CHAPTER 5: RESULTS

First the validations of the Zulu, Pedi, Tswana and Afrikaans translations of the FACT-B questionnaires will be presented. Then a short discussion of the results of the pilot project is given. A detailed description of the patient demographical data follows. The findings of the final analysis, including summary statistics, Hotelling's T-test, multivariate analysis and survival analysis are then given.

5.1 VALIDATION OF THE TRANSLATED QUESTIONNAIRES

Tables 1 and 2 list the Chronbach's reliability coefficients for the Pedi (N= 62), Tswana (N= 64), Zulu (N= 63) and Afrikaans (N= 64) translations. The values for the three black languages are compared to the findings of Mullin (1999). Table 3 lists the mean scores and standard deviations for each of the FACT subscales, the FACT-G scale and the FACT-B scale, that had been found for the Pedi, Tswana, Zulu and Afrikaans translated versions of the FACT-B. These means and standard deviations are then compared to and an English version that had been found in the literature (Cella 1993).

TABLE 1: RELIABILITY (CHRONBACH'S ALPHA) OF THE THREE AFRICAN LANGUAGE VERSIONS OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY.

SCALE		**LANGUAGE**		
	VERIFICATION	**PEDI**	**TSWANA**	**ZULU**
Physical Well Being 7 items	Mertz	0.71	0.85	0.79
	Mullin	0.78	0.79	0.64
Social/Family Well Being, 7 items	Mertz	0.54	0.48	0.47
	Mullin	0.60	0.61	0.36
Relationship with Doctor 2 items	Mertz	0.83	0.85	0.46
	Mullin	0.80	0.92	0.86
Emotional Well Being 5 items are scored	Mertz	0.78	0.84	0.61
	Mullin	0.86	0.70	0.72
Functional Well Being 7 items	Mertz	0.86	0.84	0.86
	Mullin	0.92	0.82	0.80
Additional Concerns 9 items	Mertz	0.77	0.69	0.53
TOTAL FACT-B SCORE	Mertz	0.77	0.73	0.81

Compared with values determined by Mullin (1999)

TABLE 2: RELIABILITY (CHRONBACH'S ALPHA) OF THE AFRIKAANS VERSION OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY.

SCALE		CHRONBACH'S ALPHA
Physical Well Being	(7 items)	0.87
Social/Family Well Being	(7 items)	0.65
Relationship with Doctor	(2 items)	0.58
Emotional Well Being	(5 items)	0.78
Functional Well Being	(7 items)	0.89
Additional Concerns	(9 items)	0.65
TOTAL FACT-B SCORE		0.82

TABLE 3: MEANS (M) AND STANDARD DEVIATIONS (SD) OF THE FACT-B SCALE FOR THE THREE AFRICAN LANGUAGES, AFRIKAANS AND THE ORIGINAL ENGLISH LANGUAGE VERSION

(CELLA et al 1993), (BRADY et al 1997)

Scale	Language									
	PEDI N=62		TSWANA N=64		ZULU N=63		AFRIKAANS N=64		ENGLISH N=466	
	M	SD	M	SD	M	SD	M	SD	M	SD
PWB	16.3	5.0	15.8	6.0	19.7	6.0	17.8	6.4	20.5	5.5
SWB	20.1	5.0	17.8	4.3	21.0	4.6	21.7	4.2	21.9	4.8
RWD	7.2	1.7	7.2	1.2	7.7	0.9	7.3	1.2	6.9	1.5
EWB	14.2	4.9	12.2	4.8	15.3	4.2	15.2	3.9	14.8	3.9
FWB	19.8	6.8	17.3	5.6	20.7	6.7	16.8	6.7	18.0	6.1
ADD	22.5	7.1	19.9	5.6	25.4	6.2	22.8	6.0	------	------
FACT G	77.5	17.3	70.1	15.9	84.3	17.0	78.9	17.8	82.0	15.9
FACT B	100.1	22.1	89.9	19.1	109.7	22.0	101.7	22.1	------	------

See KEY on next page

KEY FOR TABLE 3:

PWB	physical well being	SWB	social well being
RWD	relationship with doctor	EWB	emotional well being
FWB	functional well being	ADD	additional concerns

5.2 ANALYSIS OF THE PILOT PROJECT

5.2.1 PATIENT POPULATION

Data for 200 patients who had completed at least one QOL questionnaire was analyzed.

5.2.2 MISSING DATA

This is an ubiquitous phenomenon is the field of quality of life research.
Some of the reasons for missing data are:

- Patients with a poor prognosis and rapidly progressing disease die before all evaluations can be completed.
- Some patients have early progression, so that at the time when the "during" QOL measurement is scheduled, treatment has to be changed and this time point has to be designated "after" treatment.
- Patient non-compliance, especially at time of disease progression, when the QOL evaluation becomes paramount.
- Staff non-compliance or oversight. This is a particularly vexing problem and the only factor that could be improved, resulting in less missing data.

5.2.3 SUMMARY OF THE MOST IMPORTANT FINDINGS

In table 4 the effect of different types of treatment on individual quality of life domains is shown. And in tables 5 and 6 the findings about race related differences in quality of life is detailed.

TABLE 4: FINDINGS ABOUT THE EFFECTS OF DIFFERENT TYPES OF TREATMENT ON QUALITY OF LIFE

TREATMENT	DOMAIN (P-value)	RESULTS
Hormonal vs. chemotherapy.	Functional well being P=0.044	Before, during and after treatment patients on **hormones** describe their condition as **worse.**
Any treatment.	Physical well being P=0.002	For any treatment patients describe their condition as **worse** during treatment.
Hormonal or chemotherapy.	Relationship with doctor P=0.044	Relationship with dr. is **worse** during therapy.
Hormonal or chemotherapy.	Emotional P=0.002 and functional P=0.019	Emotional and functional well-being is better during treatment than before.
Hormonal or chemotherapy.	Relationship with doctor P=0.027	Relationship with the doctor is **worse during treatment** than thereafter.
Chemotherapy	Additional concerns P=0.025	Patients on **chemotherapy are feeling worse after treatment** than before.

TABLE 5: COMPARISONS BETWEEN THE QUALITY OF LIFE OF THE DIFFERENT RACE GROUPS

RACE	**DOMAIN**	**RESULTS**
Black patients.	Physical well being P=0.043	All patients describe their physical well-being as deteriorating during treatment (chemo or hormonal), but **black** patients feel even worse than white patients.
Black patients.	Social and family well being P=0.000	The social and family well being of **black patients is worse**, than that of white patients during treatment (chemo or hormonal).
Black patients.	Physical well being P=0.018 Social and family well being P=0.000 Emotional well being P=0.016 Total score P=0.008	Already before treatment the quality of life of **black** patients is **worse** than that of white patients.
Black patients.	Physical well being P=0.013 Social and family well being P=0.000	During any treatment the physical and social/family well-being is worse for black patients.
Black patients.	Additional concerns P=0.041	After treatment (any treatment) additional concerns are worse for black patients

TABLE 6: COMPARISONS OF TOTAL FACT SCORES SHOWING THE EFFECT OF RACE MEASURED AT A SINGLE TIME POINT (BEFORE ANY TYPE OF TREATMENT)

DOMAIN	RACE	N	MEAN SCORE
PHYSICAL WELL BEING	White	57	21.19
	Black	70	18.77
SOCIAL/FAMILY WELL BEING	White	57	23.57
	Black	70	19.82
RELATIONSHIP WITH DOCTOR	White	57	7.71
	Black	70	7.55
EMOTIONAL WELL BEING	White	57	14.64
	Black	70	12.67
FUNCTIONAL WELL BEING	White	57	21.31
	Black	70	19.53
ADDITIONAL CONCERNS	White	57	23.75
	Black	70	23.98
TOTAL SCORES	White	57	111.73
	Black	70	102.11

5.3 DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE PATIENT POPULATION

5.3.1 DATA

Demographic and clinical data for the patients are listed in tables 7 to 14. Seventeen of the patients also completed FACT-B questionnaires for either second- or thirdline treatment with chemotherapy. That is the reason why the final analysis was performed with 100 sets of data. Demographics are principally recorded for the actual number of patients (83) and only for the total number of data-sets (100) in cases where a characteristic (for example performance status or disease stage) could change for a subsequent treatment line.

