Breast Cancer Res Treat (2013) 139:115–123
DOI 10.1007/s10549-013-2508-z

CLINICAL TRIAL

The impact of breast cosmetic and functional outcomes on quality of life: long-term results from the St. George and Wollongong randomized breast boost trial

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Received: 15 January 2013 / Accepted: 27 March 2013 / Published online: 12 April 2013

Abstract The aims of this study were to evaluate the impact of cosmetic and functional outcomes after breast-conserving surgery (BCS) and radiation on quality of life (QOL). In this exploratory analysis; baseline, 5 and 10 years data of patient's assessment of breast cosmesis, arm swelling/pain, limitation of movement, loss of feeling in fingers and breast sensitivity/tenderness were dichotomized and their impact on QOL (QLQ-C30) were assessed. Multivariable modelling was also performed to assess associations with QOL. The St. George and Wollongong randomized trial randomized 688 patients into the boost and no boost arms. 609, 580, and 428 patients had baseline, 5 and 10 years cosmetic data available, respectively. Similar numbers had the various functional assessments in the corresponding period. By univariate analysis, cosmesis and a number of functional outcomes were highly associated with QOL. Adjusted multivariate modelling showed that cosmesis remained associated with QOL at 5 and

Annual scientific meeting in Cairns, Australia as poster presentation in July 2012.

Electronic supplementary material The online version of this article (doi:10.1007/s10549-013-2508-z) contains supplementary material, which is available to authorized users.

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10 years. Breast sensitivity, arm pain, breast separation, age and any distant cancer event were also associated with QOL on multivariate modelling at 10 years. This study highlights the importance of maintaining favorable cosmetic and functional outcomes following BCS. In addition, the clinically and statistically significant relationship between functional outcomes and QOL shows the importance for clinicians and allied health professionals in identifying, discussing, managing, and limiting these effects in women with breast cancer in order to maintain QOL.

Keywords Breast cancer · Cosmesis · Functional outcome · Quality of life

Introduction

The cosmetic and functional outcome after breast-conserving surgery (BCS) is an important consideration in selecting the optimal surgical procedure for a particular patient. BCS, followed by the radiation therapy, is generally thought to be the least disfiguring surgical option but the outcomes vary widely and up to 30 % of cases may result in significant breast deformity [1] following the combined treatment. Although a large body of work has been published regarding the differences in quality of life (QOL) between mastectomy and BCS [2–7], relatively little is known regarding the effect of cosmetic outcomes for breast conservation and radiation treatment on postoperative QOL with long-term follow-up.

In addition, a recent review has found that although functional impairment was amongst the most common adverse effects in patients receiving BCS and radiation therapy, most studies focused on the relationship between lymphoedema and QOL rather than other issues such as limitation of movement and arm pain [8]. Such information is necessary for both the patients and the clinicians to make an informed decision regarding the appropriate surgical procedure and pre- and post-treatment counselling [9].

The St. George and Wollongong trial (SGW) is a multicentre, prospective randomized study designed to test if local control was improved by adding a boost to tangential whole breast radiotherapy without compromising cosmesis [10, 11]. The primary outcome of the study was local recurrence but the study also collected extensive cosmetic, functional, and quality of life data from participants longitudinally and was an ideal platform for exploring the relationship between these factors. The aim of this exploratory analysis is to assess the hypothesis that patient scored cosmetic and local functional outcomes were associated with their quality of life.

Patients and methods

Study population

The SGW trial has been previously described [12]. Ethics approval was obtained for the study and the trial was registered with www.clinicaltrials.gov (NCT00138814). In brief, from September 1996 the trial recruited patients >18 years of age with histologically proven Tis-2, N 0-1, M0 carcinoma of the breast. After informed consent, patients were randomized between the control arm of 50 Gy in 25 fractions to the whole breast and the boost arm of 45 Gy in 25 fractions to the whole breast followed by a 16 Gy in eight fraction electron boost. Patient questionnaires regarding cosmetic, functionality, and QOL were collected at baseline (post surgery, prior to radiotherapy), completion of radiotherapy, 6 weeks post-radiotherapy and then yearly until 10 years. Patients who attended follow up clinic were given the questionnaires to complete while those who were unable to attend had it posted to them. For the purpose of this cross-sectional study; baseline, 5 and 10 years data were analyzed. The longitudinal analysis of quality of life and functional outcomes over time will be reported separately.

Dependent variables

The QOL of the women was assessed using the EORTC QLQ C-30 (version 2.0). The score for global quality of life was linearly transformed to a score from 0 (worst) to 100 (best) according to EORTC scoring procedures with resulting scores being roughly symmetrical [13].

