

Responsiveness of Urogenital Distress Inventory-6 and Incontinence Impact Questionnaire-7 after pelvic floor muscle training and surgical treatment

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Introduction: Urinary incontinence (UI) and pelvic organ prolapse (POP) significantly impair quality of life (QoL). Pelvic floor muscle training (PFMT) is the first-line intervention. This study aims to evaluate the responsiveness of the Chinese version of Urogenital Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7) after PFMT and surgical treatment in women with UI and/or POP.

Methods: Between April 2017 and December 2018, women who were referred to our urogynaecology clinic to undergo PFMT and/or surgery for UI and/or POP were recruited. They were instructed to perform three sets of pelvic floor muscle contractions per day. Women were followed up after 3 to 6 months. Women with moderate or severe urodynamic stress incontinence after PFMT were offered tension-free vaginal tape procedure. Women were asked to complete the UDI-6 for urinary symptoms and IIQ-7 for QoL before and after treatment. The responsiveness of UDI-6 and IIQ-7 were evaluated by effect size and standardised response mean.

Results: In 452 women who received PFMT, the most common diagnosis was UI (n=318, 70.4%), followed by POP (n=47, 10.4%), and concomitant UI and POP (n=87, 19.2%). 44 women underwent tension-free vaginal tape procedure after PFMT failed. After PFMT, the UDI-6 score improved from 38.9 to 29.4 ($p<0.001$) and the IIQ-7 score improved from 27.1 to 19.8 ($p<0.001$). After tension-free vaginal tape procedure, the UDI-6 score improved from 60.3 to 22.1 ($p<0.001$) and the IIQ-7 score improved from 39.1 to 8.1 ($p<0.001$). Responsiveness to change in scores of UDI-6 and IIQ-7 was moderate and small, respectively.

Conclusion: The UDI-6 and IIQ-7 are modestly responsive to change after PFMT and tension-free vaginal tape procedure in women with UI and/or POP.

Keywords: Pelvic organ prolapse; Quality of Life; Urinary incontinence

Introduction

Urinary incontinence (UI) and pelvic organ prolapse (POP) are common health problems among women worldwide. The prevalence of UI is about 25% to 45% among women aged ≥ 40 years¹. Up to 50% of cases presenting to gynaecological clinics involve POP². Both UI and POP impair quality of life (QoL) and physical and psychosocial wellbeing^{3,4}. Compared with patients with chronic diseases (eg, heart failure and interstitial lung disease), women with UI have poorer QoL⁴. Pelvic floor muscle training (PFMT) is an effective first-line intervention to improve UI and POP symptoms and daily activities^{5,6}.

The International Continence Society Committee recommends the use of Urogenital Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7) to assess the severity of UI and the impact of UI on QoL,

respectively, and to complement clinical assessment⁷. Both UDI-6 and IIQ-7 are UI-specific psychometric questionnaires^{8,9}.

Assessment of the responsiveness is an important step in validating a questionnaire. The responsiveness of the long form of the two questionnaires has been reported in Caucasian women with UI following conservative or surgical treatment¹⁰. The Chinese versions of UDI-6 and IIQ-7 have been validated for clinical use¹¹. However, their responsiveness has not been assessed. Thus, this study aims to evaluate the responsiveness of the Chinese version of UDI-6 and IIQ-7 after PFMT and/or tension-free vaginal tape procedure in women with UI and/or POP.

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Methods

This study was approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (reference: CRE-2015.125). Between April 2017 and December 2018, women who were referred to our urogynaecology clinic at Prince of Wales Hospital to undergo PFMT and/or surgery for UI and/or POP were recruited. Those who were mentally incapable or who declined PFMT were excluded. The attending gynaecologists then assessed the staging of POP and UI and determined the individual treatment plan.

Women were then referred to a continence advisor for PFMT. They were asked to complete the Chinese version of UDI-6 and IIQ-7. A research assistant was available for those who were illiterate and/or unable to complete the questionnaires. They were instructed to perform three sets of pelvic floor muscle contractions per day. Each set consists of ten cycles of contraction and relaxation of the pelvic floor muscles that last for 10 seconds each¹². The continence advisor conducted vaginal examination to confirm their skills and strength in PFMT.

