Pelvic organ prolapse surgery with and without Tension-free Vaginal Tape in women with occult or asymptomatic urodynamic stress incontinence: a randomized controlled trial

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Abstract:

Introduction: To determine if insertion of a retropubic tension free vaginal sling (TVT) at the time of pelvic organ prolapse surgery improves continence outcome in women with pre-operative occult stress incontinence (OSI) or asymptomatic urodynamic stress incontinence (USI).

Methods: We conducted a randomized controlled study of prolapse surgery with or without TVT midurethral sling. The pre- and post-operative assessment at 6 months included history, physical examination and urodynamic testing. Quality of life (QOL) and treatment success was assessed with the UDI-6 SF, IIQ-7 SF and a numerical success score. The primary outcome was symptomatic stress urinary incontinence (SUI) requiring continence surgery (TVT) at 6 months. Long-term follow-up continued to a minimum of 24 months. Secondary outcomes were quality of life parameters.

Results: Eighty women received prolapse surgery alone (n = 43) or prolapse surgery with concurrent TVT (n = 37). Six months following prolapse surgery 3/43 (7%) patients in the no TVT group requested sling surgery compared to 0/37 (0%) in the TVT group (ARR 7% (95%CI: 3–19%), p=0.11). After 24 months there was one further participant in the no TVT group who received a TVT for treatment of SUI compared to none in the TVT group (4/43, 9.3% versus 0/37), (ARR 9.3% (95%CI: -1–22%), p=0.06). Both groups showed improvement in QOL difference scores for within group analysis, without difference between groups.

Conclusion: These results support a policy that routine insertion of a sling in women with OSI at time of prolapse repair is questionable and should be subject to shared decision making between clinician and patient..

Keywords: Occult stress urinary incontinence, prolapse surgery, Tension free vaginal tape

Brief summary: The results of our study question the routine insertion of a sling in women with occult stress incontinence at time of prolapse surgery

Introduction

Stress urinary incontinence (SUI) often coexists with pelvic organ prolapse (POP). However up to eighty percent of women with POP do not complain of urinary incontinence. This is despite clinical and/or urodynamic testing revealing leakage of urine with or without reduction of the prolapse[1-5] This phenomenon is described as occult stress incontinence (OSI). It is believed that urethral kinking due to bladder base descent prevents leakage of urine.[2, 6, 7]Reduction of prolapse leads to a correction of the kinking, a decrease in urethral closure pressure and /or a decreased pressure transmission ratio unmasking SUI.[6, 8, 9] Successful prolapse surgery performed by the vaginal or abdominal route may be disappointing for the patient due to the postoperative development of new onset incontinence.

The diagnosis of OSI has recently been defined as the presence of SUI on examination, or urodynamic stress incontinence in women with pelvic organ prolapse with reduction of prolapse, who have no symptoms of SUI.[10] The prevalence of OSI will vary depending on how the condition is defined and how the patient is examined. In the Colpopexy and Urinary Reduction Efforts (CARE) study, patients were examined with a bladder volume of 300 ml. The incidence of OSI varied with the method used for prolapse reduction: pessary 6%, manual 16%, forceps 21%, swab 20% and speculum 30%.[11] Women with OSI appear more prone to developing symptomatic post operative SUI. Several studies have addressed the question of combining an anti-incontinence procedure with POP surgery either by vaginal, abdominal or laparoscopic routes after a diagnosis of OSI.[9, 12-14] The results of these studies show less post operative SUI in women who have had the anti-incontinence procedure, however the morbidity of concomitant SUI surgery, the overall patient benefit and the cost-effectiveness is still debated.

The aim of our study is to compare the outcomes of surgery for prolapse with and without the TVT^{TM} retropubic sling in women diagnosed with OSI prior to surgery.

