

Supportive care needs, anxiety, depression and quality of life amongst newly diagnosed patients with localised invasive cutaneous melanoma in Queensland, Australia

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Abstract

Objective: The aim of this paper is to determine levels of supportive care needs, anxiety, depression and symptoms amongst patients newly diagnosed with localised invasive primary melanoma and if these varied amongst patients who had a sentinel lymph node biopsy (SLNB). We also considered quality of life compared with general population norms.

Methods: Patients newly diagnosed with clinical stage IB-II invasive melanoma were ascertained through Queensland hospitals, specialist clinics and pathology laboratories. Validated surveys measured 46 need items (Supportive Care Needs Survey–Short Form + melanoma subscale), anxiety and depression (Hospital Anxiety and Depression Scale) and quality of life and symptoms (Functional Assessment of Cancer Therapy–Melanoma). Regression models compared outcomes according to whether or not participants had a SLNB.

Results: We surveyed 386 patients, 155 before and 231 after wide local excision, of whom 46% reported ≥ 1 moderate-level or high-level unmet need. The three highest needs were for help with fears about cancer spreading (17%), information about risk of recurrence (17%) and outcomes when spread occurred (16%). Those who had a SLNB were more likely to report a moderate or high unmet need for help with uncertainty about the future or with lymphoedema ($p < 0.05$). Overall, 32% of participants had anxiety and 15% had depression regardless of performance of SLNB. Melanoma-specific symptoms were worse in SLNB patients ($p = 0.03$). Compared with the general population, emotional well-being was lower amongst melanoma patients.

Conclusions: A substantial proportion of newly diagnosed patients with localised invasive melanoma need further melanoma-specific information and support with psychological concerns. Patients who have a SLNB clear of disease may need help with symptoms after surgery.

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Introduction

Melanoma is the second most common cancer in Queensland, Australia [1], expected to occur in 1 in 14 Australian men and 1 in 23 women [2]. About 80% of melanoma patients are diagnosed when the primary tumour is localised to the skin [3], and those with thin (< 1 mm in thickness) melanomas can expect a 10-year relative survival rate of

$> 95\%$ [4]. However survival rates vary from 80% to 40% for thicker melanomas (≥ 1 mm) localised to the skin [5]. Although surgical treatment of early stage melanoma is potentially curative, the prognosis is worse, and the risk of lymph node and/or metastasis increases with lesion thickness [5]. Controversy exists about the routine performance of sentinel lymph node biopsy (SLNB) alongside wide local excision in primary melanomas with a high risk

of recurrence [6]. Whilst SLNB helps to accurately stage invasive melanoma, assess spread to the nodes and offer patients prognostic information [6], whether there is an associated survival benefit remains a source of debate [7,8], although results of recent phase III trials are supportive of a potential benefit [9]. Although present Australian guidelines recommend that SLNB be discussed with patients with primary melanomas measuring 1.2–3.5 mm in thickness [10], approaches to discussing the procedure vary amongst individual practitioners in Queensland according to the patient's age, health and site of the primary lesion and the patient's wishes regarding assessment of possible spread. Also, because SLNB is performed only by specialist surgeons, patients whose wide local excisions are performed by other practitioners may not be counselled about SLNB.

With or without SLNB, the physical effects of surgery for melanoma have significant emotional, social and psychological consequences [11]. A systematic review indicated that 30% of all melanoma patients report levels of distress requiring clinical intervention [12]. However, the psychological response to melanoma may change over time. Patients generally experience higher levels of distress during diagnosis and treatment that may dissipate after the initial acute phase [13]

Needs are also dependent on relative timing of diagnosis, treatment and recurrence [14]. Therefore, it is informative to anchor needs assessment to a narrowly defined period or event. Three studies have assessed the supportive care needs of people diagnosed with melanoma. All recruited broad cross-sectional samples of patients diagnosed between 3 months and 5 years [15] or more [16,17] previously and thus are unable to inform the planning of patient care during the diagnosis and primary treatment phase when support needs are likely to peak [14]. Furthermore, all were single [16,17] or double [15] site samples and thus lack generalisability. The first study found the greatest need for help was for melanoma-specific issues, followed by psychological concerns then general cancer information [16]. The second study was small ($n=31$) and only collected information on melanoma-specific needs. It found that the highest unmet need was for access to a second opinion [17]. The third found that very few participants reported a moderate or high level of need for help, although standardised need domain scores were not presented, so predominant supportive care domains were not identified [15].

With the potentially large impact of diagnosis and treatment on melanoma patients, it is important to assess supportive care needs in today's clinical environment and across multiple sites at narrowly defined times after diagnosis. Using a large-scale multisite design, we determined the levels of supportive care needs, anxiety, depression, melanoma-specific symptoms and quality of life amongst patients newly diagnosed with localised invasive

melanoma and the influence of SLNB. Furthermore, we compared whether the quality of life of our newly diagnosed melanoma population was significantly different than in the general population.