Independent variables

Functional assessments were performed by asking the patient to score the degree of arm swelling, arm pain, limitation of arm movement, loss of feeling in fingers. These were dichotomized into “none/a little” or “moderate/severe”. Patient assessment of breast sensitivity was dichotomised as “excellent/good/normal” or “fair/poor”. Patient assessment of breast tenderness was dichotomised as “none/minimal/moderate” or “marked/severe”.

For the cosmetic assessment, the patient was asked to compare the treated with the untreated breast and score the overall result. Results were dichotomised into “normal/excellent/good” versus “fair/poor”. Tumour recurrences were classified as loco-regional if the recurrence was in the ipsilateral breast or in the axillary, internal mammary, and supraclavicular lymph nodes. Distant recurrences included all cancer events that were not loco-regional (contralateral breast cancer, distant breast cancer metastases, or new primary cancers).

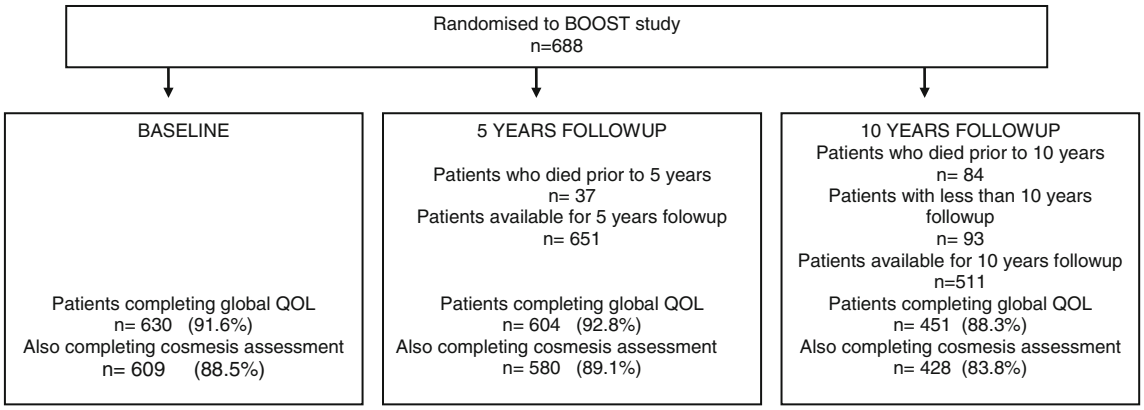

Fig. 1 Patients completing the global QOL and cosmetic assessments at baseline, 5 and 10 years

Statistics

The association of patients' functional and cosmetic assessments with global quality of life scores was analysed using *t* test or linear regression. For this study, cross-sectional analyses at timepoints of baseline and long-term outcomes at 5 and 10 years were considered. Other variables collected at baseline considered a priori as potentially associated with quality of life were treatment by boost, age (continuous), chemotherapy planned, hormonal treatment planned, tumour size (cutpoint 20 mm), breast separation (distance from medial to lateral limit of breast and chest wall encompassed in the tangential radiotherapy fields, cutpoint 25 cm), loco-regional, and distant cancer recurrences. Multivariable models were considered and assessed using backwards stepwise estimation commencing with variables where the p value was <0.25.

Due to the nature of clinical trials, incomplete response from some patients inevitably occurs. However, in order to account for missing data which may bias our results, three additional analyses were undertaken: (1) comparison of the baseline characteristics of the respondents versus non-respondents at 5 and 10 years with the p value set at 0.0008 due to the multiplicity of testing using the Bonferroni [14] method (2) sensitivity analysis under two "worse case" (WC) scenarios. WC1 where all non-responders imputed as "fair/poor" cosmesis with a QOL score equal to the mean of the "excellent/good" respondents and WC2 where all non-responders imputed as "excellent/good" cosmesis with a QOL score equal to the mean of "fair/poor" responders (3) Assessment of association between cancer recurrence and patient non completion of questionnaires. Data were analysed using STATA SE v11.

Results

A total of 688 patients were enrolled in the SGW study. Patients completing the QOL assessment at baseline, 5 and 10 years were 630, 604, and 451, respectively. With respect to patients with sufficient follow-up and remaining alive this represents 91.6, 92.8, and 88.3 %, respectively. Patients completing both QOL assessment and cosmesis assessment as above were 609 (88.5 %), 580 (89.1 %), and 428 (83.8 %), respectively (Fig. 1).

Patient baseline and treatment characteristics are shown in Table 1. Characteristics were similar in the populations at baseline, 5 and 10 years and after accounting for the multiplicity of testing, the comparison of the responders versus the non-responders with regard to the baseline characteristics revealed no difference both at 5 and 10 years suggesting there were no biases due to differential losses to follow up (data not shown).