Women with mixed UI or those self-reported to have symptoms frequently and negatively impacted QoL were referred for urodynamic study, which includes uroflowmetry study and filling and voiding cystometry, using the Maquet Radius multi-channel urodynamic machine (Maquet GMBH, Germany). The procedure and the diagnoses were based on the recommendations of the International Continence Society¹³. Vaginal pessary was inserted in those with concomitant UI and POP. Urodynamic stress incontinence is defined as involuntary leakage of urine with increased intra-abdominal pressure in the absence of a detrusor contraction. Detrusor overactivity refers to the occurrence of detrusor contraction(s), either spontaneous or provoked, during filling cystometry, with or without urgency and/or urgency incontinence or perception of contraction. Voiding dysfunction is defined as abnormally slow and/or incomplete micturition, based on urine flow rates and/or post-void residuals¹⁴.

Women were followed up after 3 to 6 months by continence advisors for urinary symptoms and PFMT techniques. Compliance with PFMT was reviewed. Women with moderate or severe urodynamic stress incontinence after PFMT were offered tension-free vaginal tape procedure. They were followed up at 2 months and then 1 year and were asked to complete UDI-6 and IIQ-7 again to assess the treatment outcome.

UDI-6 assesses the level of distress associated with lower urinary tract dysfunction. It consists of six items (frequent urination, leakage related to feeling of urgency, leakage related to activity, small amounts of leakage during coughing or sneezing, difficulty emptying the bladder, and pain or discomfort in the lower abdominal or genital area) under three subscales (irritative, stress, and obstructive symptoms). Scores of each item range from 0 to 3; total scores range from 0 to 18; higher scores indicate higher severity of symptoms. IIQ-7 evaluates the impact of UI on different aspects of QoL. It consists of seven items (household chores, physical recreation, entertainment activities, travel >30 min away from home, social activities, emotional health [nervousness, depression], and feeling frustrated) under four subscales (physical activity, travel, social activities, and emotional health). Scores of each item range from 0 to 3; total scores range from 0 to 21; higher scores indicate poorer QoL. The total and subscale scores of both questionnaires were transformed to a range between 0 and 100 by subtracting the lowest possible raw score and then divided by the possible raw score range. Higher scores of UDI-6 and IIQ-7 indicate more severity of urinary symptoms and poorer QoL, respectively.

Statistical analysis was conducted using SPSS (version 23.0 for Windows, IBM Corp, Armonk [NY], US). A *p* value of <0.05 was considered statistical significant. Pre- and post-treatment scores were compared using the paired sample *t*-test. The responsiveness of UDI-6 and IIQ-7 were evaluated by effect size and standardised response mean. Effect size was calculated as the mean change in scores divided by the standard deviation of the baseline score, whereas standardised response mean was the mean change in scores divided by the standard deviation of the change in scores. Effect size of 0.2 to <0.5 is defined as small, 0.5 to <0.8 as medium, and >0.8 as large^{15,16}. The rate of compliance to PFMT was calculated using the formula: (number of set of contraction performed / expected set of contractions) × 100%. A rate of >80% was considered high, 20%-80% moderate, and <20% low¹⁷.

Results

In 452 women who received PFMT, the most common diagnosis was UI (n=318, 70.4%), followed by POP (n=47, 10.4%), and concomitant UI and POP (n=87, 19.2%) [Table 1]. Among the 134 women with POP or concomitant UI and POP, 72 (53.7%) had stage-I POP, 55 (41%) had stage-II POP, and seven (5.3%) had stage-III or -IV POP. 35 (26.1%) of them received vaginal pessary and were followed up for a mean of 4.1±3.3 months.