Table 7 and figure 1 show the amount of patients in each ethnic group. Information also contained in table 7, separated into race groups is: patients who defaulted from treatment, participation in clinical trials, employment and marital status.

Table 8 details the menopausal status, number of metastases, receptor status, tumor grade and number of nodes at mastectomy for the different race groups. Figure 2 shows the age distribution curves for the patients, which is to be read in conjunction with the menopausal status of the patients. In table 9 treatment-related clinical characteristics for the white and black patients are given. This includes information such as "inoperable" at first diagnosis, which patients had had a mastectomy, radiotherapy, adjuvant chemotherapy and medication for depression and/or anxiety.

The hospital classification, which is indicative of financial status, is given for white and black patients in table 10. Table 11 shows the performance status, disease stage and educational level at the time of questionnaire completion. A finer distinction of educational level is given in table 13. The chemotherapy regimen received by the patients is expounded in table 12 as well as figure 3 and the medication for depression and/or anxiety in table 14.

TABLE 7: GENERAL DEMOGRAPHIC CHARACTERISTICS FOR THE PATIENT GROUP OF THE FINAL ANALYSIS

CHARACTERISTIC			N=83		
ETHNICITY	Afrikaans		33		
	English		8		
	Pedi		16		
	Tswana		11		
	Zulu		15		
DEFAULTED FROM TREATMENT			**YES**	**NO**	
	Whites		4	37	
	Blacks		10	32	
PARTICIPATED IN A STUDY			**NO**	**YES**	**>ONE**
	Whites		7	29	5
	Blacks		3	38	1
EMPLOYMENT		**Employed**	**Un-employed**	**Home-Maker**	**Retired**
	Whites	12	2	16	11
	Blacks	18	10	8	6
MARITAL STATUS		**Single**	**Married**	**Divorced**	**Widowed**
	Whites	3	30	4	4
	Blacks	25	13	2	2

TABLE 8: GENERAL CLINICAL CHARACTERISTICS FOR THE PATIENT GROUP OF THE FINAL ANALYSIS

<table>
<tr><th colspan="2">CHARACTERISTIC</th><th colspan="3">N=83</th></tr>
<tr><td rowspan="3">MENOPAUSAL STATUS</td><td></td><td colspan="2">PRE-</td><td>POST-</td></tr>
<tr><td>Whites (N=41)</td><td colspan="2">14</td><td>27</td></tr>
<tr><td>Blacks (N=42)</td><td colspan="2">21</td><td>21</td></tr>
<tr><td rowspan="3">NUMBER OF METASTASES</td><td></td><td>1</td><td>2</td><td>≥3</td></tr>
<tr><td>Whites</td><td>7</td><td>13</td><td>21</td></tr>
<tr><td>Blacks</td><td>3</td><td>5</td><td>34</td></tr>
<tr><td rowspan="3">RECEPTOR STATUS</td><td></td><td>negative</td><td>positive</td><td>unknown</td></tr>
<tr><td>Whites</td><td>12</td><td>13</td><td>16</td></tr>
<tr><td>Blacks</td><td>13</td><td>13</td><td>16</td></tr>
<tr><td rowspan="3">TUMOR GRADE
(if known)</td><td></td><td>1</td><td>2</td><td>3</td></tr>
<tr><td>Whites</td><td>1</td><td>15</td><td>13</td></tr>
<tr><td>Blacks</td><td>0</td><td>25</td><td>9</td></tr>
<tr><td rowspan="3">NUMBER OF NODES AT MASTECTOMY
(if known)</td><td></td><td>0</td><td>1-3</td><td>>3</td></tr>
<tr><td>Whites</td><td>11</td><td>9</td><td>8</td></tr>
<tr><td>Blacks</td><td>4</td><td>0</td><td>5</td></tr>
</table>

TABLE 9: TREATMENT-RELATED CLINICAL CHARACTERISTICS FOR THE PATIENT GROUP OF THE FINAL ANALYSIS

CHARACTERISTIC		N=83	
INOPERABLE AT FIRST DIAGNOSIS	**Whites**	14	
	Blacks	36	
HAD SURGERY	**Whites**	28	
	Blacks	12	
HAD RADIOTHERAPY			
No radiotherapy at all	**Whites**	21	
	Blacks	25	
Post mastectomy (adjuvant)	**Whites**	3	
	Blacks	1	
For advanced disease only	**Whites**	13	
	Blacks	14	
As adjuvant & for advanced Disease	**Whites**	4	
	Blacks	2	
HAD ADJUVANT CHEMOTHERAPY	**Whites**	9	
	Blacks	0	
RECEIVED MEDICATION FOR DEPRESSION AND/OR ANXIETY		**NO**	**YES**
	Whites	14	27
	Blacks	31	11

TABLE 10: FINANCIAL STATUS OF PATIENTS ACCORDING TO THEIR HOSPITAL CLASSIFICATION

CLASSIFICATION	02	03	04	08	67	Misc.
Whites	9	3	2	1	7	8
Blacks	34	1	2	1	4	0

See chapter 4, addendum 8 (hospital classification) for explanation of classification codes. In essence a 02 patient is the poorest and earns less than R10 000 per year. Thereafter annual income increases through 03 to 04. Other patients have a medical aid.

TABLE 11: PERFORMANCE STATUS, DISEASE STAGE AND EDUCATIONAL LEVEL AT THE TIME OF INITIAL QUESTIONNAIRE COMPLETION (N=100)

<table>
<tr><td>DISEASE STAGE:</td><td colspan="2">III</td><td colspan="2">IV</td></tr>
<tr><td>Whites</td><td colspan="2">11</td><td colspan="2">39</td></tr>
<tr><td>Blacks</td><td colspan="2">14</td><td colspan="2">36</td></tr>
<tr><td>EDUCATIONAL LEVEL:</td><td colspan="2">Less than grade 12</td><td colspan="2">Grade 12 or higher</td></tr>
<tr><td>Whites</td><td colspan="2">18</td><td colspan="2">32</td></tr>
<tr><td>Blacks</td><td colspan="2">37</td><td colspan="2">13</td></tr>
<tr><td>PERFORMANCE STATUS:</td><td>PS=0</td><td colspan="2">PS=1</td><td>PS=2</td></tr>
<tr><td>Whites</td><td>16</td><td colspan="2">30</td><td>4</td></tr>
<tr><td>Blacks</td><td>5</td><td colspan="2">40</td><td>5</td></tr>
</table>

TABLE 12: CHEMOTHERAPY REGIMEN RECEIVED BY PATIENTS

CHEMOTHERAPY	WHITE PATIENTS	BLACK PATIENTS
Adriamycin	6	6
Adriamycin + Taxane	13	15
Adriamycin-combination (AC or FAC)	6	9
Taxane	12	6
CMF	3	6
MMM	1	0

TABLE 13: EDUCATIONAL LEVEL OF PATIENTS

	No education	< Grade 8	Grade 6 - 9	Grade 12	> Grade 12
Whites (41)	0	0	16	16	10
Zulu (15)	6	4	4	0	1
Pedi (16)	1	7	6	1	1
Tswana (11)	1	1	4	4	1

TABLE 14: USAGE OF MEDICATION FOR DEPRESSION AND/OR ANXIETY

DRUG	WHITE PATIENTS (N=41)	BLACK PATIENTS (N=42)
None	14	31
Paroxetine	1	0
Lorazepam +perphenazine +amitriptyline	1	0
Fluvoxamine +bromazepam	1	0
Temazepam	4	4
Haloperidol	1	0
Oxazepam	10	6
Oxazepam +amitriptyline	2	1
Amitriptyline	4	0
Diazepam	1	0
Usage unknown	2	0

5.3.2 DISCUSSION OF DEMOGRAPHY AND CLINICAL CHARACTERISTICS

A number of very interesting and pertinent findings came to light during examination of the baseline demographic information of this patient group. Participation in this quality of life study was offered to all patients with locally advanced and metastatic breast cancer for the study period and the patient sample is thus considered as representative of the breast cancer patients in the Pretoria area of Gauteng, for the period ranging from 1993 to 1999. The ethnic groups were well balanced in numbers for the black patients but there was a bias for the number of Afrikaans patients (see table 7 and figure 1). The question arose whether there are in fact more Afrikaans females with breast cancer, or whether this was a geographical phenomenon. Data supplied by Statistics South Africa, for the 1996 census, supported the fact that the larger number of Afrikaans patients is due to a higher number of Afrikaans-speaking people living in the Pretoria area, than English-speaking people (75.8% Afrikaans versus 24.2% English).