Methods

A multicentre randomized controlled study was conducted after approval by the Human ethics and research committee of the 2 participating hospitals (Mercy Hospital for Women, Monash Medical Centre). All methods and definitions conformed to standards recommended by the ICS and IUGA[10] except where specifically noted. Occult stress incontinence was defined in this study as stress urinary incontinence occurring and visualized in symptomatically stress continent women either with or without prolapse reduction during urodynamic assessment. All women who needed surgical correction of POP routinely underwent urodynamic testing as part of their preoperative assessment. Only those women who had occult stress incontinence were invited to participate. Written informed consent was obtained.

Inclusion criteria for participation were pelvic organ prolapse greater than or equal to Stage 2 requiring surgical correction, the absence of stress urinary leakage on history and demonstration of OSI utilizing urodynamic assessment. Exclusion criteria included contraindications to pelvic surgery such as a pelvic infection, fistula, congenital or neurogenic bladder disorder, malignancy, or medically unfit.

The pre- and post-operative protocol consisted of a comprehensive urogynecological history, physical examination, and multi-channel urodynamic testing. This included uroflowmetry (free flow study at the start and pressure flow study at the end of testing), resting urethral pressure profilometry before and after cystometry to a capacity up to 500 ml if tolerated. An estimation of valsalva and cough leak point pressure in the semi-recumbent position with and without reduction of the prolapse and in the standing position without reduction of prolapse by direct visualisation of urinary incontinence was performed. A voiding pressure study completed the assessment. Prolapse reduction was performed in semi- recumbent position utilising a Sims speculum or opened sponge

forceps avoiding direct support of the urethra / anterior vaginal wall. The severity of prolapse was evaluated using the standard terminology of Pelvic Organ Prolapse Quantification (POPQ) recommended by the ICS [9].

The short form of the Urogenital Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7)) were used for subjective assessment of quality of life (QOL). Patients self evaluated the success of their procedure with a numerical success score ranging from 0 – 100 (0 corresponding with complete failure and 100 to complete cure).

Randomization, was performed by the research nurse, in fixed blocks of 10 using a software package (Ranlist, University of Houston, Texas, USA 1996). Women were allocated to receiving TVT or not as part of their surgical treatment for pelvic organ prolapse. The surgeon was not involved in the randomisation and was informed about the allocation at the time of the surgery. The decision regarding the most suitable operation for prolapse treatment was not influenced by participation in this study. Prolapse repair was performed according to surgeon and patient preference. Participants were not blinded regarding their group allocation.

Regional or general anaesthesia was used accordingly after anaesthetic assessment. Prophylactic antibiotics were given at commencement of surgery. The TVT procedure (Gynecare, Ethicon Inc., Somerville, NJ) was performed as previously described by Ulmsten.[15-17]. Cystoscopy was used routinely to verify the absence of ureteric, bladder and urethral injury after all procedures (TVT and no TVT). Sling tensioning was achieved by a tension-free placement of fine dissecting scissors between urethra and tape without the aid of a cough test.

The postoperative catheter management depended on the duration of the vaginal pack (24 to 48h postoperatively). A successful trial of void was defined by two post void residual urine volumes <150ml on ultrasound after removal of pack and catheter. Short-term urinary

retention or voiding difficulty was managed by reinsertion of an indwelling catheter for drainage and if persisting, the use of clean intermittent catheterization until post void residuals were satisfactory.

All women were reviewed at 6 weeks, 6 and 12 months following surgery and annually thereafter. At 6 months, urodynamic assessment, QOL questionnaires and numerical success score were completed. Yearly follow up continues with clinical examination, quality of life questionnaires and numerical success score. Neither participants nor assessors were blinded to group allocation. Participants would be reviewed randomly by one doctor of the team in the participating hospitals, who often was not the surgeon that performed the procedure.

