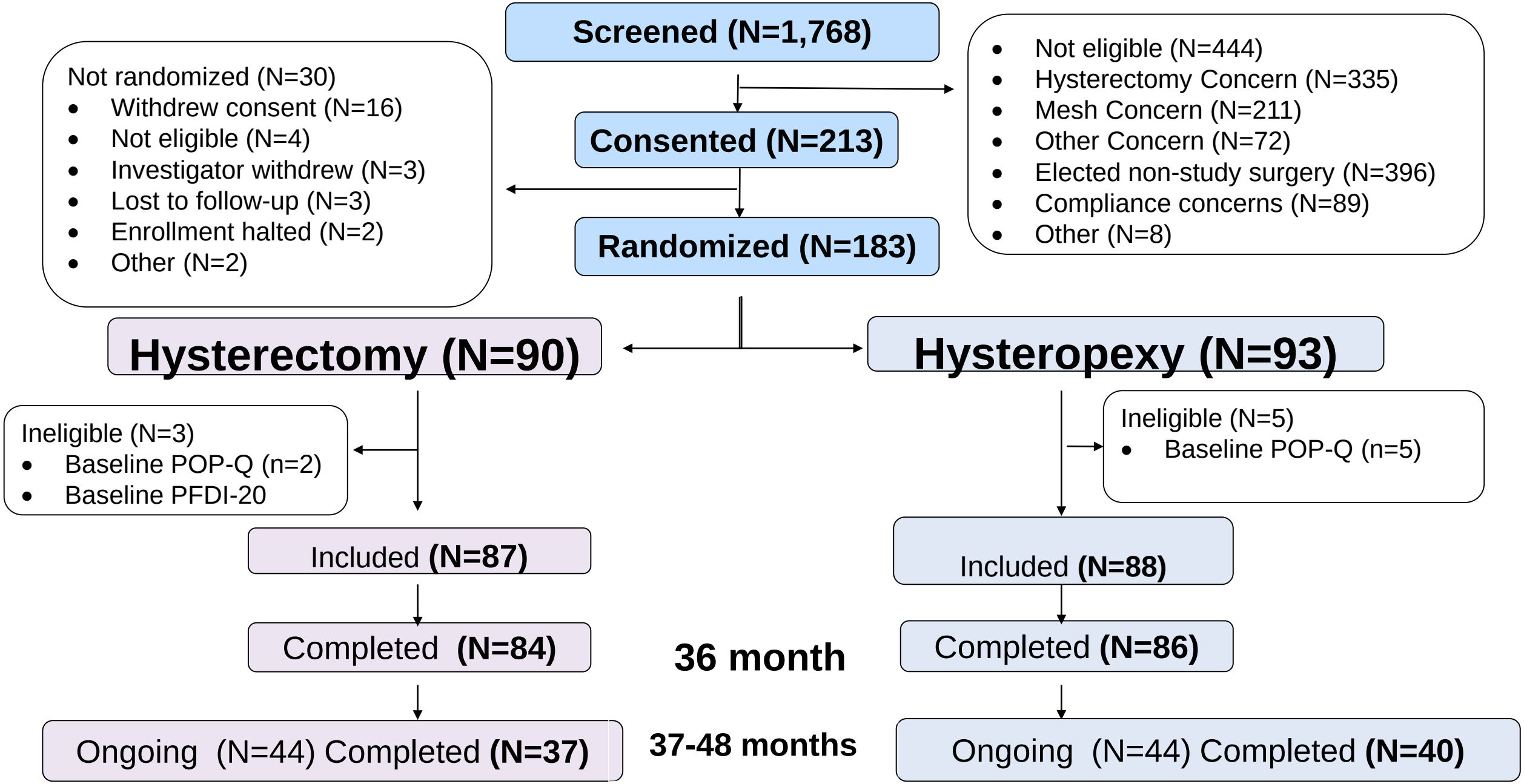
- **Retreatment**
- **POPQ beyond the hymen**
- **Bulge symptom**

Secondary outcomes

- **Functional** outcomes measured by numerous validated questionnaires
- **Safety and adverse event** outcomes

Methods

- **Participants masked** throughout duration of study
- **Anatomic outcome** (POPQ) exams by non-surgeons
- **PRO questionnaires** were administered by masked study personnel.