Seven percent more black patients defaulted from treatment than white patients, which can probably be ascribed to less resources to be able to come for treatment (transport and money), ignorance and the influence of a different philosophical culture to healing. In the black cultures the sangoma (traditional healer) is consulted and the prescribed treatment takes place in the patient's home and family environment, whereas the patient is "isolated" from her family in a hospital environment in white cultures.

Seven percent more black patients than white patients were employed, while 9.6% more white patients were staying at home. This reflects the economical realities of the traditionally disadvantaged black population. The pattern for marriage showed that while 73% of the white patients were married, only 31% of the black patients were married.

In general breast cancer is a disease of older women and this general trend is also found for patients in the Johannesburg area as well as for the total female breast cancer population in South Africa. There are thus more post-menopausal females diagnosed with breast cancer in South Africa. At Pretoria Academic Hospital however, the amount of black pre- and post-menopausal breast cancer patients is identical for our sample (see table 8). This same finding was also made by professor L van Rensburg at the Genetics Department of Pretoria Academic Hospital.

This finding needs to be seen in proportion to the population distribution of South African females. My data was collected between 1993 and 1999 and the population figures, and incidence of breast cancer figures for South African females between 1993 and 1995 were used as comparison (Sitas 1998). When the amount of patients in each age group is expressed as a ratio of the total population a bimodal distribution is found for the black patients with a peak at age group 40 – 44 and again at age group 55 – 59 (see table 27). For the white patients a unimodal peak is found in the 55 – 59 age group. For black patients the ratio of patients in the 40 – 44 group is smaller than the ratio of patients in the 55 –-59 age group. This serves to illustrate that there are in fact not more pre-menopausal black females than post-menopausal females in our group, when corrected for population numbers.

There is however an undeniable peak in the incidence of breast cancer in our black patients in the 40 – 44 age group. Whether this is in fact significant is hard to say and needs further investigation.

It is interesting to note that relative to population numbers, the incidence of breast cancer in our white patients is much higher than in the black patients and this is in accordance with the general findings for South African females (Sitas 1998).

A certain bias has however been introduced in that we lose a lot of black patients in the higher age groups because they tend to wait until they have such dire disease and are in such a poor condition, that they have become untreatable are not seen by us at all.

Eighty percent of the black patients had three or more metastases at first diagnosis, versus 51% of white patients, demonstrating that black patients wait longer to seek medical help than the white patients. White patients with an excellent performance status (PS=0) numbered 39% versus 12% of the blacks. Receptor status, was however almost identical for the black and the white patients. At mastectomy 27% of the white patients and 10% of the black patients were node negative. The node negative patients are much less likely to recur than node positive patients.

Thirty four percent of the white patients were inoperable at first diagnosis versus eighty six percent of the black patients. Patients who had had a mastectomy were 29% black versus 68% white. None of the black patients in this sample had adjuvant chemotherapy. This is particularly worrying in the light of the latest findings about the benefits of adjuvant chemotherapy for breast cancer patients.

Substantially more white, than black patients, 66% versus 26% received medication for depression and/or anxiety. Black patients are culturally inclined to be stoical and do not complain readily. There may also be communication barriers between the predominantly white physicians and black patients.

Hospital classification, which is an indicator of financial status, reflects the current disadvantaged status of black patients. Eighty one percent of blacks versus 22% of whites are in the lowest income group. The educational level of the whites shows that 78% have a grade 12 or higher qualification. Only 31% of black patients fall into this educational category.

It is therefore clear that the black patients are very disadvantaged and a huge educational effort is needed to inform the black women of South Africa about the dangers, signs and symptoms of breast cancer. All females should be educated through the media and at the local health care levels about the advantages of seeking medical attention timeously. A guide to the monthly breast examination is also included in chapter 1 addendum 7. Hopefully the Reconstruction and Development Program will contribute towards ameliorating some of these disadvantages in the black population.

5.4 SUMMARY STATISTICS FOR THE FINAL ANALYSIS

Summary statistics for the total sample (N= 100), the white patients (N=50) and the black patients (N=50) separately are shown in tables 15, 16 and 17.

TABLE 15: SUMMARY STATISTICS OF THE INDIVIDUAL QUALITY OF LIFE DOMAINS AND TOTAL SCORES, BEFORE AND DURING TREATMENT FOR THE TOTAL SAMPLE (N= 100)

VARIABLE		MEAN	STD. DEV.	MINIMUM	MAXI-MUM
BEFORE TREATMENT	Age	49.31	10.20	26	69
	Physical wellbeing	20.46	5.39	7	28
	Social/family wellbeing	21.37	4.51	11	28
	Relationship with doctor	7.59	1.04	3	8
	Emotional wellbeing	14.07	4.50	1	20
	Functional wellbeing	21.04	5.57	4	28
	Additional concerns	23.52	5.93	8	36
	Total FACT-B score	108.05	18.03	58	144
DURING TREATMENT	Physical wellbeing	18.74	5.71	6	28
	Social/family wellbeing	21.77	4.72	6	28
	Relationship with doctor	7.55	1.14	0	8
	Emotional wellbeing	15.78	4.34	4	20
	Functional wellbeing	20.08	5.98	0	28
	Additional concerns	22.90	6.02	7	36
	Total FACT-B score	106.82	18.42	58	145

TABLE 16: SUMMARY STATISTICS OF THE INDIVIDUAL QUALITY OF LIFE DOMAINS AND TOTAL SCORES, BEFORE AND DURING TREATMENT FOR THE WHITE PATIENTS (N= 50)

VARIABLE		MEAN	STD. DEV.	MINIMUM	MAXIMUM
BEFORE TREATMENT	Age	50.74	10.19	27	69
	Physical wellbeing	21.72	5.14	7	28
	Social/family wellbeing	23.54	3.47	13	28
	Relationship with doctor	7.62	1.09	3	8
	Emotional wellbeing	14.78	4.15	1	20
	Functional wellbeing	21.62	5.44	9	28
	Additional concerns	25.02	5.22	12	34
	Total FACT-B score	114.3	16.24	73	138
DURING TREATMENT	Physical wellbeing	19.52	5.94	6	28
	Social/family wellbeing	23.18	4.11	10	28
	Relationship with doctor	7.64	0.92	4	8
	Emotional wellbeing	16.22	4.51	4	20
	Functional wellbeing	20.1	6.16	6	28
	Additional concerns	23.54	5.15	12	36
	Total FACT-B score	110.2	19.62	70	145

TABLE 17: SUMMARY STATISTICS OF THE INDIVIDUAL QUALITY OF LIFE DOMAINS AND TOTAL SCORES, BEFORE AND DURING TREATMENT FOR THE BLACK PATIENTS (N=50)

VARIABLE		MEAN	STD. DEV.	MINIMUM	MAXI-MUM
BEFORE TREATMENT	Age	47.88	10.11	26	67
	Physical wellbeing	19.2	5.40	7	28
	Social/family wellbeing	19.2	4.41	11	28
	Relationship with doctor	7.56	0.99	4	8
	Emotional wellbeing	13.36	4.75	3	20
	Functional wellbeing	20.46	5.69	4	28
	Additional concerns	22.02	6.26	8	36
	Total FACT-B score	101.8	17.71	58	144
DURING TREATMENT	Physical wellbeing	17.96	5.41	7	28
	Social/family wellbeing	20.36	4.91	6	28
	Relationship with doctor	7.46	1.33	0	8
	Emotional wellbeing	15.34	4.15	5	20
	Functional wellbeing	20.06	5.86	0	28
	Additional concerns	22.26	6.76	7	34
	Total FACT-B score	103.44	16.66	58	135

5.5 VALIDATION OF THE FACT-B FOR SOUTH-AFRICAN PATIENTS (TOTAL SAMPLE)

Table 18 lists the means, standard deviations (SD) and Chronbach's alpha coefficients generated for the total group, for each of the FACT-B subscales as well as for the FACT-B total score. High mean scores reflect a better quality of life. An alpha of 0.7 or above is indicative of internal consistency of the items. In table 19 the mean scores and Chronbach's reliability coefficients for our sample is compared to the values found by Brady (1997) for American patients.

