Title: The Australian Pelvic Floor Questionnaire is a valid measure of pelvic floor symptoms in patients following surgery for colorectal cancer

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Abstract

Aims:

This study evaluated the construct validity of the Australian Pelvic Floor Questionnaire against two alternative measures of the severity of bladder and bowel symptoms.

Methods:

This was an exploratory analysis of data from two prospective studies. Patients who had undergone surgery for colorectal cancer were analysed. Bladder and bowel symptoms were measured using three validated questionnaires: the Australian Pelvic Floor Questionnaire, the International Consultation on Incontinence Questionnaire Short Form Questionnaire for urinary incontinence, and the International Consultation on Incontinence Questionnaire-Bowel Module post-cancer treatment.

Results:

The study sample consisted of 44 participants, including 25 men and 19 women. The Australian Pelvic Floor Questionnaire bladder and bowel domain scores demonstrated moderate positive correlations with the International Consultation on Incontinence Questionnaire Short Form Questionnaire for urinary incontinence ($r = 0.74$, $p < 0.01$) and the International Consultation on Incontinence Questionnaire-Bowel Module ($r = 0.69$-0.78, $p < 0.01$). Similar results were obtained in each gender subgroup.

Conclusions:

This study suggested that the Australian Pelvic Floor Questionnaire may be a valid measurement tool for use in colorectal cancer populations in clinical trials and practice. Future research using larger cohorts is warranted.

Key Words: colorectal neoplasms; questionnaires; pelvic floor dysfunction; bowel dysfunction; bladder dysfunction; validity

Introduction

In Australia, 10,037 (66.2%) new cases of colon cancer and 5,114 (33.8%) new cases of rectal cancer were diagnosed in 2011.[1, 2] Following surgery for colorectal cancer (CRC), patients often experience bladder (37.5% - 60%) [3, 4] and bowel (38% - 75%) [5] dysfunction, which may significantly impact on their health related quality of life (HRQoL).[6, 7] Although urinary dysfunction following CRC treatment remains poorly understood, it is reported to be worse with increasing age, female gender, advanced stage tumours, nerve injury, and abdominoperineal resection.[8] A previous review reported that bowel dysfunction after rectal cancer treatment is closely related to tumour height, pouch reconstruction, and radiotherapy.[8] While differences exist in the patho-physiology of bladder and bowel function between males and females,[9, 10] males and females are usually analysed together in studies investigating bladder and bowel symptoms following CRC surgery. Therefore, individual sex differences are not apparent.

Although the Low Anterior Resection (LAR) Syndrome Score has been developed and used to measure bowel dysfunction in patients after LAR for rectal cancer,[11] to date, there are no validated measures which are applicable to assess bladder and bowel symptoms for both colon and rectal cancer. As the ratio of colon to rectal cancer is approximately 2:1, it is potentially useful to have a tool which is applicable across both tumour streams. While the European Organisation for Research and Treatment of Cancer (EORTC) questionnaire colorectal cancer module (QLQ-CR29), a reliable and valid tool to use in CRC, includes scales for bladder and bowel dysfunction, it is a measure to assess HRQoL and needs to be administered with the EORTC core questionnaire (QLQ-C30). Together, the total number of items is 59, which is lengthy and time-consuming to complete. Furthermore, the EORTC QLQ-C30 and the CRC module have been found to be insensitive in delineating differences in postoperative bowel function in patients with CRC.[12] To determine

functional pelvic floor outcomes, a validated, pelvic floor–specific instrument applicable for patients with CRC is necessary.