Baseline

At baseline the mean global QOL was 71.2 and 89 % reported excellent/good/normal cosmesis. Patients who reported "excellent/good/normal" breast cosmetic scores had a higher QOL compared to those who reported a "fair/poor" cosmesis (72.4 vs 61.4, $p < 0.001$). Patients who reported "fair/poor" breast sensitivity or "marked/severe" breast tenderness also had worse QOL by 10.2 and 13.4, respectively, (both p values <0.001) compared to those with "excellent/good/normal" or "none/minimal/moderate" Patients who reported "none/a little" arm swelling, arm pain, and limitation of movement also had significantly better QOL compared to those who reported "moderate/severe" in the above symptoms (Table 2).

Multivariable modelling at baseline showed that breast sensitivity, arm pain, and limitation of movement were associated with QOL with linear coefficient estimates of 6.3, 9.0, and 9.9, respectively (all p values <0.001). These estimates reflect the mean decrease in QOL for patients with poorer symptoms compared with those with better symptoms following adjustment for other variables in the model. Breast separation ≥ 25 cm and whether chemotherapy

Table 1 Patient baseline characteristics and treatment

Patient baseline and treatment	Baseline ($n = 609$) n (%)	5 years ($n = 580$) n (%)	10 years ($n = 428$) n (%)
Age at randomization mean (range)	59 (24–85)	58 (24–85)	58 (24–81)
Menopausal status			
Pre	123 (20)	119 (20)	89 (21)
Post	450 (74)	428 (74)	309 (72)
Peri	36 (6)	33 (6)	30 (7)
Bracup size			
A	46 (8)	41 (7)	33 (8)
B	213 (35)	194 (33)	143 (33)
C	185 (30)	185 (32)	142 (33)
>C	160 (26)	157 (27)	108 (25)
Not known	5 (1)	3 (1)	2 (1)
Primary site			
UIQ	104 (17)	98 (17)	72 (17)
UOQ	274 (45)	272 (47)	201 (47)
LIQ	33 (6)	31 (5)	22 (5)
LOQ	69 (11)	70 (12)	48 (11)
Central	42 (7)	39 (7)	28 (7)
Midline sup	61 (10)	55 (9)	44 (10)
Midline inf	23 (4)	14 (2)	13 (3)
Not known	3 (<1)	1 (<1)	0
Skin type (*)			
Celtic	225 (37)	209 (36)	156 (36)
Caucasian/tan	347 (57)	341 (59)	252 (59)
Indian/negroid	14 (2)	11 (2)	5 (1)
Asian/chinese	22 (4)	18 (3)	15 (4)
Not known	1 (<1)	1 (<1)	0
Number of excisions			
1	438 (72)	418 (72)	299 (70)
2	157 (26)	150 (26)	118 (27)
3 or more	14 (2)	12 (2)	11 (3)
Scar length (cm) mean (range)	7.0 (2–21.5)	7.0 (2–21.5)	7.0 (2–21.5)
Scar site			
Breast	529 (87)	505 (87)	367 (86)
Breast + nipple	40 (7)	35 (6)	29 (7)
Areolar margin	38 (6)	38 (7)	30 (7)
Not known	2 (<1)	2 (<1)	2 (<1)
Scar orientation			
Radial	114 (19)	116 (20)	89 (21)
Circumareolar	494 (81)	463 (80)	339 (79)
Unknown	1 (<1)	1 (<1)	0
Number of nodes sampled			
0	69 (11)	66 (11)	43 (10)
1–4	104 (17)	106 (18)	63 (15)
>4	436 (72)	408 (71)	322 (75)
Max tumour diameter (mm) mean (range)	18.0 (1–85)	17.4 (1–85)	17.0 (1–85)
Breast separation (cm) mean (range)	22.5 (15–32)	22.6 (14–35)	22.6 (14–35)
Axillary irradiation			
Yes	7 (1)	7 (1)	5 (1)
No	596 (98)	568 (98)	420 (98)
Not known	6 (1)	5 (1)	3 (1)
Supraclavicular irradiation			
Yes	32 (5)	29 (5)	17 (4)
No	572 (94)	547 (94)	409 (96)
Not known	5 (1)	4 (1)	2 (<1)
Chemotherapy planned			
None	485 (80)	466 (80)	346 (81)
AC[a]	60 (10)	58 (10)	35 (8)
CMF/LMF[b]	64 (10)	56 (10)	47 (11)
Hormonal therapy planned			
Yes	238 (39)	233 (40)	165 (39)
None	370 (61)	346 (60)	262 (61)
Not known	1 (<1)	1 (<1)	1 (<1)
Allocation			
Boost	304 (50)	287 (49)	211 (49)
No Boost	305 (50)	293 (51)	217 (51)
Tangent dose gray mean (SD)	47.5 (2.6)	47.5 (2.5)	47.5 (2.5)
Tangent max gray mean (SD)	52.3 (3.1)	52.3 (3.1)	52.3 (2.8)
Breast max gray mean (SD)	59.8 (5.6)	59.8 (5.6)	60.0 (5.4)

[a] Doxorubicin/cyclophosphamide

[b] Cyclophosphamide, methotrexate and fluorouracil/Leukeran, methotrexate and fluorouracil

planned was also associated with worse QOL (Table 3). Breast cosmesis was not significant with a p value of 0.0675.