Methods

Participants and procedures

People in Queensland newly diagnosed with a primary cutaneous melanoma clinical stage IB or II (i.e. locally invasive with no metastatic spread who potentially may be offered SLNB) [5] were ascertained between October 2010 and May 2013 from several sources, namely, the Multidisciplinary Melanoma Clinic at the Princess Alexandra Hospital, Specialist Outpatient Departments of the Townsville, Nambour and Royal Brisbane and Women's Hospitals and private practices of associated melanoma surgeons and three private pathology companies. Patients ascertained through hospital clinics and private practices were invited to participate by their treating doctors or by study personnel with doctors' permission. For pathology laboratory ascertainment, dermatopathologists identified eligible patients and asked the referring doctors to inform the pathology company if their patients should not be contacted about study participation. If no objection was received within 2 weeks, the pathology company requested patients' permission to release their details to study personnel who then invited them to participate.

Patients were excluded if they were aged younger than 16 years (Queensland Health deems 16 years to be the age of consent) or if they were physically or mentally unable to complete a written questionnaire, if they had a SLNB showing nodal spread of microscopic disease, if satellitosis was found, if they were confirmed as having metastatic disease before completion of the baseline study questionnaire (the aim was to have patients complete this questionnaire when no known metastatic disease was present) or if they did not complete the questionnaire within 2½ months of definitive surgery.

All study participants provided written informed consent, and the study was approved by the Ethics Committees of the Metro South Hospital and Health Service of the Princess Alexandra Hospital and of the QIMR Berghofer Medical Research Institute. No conflicts of interest were declared by any authors.

Measures

Supportive care needs were assessed using the Supportive Care Needs Survey–Short Form (SCNS-SF34) [18] and its supplementary melanoma-specific module [19]. The SCNS-SF34 has a total of 34 items in five domains: psychological (10 items), physical and daily living (5 items), health system and information (11 items), patient care and

support (5 items) and sexuality (3 items). The melanoma-specific module additionally considers 12 specific items. Participants rate their need for help with each item over the past month on a 5-point scale: 1 = not applicable (no need), 2 = satisfied (need met), 3 = low unmet need, 4 = moderate unmet need and 5 = high unmet need. Summated Likert scale domain scores were standardised (range 0–100) to allow direct comparison across need domains [18]. The SCNS-SF34 is a validated measure; its five domains collectively accounted for 73% of the variance, with Cronbach's alpha for domains ranging from 0.86 to 0.96 [18]. Additionally, two dichotomous need domain scores were classified: (a) no need versus any need (from met need to unmet need) and (b) no-to-low need versus moderate-to-high need.

Anxiety and depression were assessed using the 14-item Hospital Anxiety and Depression Scale [20]. Two subscales distinguish between anxiety and depression (coefficient alphas of 0.93 and 0.90, respectively). Scores on both subscales range between 0 and 21. Within each subscale, scoring cut-offs distinguish between 'normal' (0–7), 'subclinical' (8–10) and 'clinical' (11–21) levels.

Quality of life was measured using the 51-item Functional Assessment of Cancer Therapy–Melanoma (FACT-M) [21]. The FACT-M is a multidimensional, melanoma-specific, quality of life instrument, assessing four general subscales (physical, social, emotional and functional well-being) and a disease and treatment melanoma-specific subscale. Overall quality of life was derived from combining all five subscales. Higher scores indicate better well-being.

Personal variables including age, sex, relationship status and education level were also collected. *Clinical variables* were extracted from histopathology reports and included details of participants' primary melanomas, namely, site; histological classification; thickness (mm); and presence of mitosis, ulceration or satellites. In addition, if definitive excision of the primary had taken place, we recorded whether this was performed by general practitioner or specialist and, if the latter, whether SLNB had been performed.

Statistical analysis

The proportion of melanoma patients who endorsed each supportive care need item and domain was calculated overall and amongst patients who had definitive surgery; chi-square tests were used to determine if these proportions differed according to performance or not of SLNB. Backward stepwise logistic regression, adjusting for patient's age, education, primary site, level of training of practitioner performing definitive surgery and ascertainment source, was applied to dichotomous need domain scores to determine the association with SLNB in those seen after definitive surgery. At each step, removal of the variables from the

model was based on a p -value ≥ 0.1 . Variables with p -value ≤ 0.05 were considered statistically significant. Variables with odds ratios ≥ 2 or ≤ 0.5 were considered clinically significant. The final model was reduced to patient's age as the only significant confounder.

Unadjusted mean quality of life, anxiety and depression scores were also calculated overall and within patients according to whether SLNB was performed. General linear models were used to provide age-adjusted marginal means of quality of life, anxiety and depression and to determine if there was a statistically significant difference by performance of SLNB.

Well-being subscale scores and overall quality of life were compared with Australian norms [22]. As there were no differences in general population scores by sex or age, standardisation was not necessary. A two-point difference in subscale scores and a five-point difference in overall scores greater or less than the general population mean score was considered clinically different in line with the minimum important differences established for FACT-General [23].