Screened (N=1,768)
Not eligible (N=444)
Hysterectomy Concern (N=335)
Mesh Concern (N=211)
Other Concern (N=72)
Elected non-study surgery (N=396)
Compliance concerns (N=89)
Other (N=8)
Consented (N=213)
Not randomized (N=30)
Withdrew consent (N=16)
Not eligible (N=4)
Investigator withdrew (N=3)
Lost to follow-up (N=3)
Enrollment halted (N=2)
Other (N=2)
Randomized (N=183)
Hysterectomy (N=90)
Hysteropexy (N=93)
Ineligible (N=3)
Baseline POP-Q (n=2)
Baseline PFDI-20
Ineligible (N=5)
Baseline POP-Q (n=5)
Included (N=87)
Included (N=88)
Completed (N=84)
36 month
Completed (N=86)
Ongoing (N=44) Completed (N=37)
37-48 months
Ongoing (N=44) Completed (N=40)

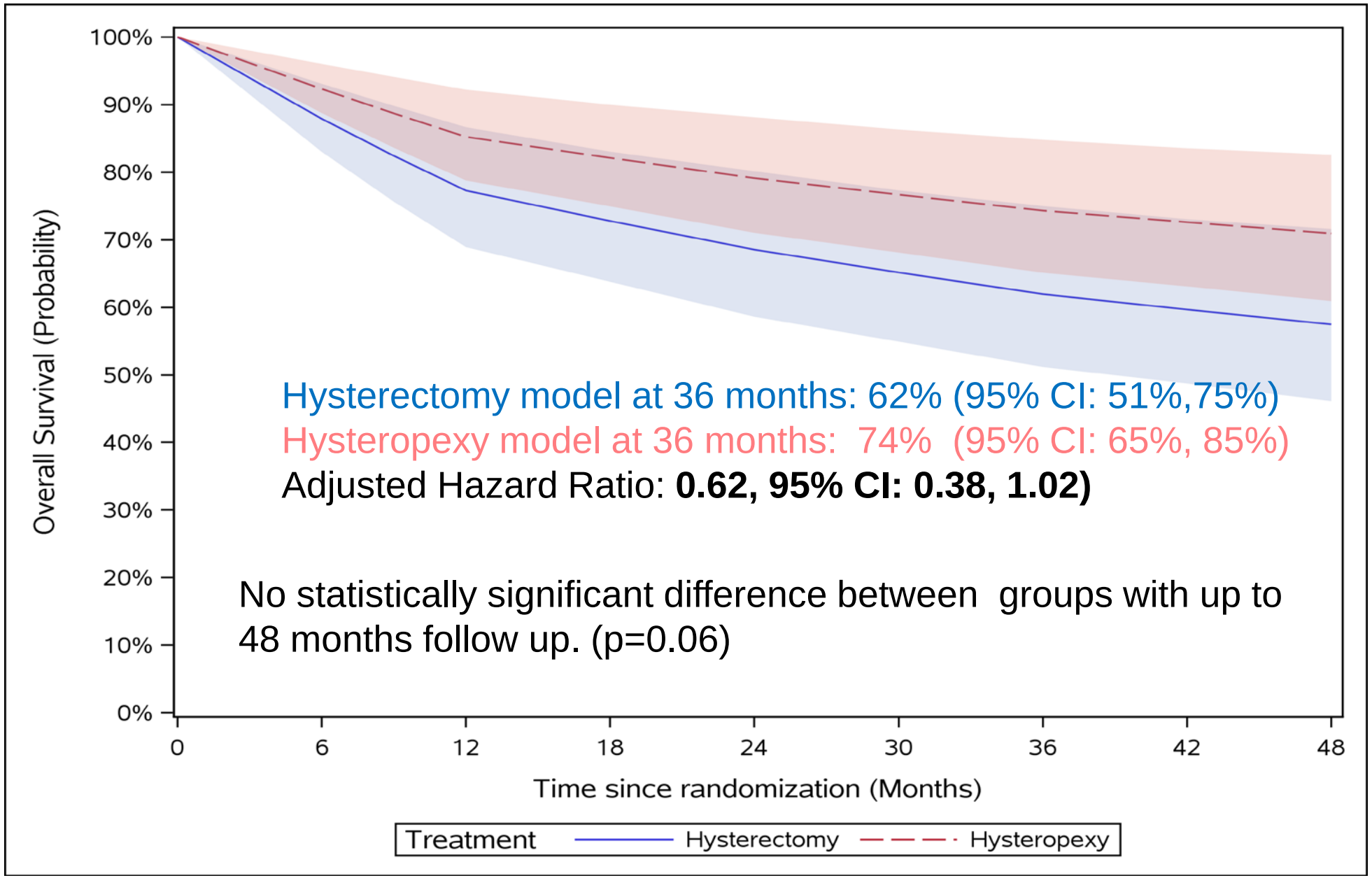
Baseline Demographic and Clinical Characteristics
Results are expressed as percent and (n) unless otherwise stated