Five years

At 5 years follow up the mean global QOL was 76.0 and 92 % reported excellent/good/normal cosmesis. Patients who reported "excellent/good/normal" breast cosmetic outcomes had a greater difference in overall QOL scores, compared to those with "Fair/Poor" outcomes (77.4 vs 59.8, $p < 0.001$) (Table 2). In addition, the impact of functional

Table 2 Univariate quality of life scores

	n (%)	QOL mean (SD)	*n* (%)	QOL mean (SD)	QOL difference (95 %CI)	*p* value
Baseline						
	Excellent good or normal		Fair or poor			
Cosmesis overall result	542 (89)	72.4 (20)	67 (11)	61.4 (20)	11.0 (6–16)	<0.001
Breast sensitivity	457 (75)	73.6 (19)	150 (25)	63.4 (20)	10.2 (7–14)	<0.001
	None minimal or moderate		Marked or severe			
Breast tenderness	554 (90)	72.7 (19)	65 (10)	59.2 (20)	13.4 (8–18)	<0.001
	None or little		Moderate or severe			
Arm swelling	549 (90)	72.5 (19)	60 (10)	57.9 (19)	14.6 (9–20)	<0.001
Arm Pain	491 (80)	74.3 (19)	121 (20)	58.7 (20)	15.6 (12–19)	<0.001
Limitation of movement	536 (87)	73.2 (19)	77 (13)	56.0 (19)	17.3 (13–22)	<0.001
Loss of feeling in fingers	600 (98)	71.1 (20)	10 (2)	63.3 (27)	7.8 (−5–20)	0.22
5 Years						
	Excellent good or normal		Fair or poor			
Cosmesis overall result	533 (92)	77.4 (19)	47 (8)	59.8 (20)	17.7 (12–23)	<0.001
Breast sensitivity	447 (77)	78.6 (18)	131 (23)	67.3 (20)	11.3 (8–15)	<0.001
	None minimal or moderate		Marked or severe			
Breast tenderness	531 (92)	77.1 (18)	48 (8)	63.8 (23)	13.3 (8–19)	<0.001
	None or little		Moderate or severe			
Arm swelling	541 (93)	76.5 (19)	42 (7)	67.5 (20)	9.0 (3–15)	0.004
Arm pain	542 (92)	77.1 (19)	45 (8)	60.4 (19)	16.7 (11–22)	<0.001
Limitation of movement	561 (96)	76.5 (19)	21 (4)	54.8 (19)	21.7 (13–30)	<0.001
Loss of feeling in fingers	570 (98)	76.3 (19)	14 (2)	59.5 (30)	16.8 (7–27)	0.001
	No		Yes		–	–
Locoregional recurrence	585 (97)	75.9 (19)	19 (3)	74.6 (18)	1.4 (–7–10)	0.76
Distant recurrence	558 (92)	76.3 (19)	46 (8)	71.4 (19)	4.9 (–1–11)	0.098
10 Years						
	Excellent good or normal		Fair or poor			
Cosmesis overall result	391 (91)	74.8 (20)	37 (9)	62.4 (21)	12.4 (6–19)	<0.001
Breast sensitivity	329 (77)	76.2 (20)	97 (23)	66.9 (21)	9.2 (5–14)	<0.001
	None minimal or moderate		Marked or severe			
Breast tenderness	400 (94)	74.7 (20)	25 (6)	60.7 (20)	14.0 (6–22)	0.001
	None or little		Moderate or severe			
Arm swelling	412 (95)	73.9 (21)	24 (5)	61.5 (24)	12.5 (4–21)	0.005
Arm Pain	400 (92)	74.5 (20)	36 (8)	60.2 (23)	14.3 (7–21)	<0.001
Limitation of movement	410 (94)	74.1 (21)	24 (6)	57.6 (18)	16.5 (8–25)	<0.001
Loss of feeling in fingers	422 (97)	73.7 (21)	13 (3)	59.0 (15)	14.7 (3–26)	0.013
	No		Yes			
Locoregional recurrence	426 (94)	73.5 (21)	25 (6)	67.3 (23)	6.2 (–2–15)	0.15
Distant recurrence	399 (88)	74.4 (21)	52 (12)	63.9 (23)	10.4 (4–16)	0.001

outcomes on QOL was maintained at 5 years. Patients with "fair/poor" breast sensitivity had a lower QOL score (78.6 vs 67.3, $p < 0.001$). Patients with "moderate/severe" arm swelling, arm pain and limitation of movement and loss of feeling in fingers had significantly worse QOL than those reporting "none/little" symptoms. Lower QOL scores were also seen in the group with "marked/severe" breast tenderness (77.1 vs 63.8, $p < 0.001$). The presence of neither locoregional or distant recurrent disease had a statistically significant impact on QOL.