A previous systematic review[13] recommended the International Consultation on Incontinence Questionnaire (ICIQ) Short Form Questionnaire for urinary incontinence (ICIQ-UI SF) as a Grade A questionnaire to assess combined symptoms of urinary incontinence/lower urinary tract symptoms/overactive bladder in males and females. The ICIQ-UI SF is the first module developed by the World Health Organisation (WHO)-sponsored International Consultation on Incontinence (ICI) to assess urinary incontinence and its impact on HRQoL.[14] Subsequently, the ICIQ-Bowel module (ICIQ-B) was developed as one of the series questionnaires included in the ICIQ project.[15] Both ICIQ-UI-SF (Grade A) and ICIQ-B (Grade A+) are highly recommended by the ICI as the outcome measures for the symptoms and impact of urinary and faecal incontinence in clinical practice and research trials.[16] Both questionnaires have undergone extensive psychometric testing in different patient groups, however not in CRC-specific populations.[16, 17]

The Australian Pelvic Floor Questionnaire (APFQ) is one of the few validated questionnaires that integrate bladder, bowel, and sexual function as well as pelvic organ prolapse symptoms.[18, 19] Although the APFQ was designed for females in the community [20] and females with pelvic floor disorders,[18] the questions in the bladder and bowel function domains of the APFQ may also be applicable to males. Additionally, the total number of questions in the bladder and bowel function domains of APFQ is 27, which is less than the total number of 48 questions or items in the ICIQ-UI SF and ICIQ-B combined.

Although the psychometric properties of the APFQ have been previously established,[18-20] it has not been evaluated in a sample of patients with CRC. We hypothesized that the bladder and bowel domains of the APFQ, which are less lengthy and more symptom specific than the corresponding

questions in the LAR Syndrome Score and the EORTC QLQ-CR29, are also valid and applicable to patients with CRC. As a gold standard tool is not available, the primary aim of this study was to assess the construct validity,[21] and clinical utility of the bladder and bowel function domains of the APFQ compared with two existing bladder and bowel questionnaires (i.e. ICIQ-UI SF and ICIQ-B) in patients following surgery for CRC.

Materials and Methods

Study design

This was an analysis of data from two ongoing prospective clinical studies at three large hospitals in Melbourne Australia, two private and one public.

Study 1 is a prospective observational study to assess pelvic floor symptoms, anorectal muscle function, functional outcomes, emotional distress, and HRQoL in patients who undergo surgery for CRC. The study was approved by the Melbourne Health Human Research Ethics Committee.

Study 2 is a prospective observational pre-post study to investigate the feasibility of a multidisciplinary general oncology rehabilitation program for patients following surgery for abdomino-pelvic cancer (Australian New Zealand Clinical Trials Registry [ANZCTR]: 12614000580673). The study had ethics approval from Cabrini Hospital Human Research Ethics Committee.

Participants

Participants included patients who had undergone surgery for histologically confirmed stage I-III CRC; had an Eastern Cooperative Oncology Group performance status of between 0-2 (0 = fully active, 2 = up and about for 50% of a day); and had sufficient English language skills to participate.

Patients were excluded if they were aged 86 and over, were pregnant or up to 12 months postpartum, or had severe physical/psychiatric impairments. Data from all participants who were eligible from the two ongoing prospective clinical studies and recruited between October 2013 and August 2015 were used for analysis. Written informed consent was obtained from all participants before completing the measurements.

Measures

Bladder and bowel symptoms were assessed using the bladder and bowel function domains of the APFQ, ICIQ-UI SF, and ICIQ-B at six to eight weeks post-cancer treatment.

The APFQ is an instrument consisting of 42 questions in 4 domains (bladder, bowel, and sexual function and pelvic organ prolapse).[19] The scores within each domain are divided by the number of relevant questions and multiplied by 10; thus, the scores range from 0 to 10 for each domain, giving a maximum total score of 40. [18] We chose to focus on the bladder and bowel function domains, which contain 15 and 12 questions respectively, and the maximum total score for both bladder and bowel function domains combined is 20. A higher score indicates more severe symptoms. The APFQ has been validated in groups of urogynaecological patients [18, 19] and applied in broad populations.[22-24]