Table 1. Baseline characteristics of participants

Characteristic	Whole sample (n=452)	Urinary incontinence alone (n=318)	Pelvic organ prolapse alone (n=47)	Concomitant urinary incontinence and pelvic organ prolapse (n=87)
Age, y	58.6±12.4	56.2±12.2	71±12.8	64±11.1
Parity	2 (0-9)	2 (0-8)	3 (1-5)	3 (0-9)
body mass index, kg/m ²	25.5±3.3	24.6±3.3	29.3±2.8	26.3±3.8
Pelvic organ prolapse staging				
No prolapse	318 (70.4)	-	-	-
Stage I	72 (15.9)	-	20 (42.6)	52 (59.8)
Stage II	55 (12.2)	-	23 (48.9)	32 (36.8)
Stage III	6 (1.3)	-	3 (6.4)	3 (3.4)
Stage IV	1 (0.2)	-	1 (2.1)	0 (0)
Follow-up duration, months	4.1±3.3	4.3±3.5	3.9±3.1	3.6±2.3
Compliance to pelvic floor muscle training				
High	4 (0.9)	47 (14.7)	0 (0)	0 (0)
Moderate	389 (86.0)	267 (84.0)	39 (83.3)	83 (95.2)
Low	59 (13.1)	4 (1.3)	8 (16.7)	4 (4.8)

Data are presented as mean±standard deviation, median (range), or No. (%) of women

The rate of compliance to PFMT was moderate in 86% of patients. 44 women (mean age, 52.6±8.9 years) who remained to have moderate or severe urodynamic stress incontinence after PFMT underwent tension-free vaginal tape procedure.

Both urinary symptoms and QoL improved after PFMT compared with baseline. The UDI-6 score for urinary symptoms improved from 38.9 to 29.4 ($p<0.001$), whereas the IIQ-7 score for QoL improved from 27.1 to 19.8 ($p<0.001$) [Table 2]. At baseline, urinary symptoms and QoL were better in women with POP alone than in those with UI and in those with concomitant UI and POP, but the improvement was greater in the latter two groups. Responsiveness to change in scores of UDI-6 and IIQ-7 was moderate and small, respectively.

Of 380 women who underwent urodynamic study, 138 (36.3%), 41 (10.8%), 17 (4.5%), and 5 (1.3%) were diagnosed with urodynamic stress incontinence, detrusor overactivity, mixed urodynamic stress incontinence and detrusor overactivity, and voiding dysfunction, respectively, and the remaining 179 (47.1%) had no abnormal urodynamic findings (Table 3). For UDI-6 score, effect size for all diagnosis groups was small (0.22 to 0.38),

except for the mixed group, which was negligible (0.1). For IIQ-7 score, effect size was even smaller and more negligible (0.06 to 0.23).

After PFMT, the UDI-6 and IIQ-7 scores improved significantly in women with stage-I or -II POP but not in those with stage-III or -VI POP (Table 4). The responsiveness of UDI-6 and IIQ-7 was small among all women with POP. 35 (26.1%) of them received vaginal pessary. The effect size of UDI-6 was large (0.81) in women with vaginal pessary but was small (0.36) in women without, whereas the effect size of IIQ-7 was small in women with or without vaginal pessary (0.38 and 0.33, respectively) [Table 4].

In 44 women who underwent tension-free vaginal tape procedure after PFMT failed, the UDI-6 score improved from 60.3 to 22.1 ($p<0.001$) and the IIQ-7 score improved from 39.1 to 8.1 ($p<0.001$) [Table 5]. All subscale scores of both questionnaires improved significantly. The effect size of subscales of both questionnaires was small (0.0 to 0.44), except for the stress subscale of UDI-6, which was medium (0.67), whereas the responsiveness of subscales of both questionnaires was small to moderate.

Table 2. Change in scores of Urogenital Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7) after pelvic floor muscle training (PFMT)