TABLE 18: FACT-B DESCRIPTIVE STATISTICS: RELIABILITY/ CONCURRENT VALIDITY FOR THE TOTAL SAMPLE (N=100)

Scale	Mean	SD	Alpha
PWB (7-item) before Rx	20.46	5.4	0.7496
SWB (7-item) before Rx	21.37	4.5	0.4698
RWD (2-item) before Rx	7.59	1.0	0.8596
EWB (5-item) before Rx	14.07	4.49	0.6997
FWB (7-item) before Rx	21.04	5.6	0.7530
AWB (9-item) before Rx	23.52	5.9	0.5020
TOTAL (37-item) before Rx	108.05	18.0	0.6950
PWB (7 item) during Rx	18.74	5.7	0.7813
SWB (7 item) during Rx	21.77	4.7	0.5698
RWD (2 item) during Rx	7.55	1.1	0.6232
EWB (5 item) during Rx	15.78	4.3	0.7650
FWB (7 item) during Rx	20.08	5.9	0.8126
AWB (8 item) during Rx	22.90	6.0	0.4927
TOTAL (37 item) during Rx	106.82	18.4	

KEY:

PWB	physical well being
RWD	relationship with doctor
SWB	social well being
EWB	emotional well being
FWB	functional well being
AWB	additional concerns

TABEL 19: COMPARISON OF THE SOUTH-AFRICAN VALIDATED FACT (DURING TREATMENT) WITH THE AMERICAN VALIDATION (BRADY 1997)

Scale	For USA patients		For RSA patients	
	Mean (SD)	**Alpha**	**Mean (SD)**	**Alpha**
Physical Well Being	22.1 (5.3)	0.81	18.7 (5.7)	0.78
Social Well Being	22.7 (5.2)	0.69	21.8 (4.7)	0.57
Relationship With Doctor	7.0 (1.6)	0.78	7.6 (1.1)	0.62
Emotional Well Being	16.3 (3.5)	0.69	12.3 (3.9)	0.77
Functional Well Being	20.6 (6.4)	0.86	16.6 (5.6)	0.81
Additional Well Being	24.1 (6.5)	0.63	21.1 (6.0)	0.49
TOTAL FACT-B	112.8 (20.9)	0.90	98.1 (18.1)	0.70

5.6 COMPARISON OF RACE GROUPS WITH RESPECT TO THE SIX DOMAINS OF THE FACT-B

Hotelling's T-square was employed to assess whether race groups differed with respect to the observation vector (total baseline scores for: physical-, social-, relationship with doctor, emotional-, functional well being and additional concerns) and in the absence of covariates, races were found not to differ.

The difference between the quality of life for each domain during treatment and at baseline is given in table 20 for white patients and table 21 for black patients.

TABLE 20: THE DIFFERENCE BETWEEN QOL SCORES FOR EACH DOMAIN DURING TREATMENT AND AT BASELINE FOR WHITE PATIENTS

VARIABLE	MEAN	STD. DEV.	MINIMUM	MAXIMUM
Physical wellbeing	- 2.20	6.27	-20	10
Social/family wellbeing	- 0.36	3.87	-8	8
Relationship with dr.	0.02	1.10	-4	3
Emotional wellbeing	1.44	5.44	-12	16
Functional wellbeing	-1.52	5.74	-19	8
Additional concerns	-1.48	4.99	-14	10

TABLE 21: THE DIFFERENCE BETWEEN QOL SCORES FOR EACH DOMAIN DURING TREATMENT AND AT BASELINE FOR BLACK PATIENTS

VARIABLE	MEAN	STD. DEV.	MINIMUM	MAXIMUM
Physical wellbeing	-1.24	6.62	-19	13
Social/family wellbeing	1.16	5.91	-19	14
Relationship with dr.	-0.1	1.68	-8	4
Emotional wellbeing	1.98	5.33	-9	16
Functional wellbeing	-0.4	7.01	-21	15
Additional concerns	0.24	5.90	-12	15

2-group Hotelling's T-squared = 5.8979035

F test statistic: ((100-6-1) / (100-2) (6)) x 5.8979035 = 0.93283167

HO: Vectors of means are equal for the two groups

F (6,93) = 0.9328

Pr > F (6,93) = 0.4754

5.7 REGRESSION ANALYSIS TO COMPARE RACES

Comparison of races with respect to:

1. Total baseline scores for: physical-, social-, relationship with doctor, emotional-, and functional well being, additional concerns and total score, initially without a covariate (model has a poor R-square).

2. Then with baseline total scores as cofactor (R-square improved markedly).

3. And then finally by adjusting for age and time between the "before" and "during" FACT-B (covariates). Performance status, stage, education, marital status and concomitant disease were included in the multivariate analysis as risk factors (R-square improved slightly). It was suspected that race and education would be confounded, but by omitting education, the results were not improved and it was therefore retained.

In this section "higher" and "lower" will refer to the sign of the effect and the correct interpretation will again depend on the formulation in the constructs. For all data a 95% confidence interval applies.

The complete regression analysis for physical well being is set out in table 22. Table 23 is a summary of all the statistically significant findings for the regression analyses for each quality of life domain and also for the total FACT-B score.

TABLE 22: THE REGRESSION ANALYSIS FOR PHYSICAL WELL BEING

Physical Well-being	**Coefficient**	**Standard Error**	**P >| t |**
1. Races compared by the change in Physical Well Being (PWB) score during treatment and at baseline:			
Black vs. white	0.96	1.29	0.458
2. Races compared by the change in PWB score during treatment and at baseline, with baseline PWB score added in as cofactor:			
Physical Well-being	-0.67	0.104	0.000
Black vs. white	-0.72	1.118	0.521
3. Races compared by the change in PWB score during treatment and at baseline & with cofactors age and treatment time. Values adjusted for performance status, stage, education, marital status and concomitant disease.			
Physical Well-being	-0.7	0.106	0.000
Age	-0.02	0.056	0.748
Treatment time*	-0.04	0.09	0.65
Black vs. white	-1.43	1.26	0.261
PS=1 vs. PS=0	2.90	1.42	0.048
PS=2 vs. PS=0	-0.83	2.24	0.416
Stage 4 vs. stage 3	0.02	1.29	0.990
Well educated vs. poor education	0.73	1.22	0.552
Divorced/widowed vs. married/single	-0.81	1.48	0.589
Concomitant disease vs. none	-1.62	1.26	0.201

Positive findings are highlighted (where P≤ 0.07).

* Treatment time = the time difference in weeks between the baseline QOL evaluation and the "during" treatment QOL evaluation.

TABLE 23: REGRESSION ANALYSIS SHOWING POSITIVE FINDINGS FOR RISK FACTORS WITH REGARD TO THE CHANGE WITHIN DOMAINS FROM BASELINE TO DURING TREATMENT, WHEN COFACTORS ARE INCLUDED.