The ICIQ-UI SF was developed to evaluate the severity of urinary incontinence and its impact on HRQoL. It consists of three scored items related to frequency and amount of urinary incontinence and quality of life and a self-diagnostic item, not scored. An overall ICIQ-UI SF score is calculated as the summation of the three scored items and ranges from 0 to 21. Urinary incontinence is defined as either absent (score 0) or present (score $\geq$ 1) on the ICIQ-UI SF.[14] Higher score indicates worse symptom severity or greater impact of symptoms on HRQoL. The ICIQ-UI SF has been shown to

have good psychometric properties in patients with incontinence or other lower urinary tract symptoms and is suitable for use in clinical practice and research.[14, 25]

The ICIQ-B is a non-gender-specific questionnaire developed to evaluate anal incontinence symptoms and impact on quality of life and contains a total of 21 questions. Seventeen of 21 questions are scored and arranged in three domains: bowel pattern (score range 1-21), bowel control (score range 0-28), and quality of life (score range 0-26). Four unscored items include other bowel symptoms and sexual impact. A five-point Likert scale is used for most questions to assess the presence or absence of a symptom and its severity, followed by visual analogue scale of 0–10 to assess associated bother.[17] Higher scores indicate greater impairment or symptoms.[17] The ICIQ-B has been shown to be a psychometrically robust instrument for use in individuals with anal incontinence of varying causes. [17]

Statistical analysis

Statistical analysis was performed using SPSS Windows Version 22.0 (SPSS, Chicago, IL, USA). Demographic and clinical outcome data of the participants were analysed using descriptive statistics, such as mean and standard deviation, median and interquartile range, or number and percentage. The differences in the participants' characteristics between male and females were compared using the independent t-test or Mann-Whitney U test for continuous variables, and χ^2 test for categorical variables. Pearson's correlation coefficients were used to examine the bivariate relationships among the bladder domain of the APFQ and the total score of ICIQ- UI SF, as well as the correlations between the bowel domain of the APFQ and ICIQ-B subscales. The strength of the correlation was determined by the correlation coefficient values (0.00–0.30 = negligible; 0.30–0.50 = low positive correlation; 0.50–0.70 = moderate positive correlation; 0.70–0.90 = high positive correlation; and 0.90–1.00 = very high positive correlation).[26]

The score of each tool was categorized as symptomatic or asymptomatic using a cut-off score of greater than or equal to 1, based on the cut-off value reported in previous studies.[14, 18] Kappa coefficients were calculated to determine the agreement between questionnaires. A kappa value of less than 0.40 was considered poor-to-fair agreement, 0.41-0.60 moderate agreement, 0.61-0.80 substantial agreement, and 0.81-1.00 almost perfect agreement.[27]

As this study was an exploratory analysis, no power calculation was carried out. *P* values < 0.05 were considered statistically significant.

Results

Participant characteristics

Data from 44 participants (25 males and 19 females) with a mean age of 64.8 years (SD = 14.1, range 26-85 years) were collected from the two studies (Figure 1). Eighty-two percent had a confirmed diagnosis of colon cancer, and 75% had not undergone any adjuvant therapies at the time of diagnosis. Thirty-six percent had bladder symptoms and 66% had bowel symptoms as assessed using the APFQ bladder and bowel domains; conversely, 64% did not have bladder symptoms and 34% did not have bowel symptoms six to eight weeks following cancer treatment (Table 1). No statistically significant differences were found in socio-demographic and clinical characteristics and the number of participants being symptomatic (APFQ bladder and APFQ bowel ≥ 1) between males and females. Table 2 shows the descriptive statistics for APFQ bladder and bowel domains, total score of ICIQ-UI SF, and ICIQ-B subscales as well as the number of participants with a score above the cut-off score of being symptomatic. No statistically significant differences existed in the number of participants being symptomatic as assessed using the APFQ, ICIQ-UI SF, and ICIQ-B between males and females (Table 2). Age ($p = 0.002$) was significantly different between individuals with or without bladder symptoms (data not shown). However, no significant

differences were found in demographic and clinical variables between groups with or without bowel symptoms (data not shown).