Multivariable modelling at 5 years show that "fair/poor" cosmesis and breast sensitivity, arm pain, breast separation ≥25 cm were associated with worse QOL with linear coefficient estimates of 9.6, 7.5, 13.1, and 5.6, respectively (p values 0.001, <0.001, <0.001, 0.002). In addition, age was also statistically significant (coefficient $= -0.22$, $p = 0.002$) (Table 3).

Table 3 Quality of life: multivariable models

	n	Effect estimate	95 % CI	*p* value
Baseline				
Breast sensitivity: normal/excellent/good vs fair/poor	445 vs 141	6.3	3–10	0.001
Arm pain: none/little vs moderate/severe	470 vs 116	9.0	5–13	<0.001
Limitation of movement: none/little vs moderate/severe	511 vs 75	9.9	5–15	<0.001
Breast separation (cm) <25 vs ≥25	452 vs 134	6.3	3–10	<0.001
Chemotherapy planned No vs Yes	466 vs 120	4.2	0.6–8	0.024
5 Years				
Cosmesis: excellent/good/normal vs fair/poor	520 vs 45	9.6	4–15	0.001
Breast sensitivity: normal/excellent/good vs fair/poor	435 vs 130	7.5	4–11	<0.001
Arm pain: none/little vs moderate/severe	521 vs 44	13.1	7–19	<0.001
Breast separation (cm) <25 vs ≥25	431 vs 134	5.6	2–9	0.002
Age (years)		−0.22	−0.08–0.35	0.002
10 Years				
Cosmesis: excellent/good/normal vs fair/poor	381 vs 34	7.3	0.2–14	0.043
Breast sensitivity: normal/excellent/good vs fair/poor	322 vs 93	6.7	2–11	0.005
Arm pain: none/little vs moderate/severe	380 vs 35	12.5	6–19	<0.001
Breast separation (cm) <25 vs ≥25	316 vs 99	7.2	3–12	0.001
Distant cancer no vs yes	369 vs 46	8.6	3–14	0.004
Age (years)		−0.36	−0.18–0.53	<0.001

Ten years

At 10 years follow up the mean global QOL was 73.7 and 91 % reported excellent/good/normal breast cosmesis.

Among women undergoing breast conservation, 6 % reported marked or severe breast tenderness at 10 years and 9 % reported fair or poor cosmesis. Similarly, in this population, >70 % of whom had four or more lymph nodes sampled, 3, 5, 6, and 8 %, respectively, reported moderate or severe loss of feeling in fingers, arm swelling, limitation of arm movement, and arm pain at 10 years.

The effect of cosmetic outcomes on QOL remained clinically and statistically significant; with a difference of 12.4 between patients with an "normal/excellent/good" cosmetic versus "fair/poor" outcomes (74.8 vs 62.4, $p < 0.001$). At 10 years, results were similar to 5 years with arm sensitivity, tenderness, swelling, pain, limitation of movement, and loss of feeling in fingers all significant on univariate analysis (Table 2). Distant recurrent disease was also significant though the impact on QOL is smaller than cosmesis with a difference of 10.4(74.4 vs 63.9, $p = 0.001$). Multivariable modelling showed that arm pain had the greatest impact on QOL with an effect difference of 12.5 (95 % CI 6–19). Breast cosmesis, breast sensitivity, breast separation ≥25 cm continued to remain significant at 10 years. Age and distant cancer recurrence were also associated with lower QOL (Table 3).

To account for missing data which may bias the results of this study, additional analyses were undertaken. We modelled two "worse case" scenarios. In WC1, all non-responders were imputed as "fair/poor" cosmesis with a QOL equal to the mean of the "excellent/good" responders and in WC2 the reverse was performed. Univariate analysis at baseline, 5 and 10 years show that breast cosmesis continue to show a significant impact on QOL (see supplementary material, Table 4).

Further it was considered that patient response may be associated with cancer recurrences. This was not the case as patients who had cancer recurrence were not more likely to not complete their QOL questionnaires (see supplementary material, Table 5).

Discussion

Although several studies have reported favourable cosmetic outcomes in up to 80 % of patients following BCS, a significant proportion will suffer poor sequelae [15]. In our study, approximately 90 % of patients rated their cosmetic outcome as good or excellent and, depending upon the breast/arm symptom outcome selected, moderate or severe symptoms were present in 2–25 % of patients from baseline to 10 years. These adverse symptom rates are lower than the recently published START trials results in very similar patient populations [16].