Scale	Pre-PFMT*	Post-PFMT*	Mean change in score*	Effect size	Standardised response mean	p Value
UDI-6						
Whole sample (n=452)						
Total score	38.9±19.8	29.4±18.2	-9.4±17.2	0.47	0.55	<0.001
Irritative	48.5±26.7	39.0±25.1	-9.4±24.9	0.35	0.38	<0.001
Stress	45.1±25.7	35.0±25.0	-10.1±23.6	0.39	0.43	<0.001
Obstructive	23.0±23.5	14.3±20.0	-8.6±22.0	0.37	0.39	<0.001
Urinary incontinence alone (n=318)						
Total score	41.2±19.4	31.2±18.0	-10.0±17.8	0.52	0.56	<0.001
Irritative	51.5±26.9	41.8±25.3	-9.6±26.1	0.36	0.37	<0.001
Stress	48.8±25.3	38.0±24.9	-10.8±24.0	0.43	0.45	<0.001
Obstructive	23.4±24.3	13.9±18.8	-9.4±21.6	0.39	0.44	<0.001
Pelvic organ prolapse alone (n=47)						
Total score	21.5±13.3	15.2±13.2	-6.3±8.6	0.47	0.73	<0.001
Irritative	38.3±22	29.4±17.5	-8.9±15.5	0.45	0.57	<0.001
Stress	16.3±18.9	9.9±15.4	-6.4±12.8	0.34	0.50	0.001
Obstructive	9.9±15.0	6.4±16.5	-3.5±13.4	0.23	0.26	0.077
Concomitant urinary incontinence and pelvic organ prolapse (n=87)						
Total score	35.8±18.8	27.8±18.1	-8.1±16.7	0.43	0.49	<0.001
Irritative	43.6±24.1	33.7±24.3	-9.9±22.8	0.41	0.43	<0.001
Stress	38.7±24.0	31.7±22.6	-7.0±22.4	0.29	0.31	0.003
Obstructive	25.2±22.6	17.9±22.6	-7.3±25.1	0.32	0.29	0.006
IIQ-7						
Whole sample (n=452)						
Total score	27.1±23.5	19.8±23.5	-7.4±20.0	0.31	0.37	<0.001
Physical activity	26.9±26.0	20.2±23.9	-6.7±25.2	0.26	0.27	<0.001
Travel	23.6±26.5	17.0±24.2	-6.6±24.5	0.25	0.27	<0.001
Social activities	26.5±29.3	21.4±28.4	-5.2±29.8	0.17	0.17	<0.001
Emotional health	31.1±30.0	21.1±26.2	-10.0±27.4	0.33	0.36	<0.001
Urinary incontinence alone (n=318)						
Total score	29.3±24.2	21.8±22.9	-7.7±19.9	0.31	0.39	<0.001
Physical activity	29.2±26.5	22.4±23.9	-6.9±24.6	0.26	0.28	<0.001
Travel	25.7±27.4	19.0±25.8	-6.7±24.3	0.24	0.28	<0.001
Social activities	28.4±29.7	23.6±29.7	-4.8±29.8	0.16	0.16	<0.001
Emotional health	33.6±30.7	22.8±26.6	-11.0±27.8	0.35	0.40	<0.001
Pelvic organ prolapse alone (n=47)						
Total score	7.9±13.7	4.4±8.9	-3.5±11.6	0.26	0.30	<0.001
Physical activity	7.1±15.4	4.3±4.1	-2.8±16.0	0.18	0.18	0.004
Travel	6.4±16.5	2.8±8.7	-3.5±13.4	0.22	0.26	<0.001
Social activities	7.1±16.9	3.5±12.5	-3.5±15.9	0.21	0.22	0.002
Emotional health	10.6±20.1	6.4±12.3	-4.3±20.1	0.21	0.21	0.037
Concomitant urinary incontinence and pelvic organ prolapse (n=87)						
Total score	25.1±21.8	17.3±19.2	-7.8±21.6	0.36	0.36	0.001
Physical activity	24.1±23.8	17.4±23.2	-6.7±27.5	0.28	0.24	0.022
Travel	22.8±25.2	14.5±19.5	-8.2±26.3	0.33	0.31	0.003
Social activities	25.8±29.1	19.0±24.8	-6.8±32.4	0.23	0.21	0.046
Emotional health	28.3±27.8	19.2±26.6	-9.1±26.4	0.33	0.34	0.001

* Data are presented as mean±standard deviation

Table 3. Change in scores of Urogenital Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7) after pelvic floor muscle training (PFMT) in women assessed by urodynamic study (n=380)