Correlations

The correlation coefficients between the APFQ and ICIQ-UI SF or ICIQ-B in this cohort / study are given in supplementary table 1 (total cohort), Table 3 (males) and Table 4 (females). In the total cohort, moderate correlations were observed between the APFQ bladder domain and the ICIQ-UI SF total score (r = 0.74), and the APFQ bowel domain and all ICIQ-B subscales (range r = 0.69-0.78), which support good convergent validity of APFQ in patients following CRC surgery (supplementary table 1). Gender subgroup analyses yielded similar results. In males, the APFQ bladder domain was significantly and moderately correlated with the total ICIQ-UI SF score (r = 0.71) and APFQ bowel domain with all ICIQ-B subscales (range r = 0.69-0.79) (Table 3). In females, the APFQ bladder domain and ICIQ-UI SF showed a significant and high positive correlation (Table 4). Nonetheless, APFQ bladder domain was also moderately correlated with ICIQ-B bowel control (r = 0.80) and weakly correlated with ICIQ-B quality of life (r = 0.51). The APFQ bowel domain showed moderate correlations with ICIQ-B subscales - bowel pattern, bowel control, and quality of life in females (Table 4). The three ICIQ-B subscales significantly correlated with each other in the total cohort and both sexes.

Agreement

The results for agreement were similar to the correlation analysis: moderate level of agreement between APFQ bladder domain and ICIQ-UI SF with a kappa coefficient value of 0.56 in males and 0.51 in females. The agreement between APFQ bowel domain and ICIQ-B subscales was low to moderate with a range of kappa values from 0.34 to 0.56 (Supplementary table 2). All agreements were statistically significant, except the kappa values in females ($p = 0.05$).

Discussion

This exploratory analysis showed moderate correlations between the bladder and bowel function domains of APFQ and the ICIQ-UI SF and ICIQ-B in patients following surgery for CRC surgery. The positive associations observed with the bladder and bowel function domains of APFQ and the other two symptom severity questionnaires support the construct validity of the APFQ. The results of this study suggest that the APFQ may be valid in the CRC population, and also that its utility can be generalized beyond female CRC populations.

In the original validation for the APFQ, the bladder function domain score was validated against the short version of the Urogenital Distress Inventory (UDI) in females with pelvic floor disorders,[18] and the authors found a significant correlation with the UDI score (Spearman's rho 0.80; $p < 0.001$). The findings of our study using a smaller cohort of males and females following surgery for CRC suggested a significant and similar correlation of the APFQ bladder function domain in comparison to the ICIQ-UI SF scores (total: r = 0.74; $p < 0.01$; male: r = 0.71; $p < 0.01$; female: r= 0.83; $p < 0.01$). The slightly lower correlation in males may be accounted for by a relatively lower prevalence of urinary symptoms among the majority of the males than females in the CRC populations.[28]

Baessler et al. validated the bowel function domain of the APFQ against the Heaton's bowel questionnaire, and found a high correlation between the two questionnaires (Spearman's rho 0.81 - 0.92, $p < 0.001$).[18] Although the correlations in our findings were lower (r = 0.69 - 0.78 in total cohort; r = 0.69 - 0.79 in males; r = 0.70 - 0.77 in females), it should be noted that our study may not be directly comparable with the study by Baessler et al. due to the population differences.[18] The inclusion of male participants and the effects of cancer and cancer treatment (surgery, radiotherapy, chemotherapy) on bladder and bowel function in patients with CRC [29, 30] may affect the comparisons.

Nevertheless, the moderate correlations between APFQ, ICIQ-UI SF, and ICIQ-B in our study suggested that these questionnaires measure similar constructs in the CRC population. Although a combination of different self-reported questionnaires on bladder and bowel symptoms are often used in research studies to obtain a comprehensive understanding of a patient's condition, these are likely to be too time-consuming and burdensome for patients and clinicians in a clinical practice setting. The use of one questionnaire (i.e. APFQ) which is applicable to male and female CRC populations and evaluates both bladder and bowel domains instead of two separate questionnaires (i.e. ICIQ-UI SF and ICIQ-B) can reduce participant burden in both research and clinical settings.