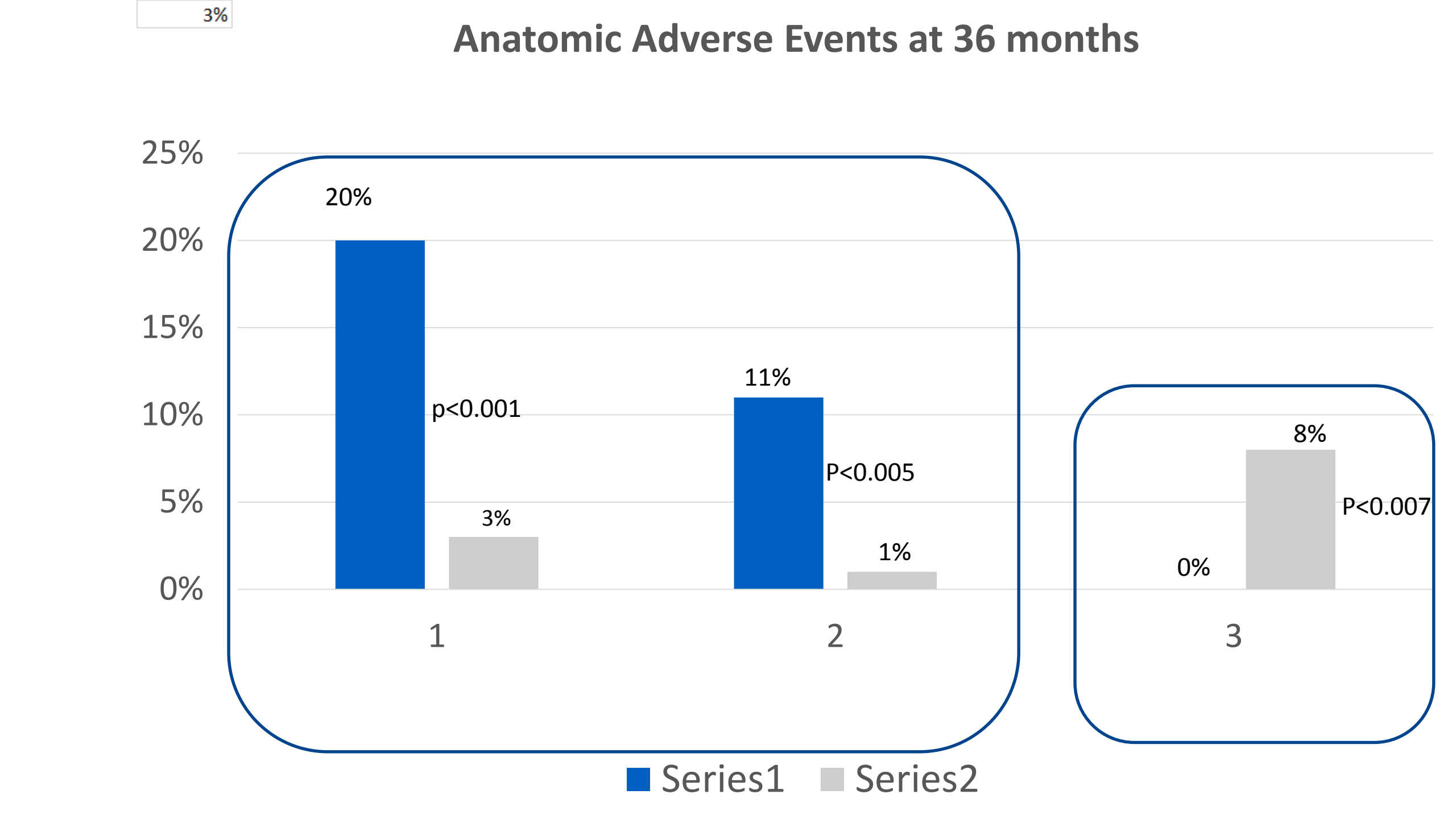
	Hysterectomy N=87	Hysteropexy N=88
Age y, mean (SD) [range]	66.2 (7.4) [49-80]	65.5 (7.3) [47-82]
Race		
White	89% (77)	83% (73)
Black/African-American	3% (3)	9% (8)
American Indian/Alaska Native	5% (4)	0% (0)
Ethnicity, No. (%)		
Hispanic/Latina	8% (7)	10% (9)
Not Hispanic/ Not Latina	90% (78)	86% (76)
Gravidity, median (IQR)	3 (2)	3 (3)]
Parity, median (IQR)	2 (1)	3 (1)
BMI, mean (SD) [range]	28.2 (4.4)	28.9 (4.0)
Postmenopausal, % (n)	98% (85)	98% (86)