Urodynamic diagnosis	Pre-PFMT*	Post-PFMT*	Mean change in score*	Effect size	Standardised response mean	p Value
UDI-6						
Urodynamic stress incontinence (n=138)	39.9±19.0	31.2±19.2	-8.7±16.8	0.22	0.52	<0.001
Detrusor overactivity (n=41)	42.4±21.9	29.2±19.5	-13.2±21.5	0.38	0.61	<0.001
Mixed urodynamic stress incontinence and detrusor overactivity (n=17)	32.2±17.6	28.5±19.3	-3.7±16.8	0.10	0.22	0.020
Voiding dysfunction (n=5)	34.4±12.7	23.3±20.2	-11.1±10.4	0.31	1.1	0.038
No urodynamic abnormality (n=179)	39.8±20.7	30.0±18.4	-9.84±18.0	0.24	0.55	<0.001
IIQ-7						
Urodynamic stress incontinence (n=138)	27.2±23.8	20.3±22.4	-6.9±21.1	0.15	0.33	<0.001
Detrusor overactivity (n=41)	29.6±21.5	18.8±24.8	-10.8±21.6	0.23	0.50	0.001
Mixed urodynamic stress incontinence and detrusor overactivity (n=17)	26.9±21.2	24.4±20.5	-2.5±18.1	0.06	0.14	0.013
Voiding dysfunction (n=5)	36.6±35.7	23.8±28.2	-12.8±15.9	0.20	0.81	0.036
No urodynamic abnormality (n=179)	29.2±23.7	22.2±23.1	-7.0±20.4	0.12	0.34	<0.001

* Data are presented as mean±standard deviation

Table 4. Change in scores of Urogenital Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7) after pelvic floor muscle training (PFMT) in women with pelvic organ prolapse (POP) with or without vaginal pessary (n=134)

POP stage	Pre-PFMT*	Post-PFMT*	Mean change in score*	Effect size	Standardised response mean	p Value
UDI-6						
POP stage I (n=72)	26.2±16.4	18.6±14.5	-7.6±11.2	0.49	0.68	<0.001
POP stage II (n=55)	35.2±18.2	28.1±18.7	-7.1±18.0	0.38	0.39	0.005
POP stage III & IV (n=7)	41.5±16.9	38.5±21	-3.0±13.7	0.16	0.22	0.447
With vaginal pessary (n=35)	32.9±19.8	18.6±15.1	-10.0±15.5	0.81	0.65	0.001
Without vaginal pessary (n=99)	30.4±17.9	23.8±18.4	-6.6±14.1	0.36	0.39	<0.001
IIQ-7						
POP stage I (n=72)	13.0±18.4	8.4±14.9	-4.6±15.0	0.28	0.31	<0.001
POP stage II (n=55)	24.3±20.4	15.7±18.0	-8.7±22.1	0.45	0.39	0.01
POP stage III & IV (n=7)	31.8±26.8	25.6±21.9	-6.2±23.7	0.26	0.26	0.362
With vaginal pessary (n=35)	22.1±20.5	14.7±18.6	-7.4±18.1	0.38	0.41	0.026
Without vaginal pessary (n=99)	18.7±21.5	12.3±17.4	-6.4±20.2	0.33	0.32	0.002

* Data are presented as mean±standard deviation

Table 5. Change in scores of Urogenital Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7) in women with tension-free vaginal tape procedure (n=44)

Scale	Pre-surgery	Post-surgery	Mean change in score	Effect size	Standardised response mean	p Value
UDI-6 total score	60.3±19.5	22.1±23.6	-38.2±29.6	0.44	1.29	<0.001
Irritative	68.6±37.2	28.8±31.6	-39.8±45.1	0.25	0.88	<0.001
Stress	96.9±25.8	22.1±29.0	-74.8±38.6	0.67	1.94	<0.001
Obstructive	16.3±21.1	15.9±24.6	-0.4±31.0	0.00	0.01	<0.001
IIQ-7 total score	39.1±24.6	8.1±13.2	-31.0±21.8	0.39	1.42	<0.001
Physical activity	43.9±27.2	7.6±12.7	-36.3±29.7	0.43	1.22	<0.001
Travel	31.4±29.4	4.9±12.2	-26.5±25.8	0.26	1.03	<0.001
Social activities	35.6±34.8	7.6±15.9	-28.0±31.3	0.22	0.89	<0.001
Emotional health	41.7±31.6	12.1±21.1	-29.6±30.5	0.24	0.97	<0.001