The primary endpoint was the need for subsequent anti-incontinence surgery due to symptomatic SUI after 6 months. This report also includes further follow up to 24 months and beyond. The decision regarding sling surgery in symptomatic women was based on the participant's wishes and repeat urodynamic assessment. A TVT (or repeat TVT) procedure was offered regardless of group allocation. Secondary outcomes were subjective cure rates, intra- and post-operative complications, voiding function, urgency and urge urinary incontinence (UUI) symptoms, change in quality of life as assessed by the UDI-6 and IIQ-7. The patient also reported a numerical success score which rated the overall satisfaction with the prolapse repair in addition to continence status after surgery.

The sample size calculation was performed based upon a reduction from 50% to 10% (absolute risk reduction of 40%) in SUI after prolapse repair in the TVT group being clinically important. At a power of 90% and a significance level of 0.05, the sample size estimate was 31 patients per group. The demographic data is tabulated but no hypothesis testing is used to compare demographic data groups. Data is presented as mean (SD), median [25^{th} -75^{th} percentile]{minimum, maximum} depending upon distribution or count (%). The primary outcome, the time until patient requested repeat surgery for stress incontinence, is

presented graphically using the Kaplan-Meier survival curve with survivorship between treatment groups tested using the log-rank test. Absolute risk reduction (ARR), number needed to benefit (NNTB) and numbers needed to harm (NNTH) for the combined procedure compared to prolapse repair alone were derived at 24 months postoperatively.[18] The UDI-6 and IIQ-7 quality of life scores hypothesis testing was based on postoperative – preoperative difference scores used Wilcoxon sign rank test (WST) for within group change and Wilcoxon rank sum test (WRST) for between group analysis for continuous data. Count data used exact two-sided hypothesis testing for between group comparisons where appropriate. Significance level was set at 0.05 and adjusted for multiple comparisons using Holm's step down procedure.[19] Analysis was performed using Stata v11 statistical software [Stata College Station, Texas:Stata Corporation, 2009] with StatXact v9 [Cytel Software Corporation, Cambridge MA, USA, 2010] used to perform exact hypothesis testing

The trial is registered with the Australian New Zealand Clinical Trials Registry, ACTRN: 12611000844943. This study is reported according to the CONSORT checklist.(Fig.1)

Results

From June 2003 to August 2009 a total of 845 women with pelvic organ prolapse greater than or equal to Stage 2 requiring surgical correction were screened and 146 women with occult stress incontinence were eligible. Therefore, the prevalence of occult stress incontinence using the study definition in our population was 17 % (95%CI 15% to 20%). Eighty women who met the inclusion criteria and consented to participate were randomly assigned to prolapse surgery alone without sling (n = 43) or prolapse surgery with concurrent TVT (n = 37). Sixty six women declined participation due to personal preference regarding surgery or inconvenience of the trial commitments. (Fig 1) All randomized participants received the allocated treatment. There was no difference in demographic characteristics such as age,

parity, menopausal status, use of hormone replacement and prior continence or prolapse surgery between the two groups. (Table 1) There was no difference in the number of participants with previous anterior vaginal repair as this could be considered a confounding factor between the two groups affecting continence status postoperatively. The type of prolapse surgery including anterior repair performed for participants was similar in the no TVT and TVT groups. (Table 2)

The median follow-up time was 49.3 months (minimum 6 months to maximum 93.9)., At 24 months 60 /77 (78%) patients were still under observation. The overall completeness of follow-up (sum of active follow-up time for each patient / sum of potential follow-up time for each patient) was 69%. The primary endpoint was the clinical need for stress incontinence surgery postoperatively. At six months following prolapse surgery 3/43 (7%) of patients in the no TVT group requested sling surgery compared to 0/37 (0%) in the TVT group, ARR 7% [95%CI 3% to 19%], p=0.11. After 24 months follow-up there was one further participant in the no TVT group who received a TVT for treatment of symptomatic SUI compared to none in the TVT group. The time from prolapse repair to sling insertion in the group of women with prolapse surgery alone was 1.8, 7.5, 9.3 and 27 months. The Kaplan Meier survivorship curve of time to request for repeat surgery is presented in Fig.2. There is some evidence for a difference in the proportion requiring repeat surgery between the prolapse alone and prolapse with TVT group (log-rank test p = 0.06). Assuming patients lost to follow-up did not require repeat surgery, the ARR at 24 months was 9.3% [95%CI -1.2 % to 22.2%], p = 0.06 with NNTB 11 (95%CI NNTH 83 - ∞, NNTB 5). If all patients lost to follow-up were treated as failures (no TVT =15/43, TVT 6/37) the ARR at 24 months was 18.7% [95%CI -1.3 % to 37.1%], p = 0.06 with NNTB 6 (95%CI NNTH 77 - ∞, NNTB 3).