At the time the SGW trial was initiated the breast module of the EORTC QOL instrument was not available, however, items in the SGW questionnaire are similar. Our instrument has been a useful discriminator for patient outcomes that are associated with significant changes in overall QOL.

At 10 years, we identified a 12.4 difference in QOL between those patients with "excellent/good/normal" cosmetic outcome versus those with "fair/poor". For functional outcomes, the difference between having a favorable versus an unfavorable outcome in breast sensitivity, breast tenderness, arm swelling, arm pain, limitation of movement, and loss of sensation in fingers was associated with a 9.2, 14.0, 12.5, 14.3, 16.5, and 14.7 difference, respectively, in the QOL. Although the interpretation of QOL results remains essentially qualitative and the values and opinions of individual patients will differ, some studies are finding that for overall QOL and some specific QOL dimensions, changes of between 5 and 10 % (i.e., between 5 and 10 points on the 1–100 scales of the QLQ-C30) are noticed by patients and can be regarded as clinically significant changes [17, 18]. It is intriguing to note that the cosmetic and the majority of functional outcomes had a larger impact on QOL than either loco-regional or distant recurrent disease though the number of patients with loco-regional recurrences were quite small. There are several possibilities other than the large effect of cosmetic and functional outcomes on QOL. The analyses are at 5 and 10 years when the recurrence events could have occurred some considerable time previously and have faded as impact events at the time of QOL assessment, particularly if those events were new early cancers also treated with curative intent and in remission. It is possible that patients with recent or older new cancer events who complete QOL assessments may have a more optimistic adjustment to such events than those who do not complete QOL assessments. A poor cosmetic or functional outcome is a long-term persistent conditioner of QOL, and this may also help explain their degree of impact as large or larger than distant cancer events which may be episodic and even isolated events without durable impact.

A number of other studies have supported our hypothesis that cosmetic, as well as local functional, outcomes have important QOL effects. A recent study found that women with pronounced breast asymmetry were much more likely to have negative psychosocial and QOL outcomes [9]. Heil et al. [19] concluded that aesthetics, as assessed using the breast treatment outcomes scale, are valuable indicators of QOL in general as they retain their impact over the 12 months of follow up in their study. Nesvold et al. [20] have found that not only lymphodema but pain and restricted mobility in the arm/shoulder were significantly associated with poor QOL. In addition, other studies have demonstrated that although cosmetic status predicted QOL related to physical health, functional outcomes such as breast-specific pain and arm edema were stronger predictors of QOL and other psychological measures [15, 19, 21, 22].

Since January 2005 at St. George Hospital the rate of axillary dissection in our breast conserved patients has been only 25 % instead of 71 % of patients with four or more nodes dissected in this trial. In current treatment populations, arm symptoms are likely to be less frequent, and breast tenderness more important [23]. In either case, we have demonstrated that the impact of these on QOL is enduring for at least a decade. Given the consistent durability of this impact, there is little reason to assume that it will suddenly diminish after this time. Breast separation is a reflection of breast size and our results suggest larger breasted women have a higher chance of decreased QOL. Larger breast separation is associated with worse cosmetic outcomes [24–26] and IMRT can be used to reduce dose heterogeneity and to potentially improve cosmesis. A randomized trial in the patients with inhomogeneous plans was randomized to a simple method of forward-planned IMRT or standard radiotherapy (RT). At an early follow up of 2 years, no significant difference was found in the development of any photographically assessed breast shrinkage between the two arms although the standard arm was more likely to develop telangiectasia than those in the IMRT group. However, the authors pointed out that the cosmetic differences at this early stage could be potentially masked by the effects of surgery [27]. Our trial intrinsically has greater heterogeneity in dose between the treatment arms but this did not persist as an independent variable in the dependent variables in his study. This suggests that there may be other factors other than dose heterogeneity of relevance to determining QOL and breast symptoms in larger compared to smaller breasted women.

The important strengths of our study are the long-term follow-up in a large study population with reliable uniform data collection in the setting of a randomized controlled trial. We have demonstrated the significant and persistent impact of cosmetic and local functional outcomes for breast conservation on QOL over a decade.

Our study does have a number of limitations. It is possible that patients' cosmetic results are influenced by QOL and not the other way round. Despite the longitudinal nature of this study, it still does not establish a causal relationship and we cannot differentiate between cause and effect. However, the interpretation that cosmesis, breast sensitivity, arm pain, and limitation of movement contribute to lower QOL is much more plausible than the reverse suggestion that lower QOL contributes to poorer cosmesis and functional outcomes. Clinician, expert panel, and computer assessments of cosmesis were also

performed but there were discrepancies between each assessment method [12] and a more detailed analysis of the impact of different assessment methods on QOL will be presented separately. In addition, analysis on the predictors of cosmetic and functional outcome in this study is currently being undertaken and will be reported separately.

