

Initial Clinical Experience with a New PVA Microsphere (Bead Block™) for Uterine Artery Embolisation for Fibroids

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Study Purpose

- To evaluate the effectiveness of Bead Block Embolic Microspheres in patients undergoing Uterine Artery Embolisation (UAE)
 - Improvements in symptom severity
 - Uterine volume reduction and dominant fibroid volume reduction
 - Improvements in health-related quality of life

Data Evaluation

- Technical assessment
- Clinical assessment
 - Three and six months' follow-up
 - Volume and perfusion changes (Contrast enhanced MRI)
- Patient assessment
 - Quality of life
 - Satisfaction with treatment results

Study Population/Demographics

Demographic Characteristics			
Age in years (median)		n=42 44	
Volume of uterus to UAE in cm³ (median)			
	Total	484.50	
	Berlin (n=23)	422.74	
	Tilburg (n=19)	633	p=0.022 Mann-Whitney test
Volume of dominant fibroid* prior to UAE in cm³ (median)			
	Total	223.17	
	Berlin (n=23)	164.18	
	Tilburg (n=19)	276	p=0.031 Mann-Whitney test
Dominant symptom			
	Heavy menstrual bleeding	66.67%	
	Intermenstrual or menstrual pelvic pain	11.90%	
	Bulk related symptoms	21.43%	
Number of fibroids			
	Singular	33.33%	
	2 to 4	28.57%	
	5 or more	38.10%	
Location of dominant fibroid*			
	Subserosal pedunculated	4.76%	
	Subserosal	21.43%	
	Transmural	28.57%	
	Intramural	28.57%	
	Submucosal	14.29%	
	Submucosal pedunculated	2.38%	

* dominant fibroid defined as largest fibroid at baseline imaging

Embolisation Protocol

- Large lumen microcatheter (2.8F), inner lumen 0.026 - 0.027
- 500-700 micron beads, upsize after 6 cc
- Angiographic endpoint
 - Left to the discretion of operator: "Preserved antegrade flow" within UA (limited technique) or "(near) stasis" was acceptable
 - Endpoint checked after 5 minutes; if necessary additional beads were delivered

Results

Technical Assessment

- 100% technically successful bilateral UAE
- No microcatheter occlusion

Notes: 1/42 patient with a proven ovarian artery supply of a subserosal fluid

2/42 patients were re-embolised after three months because of persistent symptoms

Clinical Assessment

Three month follow-up

- 90-100% infarction of fibroid tissue load (all fibroids seen on MRI) in 26/35 pts (74.3%)
- Comparison of angiographic endpoint and infarction rate in individual patients indicates that best results were obtained with an endpoint close to stasis
- Extended study to optimise overall infarction rate by modifying endpoint and particle size

3 Month MRI Follow-up				
	n	Volume before UAE* median	3 month follow-up* median	Decrease in volume (%) mean
Uterus				
Total	35	471	337.79	30.45 p<0.001
Berlin	17	414.45	326.8	25.07 p<0.001
Tilburg	18	630.5	491	35.53 p<0.001
Dominant Fibroid**				
Total	35	220.88	96.79	49.77 p<0.001
Berlin	17	135	72.94	53.29 p<0.001
Tilburg	18	267	144.5	46.45 p<0.001

* data given in ccm
 ** dominant fibroid defined as largest fibroid at baseline MR imaging
 p-values belong to Wilcoxon-test for paired samples and belong to the values presented in the line above

Imaging Results



3 months post UAE



6 months post UAE

6 Month MRI Follow-up

	n	Volume before UAE* median	6 month follow-up* median	Decrease in volume (%) mean
Uterus				
Total	24	465.09	302.92	39.13
Berlin	12	407.8	356.96	p<0.001 33.75
Tilburg	12	550.5	341.5	p<0.003 44.5 p<0.002
Dominant Fibroid**				
Total	24	212.87	88	56.66
Berlin	12	183.87	86.4	p<0.001 54.72
Tilburg	12	234.5	88	p<0.002 58.6 p<0.002

* data given in ccm

** dominant fibroid defined as largest fibroid at baseline MR imaging

p-values belong to Wilcoxon-test for paired samples and belong to the values presented in the line above

Patient Assessment

Uterine Fibroid Symptom and Quality of Life (UFS-QUL) Questionnaire Results

Normal* mean (SD)		n	Before UAE mean (SD)	3 month follow-up mean (SD)	Difference mean (SD)	p-value paired t-test
22.50 (21.10)	Symptom severity	34	43.11 (15.13)	25.00 (15.33)	18.11 (17.03)	<0.001
84.00 (23.50)	Concern	34	67.79 (26.18)	79.71 (21.17)	-11.91 (22.86)	=0.005
90.80 (14.70)	Activities	33	60.28 (24.93)	79.33 (20.99)	-19.05 (28.09)	<0.001
83.90 (20.60)	Energy/mood	33	60.17 (23.32)	75.65 (20.78)	-15.48 (25.50)	=0.001
93.30 (17.20)	Control	32	64.53 (16.82)	78.28 (18.52)	-13.75 (22.03)	=0.001
79.00 (29.00)	Self-consciousness	34	72.30 (20.59)	84.56 (17.42)	-12.25 (21.64)	=0.002
80.20 (32.00)	Sexual function	33	66.67 (27.18)	74.24 (26.87)	-7.58 (36.57)	=0.243
86.40 (17.70)	HRQL total	29	63.97 (18.12)	78.75 (18.30)	-14.77 (21.36)	=0.001

*Figures taken from Spies et al. Obstet Gynecol 2002 (N=29) and do not refer to same patient population

UFS-QOL = uterine fibroid symptom and quality of life

HRQL = health-related quality of life

SD = standard deviation

Patient Satisfaction at 3 and 6 Month Follow-up

Satisfaction	3 months	6 months
Very satisfied	51.43%	79.17%
Satisfied	17.14%	16.67%
Mixed results	20.00%	4.17%
Unsatisfied	5.71%	-
Very unsatisfied	5.71%	-

Conclusions

- Our initial experience suggests that Bead Block PVA microspheres are a safe and effective embolic agent for UAE
- Short-term clinical and MR imaging data show a significant improvement in fibroid related symptoms and quality of life as well as volume reduction
- Preliminary analysis of angiographic images and contrast enhanced MRI suggest that a “(near) stasis” approach results in a higher overall infarction rate of fibroid tissue