Domain Cofactor	**Coefficient**	**Standard Error**	**P >| t |**
Physical well being PS=1 vs. PS=0	2.87	1.43	0.048
Social well being Black vs. white	-1.84	1.08	0.094 tendency
Social well being PS=2 vs. PS=0	4.16	1.77	0.021
Relationship with dr. Stage 4 vs. stage 3	0.59	0.27	0.034
Emotional well being Treatment time	-0.15	0.07	0.036
Emotional well being PS=2 vs. PS=0	3.53	1.71	0.042
Emotional well being Marital status	-1.89	1.13	0.099 tendency
Functional well being Better educated vs. not	2.39	1.27	0.062 tendency
Total FACT-B score PS=1 vs. PS=0	8.2	4.28	0.058

1. There is a significant (p = 0.048) increase of 2.87 in the change of physical well being from performance status PS = 0 to PS = 1.
2. There is a significant (p = 0.015) decrease of 4.7 in the change of physical well being from performance status PS = 1 to PS = 2.
3. There is a tendency toward a significant (0.094) decrease of 1.84 in the change of social well being from white to black.
4. There is a significant (p = 0.021) increase of 4.16 in the change of social well being from performance status PS = 0 to PS = 2.
5. There is a significant (p = 0.034) increase of 0.59 in the change of relationship with doctor from stage 3 to stage 4 disease.
6. There is a significant (p = 0.042) increase of 3.53 in the change of emotional well being from performance status PS = 0 to PS = 2.
7. There is a tendency towards a significant (p = 0.099) decrease of 1.89 in the change of emotional well being from being married or single to being divorced or widowed.
8. There is a tendency toward a significant (p = 0.062) increase of 2.39 in the change of functional well being from being less educated to being better educated.
9. There is a significant (p = 0.058) increase of 8.2 in the change of the total FACT-B score from performance status (PS) = 0 to PS = 1.

5.8 ANALYSIS OF SURVIVAL

The log-rank test for the difference in the survival of the white versus the black patients is shown in tables 24 and 25. The median survival for the total group was 67 weeks, with a range of 9 to 325 weeks (see table 26). A Kaplan-Meier curve by race is shown in figure 5.

TABLE 24: COMPARISON OF SURVIVAL FOR WHITE AND BLACK PATIENTS

Race	Time at risk	Incidence rate	N	Survival time (weeks)		
				25%	50%	75%
White	6204	0.0058027	50	51	141	235
Black	4543	0.0070438	50	48	86	180
TOTAL	10747	0.0063273	100	50	96	333

TABLE 25: LOG-RANK TEST FOR EQUALITY OF SURVIVOR FUNCTIONS

Race	Events observed	Expected
White	36	39.90
Black	32	28.10
TOTAL	68	68.00

$\text{Chi}^2(1) = 0.98$
$\text{Pr} > \text{Chi}^2 = 0.3216$

TABLE 26: MEDIAN SURVIVAL OF THE PATIENT GROUP BY RACE

GROUP	MEDIAN SURVIVAL (WEEKS)
White patients (N=36)	87 (09 – 325)
Black patients (N=32)	57 (18 – 180)
TOTAL (N=68)	67 (09 – 325)

TABLE 27: THE INCIDENCE OF BREAST CANCER IN OUR PATIENTS EXPRESSED AS A RATIO OF THE TOTAL POPULATION

AGE GROUP	BLACK PATIENTS	WHITE PATIENTS
30 – 34	0.0043	0.0098
35 – 39	0.0043	0.0156
40 – 44	0.0190	0.0380
45 – 49	0.0050	0.0360
50 – 54	0.0130	0.0570
55 – 59	0.0244	0.1140
60 – 64	0.0125	0.0670
65 – 69	0.0090	0.0220

Peak incidences are highlighted.