There was no difference in intra or post operative complications between the two groups in particular those associated with insertion of a retropubic sling, such as bladder perforation,

voiding difficulty (immediate with reinsertion of IDC for 24 hours or clean intermittent self catheterization for 6-10 days postoperative) and hemorrhage (blood loss > 500ml or need for blood-transfusion).(see Table 2 for p-values) No long-term voiding difficulty requiring catheterization, loosening or division of sling were detected in either of the groups.

Urodynamic assessment was repeated six months following surgery in 60 of the participants (27 TVT and 33 no TVT). Twelve subjects (5 TVT and 7 no TVT) declined the repeat assessment as they were asymptomatic of stress urinary incontinence and declined further testing performed. There were eight participants (5 TVT (including 2 participants that are deceased) and 3 no TVT) who failed to attend the urodynamic assessment. Of the 60 women tested, in the TVT group 4/27 (15%) had USI demonstrated during repeat urodynamic assessment, compared to 22/33 (66%) in the no TVT group with an ARR of 52% [95%CI -71% to -27%, $p < 0.001$]. In these 26 women with USI 4/4 (100%) in the TVT group and 18/22 (81%) in the no TVT group reported no incontinence symptoms, ARR 18% [95%CI -40% to 39%, $p = 0.40$].

Based on the overactive bladder symptoms recorded preoperatively, there was no significant difference in the incidence of urgency ($p = 0.47$) and UUI $p = 0.73$ between groups. Cure rates were similar in both groups for preexisting urgency (TVT 20/23, 87% and no TVT 20/23, 87%) and UUI (TVT 13/20, 65% and no TVT 12/23, 52%). The development of de novo urgency was also similar in both groups; (TVT 1/6 ,17% and no TVT 3/13 ,23%) at 6 months compared to 2/5 (40%) and 0/13 at 24 months. De novo UUI was more frequent in the TVT group than the no TVT group with 5/10 (50%) compared to 2/13 (15%) at 6 months and 5/12 (42%) compared to 2/13 (15%) at 24 months but this did not reach statistical significance. The analysis of the treatment effect on overactive bladder symptoms is limited by the small numbers and some missing data.

The baseline QOL assessment (UDI-6, IIQ-7) did not differ between the two groups. Both groups showed improvement in QOL difference (postoperative - preoperative) scores for within group analysis (WST, p-values< 0.001), however no change was demonstrated between the 6 and 24 months assessments (WST, p-values >0.1). There was no evidence of a difference in either QOL measure between groups, adjusted for baseline score (WRST, p-values> 0.2). (Table 3) The numerical success score was high in both groups with no difference detected between TVT and no TVT groups at 6 months (90 [95% CI 80-100] vs 90 [95% CI 80-95] and 24 months (85 [95% CI 70-95] vs. 90 [95% CI 80-98] with Wilcoxon rank sum test p-values >0.3). Combined success scores were 90 [95% CI 80- 100] and 90[95% CI 80-95] at 6 and 24 months respectively.