In this study, the APFQ bladder domain was significantly correlated not only with ICIQ-UI SF total score but also with some ICIQ-B subscales in the female cohort. One possible explanation is that urinary and faecal incontinence are not only highly prevalent but also co-existing among women in the community;[31, 32] therefore, preoperative bladder and bowel dysfunction may influence post-operative function.[30] Nevertheless, further evaluation is required to determine the prevalence and the impact of preoperative bladder and bowel dysfunction in females who are scheduled to undergo CRC surgery.

With a score of greater than or equal to one as the cut-off value for symptomatic patients, the APFQ bladder domain had a moderate agreement with ICIQ-UI SF, and low to moderate agreement was found between APFQ bowel domain and ICIQ-B. A cut-off score of one was chosen based on previous validation study.[14] However, it is important to note that no cut-off values have been established for APFQ and ICIQ-B. All of the correlations and agreements should be interpreted with caution due to the possible over- or under-estimation of the number of symptomatic individuals and the small sample size. More research is warranted to establish the sensitivity, specificity, and positive and negative predictive values of the APFQ in a cancer population.

This study has some limitations. First, as this study was a retrospective analysis of two prospective studies, a selection bias must be considered. Second, other potential confounding factors that may have an impact on post-operative bladder and bowel symptoms, such as pre-operative bladder and bowel function,[8, 30] history of childbirth and hormonal status of the female participants,[8, 33] were not addressed in the study due to the lack of available pre-operative data. Moreover, given the small sample size, it was difficult to conduct subgroup analyses to investigate the validity of APFQ in patients who have undergone surgery for rectal cancer *versus* colon cancer and those who have undergone adjuvant therapies *versus* no adjuvant therapies. Due to a higher percentage of patients treated for colon cancer (82%) compared to 18% of patients with rectal cancer in our study, the findings of this study may not be generalized to all CRC population. Lastly, the ICIQ-UI SF and ICIQ-B do not include all bladder and bowel symptoms that could affect a patient following CRC surgery. Despite the inherent differences between the three questionnaires and the limitations, the relationships observed in this study were in the direction hypothesized. This work has clinical implications for health care professionals working with the CRC population. In view of reducing the burden for patient, researcher and clinician, the APFQ would be a potentially appropriate and easy to administer instrument to measure the severity of bladder and bowel symptoms in patients following surgery for CRC.

Conclusions

The APFQ is moderately correlated with the ICIQ-UI SF and ICIQ-B and appears to be a useful instrument for clinical and research use. Further research using larger cohorts is warranted to evaluate additional psychometric properties including reliability, responsiveness, sensitivity, and specificity of the APFQ in CRC to further demonstrate the utility of the instrument within this population.References

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Figure legends

Figure 1 Flow chart of the two studies.

Table 1 Characteristics of participants

Variables	Total (n=44)	Males (n=25, 56.8%)	Females (n=19, 43.2%)
Age, years (mean ± SD)	64.8±14.1 (range 26-85)	64.1±13.8 (range 30-84)	65.8±14.7 (range 26-85)
Level of tumour, n (%)			
Colon	36 (81.8)	20 (80)	16 (84.2)
Rectum	8 (18.2)	5 (20)	3 (15.8)
Adjuvant treatment, n (%)			
Preoperative chemoradiotherapy	2 (4.5)	2 (8)	0 (0)
Postoperative chemotherapy	8 (18.2)	7 (28)	1 (5.3)
Preoperative chemoradiotherapy +	1 (2.3)	0 (0)	1 (5.3)