Baseline Demographic and Clinical Characteristics

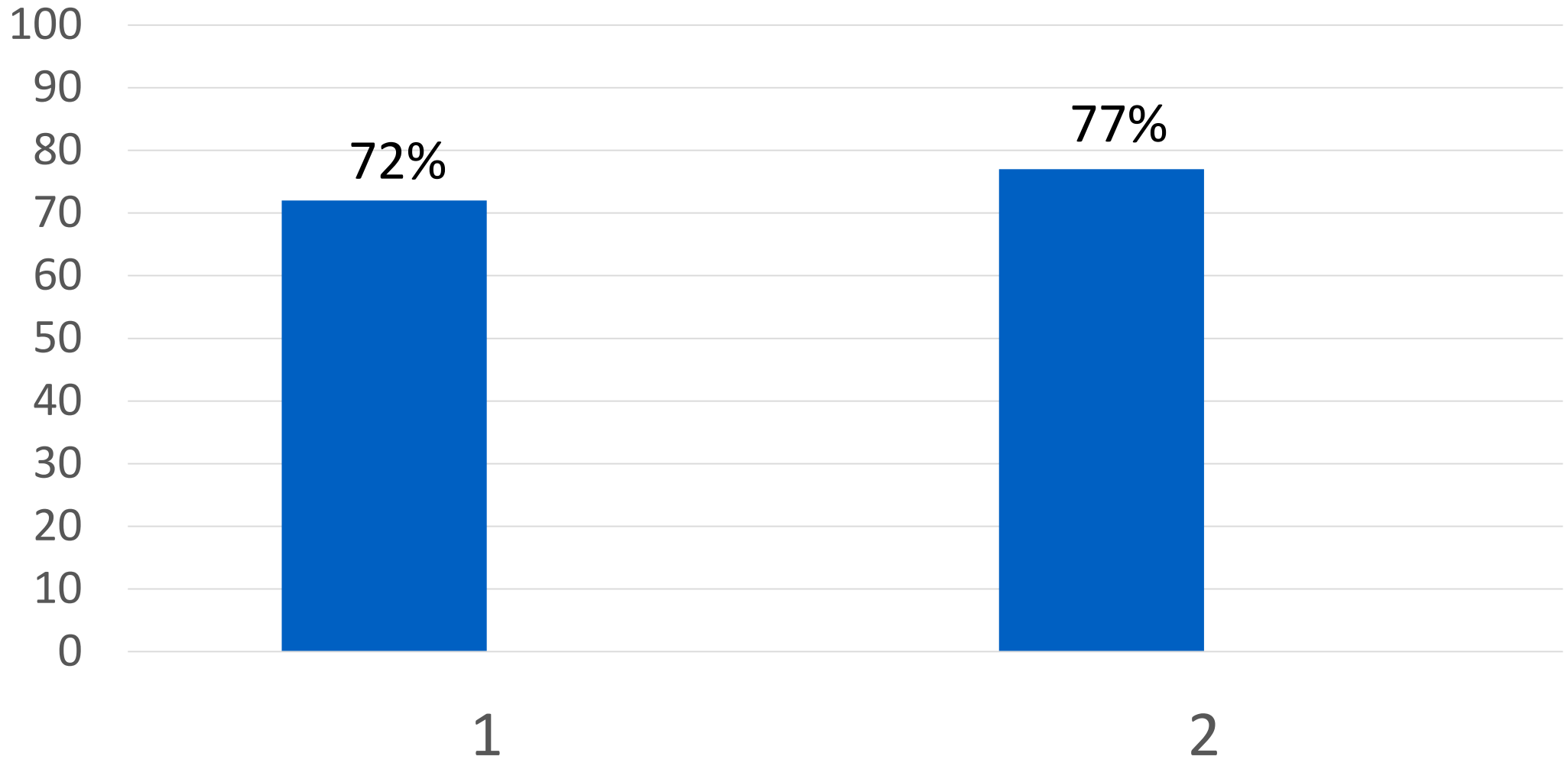
	Hysterectomy (N=87)	Hysteropexy (N=88)
POPQ value, mean, (SD)		
Ba	3.0 (2.2)	3.3 (2.0)
Bp	0.7 (3.0)	0.4 (3.0)
C	0.7 (3.6)	0.4 (3.5)
TVL	9.1 (1.1)	9.1 (1.1)