Discussion

There has been increased interest in the condition of occult stress incontinence and the most appropriate way to identify, counsel and treat women with this condition at the time of pelvic organ prolapse surgery. Two recent surveys in the UK and Australia/ New Zealand showed that gynecologists were evenly divided on whether they would routinely insert a mid urethral sling in a women with symptomatic POP and OSI at the time of surgery.[20],[21] Anecdotally, there appears to be a large geographic variation in the practice of "prophylactic" sling insertion.[22]

The results of this study question the value of routine insertion of sling in women with OSI at the time of prolapse repair. If all participants lost to follow up are assumed as treatment successes or as treatment failures, either 11 or 6 TVT slings would need to be performed to prevent one patient requiring a TVT procedure within a median follow up time of 49 months after prolapse correction.

Urodynamic stress incontinence persisted at 6 months in two thirds of women following prolapse surgery without TVT although over 80% were asymptomatic and did not require further surgical intervention during the follow up period. It remains to be seen how many of these women and of the 15% of the TVT group who also had USI at 6 months but were asymptomatic will require continence surgery in the future.

Other studies have investigated the value of different anti-incontinence procedures such as needle suspensions, pubovaginal slings or fascial plication[9, 12, 13, 14] in women with POP and OSI.

Brubaker et al. compared the abdominal sacrocolpopexy with and without Burch colposuspension in 302 women with POP and no symptoms of stress incontinence. Stress incontinence was present in women with POP and a concomitant Burch colposuspension in 23.8% vs 44.1% without Burch colposuspension at 3 months and in 32% vs. 45% at 2 years respectively. The conclusion drawn from this study is that the addition of Burch colposupension to sacral colpopexy, results in less stress urinary incontinence postoperatively.[23, 24]

The outcomes following vaginal prolapse repair and midurethral sling (OPUS) trial compared anterior vaginal prolapse repair with or without concurrent TVT sling procedure in stress continent women; one third of whom had OSI. At 12 months, urinary incontinence (positive stress test and/or bothersome urinary incontinence) was present in 45 of 165 women (27%) with a TVT and 74 of 172 women (43%) with no TVT. Complications of major haemorrhage and urinary retention were greater in the TVT group. The authors estimated that at 12 months 6.3 prophylactic slings would have to be inserted to prevent one woman from becoming stress incontinent after prolapse repair.[25]

The assessment of overactive bladder symptoms did show a significant cure rate of preexisting urinary urgency and UUI at 6 and 24 months in both groups with no statistical

difference between groups. This is most likely due to correction of prolapse. The de novo occurrence of UUI was higher in the TVT group however statistical significance was not reached. This possible trend towards increased UUI with TVT is in agreement with other studies.[26]

The numerical success scores and QOL questionnaires did not show a difference between the two groups. These scores indicate overall satisfaction with the surgery and may not be directly associated with sling insertion as the urinary incontinence was asymptomatic prior to the surgery and hence could not really be improved afterwards.

The strengths of this study include the randomized design, the length of follow up that exceeds follow up length of most other trials [25] , minimization of loss to follow-up and the use of validated outcome measures. The participants were identified through a stringent clinical screening process and urodynamic testing before prolapse correction. This allowed the inclusion of participants who satisfied the trial definition of OSI based on the information available at the start of the trial in 2003. We acknowledge that OSI is now defined as “stress incontinence on prolapse reduction” by the ICS/IUGA committee for standardization of terminology in 2010.[10]

The limitations of this study include no treatment allocation concealment and no blinding of participants or assessors. Any future study design would benefit from a double blinded design with sham dressings in the no treatment arm although it is difficult to see how this would have an effect on the 6 month urodynamic findings or the 24 month long term follow up. It is likely that our study is underpowered to detect a difference in SUI between the two study groups. Our power calculation was based upon a 50% incidence of SUI in the no TVT group, however the actual incidence was found to be only 9.3%. Given a true SUI rate of 10% in a control group, a clinically important difference considered to be a 50% absolute risk reduction (ARR) to 5% in the TVT group would require a sample size of 620 per group to provide a

power of 0.9.

