434

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HYSTERECTOMY OR UPHOLD UTERINE CONSERVATION IN WOMEN WITH APICAL PROLAPSE: A PARALLEL COHORT STUDY OF 6 MONTHS

Hypothesis / aims of study
To compare objective and subjective cure rates in Uphold and vaginal hysterectomy.

Study design, materials and methods
This study was planned and designed as a multicentre RCT but due to poor recruitment it was changed to patient preference study. Women with symptomatic uterine descent referred for vaginal prolapse surgery were included. Women who chose Uphold™ were required to have an endometrial assessment. Uphold™ was initially performed as a vertical incision however changed to a horizontal incision with plication and single layer closure with IV antibiotics and gentamicin irrigation, concomitant prolapse surgery was at the discretion of the surgeon. VH was performed in standard fashion, together with concomitant modified McCall Culdoplasty or high intra-peritoneal uterosacral suspension. Routine clinic follow up was scheduled at 6 weeks, 6 & 12 months, involving a clinical review, examination with symptom & quality of life questionnaires. Primary outcome was incidence of stage 2 prolapse in any compartment and a composite cure of no leading edge beyond the hymen, absence of bulge symptoms on questionnaire and no retreatment. Secondary outcomes were quality-of-life measures (PFDI-20, PFIQ-7, PISQ, Patient Global impression of improvement, EQ5D and a health score). Assuming a recurrence rate of 30% for VH, with a power of 80%, a sample size of 49 each arm would be required to detect a clinical difference of 20% with Uphold™, using a one sided a of 0.05. Allowing for attrition rate of 15%, we propose to recruit a total of 114 subjects for the trial. Outcomes were compared with Pearson chi^2 test for categorical data and Student t test or Wilcoxon rank-sum for continuous data as appropriate.

Results
We performed 50 VH and 52 Upholds from August 2011 to June 2016, a long recruitment period for Uphold as it coincided with transvaginal mesh FDA notification. Table 1 showed balanced demographics and POP-Q measurements between groups. Table 2 displays the prolapse outcomes at 6 months. The incidence of stage 2 prolapse in any compartment at 6 months was 64% in VH and 46% in Uphold. The composite cure rate was 82% in VH and 86.5% in Uphold. PGI-I was not different between the groups with 44/47 in VH and 38/40 in Uphold reporting very much better or much better. There was significant change in POPDI-6 ($p<0.0001$), CRAD-8 ($p=0.0004$), UDI-6 ($p<0.0001$), total PFDI 20 ($p<0.0001$) and PFIQ7 scores ($p =0.0004$) between the two time points but not between two comparators. There was no significant difference in surgical complication ($p=0.0797$), assessed using Clavien-Dindo classification. In the Uphold group, there were 9 grade 1 for prolonged catheterization, 3 grade 2 (2x UTI's and 1 mesh exposure that resolved with oestrogen) and 4 grade 3, one mesh exposure requiring excision (2AT2S1), 1 vaginal adhesion separated without anaesthetic and 2 repeat surgery for stress urinary incontinence. In the vaginal hysterectomy group, there was 1 grade 1 for prolonged catheterization, 7 grade 2 (1x vault infection requiring readmission for IVAB, 1 vault haematoma with readmission, 1 PE, 4 UTI's).

Interpretation of results
Uphold is an option for uterine conservation with equivalent cure and low morbidity to VH.

Concluding message
Uphold and VH appear to have equivalent objective and subjective cure at 6 months with no significant difference in surgical complications. Longer-term follow-up is anticipated.

Table 1: baseline characteristics

	VH n= 50	Uphold n=52	P value
Age M± SD	61.7±9.2	63.6±9	0.2981
Menopause n (%)	42 (84%)	48 (92.3%)	0.1930
Sexually active n(%)	29 (58%)	26 (50%)	0.4178
HRT	Local = 5 Oral = 2	Local = 11 Oral = 1	0.2392
Parity median (IQR)	3(2, 3.25)	2 (2,3)	0.105
BMI M± SD	25.8± 6	26.3±3.8	0.6736
Prev POP/UI op n	2	5	0.2621
Point Aa median (IQR)	2 (0.5, 2)	1 (1,2)	0.4973
Point Ba	2 (0.5, 2)	1 (1, 2)	0.6148
Point C	1(-1.5, 2)	0 (-2, 1)	0.1954
TVL	9.5(8,10)	9 (9, 10)	0.9789
Ap	-2(-2, 0.5)	-2(-3, 0)	0.2361
Bp	-2(-2, 0.5)	-2(-3, 0)	0.2596
Stage 2 POP n(%)	23 (46%)	27 (51.9%)	0.5497
Stage 3 POP	25 (50%)	23 (44.2%)	0.5595
Stage 4 POP	1 (2%)	1 (1.9%)	1
PGI-S median(range)	3(1-4)	3(1- 4)	0.6599

Table 2: results

6month	VH (n =50)	Uphold (n=52)	P value
PGII (median &range)	1 (1-3)	1(1-3)	0.3745
POPDI-6 M± SD	9.6 ±13.7	12.6±16.5	0.3644
CRAD-8	12.7±10	15.4±14.7	0.3112
UDI-6	19.2± 18.1	18.3± 19.4	0.8220
PFDI 20	41.65± 32.5	46.4± 40.7	0.5492
PISQ12	34.9± 4.9	33.6± 8.7	0.5221
PFIQ7	11.5± 27.5	12.6± 24	0.8416
EQ5D	6.1± 0.4	5.8 ±0.3	0.5355
EQ5D Health score	85	80	0.6069
Ba median (IQR)	-1(-2, -0.75)	-2 (-2, -1)	0.1280
C	-6(-8, -4.75)	-6.5 (-7,-5)	0.6291
Bp	-3(-3,-2)	-2 (-3, -2)	0.6059
TVL	9 (8, 10)23	10 (9, 10)	0.0054
Apex stage ≥2 n	0	0	1
Ant Stage ≥2 n	27 (54%)	21 (40.4%)	0.1684
Post Stage ≥2 n	10 (20%)	8 (15.4%)	0.5410
Stage ≥2 in any compartment n(%)	32 (64%)	24 (46%)	0.0702
Incidence of SUI	12/50 (24%)	18/46 (39%)	0.1101
Reoperation	0	3 (5.8%)	0.2329
Composite cure n(%)	41 (82%)	45 (86.5%)	0.5287

References

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Disclosures

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