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FIGURE 1: PERCENTAGE OF PATIENTS IN EACH ETHNIC GROUP

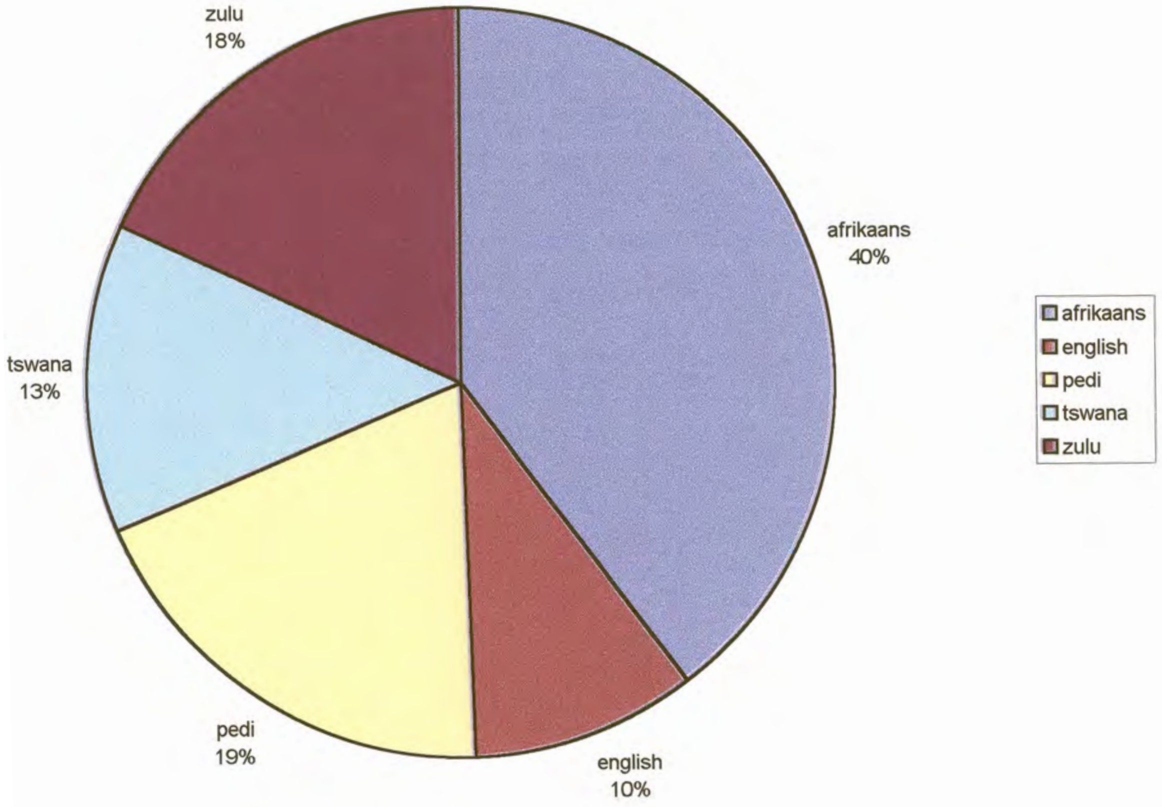


FIGURE 2: MENOPAUSAL STATUS BY RACE

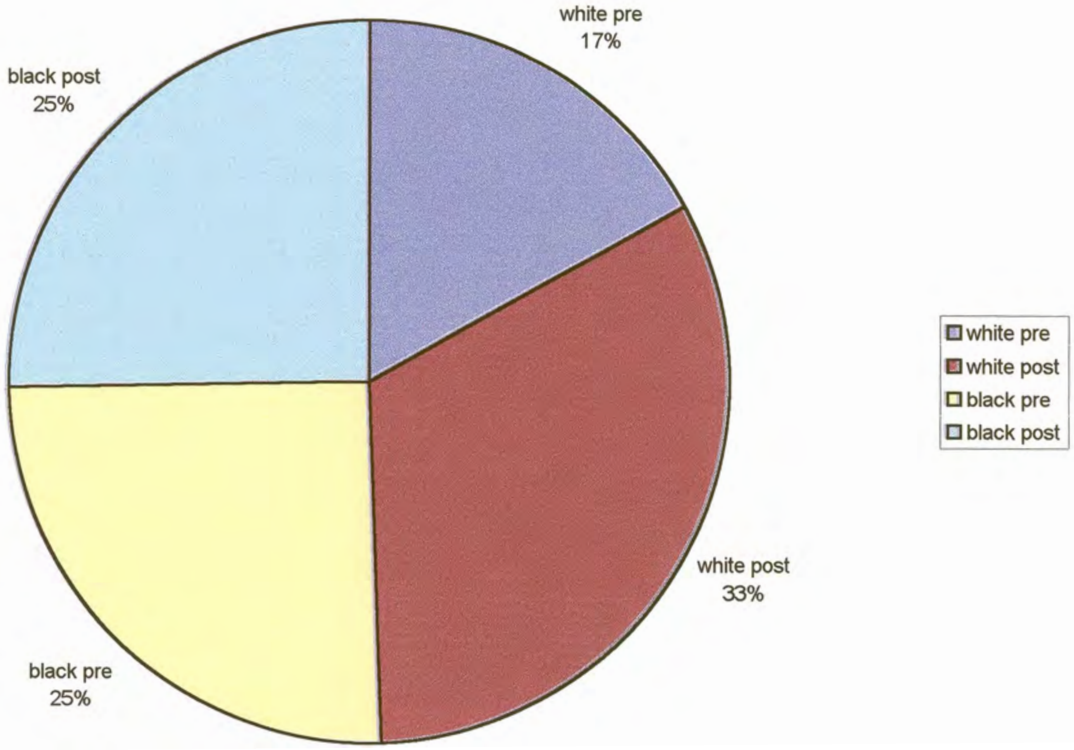


FIGURE 3: AGE DISTRIBUTION OF BLACK AND WHITE PATIENTS

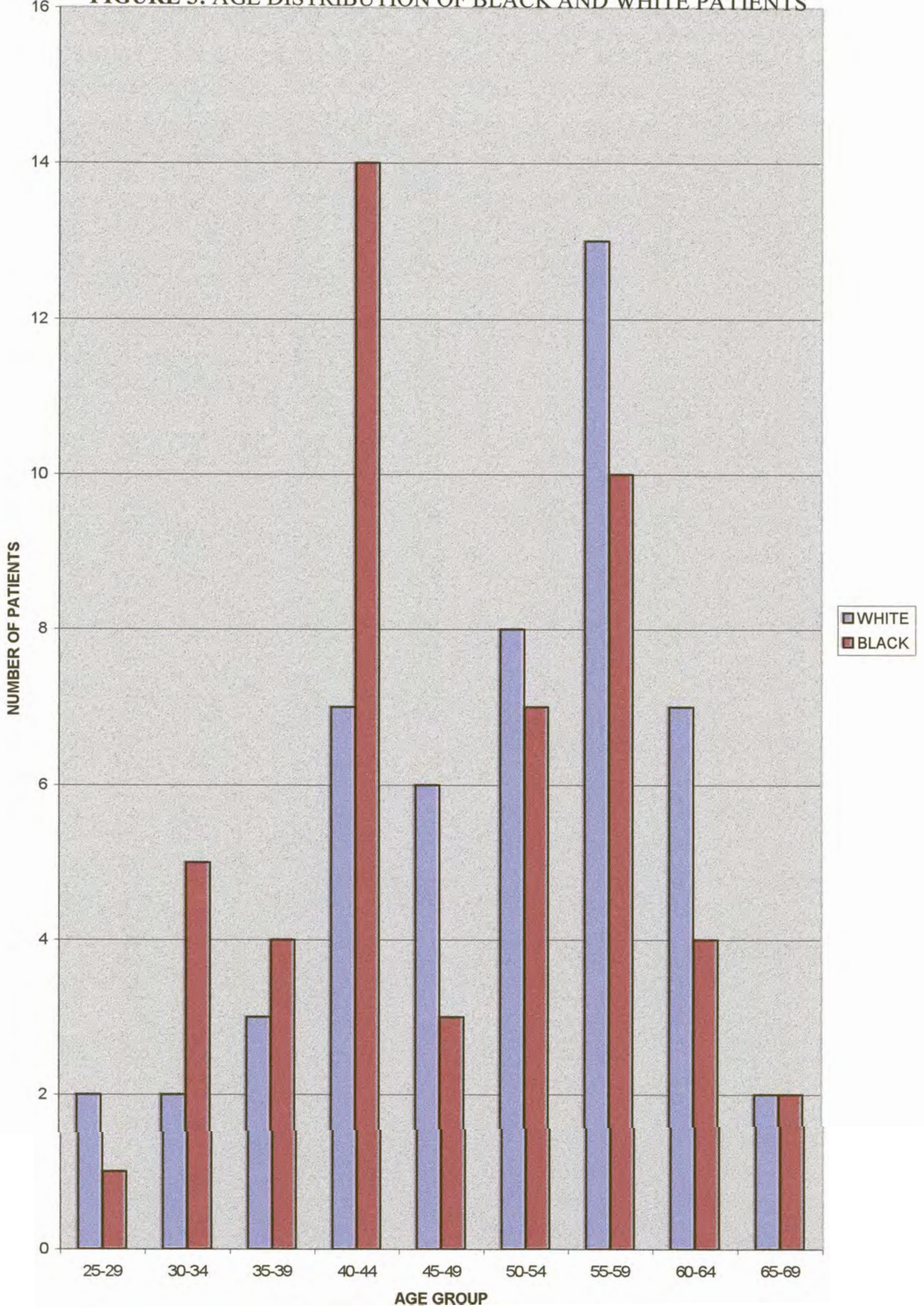


FIGURE 4: CHEMOTHERAPY REGIMEN ADMINISTERED

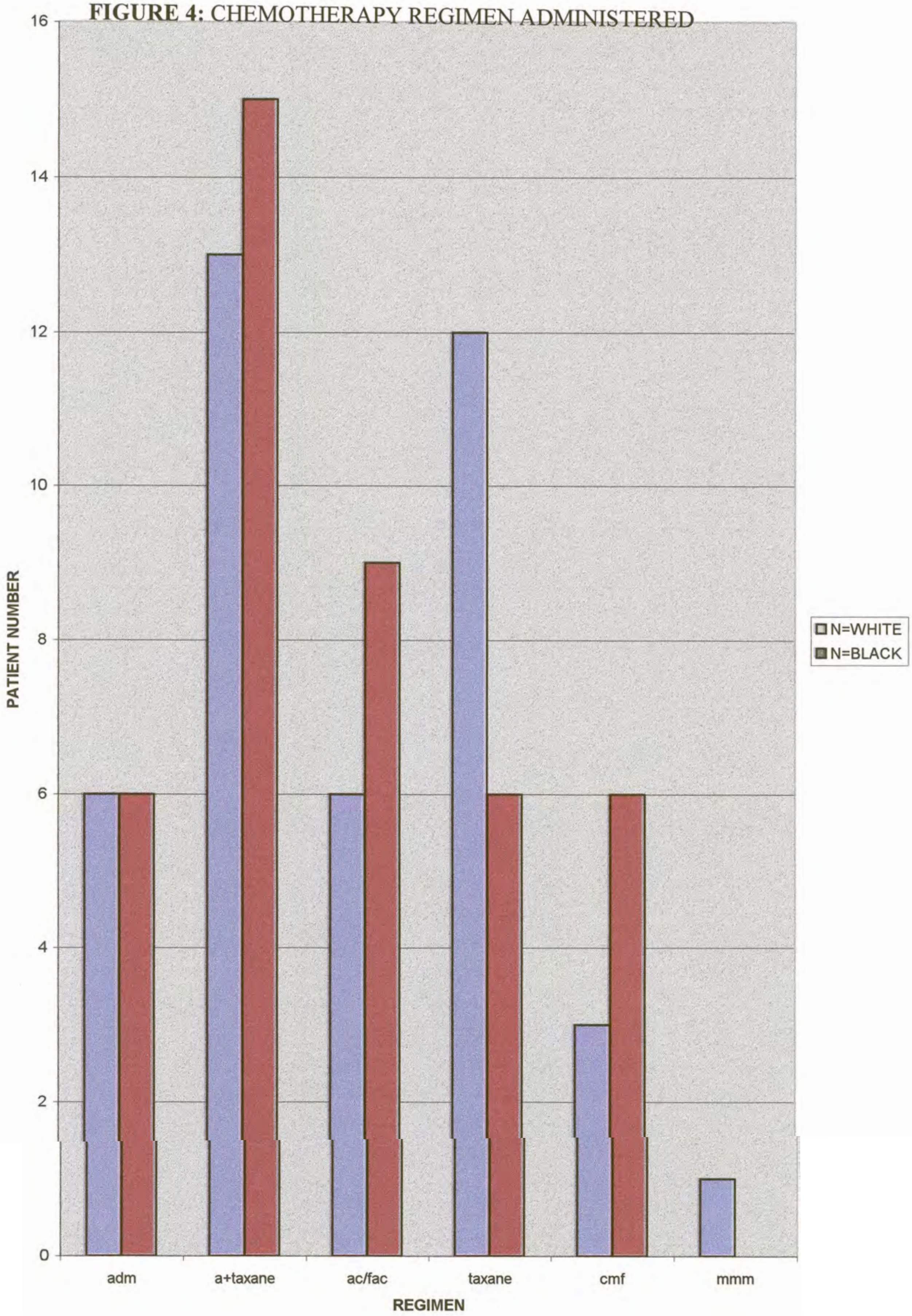
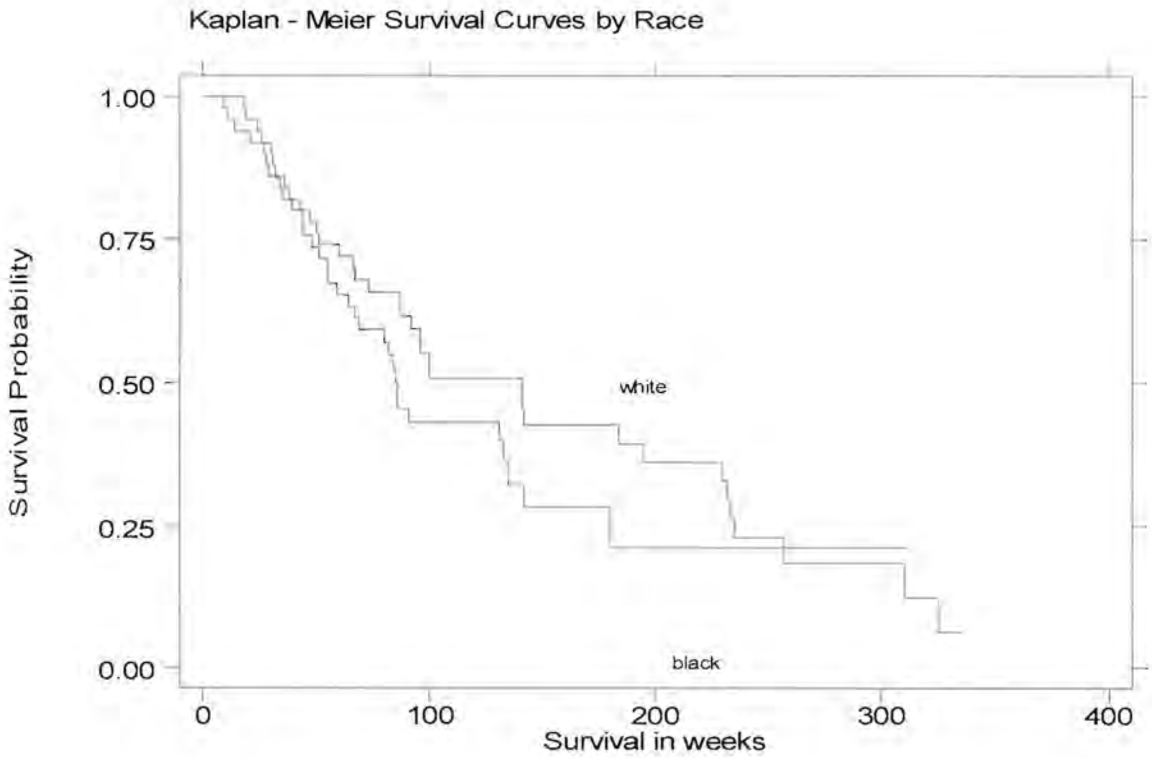