Conclusion

The low number of sling procedures required in the non intervention group to correct symptomatic stress urinary incontinence after more than 24 months follow up supports the view that routine insertion of a sling in women with OSI at time of prolapse repair is questionable and should be subject to shared decision making. Women should be carefully counseled regarding the possibility of SUI occurring postoperatively and the risks as well as the benefits of concomitant sling surgery. These findings also have implications for the routine use of urodynamic assessment in the detection of OSI and would suggest that they are not warranted for this purpose in the patient asymptomatic for SUI prior to prolapse surgery. Further randomized studies including analyses of health economic costing of both approaches are needed to support either a prophylactic or a secondary procedure.

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Table 1: Demographic Data

	TVT (n=37)	**No TVT (n=43)**
Age (years)	67 (10.9) {36, 86}	66 (9.1) {48, 84}
BMI (kg/m^2)	26 (3.5) {21, 36}	27 (4.3) {28, 37}
Parity	3 [2- 3] {0, 8}	2 [2-3] {0, 7}
Menopausal status		
Premenopausal	0	2 (5%)
Postmenopausal no HRT	2 (6%)	2 (5%)
Postmenopausal with HRT (Including vaginal estrogen treatment)	35 (94%)	39 (90%)
Prior Incontinence Procedures		
Burch Colposuspension	2 (5%)	3 (7%)
Retropubic Sling / TOT	0 / 0	0 / 1
Fascial sling / Bulking Agent	0 / 0	0 / 0
Prior hysterectomy	11 (30%)	8 (19%)
Prior Prolapse surgery	9 (24%)	8 (19%)
Anterior vaginal repair	5 (14%)	5 (12%)

Data presented as mean (SD), median [25th – 75th percentile], {minimum, maximum} or count (%)

Table 2: Concomitant Surgery, Anaesthesia, Complications

	TVT	No TVT	p-value*
	(n = 37)	(n = 43)	
(i) Type of Prolapse surgery			
Vaginal hysterectomy, repair, vault suspension sususpensionsuspension	11 (30 %)	22 (51 %)	0.07
Vaginal vault suspension and repair	20 (54 %)	17 (39 %)	0.26
Anterior repair	20 (54 %)	31 (72 %)	0.61
Posterior repair	31 (84 %)	26 (60 %)	0.03
Abdominal sacrocolpopexy	1 (3 %)	1 (2%)	0.91
(ii) Anaesthesia			
General	29 (78%)	39 (91%)	0.21
(iii) Complications			
Bladder Perforation	0	0	-
Hemorrhage (> 500ml or requiring blood transfusion) (>500 ml, no BT required)	1 (4%)	2 (7%)	0.99
Voiding difficulty immediate postop (IDC)	2 (5%)	2 (4%)	0.99
Voiding difficulty (CISC for 6-10 days postop)	2 (5%)	0 (0%)	0.21
(iv) Urodynamics at 6 months follow up			
USI	4/27 (15 %)	22/33 (66 %)	< 0.001
- USI and asymptomatic	4 / 4 (100	18/22 (82 %)	0.35

No USI	23/27 (85%) (89%) (89%)	11/33 (33 %)	
Declined as asymptomatic	5/37 (13%)	7/43 (16%)	
LTF / FTA / Missing / Deceased Deceased	5/37 (13%)	3/43 (7%)	
(v) Sling procedure after primary surgery	0/37	4/43 (9.3%)	0.06

Data presented as count (%), Data as a number (%),*Exact test.
For (i) none significant after adjusting for the four multiple comparisons using Holm's step down procedure.
IDC indwelling catheter, CISC clean intermittent catheterisation, USI urodynamic stress incontinence, LTF lost to follow up, FTA failed to attend