Survival Analysis of Composite Primary Outcome for Hysterectomy and Hysteropexy Groups




3%
Anatomic Adverse Events at 36 months
25%
20%
15%
10%
5%
0%
20%
p<0.001
3%
11%
P<0.005
1%
0%
8%
P<0.007
1
2
3
Series1
Series2

Percent who remained masked in each group at 36 months



P = 0.46

Dyspareunia (SA= Sexual Activity)

		Hysterectomy		Hysteropexy		P value between groups at baseline	P value between groups at 36 mo.
Data Source	Outcome	Baseline	36 mo	Baseline	36 mo		
PISQ-IR; Dyspareunia (usually or always)	SA	46% (40/87)	47% (34/73)	34% (30/88)	39% (29/74)	0.11	0.37
	SA, have dyspareunia	46% (17/37)	16% (5/31)	38% (10/26)	19% (5/26)	0.55	0.76
	No SA b/o of dyspareunia	33% (15/45)	11% (4/35)	33% (19/58)	24% (10/42)	0.95	0.16
	SA- de novo dyspareunia		4% (1/25)		0% (0/19)		0.38
	No SA b/o de novo dyspareunia		7% (2/27)		5% (2/38)		0.72
AE questions q 6 months	All dyspareunia – worsening, de novo, or preventing intercourse		2% (2/90)		10% (9/93)		0.03

Pelvic Pain (captured from Adverse Event Questions every 6 months)

	Hysterectomy	Hysteropexy	P value
Pelvic Pain	10% (9/90)	6% (6/93)	0.38
Daily Pelvic Pain	5% (4/87)	3% (3/88)	0.69

Discussion –Major Findings

- Hysterectomy and hysteropexy had **comparable primary outcome** success rates through 36 months. We are following patients for 60 months. Conclusions could change with more extended follow-up.
- **When groups were masked to the procedure:**
  - **No differences in Patient Reported Outcomes.**
  - **Both groups** had improvement in sexual function and decreases in dyspareunia.
  - De novo dyspareunia and pelvic pain **rates are low** with no difference between groups

What I would like to tell the panel- C. Nager

- Newer, non-trocar current anterior/apical mesh kits may end up with superior anatomic outcomes compared to native tissue procedures. We will know in 2 years.
- Mesh exposure rates are approximately 8% but none of these required OR management and this has to be compared to 11-20% suture exposure and granulation tissue rates which also did not require OR management.
- Using validated questionnaires, dyspareunia is common before surgery in postmenopausal uterovaginal prolapse patients and improves with surgery in most cases for native tissue and mesh procedures
- De novo dyspareunia and pelvic pain are uncommon with no difference between native tissue or vaginal mesh procedures.
- Even assuming there could be more sexual pain with transvaginal mesh, in my experience there are patients who may still select mesh during shared decision making if prolapse outcomes are superior. These are usually older, rarely or non-sexually active, women and they should have that option.