FIGURE 5: KAPLAN-MEIER SURVIVAL CURVES BY RACE



CHAPTER 6: CONCLUSION

The aim of the study was to investigate the quality of life of South African breast cancer patients and to determine the factors that influence quality of life, to determine the impact of treatment on quality of life and to ascertain whether ethnicity has any influence in this context. The findings of this investigation should ultimately be used to establish the utility of quality of life studies and be implemented to improve patient care. All tables referred to in this chapter are to be found in chapter 5.

6.1 VALIDATION OF QUESTIONNAIRES

6.1.1 PEDI TRANSLATIONS

As can be seen from table 1, the reliability of the scale as demonstrated by the Chronbach alpha coefficients is acceptable, ranging from 0.71 to 0.86. The social/family well being scale has a poor alpha of 0.54. None of the items of this scale had negative correlations, but the following items had a very low correlation:

10. I get emotional support from my family.
12. My family has accepted my illness.
13. Family communication about my illness is poor.

For item 13, the word "kgokagano" is used as the translation for "communication". It has been suggested by Pedi-speaking staff memebers that "poledisano" might be a better word to use, because it is closer to the term "communication".

The social/family well being scale was the scale where the most "missing" values had been found after patients had completed the FACT-B. However, a sufficient number of questions had been answered for this subscale and for the total questionnaire to still be acceptable for analysis according to Cella (1994). In view of the poor reliability coefficient for this scale any results involving the social/family well being scale must be ignored or interpreted with great caution.

6.1.2 TSWANA TRANSLATIONS

Reliability coefficients for the individual domains, as seen in table 1, are all 0.84 or above, except the social/family well being alpha, which is again problematic. Any results concerning this domain should be ignored or cautiously interpreted. The additional concerns alpha is borderline 0.69, but still acceptable. Four of the questions of the social/family well being construct were found to have a negative correlation, namely question number:

10. I get emotional support from my family.
11. I get support from my friends and neighbors.
12. My family has accepted my illness and
13. Family communication about my illness is poor.

6.1.3 ZULU

For the Zulu translations, three of the domains have low reliability coefficients (see table 1). The domains are social/family well being, relationship with doctor and additional concerns. Any results for the social/family well being scale should be interpreted with caution or discarded altogether. Items with negative or low reliability coefficients were:

9. I feel distant from my friends.
13. Family communication about my illness is poor.
35. I have been short of breath.
36. My arms are swollen or tender.
37. I feel sexually attractive.
43. I am able to feel like a woman.

For item 13, Zulu-speaking staff suggested that the word “awuxoxi” is a better translation for the term “communication”, than “awu**sa**xoxi”. The staff also says that the Zulu translation for item 38 (“I feel sexually attractive”) is extremely non-specific.

6.1.4 AFRIKAANS

The Afrikaans validations seen in table 2, are all 0.7 or above, when rounded off to one decimal point, except for the relationship with the doctor. Relationship with the doctor shows an alpha of 0.58, which when rounded off to one decimal point, is still acceptable according to Nunally 1978 page 245. The Afrikaans translation is thus completely acceptable.

6.1.5 DISCUSSION

The social/family well being scale is the only quality of life construct, which was unacceptable for all the black language translations. It had the lowest reliability of any subscale for all the languages excepting Afrikaans. It was also the subscale where the most missing items were found after patients had completed their questionnaires, indicating that some of the questions were being misinterpreted or patients felt uncomfortable about answering them. It is important to note that attitudes towards sex and sexuality are much more conservative in South Africa than in the USA and Europe. A lot of patients had difficulty in answering these items. In the black patient group, the questions about sexuality became even more problematic. When a black patient was given the FACT-B as an interview, the patient first had to be asked: "I am about to ask you a question of a very personal nature, may I proceed?" This is mandatory in the South African black cultures.

Another reason for the poor reliability of the social/family well being scale is item 13 ("family communication about my illness is poor"). It has a low correlation in Pedi and Zulu and a negative correlation in Tswana. One explanation for the inconsistency with scoring is that in these cultures, some families do not talk about the illness with the patient once the diagnosis is made. Mtalane (1993) found that although the patients that he had studied informed their families of their diagnosis and prognosis, there was no further discussion of the issue between patient and family. The dying patient was given false reassurance, because family members saw any open discussion or acceptance on their part as hastening death.

Some black patients do not want to discuss their condition with family members at all. Some black men will only discuss their condition with other men. Whereas other black men may discuss an illness with their wives but not with their children.

In the black culture groups saying "my family talks very little about my illness" is possibly not an indication of a poor quality of life, but rather the opposite. Family support to the patient is extremely important, but is limited in some cases, due to the distance and traveling expense for the patient to reach the treatment site. Some black patients even go and stay with distant family members or friends, just to be near to the treatment center.