It is also possible that patients with poorer QOL-responded negatively across all self reported measures including cosmesis. A study by Deshields et al. [28] have found that distress and QOL at the time if diagnosis predicted patients' and physicians' rating of cosmesis at the end of treatment. However, due to lack of psychological data at the end of treatment, they were not able to establish the stability of psychological status from time of diagnosis to end of treatment or to determine the relationship of post-treatment psychological status with ratings of cosmesis.

Shared decision making is now advocated as the preferred model of treatment planning [29–31].

It is particularly critical when there is more than one treatment option with different possible outcomes as is the case in breast cancer treatments [29]. The first step in shared decision making is that the two parties, patient and physician, share information. The patient provides information regarding his or her beliefs, preferences, values and future goals, and the physician provides information about the treatment options in terms of the expected outcomes, including disease control, potential side-effects, and impact on quality of life. [30] In this study, we have shown the association between patient self-assessed cosmetic and functional outcomes and QOL. We have shown that poor cosmetic and functional outcomes were associated with lower QOL and that this association largely persisted even 10 years after treatment. This knowledge is essential in facilitating the shared decision making model of treatment planning by allowing the patient to be fully informed of the long term sequelae of treatment. Another potential implication is that patients with a poor cosmetic result could be targeted for psychological assessment and early intervention.

Conclusion

Although the majority of women experience favourable cosmetic and functional outcomes following BCS, a significant proportion are negatively affected. This exploratory analysis highlights the importance of maintaining a favourable cosmetic outcome on the QOL even many years beyond treatment.

In addition, the significant relationship between functional outcomes and QOL shows the importance for clinicians and allied health professionals in identifying, discussing, managing, and limiting these effects in women with breast cancer in order to maintain QOL.

Conflict of interest None.

Ethical standard Ethics approval was obtained for the St George and Wollongong Randomized Trial. The trial is registered with www.clinicaltrials.gov (NCT00138814).

References

1. Nano MT, Gill PG, Kollias J, Bochner MA, Malycha P, Winefield HR (2005) Psychological impact and cosmetic outcome of surgical breast cancer strategies. ANZ J Surg 75(11):940–947
2. Al-Ghazal SK, Fallowfield L, Blamey RW (2000) Comparison of psychological aspects and patient satisfaction following breast conserving surgery, simple mastectomy and breast reconstruction. Eur J Cancer 36(15):1938–1943
3. Moyer A (1997) Psychosocial outcomes of breast-conserving surgery versus mastectomy: a meta-analytic review. Health Psychol 16(3):284–298
4. Pusic A, Thompson TA, Kerrigan CL, Sargeant R, Slezak S, Chang BW, Kelzlsouer KJ, Manson PN (1999) Surgical options for the early-stage breast cancer: factors associated with patient choice and postoperative quality of life. Plast Reconstr Surg 104(5):1325–1333
5. Curran D, van Dongen JP, Aaronson NK, Kiebert G, Fentiman IS, Mignolet F, Bartelink H (1998) Quality of life of early-stage breast cancer patients treated with radical mastectomy or breast-conserving procedures: results of EORTC Trial 10801. The European Organization for Research and Treatment of Cancer (EORTC), Breast Cancer Co-operative Group (BCCG). Eur J Cancer 34(3):307–314
6. de Haes JC, van Oostrom MA, Welvaart K (1986) The effect of radical and conserving surgery on the quality of life of early breast cancer patients. Eur J Surg Oncol 12(4):337–342
7. Ganz PA, Schag AC, Lee JJ, Polinsky ML, Tan SJ (1992) Breast conservation versus mastectomy. Is there a difference in psychological adjustment or quality of life in the year after surgery? Cancer 69(7):1729–1738
8. Montazeri A (2008) Health-related quality of life in breast cancer patients: a bibliographic review of the literature from 1974 to 2007. J Exp Clin Cancer Res 27:32
9. Waljee JF, Hu ES, Ubel PA, Smith DM, Newman LA, Alderman AK (2008) Effect of esthetic outcome after breast-conserving surgery on psychosocial functioning and quality of life. J Clin Oncol 26(20):3331–3337
10. Graham P, Browne L, Capp A, Fox C, Delaney G, Kearsley H, Millar E, Nasser E, Papadatos G (2010) Randomized trial shows reduced whole breast dose negates benefit of lumpectomy radiotherapy boost. Radioth Oncol 96(Suppl 1):S145
11. Graham P, Capp A, Fox C, Nasser E, Delaney G, Ahern V, Wratten C (2003) Why a breast boost should remain a controversial aspect of routine breast conservation management in Australia and New Zealand in 2002. Australas Radiol 47(1):44–49
12. Hau E, Browne LH, Khanna S, Cail S, Cert G, Chin Y, Clark C, Inder S, Szwajcer A, Graham PH (2012) Radiotherapy breast boost with reduced whole-breast dose is associated with improved cosmesis: the results of a comprehensive assessment from the St. George and Wollongong randomized breast boost trial. Int J Radiat Oncol Biol Phys 82(2):682–689
13. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, Filiberti A, Flechtner H, Fleishman SB, de Haes JC et al (1993) The European organization for research and treatment of cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 85(5):365–376