postoperative chemotherapy			
No adjuvant therapies	33 (75.0)	16 (64)	17 (89.5)
Length of stay, days (median, IQR)	7.0 (6.0-11.5)	8.0 (6.0-11.0)	6.0 (5.0-12.8)
Type of surgery, n (%)			
Right hemicolectomy	16 (36.4)	7 (28)	9 (47.4)
Left hemicolectomy	2 (4.5)	2 (8)	0 (0)
Subtotal or total colectomy	5 (11.4)	2 (8)	3 (15.8)
Abdominoperineal resection/excision	1 (2.3)	1 (4)	0 (0)
High anterior resection	10 (22.7)	8 (32)	2 (10.5)
Ultra-low anterior resection	10 (22.7)	5 (20)	5 (26.3)
Stage of cancer, n (%)			
I	15 (34.1)	7 (28)	8 (42.1)
IIA	11 (25.0)	7 (28)	4 (21.1)
IIB	2 (4.5)		2 (10.5)
IIC	1 (2.3)		1 (5.3)
IIIA	7 (15.9)	7 (28)	
IIIB	4 (9.1)	2 (8)	2 (10.5)
IIIC	2 (4.5)	1 (4)	1 (5.3)
Missing	2 (4.5)	1 (4)	1 (5.3)
Symptomatic, n (%)			
Bladder (APFQ bladder $\geq$ 1)	16 (36.4)	10 (40.0)	6 (31.6)
Bowel (APFQ bowel $\geq$ 1)	29 (65.9)	17 (68.0)	12 (63.2)

Abbreviation: IQR, interquartile range; SD, standard deviation; APFQ, Australian Pelvic Floor Questionnaire.

Table 2 Severity of bladder and bowel symptoms

Variables	Total (n=44)		Males (n=25)		Females (n=19)	
	Median (IQR)	Score ≥ 1, n (%)	Median (IQR)	Score ≥ 1, n (%)	Median (IQR)	Score ≥ 1, n (%)
Bladder symptoms						
APFQ bladder	0.56 (0.22-1.33)	16 (36.4)	0.67 (0.22-1.33)	10 (40)	0.44 (0.22-1.33)	6 (31.6)
ICIQ-UI SF Total (total n=31; males n=17; females n=14)	0.00 (0.00-1.00)	8 (25.8)	0.00 (0.00-0.00)	3 (17.6)	0.00 (0.00-1.50)	5 (35.7)
Bowel symptoms						
APFQ bowel	1.47 (0.59-2.28)	29 (65.9)	1.47 (0.44-2.65)	17 (68)	1.47 (0.59-1.77)	12 (63.2)
ICIQ-B Bowel pattern	5.50 (4.00-7.00)	39 (88.6)	6.00 (4.50-9.50)	22 (88)	4.00 (3.00-7.00)	17 (89.5)
ICIQ-B Bowel control	1.00 (0.00-5.50)	27 (61.4)	2.00 (0.00-6.50)	16 (64)	1.00 (0.00-3.00)	11 (57.9)
ICIQ-B Quality of life	1.00 (0.00-4.00)	27 (61.4)	1.00 (0.00-6.00)	16 (64)	1.00 (0.00-4.00)	11 (57.9)

Abbreviations: APFQ, Australian Pelvic Floor Questionnaire; ICIQ-B, International Consultation on Incontinence Questionnaire-Bowel Module;

ICIQ-UI SF, International Consultation on Incontinence Questionnaire Short Form Questionnaire for urinary incontinence; IQR, interquartile range.

Table 3 Correlations between AFPQ bladder and bowel domains, ICIQ-UI SF, and ICIQ-B in males (n=25)

	APFQ Bladder	ICIQ-UI SF Total	APFQ Bowel	ICIQ-B Bowel pattern	ICIQ-B Bowel control	ICIQ-B Quality of life
APFQ Bladder	-	0.71**	0.40	0.11	0.16	0.04
ICIQ-UI SF Total	0.71**	-	0.42	0.09	0.11	0.14
APFQ Bowel	0.40	0.42	-	0.79**	0.69**	0.78**
ICIQ-B Bowel pattern	0.11	0.09	0.79**	-	0.74**	0.76**
ICIQ-B Bowel control	0.16	0.11	0.69**	0.74**	-	0.62**
ICIQ-B Quality of life	0.04	0.14	0.78**	0.76**	0.62**	-

** $p < 0.01$ level (2-tailed)

N = 25 for all correlations except the ICIQ-UI SF total (N = 17).