Table 3: Quality of life assessment UDI 6 and IIQ7

	No TVT			TVT		
	Baseline	6m diff	24m plus diff	Baseline	6m diff	24m plus diff
	(n = 39)	(n = 29)	(n = 27)	(n = 35)	(n = 22)	(n =27)
UDI 6 – Total	5 [3 – 9] {0, 12}	-3 [-5 – 0] {-9, 5}	-2 [-5 - 0] {-11, 3}	5 [3 – 10] {0, 18	-2 [-6 – 1] {-16, 4}	-2 [-6 – 1] {-7, 4}
UDI 6 - Question 3	0 [0 – 2] {0, 3}	0 [0 – 0] {-3, 3}	0 [-1 – 0] {-2, 2}	0 [0 – 0] {0, 3}	0 [-1 – 0] {-3, 2}	0 [-1 – 1] {-2, 2}
UDI 6 - Question 2	1 [0 – 1] {0,3}	0 [-1 – 0] {-2, 1}	0 [-1 – 0] {-2, 1}	1 [0 – 2] {0, 3}	-1 [-2 – 0] {-3, 2}	0 [-1 – 0] {-2, 2}
IIQ7 – Total	2 [0 – 9] {0, 21}	-1 [-9 – 0] {-14, 8}	-1 [-6 – 0] {-21, 2}	4 [0 – 8.5] {0, 19}	-2 [-8 – 0] {-18, 3}	-4 [-8 – 0] {-16, 6}

data presented as median [25th – 75th percentile] and {minimum, maximum}.
For within group analysis, using WST both at 6 & 24 months highly statistical different from baseline for all comparisons ($p < 0.001$) however no difference between 6 & 24 months ($p > 0.1$). No evidence of a difference between groups at 6 or 24 months (WRST, $p > 0.2$).

