🏆 Best in Category Prize – Female Stress Urinary Incontinece

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MINIARC MONARC SUBURETHRAL SLING IN WOMEN WITH STRESS URINARY INCONTINENCE – AN RCT – 60M FOLLOW UP

Hypothesis / aims of study

Single incision midurethral slings (SIS), such as Miniarc, were introduced to reduce postoperative pain, and improve recovery. We set out to examine if Miniarc had at least equivalent objective cure rates against Monarc at 60m follow up, as well as comparing their subjective and functional outcomes

Study design, materials and methods

Women who had SUI or urodynamic stress incontinence (USI) were randomised, in a 1:1 ratio, to receive either Miniarc or Monarc. Women with intrinsic sphincter deficiency, previous MUS, untreated detrusor overactivity or significant voiding dysfunctions were excluded. Assuming an objective cure rate of 85% for Monarc, this RCT was powered (80%) to detect a clinical difference of 15%, and allows for an attrition of 15% with a sample size of 220, using a one sided □□of□0.05. Computer generated random allocation was concealed and stratified to centre. Surgeons or patients were not blinded once allocation was revealed. Patients were seen at 6w, 6m, 12m, 24m, 36m, 48m and 60m with a clinical examination. Standardised proformas together with validated tools, including ICIQ UI SF, ICIQ OAB, PISQ12, IIQ7, PGII and 24 pad weigh (6m), were used to facilitate prospective collection of data to evaluate objective, subjective and functional outcomes following surgery. Objective cure was defined as negative urodynamic stress or cough stress test (CST) at follow up. Subjective cure was defined as absence of patient reported SUI at follow up. Surgeries were performed, according to manufacturer's instructions, by surgeons who had already performed at least 10 Miniarc, which was tensioned to snug. Urodynamic studies were performed pre operatively and 6m post operatively. Definitions, outcome measures and standardised reporting adhered to IUGA/ICS terminology, IUGA & CONSORT guidelines. Institution ethics approval was obtained and the trial was registered with the ANZCTR. Outcomes were compared with exact binomial tests (eg Fischer exact for dichotomous data) for categorical data and Student t test or exact versions of Wilcoxon test for numerical data as appropriate.

Results

282 women were assessed for eligibility, of which 42 declined participation, 2 indicated a preference to Miniarc (refused randomisation), and 14 were excluded post randomisation (3 did not meet criteria, 10 withdrawn from surgery, 1 unfit). 235 women aged 31-80 (51.6±9.71) received Miniarc (112) or Monarc (113). Median parity was 2 (0-7), mean BMI 27.5±5.6 (15 – 47). Baseline characteristics were balanced, with no statistically significant difference between two treatment arms for known confounders, including age, parity, BMI, prior medical history, baseline symptom severity (excluding PGI-S), urodynamic diagnosis, vaginal topography and types of concomitant prolapse surgeries. Monarc patients reported more symptom severity on PGI-S at baseline. Multivariate logistic regression for confirmed baseline PGI-S or surgeon type did not independently affect final outcome, confirming results of bivariate analysis.

Table 1 demonstrated no statistically significant difference in the subjective (absence of SUI) or objective (absence of USI or CST) cure rates between Miniarc and Monarc at 6m, 12m, 24m, 36m, 48m or 60m. Within both Miniarc and Monarc groups, there was a statistically significant improvement from baseline to all 5 time points for ICIQ UI, ICIQ OAB, PISQ12, IIQ7, PGII scores and 24h pad weigh (6m). The ICIQ UI SF score was lower in the Monarc group at 36m, 48m and 60m but the difference was less than the minimally important difference of 5 and not statistically significant. At 12m the Miniarc arm has a lower proportion using antimuscarinics, which was not statistically different at subsequent time points. At 60m, 5 in Miniarc and 4 in Monarc group underwent repeat surgery for SUI (TVT). Two women had repeat surgery 6m after their Miniarc operation, two at 12m and one at 39m. In contrast, two women had repeat surgery 12m after their Monarc operation, one at 24m and one at 36m. There were no sling divisions or excision in both arms. There were two cases of mesh exposure on each arm, one (7mm, excised L Sulcus) in a patient who underwent concurrent anterior compartment mesh repair, another in a patient who underwent Monarc sling (L Sulcus).