* Data are presented as mean±standard deviation

Discussion

UDI-6 and IIQ-7 are relatively simple and easy to use and thus facilitate clinical application and research, compared with other health-related QoL assessment tools for UI, Pelvic Floor Distress Inventory, and Pelvic Floor Impact Questionnaire¹⁸⁻²⁰. The Chinese version of IIQ-7 is more sensitive than Short Form-36 Health Survey²¹ for assessment of Cantonese-speaking patients with lower urinary tract symptoms. The Chinese versions of UDI-6 and IIQ-7 have been validated among Hong Kong women with UI (one-third with concomitant POP)¹¹. UI and POP share similar pathophysiology and commonly occur concomitantly. Approximately 50% of women with POP have symptomatic stress UI²². The Hospital Authority advocates the use of the Chinese version of UDI-6 and IIQ-7 to assess the QoL in older adults with UI²³ and the effectiveness of intensive behavioural therapy in improving UI in women²⁴.

Responsiveness is an important psychometric property; a tool with poor responsiveness may result in type II error (ie, assuming no difference when a difference in fact exists) and estimation of the treatment effect²⁵. The change in QoL scores is lower after conservative management than after surgical treatment²⁶. Overall, after PFMT, the responsiveness of UDI-6 was moderate and that of IIQ-7 was small, whereas the effect size of both questionnaires was small. Nonetheless, PFMT was effective in improving urinary symptoms and QoL in women with UI and/or POP. The effect size of UDI-6 was large (0.81) in women after vaginal pessary, which may be attributed to the relief of voiding and irritative symptoms caused by POP. Results

of the present study are consistent with those of other studies^{27,28}. After tension-free vaginal tape procedure, the effect size of UDI-6 and IIQ-7 and their subscales was small, except for the stress subscale of UDI-6, which was moderate (0.67), and the obstructive subscale of UDI-6, which was minimal (0.00). The procedure improved or cured the stress symptoms and did not cause complication of voiding difficulty.

Characteristics of our patients are similar to those in other studies involving nurse-led continence service^{6,11,29,30}. Thus, results of the present study may be generalised to other Chinese patients with UI and/or POP. Although the mean follow-up of 4.1 months is short, the effect of PFMT can still be observed. The follow-up protocol is consistent with the National Institute for Health and Care Excellence guidelines on the management of UI and POP³¹. The sample size was large, and urodynamic study was performed for women with mixed UI or more severe symptoms. Women who were referred to a tertiary unit are motivated to seek treatment. This could lead to selection bias, as women with milder symptoms in the community may not seek medical care. All UDI-6 and IIQ-7 and their subscales scores improved significantly after conservative and surgical treatment, except for the obstructive subscale score of UDI-6 in women with POP alone after PFMT ($p=0.077$), the total UDI-6 score in women with stage-III or -IV POP after PFMT ($p=0.447$), and the total IIQ-7 score in women with stage-III or -IV POP after PFMT ($p=0.362$). This may be due to the small sample size in these subgroups and lower responsiveness to conservative management (compared with surgical treatment). The

minimally important difference of UDI-6 and IIQ-7 should be addressed in future research evaluating different treatment options. A 3-day bladder diary is more objective may provide more information to the change in symptoms after PFMT.

Conclusion

The UDI-6 and IIQ-7 are modestly responsive to change after PFMT and/or tension-free vaginal tape procedure in women with UI and/or POP.

Contributors

SSCC designed the study. PNPI, RYKC, OYKW, and SSCC acquired the data. PNPI, RYKC, RKWC, and SSCC analysed the data. PNPI and SSCC drafted the manuscript. All authors critically revised the manuscript for important intellectual content. All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

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Conflicts of interest

All authors have disclosed no conflicts of interest.

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Data availability

All data generated or analysed during the present study are available from the corresponding author on reasonable request.

Ethics approval

The study was approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (reference: CRE-2015.125). The patients were treated in accordance with the tenets of the Declaration of Helsinki. The patients provided written informed consent for all treatments and procedures

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