Figure 1: Consort Flow Chart

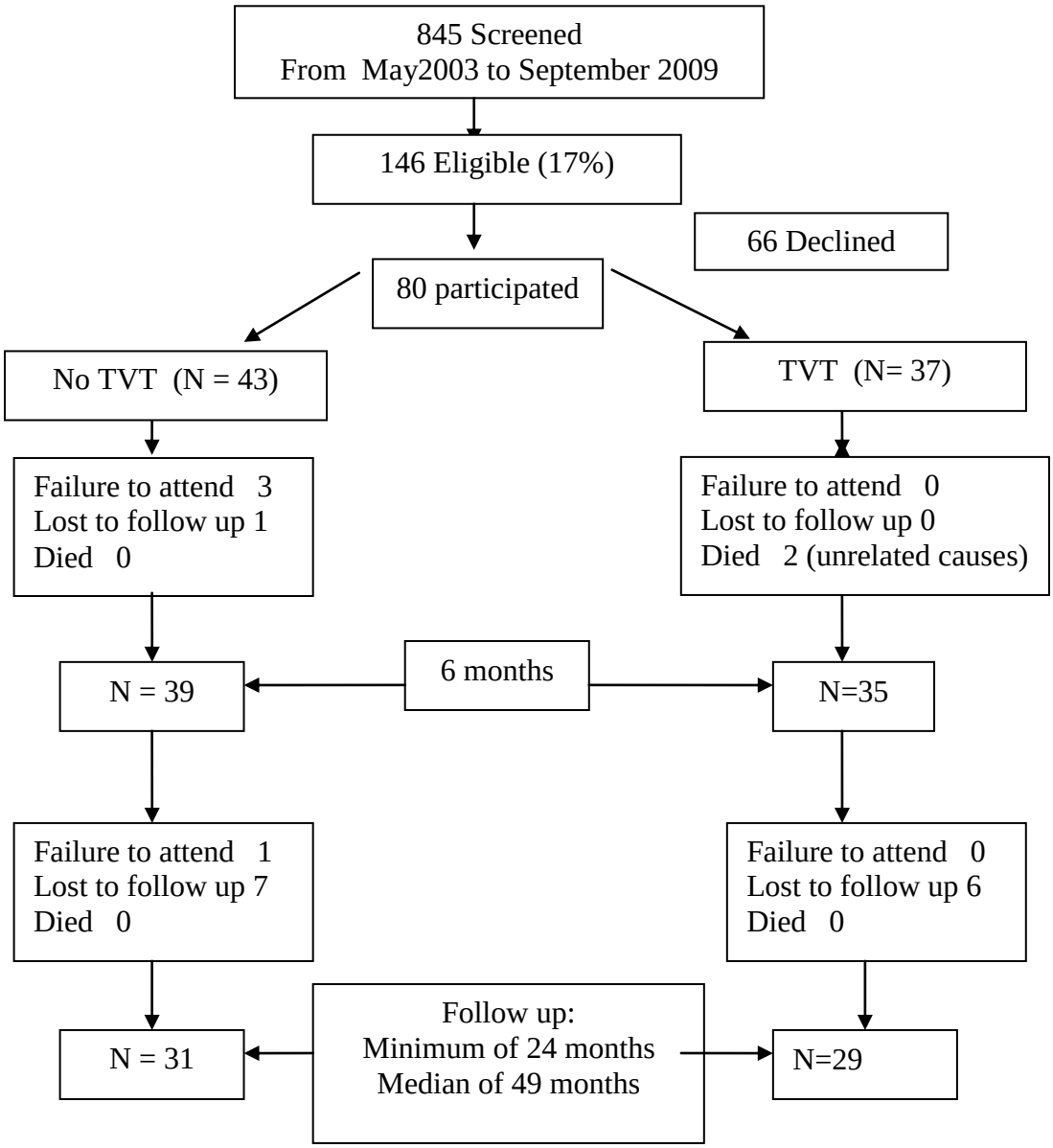
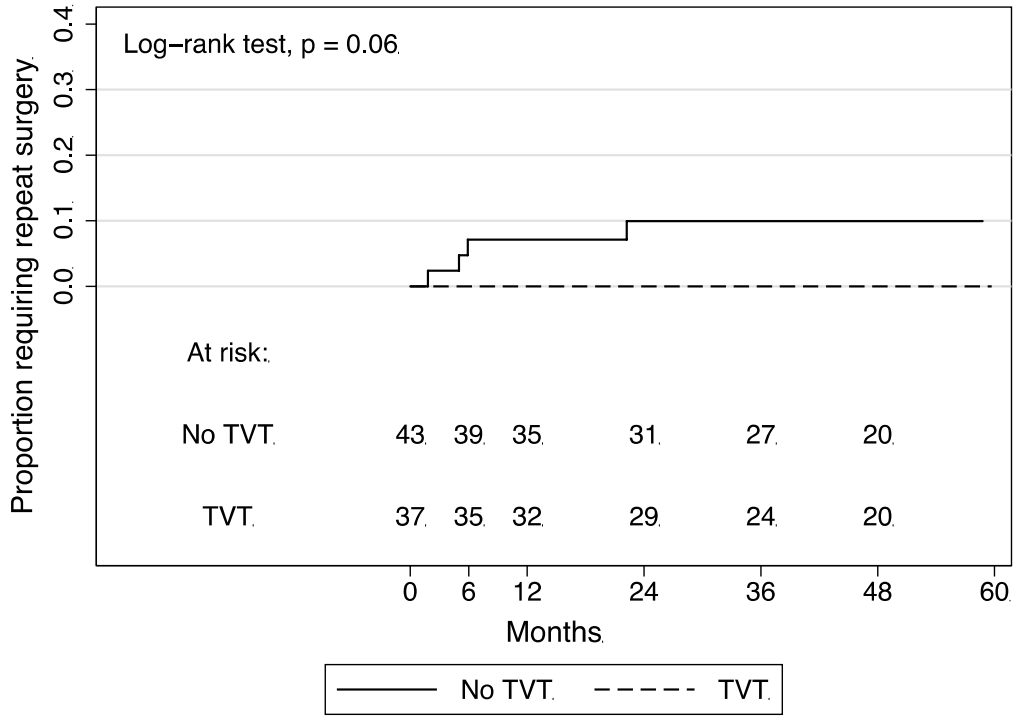


Fig 2: The Kaplan-Meier survivorship curves for the control & experimental groups



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