#405 VUE: Two UK based Multicentre Parallel Randomised Controlled Surgical Trials for Uterine and Vault Prolapse

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OBJECTIVES for BOTH TRIALS

Primary outcomes: POP-SS, Quality of Life, cost-effectiveness

UTERINE

Figure 1: Uterine CONSORT

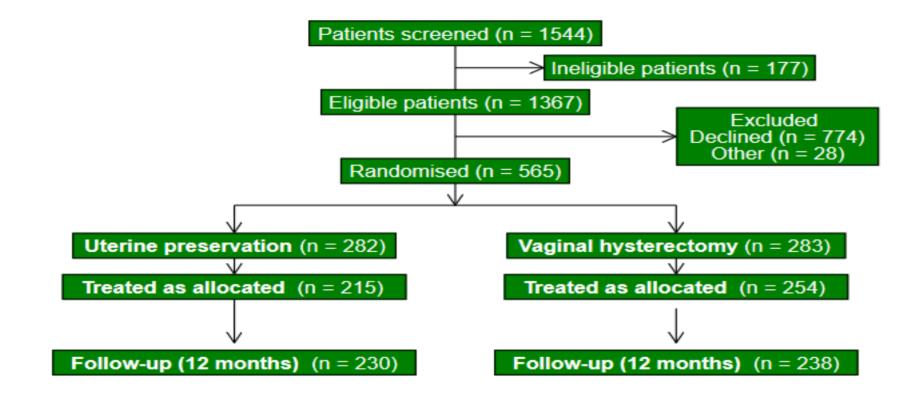


Table 1: Uterine baseline measurements **Total Participants:** 563 from 45 UK NHS sites

	Uterine Preservation Mean (SD) N	Vaginal Hysterectomy Mean (SD) N
Age, years	63.4 (10.5), 280	63.9 (9.9), 283
Duration of symptoms (years)	4.1 (5.7), 264	4.0 (6.3), 256
POP-SS at baseline	13.7 (6.4), 268	13.5 (5.9), 265
Prolapse related effect on QoL score	6.8 (2.7), 273	6.5 (2.9), 270

Surgery

 Allocation fidelity was high (Uterine preservation 76.8% (215 of 280), Vaginal Hysterectomy 89.8% (254 of 283))

12 Month Outcomes

Table 2: Uterine 12 Month Primary Outcome measurements Responses from 468 of 563 participants (84.6%)

	Uterine Preservation Mean (SD) n	Vaginal Hysterectomy Mean (SD) n	Effect Size (95% CI) p-value
POP-SS	4.2 (4.9) 230	4.2 (5.3) 238	-0.05 (- 0.91,0.81) 0.91
Prolapse related effect on QoL	1.7 (2.5) 237	1.5 (2.5) 239	0.12 (-0.26,0.49) 0.54
Cost effectiveness	Uterine preservation £235 more expensive (95% CI £6 to £464)		-0.004 (-0.026, 0.019)

Secondary outcomes

Recommend to a friend?

All participants were asked if they would recommend their procedure to a friend. Significantly more women would recommend vaginal hysterectomy to a friend (odds ratio 0.39, 95% CI, 0.18 to 0.83).

Adverse Events

30 Serious adverse events (5.7%) – NO difference between groups

KEY MESSAGES

- No difference at 12M in
 - prolapse symptoms
- symptom related QoL
- Uterine preservation was more expensive
- Low rate of surgical adverse events
- Women more likely to recommend vaginal hysterectomy

VAULT

Figure 2: Vault CONSORT

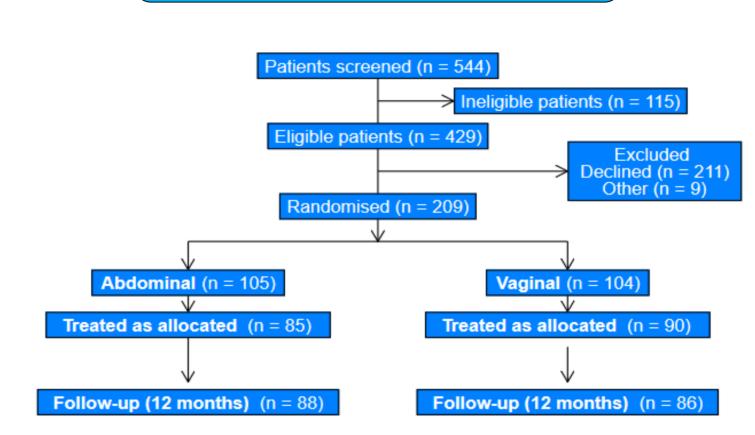


Table 3: Vault baseline measurements

Total Participants: 208 from 45 UK NHS sites

	Abdominal Mean (SD) N	Vaginal Mean (SD) N
Age, years	65.1 (8.0), 104	66.4 (8.3), 104
Duration of symptoms (years)	3.7 (4.8) 95	2.4 (2.4) 98
POP-SS at baseline	15.1 (6.5) 101	14.8 (5.7) 100
Prolapse related effect on QoL score	7.1 (2.6) 100	7.0 (2.6) 103

Surgery

 Allocation fidelity was high (Abdominal 81.8% (85 of 104), Vaginal 86.5% (90 of 104))

12 Month Outcomes

Table 4: Vault 12 Month Primary Outcome measurements Responses from 177 of 208 participants (85.0%)

	Abdominal Mean (SD) n	Vaginal Mean (SD) n	Effect Size (95% CI) p-value
POP-SS	5.6 (5.4) 88	5.9 (5.4) 86	-0.61 (-2.08,0.86) 0.42
Prolapse related effect on QoL	2.3 (3.0) 87	2.6 (2.8) 87	-0.25 (-1.10,0.59) 0.56
Cost effectiveness	Abdominal surgery £570 more expensive (95% CI £459 to £682)		+0.004 (-0.031, 0.041)

Secondary outcomes

Recommend to a friend?

All participants were asked if they would recommend their procedure to a friend. There was no difference between groups (odds ratio 0.84, 95% CI, 0.32 to 2.18).

Adverse Events

12 Serious adverse events (6.0%) – NO difference between groups

KEY MESSAGES

- No difference at 12M in
 - prolapse symptoms
 - symptom related QoL
- Abdominal surgery was more expensive
- Low rate of surgical adverse events

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