Table 1: subjective objective and functional outcomes after Miniarc Monarc at 60m

	MiniArc							Monarc							P Value between groups					
(#Median (25%,75%)	0m N = 112	6m N = 110	12m N = 103	24m N=102	36m N = 97	48m N = 72	60m N = 65	0m N=113	6m N = 107	12m N = 103	24m N=96	36m N = 97	48m N = 72	60m N = 63	6m	12m	24m	36m	48m	60m
Subj Cure		95.5% (105/110)	92.2% (95/103)	94.1% (96/102)	91.8% (89/97)	93.1% (67/72)	75.4% (49/65)		92.5% (99/107)	94.2% (97/103)	95.8% (92/96)	92.8% (90/97)	93.1% (67/72)	80.9% (51/63)	0.4	0.78	0.75	0.95	>0.99	0.52
ANY UI		80.6% (83/103)	69.4% (68/98)	67.0% (67/100)	72.4% (63/87)	62.5% (45/72)	73.8% (48/65)		79.6% (82/103)	58.9% (56/95)	58.3% (56/96)	58.4% (52/89)	59.4% (41/69)	66.6% (42/63)	>0.99	0.14	0.24	**0.058**	0.73	0.44
Obj Cure		81.1% (77/95)	94.4% (84/89)	98.4% (60/61)	100% (41/41)	96.3% (26/27)	96.5% (55/57)		86.3% (82/95)	96.7% (87/90)	100% (60/60)	97.6% (41/42)	100% (21/21)	97.8% (45/46)	0.43	0.50	0.99	0.99	>0.99	>0.99
Obj Cure RPT = FAIL@		80.2% (77/96)	91.3% (84/92)	93.8% (60/64)	91.1% (41/45)	83.9% (26/31)	88.7% (55/62)		86.3% (82/95)	94.6% (87/92)	95.2% (60/63)	91.1% (41/45)	84% (21/25)	88.2% (45/51)	0.33	0.57	0.99	0.99	>0.99	>0.99
SubJ Cure Missing = FAIL		93.8% (105/112)	84.8% (95/112)	85.7% (96/112)	79.5% (89/112)	59.8% (67/112)	43.8% (49/112)		87.6% (99/113)	85.8% (97/113)	81.4% (92/113)	79.6% (90/113)	59.3% (67/113)	45.1% (51/113)	0.17	0.85	0.54	>0.99	>0.99	0.89
ICIQ UI SF #	13 (10-16)	4 (0-7)	4 (0-6)	4(0-8)	4 (0-7)	3 (0,7)	4 (3,10)	14 (10,16)	3 (0,6)	3 (0,6)	3(0-6)	3(0-6)	1 (0,6)	4 (0,9)	0.77	0.61	0.13	**0.052**	0.30	0.32
OAB Meds	14.4% (16/111)	10.9% (10/92)	5.7% (5/87)	18.2% (12/66)	19.0% (15/79)	10.1% (7/69)	18.5% (12/65)	14.2% (16/113)	14.6% (14/96)	15.8% (15/95)	15.7% (11/70)	12.3% (10/81)	22% (11/50)	11% (7/63)	0.52	**0.034**	0.82	0.28	0.12	0.32
ICIQ OAB #	5 (3-8)	3 (2-5)	3 (1-4)	3 (2-5)	3 (2-6)	3 (0,5)	4 (2,6)	5 (3-8)	3 (2-5)	3 (2-5)	3 (2-5)	3 (2-5)	2 (0,5)	3 (2,6)	0.57	0.48	0.43	0.27	0.50	0.32
PISQ 12 #	33 (28,37)	36 (33,40)	37 (35,41)	37 (32-41)	38 (33-41)	38 (32,39)	36 (31,40)	33 (29-38)	39 (33-41)	38 (33-41)	38 (35-42)	39 (36-42)	37 (33,41)	37 (32,42)	0.06	0.91	0.07	0.23	0.32	0.57
Not sex. active	18.8% (21/112)	24.3% (25/103)	27.4% (26/95)	25.0% (24/96)	29.9% (26/87)	37.3% (25/67)	20.0% (13/65)	20.4% (23/113)	28.2% (29/103)	23.2% (22/95)	26.1% (24/92)	30.3% (27/89)	29%(20/69)	37%(23/63)	0.64	0.62	0.87	>0.99	0.36	**0.05**
IIQ 7 #	9 (5-13)	0 (0-4)	0 (0-3)	0 (0-3)	0 (0-3)	0 (0,3)	0 (0,4)	9 (5-12)	0 (0-3)	0 (0-3)	0 (0-2)	0 (0-1)	0 (0,3)	0 (0,5)	0.70	0.88	0.86	0.28	0.61	0.98
PGI I #	3 (2,3)	1 (1,2)	1 (1,2)	2 (1-2)	1 (1-2)	1 (1,2)	2 (1,2)	3 (3-3)	1 (1-2)	1 (1-2)	1 (1-2)	1 (1-2)	2 (1,2)	2 (1,2)	0.90	0.46	0.12	0.48	0.34	0.81
24h Pad M ± sd	21.1 ± 33.9	4.9± 10.1						28.5 ± 43	4.2 ± 4.4						0.89					

Interpretation of results

There was a reduction in reported subjective cure rates, sustained improvement in patient reported outcomes, including incontinence impact and global impression of improvement across all time points with no statistically significant difference between two treatment arms.

Concluding message

Although a reduction in subjective cure rate was observed between both arms across all time points to 60 months, mid to long term results suggest comparable cure rates and functional outcomes between Miniarc and Monarc.

Disclosures

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