The social/family well being domain is demonstrative of cultural differences found in the black patient population. Several of the questions in this section are subject to interpretation from the viewpoint of the traditional cultures of the patients. "Family" may not mean the same in a small rural Zulu village as to Western society. Black people sometimes define "family" in a much broader sense to include close friends or neighbors.

Another explanation for the poor reliability of the social/family well being scale is educational status. When the educational level is broken down further than what was done for the multiple regression analysis, it becomes clear that the educational level of the black patients is considerably lower than that of the white patients (see table 13). Forty eight percent of the black patients had an education and reading ability of lower than grade eight, while this did not apply to white patients at all. It is therefore perhaps no coincidence that the entire Afrikaans scale is acceptable and that all of these patients had enough scholastic ability to grasp the concepts that were being tested.

Personality may also play a role in that patients consent to the FACT-B study because they are afraid that their care may be compromised if they don't partake. This is in spite of the fact that it is clearly stated in the informed consent that refusal to take part will not compromise patient care in any way. These patients actually don't want to talk about anything and give unreliable answers. Some patients may have tried so many different remedies that they consider any intervention as useless. They feel that nothing helps them and that their prognosis is so poor and therefore give unreliable answers to the FACT-B interview.

The relationship with the doctor has low reliability coefficients for the Zulu translation. A possible explanation is that doctors tend to have a direct approach. Zulu people don't like to make eye contact they consider it as rude, especially when they are older than the doctor and this may compromise the reliability of this scale.

Overall, the results are encouraging. Although the FACT-B was initially developed in the United States with first world patients in mind, the quality of life dimensions were found to be reliable overall. The discrepancies that occur serve to elucidate the cultural and educational differences of the black patients.

6.1.6 VALIDATIONS FOR THE TOTAL GROUP

The total group validations (see table 18) will not be discussed in detail, because the separate validations for the Pedi, Tswana, Zulu and Afrikaans translations are discussed thoroughly at the beginning of the chapter. Chronbach's alphas for the total group again showed the low reliability of the social/family well being domain. A low reliability for the additional concerns scale was also found. This again confirms that any findings with these two scales should be discarded and that these scales need refinement for South African patient population use. All the other constructs demonstrated sufficient reliability.

6.2 THE INFLUENCE OF TREATMENT ON THE QUALITY OF LIFE OF BREAST CANCER PATIENTS

When comparing the mean scores for each domain and the mean FACT-B score during treatment for our total patient group with mean scores of American patients (see table 19 chapter 5), all the values are similar. The quality of life during chemotherapy, of our group of South African breast cancer patients therefore does not differ significantly from that of American breast cancer patients.

The mean age for the black (47.88 years) and white (50.74 years) South African patients was similar (see tables 16 and 17). The ages of the youngest black (26) and white (27) and oldest black (67) and white (69) patients were well balanced.

Although the pilot project demonstrated an impact of chemotherapy and hormonal therapy on quality of life, these findings can safely be ignored, because it had been found that the statistical analysis for the pilot project had been inadequate.

Despite the clinical benefit that may be associated with reduction of tumor volume, chemotherapy may produce physical or psychological distress that could compromise a patient's quality of life. Conversely, chemotherapy may palliate symptoms produced directly by the tumor, such as pain, dyspnea, or cough, or lessen psychological distress by reducing hopelessness. These effects may improve quality of life, providing benefits that are not reflected by the traditional outcomes assessed in cancer clinical trials, including tumor response, toxic effects and performance status (Seidman 1995).

The mean scores found for each of the quality of life domains "before" and "during" treatment, as well as the total FACT-B score, do not differ for the "before" and "during" treatment time periods (see table 15). Therefore the first major finding of this study is that the quality of life of this patient group was not adversely affected by the administration of chemotherapy. At the same time the quality of life of the patients was also not significantly improved by the administration of chemotherapy.

6.3 THE EFFECT OF RACE DIFFERENCES ON THE QUALITY OF LIFE OF THE PATIENTS

Already before treatment the quality of life of the black patients is worse than that of the white patients, for the following domains: Physical-, social /and family- and emotional well being, as well as for the total FACT-B score. The statistical analysis of the pilot project however, did not control for the factors that might influence quality of life and it was decided to investigate the influence of these factors, i.e. baseline quality of life, effect of treatment, ethnicity, age, educational level, living arrangement, marital status, the presence of co-morbid disease, performance status and disease stage.

A large group of patients (100) receiving chemotherapy had completed both baseline and during chemotherapy questionnaires. This group was selected for the final analysis. Patients receiving front-line, second-line and third-line chemotherapy were included in the analysis, recognizing that patients on second- or third-line chemotherapy have more advanced disease.

The second major finding is that race differences had no significant effect of the quality of life of this group of patients.

6.3.1 HOTELLING'S T-SQUARE

Hotelling's T-square (see tables 20 and 21) was employed to assess whether race groups differed with respect to the observation vector (the changes in: physical well being, social well being, relationship with doctor, emotional well being, functional well being and additional concerns). Vectors of means were not significantly different (p= 0.4754). Note that the sign of the mean values for the construct needs to be interpreted according to the formulation of the questions of the individual constructs. For example all the questions for the construct physical well being are negative (as in: I have pain). Physical well being for white patients therefore had improved during treatment, because the negative sign correlates with how bad it was going with the patient. The mean of –2.2 therefore showed an improvement in physical well being during treatment.

In the absence of covariates, races were found not to differ.

6.3.2 MULTIPLE REGRESSIONS TO COMPARE RACES

We analyzed how the dependent variables were affected by multiple independent variable by the "least squares" method to fit a line through a set of observations. The dependent variables were the individual domains and total score of the FACT-B. The baseline scores of the domains, age of the patients and treatment time were used as cofactors to adjust the relationship between the dependent and independent variables. Risk factors included in the adjustment were: race, performance status, disease stage, educational status, marital status and the presence or absence of concomitant disease (see tables 22 and 23).

All baseline FACT-scores were found to be significant co-factors. Performance status was found to be a significant risk factor. Performance status influenced the following dependent variables: physical well being, social well being, emotional well being and the overall quality of life of patients (total FACT-B score).

There was a tendency toward significance for the influence of race on the social well being of the patients. In view of the poor reliability coefficients for Chronbach's alphas that were found for the Zulu, Pedi and Tswana translations, this finding cannot be stated as an absolute.

6.3.3 SURVIVAL

The log-rank test for survival showed that there was no statistically significant difference in the survival of the white versus the black patients (see tables 24 and 25). The median survival for the total group was 67 weeks, with a range of 9 to 325 weeks (see table 26). A Kaplan-Meier curve by race confirmed that there was no significant difference in the survival curves by race (see figure 5).

6.4 FACTORS THAT INFLUENCE QUALITY OF LIFE

The third major finding was that there were certain factors that influenced the quality of life of the patients.

The factors that were found to be significant predictors of change in quality of life scores were performance status, disease stage and baseline quality of life. Factors that approached significance were race, marital status and educational status. In the analysis of the pilot project race had been found to be statistically significant, but after correcting for the factors that influence quality of life in the regression analysis, it only approaches significance. The distinction in educational status was drawn at grade 12 and higher versus less than grade 12. A finer distinction could probably have been made (see table 13). Table 13 demonstrates that 48 % of the black patients have attained less than a grade 8 education, whereas none of the white patients fall into this category.

Patients with stage four disease had a stronger relationship with the doctor than patients with stage three disease. Stage was thus found to have a significant influence on the quality of life of the patients and specifically in their relationship with the doctor.

There was a tendency towards a significant influence of marital status on the emotional well being of patients. Married or single patients, who are considered to be unstressed in comparison to the divorced and widowed group, had a better emotional well being than the latter group.

There was a tendency towards significance of educational status in that the better-educated group experienced a better functional well being than the less educated group.

The factors that influenced quality of life in this study, were all baseline characteristics of the patients and were not ameliorable to intervention.

6.5 CLOSING REMARKS

The three major findings of the study are:

1. The administration of chemotherapy did not cause an improvement or deterioration in the quality of life of this group of patients.
2. There were no significant differences between the black and the white patients with respect to their quality of life or survival data.
3. Factors that had a significant influence on the quality of life of the patients were performance status, disease stage and the baseline quality of life score.

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