Abbreviations: APFQ, Australian Pelvic Floor Questionnaire; ICIQ-B, International Consultation on Incontinence Questionnaire-Bowel Module;

ICIQ-UI SF, International Consultation on Incontinence Questionnaire Short Form Questionnaire for urinary incontinence.

Table 4 Correlations between AFPQ bladder and bowel domains, ICIQ-B, and ICIQ-UI SF in females (n=19)

	APFQ Bladder	ICIQ-UI SF Total	APFQ Bowel	ICIQ-B Bowel pattern	ICIQ-B Bowel control	ICIQ-B Quality of life
APFQ Bladder	-	0.83**	0.30	0.19	0.80**	0.51*
ICIQ-UI SF Total	0.83**	-	0.23	0.05	0.80**	0.36
APFQ Bowel	0.30	0.23	-	0.75**	0.70**	0.77**
ICIQ-B Bowel pattern	0.19	0.05	0.75**	-	0.47*	0.82**
ICIQ-B Bowel control	0.80**	0.80**	0.70**	0.47*	-	0.75**
ICIQ-B Quality of life	0.51*	0.36	0.77**	0.82**	0.75**	-

**$p < 0.01$ level (2-tailed)

*N = 19 for all correlations except the ICIQ-UI SF total (N = 14).

*p*Abbreviations: APFQ, Australian Pelvic Floor Questionnaire; ICIQ-B, International Consultation on Incontinence Questionnaire-Bowel Module; ICIQ-UI SF, International Consultation on Incontinence Questionnaire Short Form Questionnaire for urinary incontinence.

< 0.05 level (2-tailed)

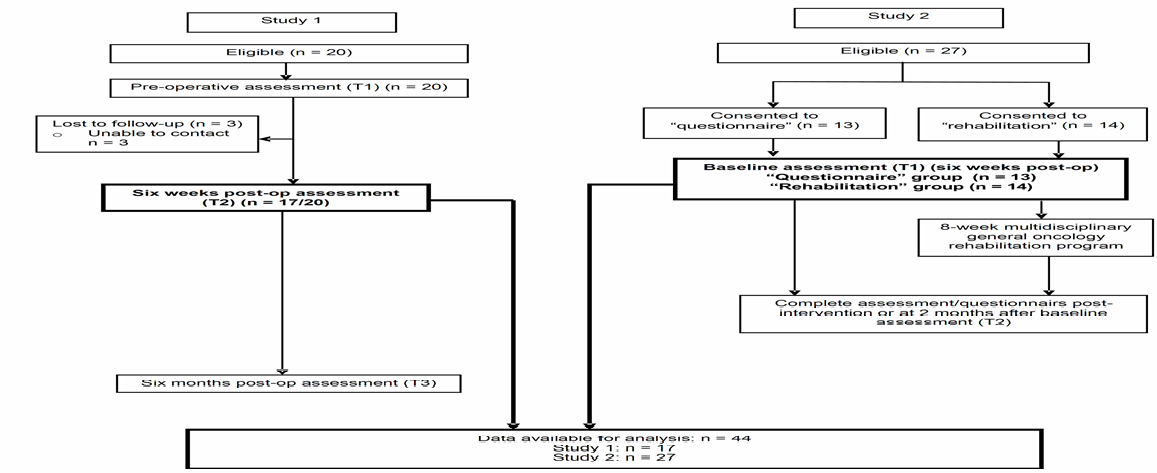

Figure 1 .