14. Bland M (2000) An introduction to medical statistics, 3rd edn. Oxford University Press, Oxford
15. Patterson MP, Pezner RD, Hill LR, Vora NL, Desai KR, Lipsett JA (1985) Patient self-evaluation of cosmetic outcome of breast-preserving cancer treatment. Int J Radiat Oncol Biol Phys 11(10):1849–1852
16. Hopwood P, Haviland JS, Sumo G, Mills J, Bliss JM, Yarnold JR (2010) Comparison of patient-reported breast, arm, and shoulder symptoms and body image after radiotherapy for early breast cancer: 5 year follow-up in the randomised standardisation of breast radiotherapy (START) trials. Lancet Oncol 11(3):231–240
17. Osoba D, Rodrigues G, Myles J, Zee B, Pater J (1998) Interpreting the significance of changes in health-related quality-of-life scores. J Clin Oncol 16(1):139–144
18. King MT (1996) The interpretation of scores from the EORTC quality of life questionnaire QLQ-C30. Qual Life Res 5(6):555–567
19. Heil J, Czink E, Golatta M, Schott S, Hof H, Jenetzky E, Blumenstein M, Maleika A, Rauch G, Sohn C (2011) Change of aesthetic and functional outcome over time and their relationship to quality of life after breast conserving therapy. Eur J Surg Oncol 37(2):116–121
20. Nesvold IL, Reinertsen KV, Fossa SD, Dahl AA (2011) The relation between arm/shoulder problems and quality of life in breast cancer survivors: a cross-sectional and longitudinal study. J Cancer Surviv 5(1):62–72
21. Stanton AL, Krishnan L, Collins CA (2001) Form or function? Part 1. Subjective cosmetic and functional correlates of quality of life in women treated with breast-conserving surgical procedures and radiotherapy. Cancer 91(12):2273–2281
22. Krishnan L, Stanton AL, Collins CA, Liston VE, Jewell WR (2001) Form or function? Part 2. Objective cosmetic and functional correlates of quality of life in women treated with breast-conserving surgical procedures and radiotherapy. Cancer 91(12): 2282–2287
23. Ashikaga T, Krag DN, Land SR, Julian TB, Anderson SJ, Brown AM, Skelly JM, Harlow SP, Weaver DL, Mamounas EP et al (2010) Morbidity results from the NSABP B-32 trial comparing sentinel lymph node dissection versus axillary dissection. J Surg Oncol 102(2):111–118
24. Deutsch M, Flickinger JC (2003) Patient characteristics and treatment factors affecting cosmesis following lumpectomy and breast irradiation. Am J Clin Oncol 26(4):350–353
25. Wazer DE, DiPetrillo T, Schmidt-Ullrich R, Weld L, Smith TJ, Marchant DJ, Robert NJ (1992) Factors influencing cosmetic outcome and complication risk after conservative surgery and radiotherapy for early-stage breast carcinoma. J Clin Oncol 10(3):356–363
26. Barnett GC, Wilkinson JS, Moody AM, Wilson CB, Twyman N, Wishart GC, Burnet NG, Coles CE (2011) The Cambridge breast intensity-modulated radiotherapy Trial: patient-and treatment-related factors that influence late toxicity. Clin Oncol (R Coll Radiol) 23(10):662–673
27. Barnett GC, Wilkinson JS, Moody AM, Wilson CB, Twyman N, Wishart GC, Burnet NG, Coles CE (2012) Randomized controlled trial of forward-planned intensity modulated radiotherapy for early breast cancer: interim results at 2 years. Int J Radiat Oncol Biol Phys 82(2):715–723
28. Deshields TL, Reschke A, Walker MS, Brewer A, Taylor M (2007) Psychological status at time of diagnosis and patients' ratings of cosmesis following radiation therapy for breast cancer. J Psychosoc Oncol 25(2):103–116
29. Charles C, Gafni A, Whelan T (1997) Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). Soc Sci Med 44(5):681–692
30. NHMRC/NBCC: National Breast Cancer Centre and National Cancer Control Initiative (2003) National guidelines for the psychosocial care of adults with cancer. NBCC, Camperdown
31. Charles C, Whelan T, Gafni A (1999) What do we mean by partnership in making decisions about treatment? BMJ 319(7212):780–782