Results

Participants

We approached 703 potentially eligible patients between 29 October 2010 and 10 May 2013, of whom 78 were excluded (15 had positive lymph nodes, 29 were not clinical stage IB or II, 4 were highly dependent on medical care and 30 did not complete the survey within time). Of the remaining 625 patients, 234 did not consent to participate and 5 were excluded because their clinical data were unavailable at time of analysis. Thus, 386 participants contributed to the overall analysis (62% participation rate) including 4 (1%) patients who were classified as stage IB before the change in the American Joint Committee on Cancer [5] and were counselled identically to other study participants. The overall group had a mean age of 61 years, just over half were men (55%), three quarters (74%) had a partner, 22% completed higher education, 70% had tumours ≤ 2 mm and the trunk was the most common site (36%) (Table 1). Age and sex distributions were similar to those in the population-based Queensland Cancer Registry (comparison of clinical stage was not possible because these data are not registered) [1].

Analyses comparing SLNB results were restricted to the subgroup of 231 (60%) participants who had completed the questionnaire after they had undergone definitive surgery. The remaining 155 participants completed the questionnaire before definitive surgery. Of the participants who completed the questionnaire after definitive surgery, almost one third (31%) had a SLNB performed (all of which showed no micrometastases at time of

Table 1. Characteristics of 386 participants with primary invasive melanoma and amongst participants seen after definitive surgery ($n=231$), according to whether or not sentinel lymph node biopsy (SLNB) was performed

	Overall ($n=386$) (%)	SLNB ($n=72$) (%)	No SLNB ($n=159$) (%)	<i>p</i> -value ^a
Age (years)				
≤59	38	56	30	<0.001
60–69	30	32	32	
70+	32	13	38	
Sex				
Male	55	57	50	0.350
Female	45	43	50	
Relationship status				
Partner	74	81	74	0.295
No partner	25	19	26	
Level of education				
University/college	22	19	31	0.051
Senior school/diploma/trade	39	49	33	
Junior school	39	32	37	
Thickness of primary				
≤1.0–2.0 mm	70	69	73	0.602
≥2.01 mm	30	31	27	
Primary site				
Head/Neck	20	8	26	0.013
Trunk	36	46	31	
Upper Limb	21	24	21	
Lower Limb	23	22	23	
Histological type				
SSM	43	49	41	0.174
Nodular	22	25	20	
Other	34	26	39	
Ascertainment source				
Public hospital	54	32	37	<0.001
Specialist practice	30	65	27	
Pathology laboratories	17	3	36	
Doctor performing definitive surgery				
GP and skin cancer clinic	10	0	23	<0.001
Specialist	89	100	77	
Did not have definitive surgery	1	—	—	

^aSignificant difference ($p < 0.05$, chi-square) by SLNB.

questionnaire completion). The SLNB node-negative subgroup was significantly younger and tended to be less highly educated (Table 1). Whilst thickness and histological type were no different by SLNB performed or not, those who did not have a SLNB were more likely to have primary melanoma of the head or neck (Table 1). In this sample, participants undergoing SLNB were more likely to be recruited through specialist practices than through public hospitals or pathology laboratories.

Supportive care needs

The top 10 moderate-to-high level unmet needs came from the melanoma-specific and psychological need domains and are shown in Table 2. There were 5 out of 46 need items that were significantly or near significantly

different by SLNB status. Compared with participants who had no SLNB, a higher proportion who had SLNB reported moderate-to-high needs for help with uncertainty about the future (23% vs. 12%, $p=0.039$) and the worries of loved ones (17% vs. 9%, $p=0.08$), for information about surgical treatment of melanoma (19% vs. 11%, $p=0.071$), about important aspects of their care (10% vs. 3%, $p=0.053$) and for help with lymphoedema (7% vs. 1%, $p=0.005$).

Overall, 94% of participants reported having ≥ 1 need for help and 46% reported having ≥ 1 moderate-to-high level unmet need (Table 3). In particular, melanoma-specific and psychological need domains were predominant. Almost one third (32%) reported ≥ 1 moderate-to-high unmet melanoma-specific need and 25% ≥ 1 moderate-to-high unmet psychological need.

All patients (100%) who had a SLNB reported having ≥ 1 need compared with 91% of patients who did not have SLNB ($p=0.009$). Patients who underwent SLNB also had clinically higher odds (odds ratio 2.8, confidence interval 0.9–8.5) of having a melanoma-specific need than those not undergoing SLNB.

Anxiety and depression

Overall, 32% of participants were experiencing anxiety and 15% were experiencing depression. Mean scores were 6.1 (4.1 standard deviation (SD)) and 3.7 (3.5 SD), respectively. The proportion of patients with anxiety or depression was not statistically different according to the performance of SLNB.

Quality of life

After adjustment for age melanoma-specific well-being remained significantly lower amongst patients who underwent SLNB compared with those who did not (Table 4). Compared with the general population, the melanoma patients had clinically lower emotional well-being.

Discussion

Almost half of the newly diagnosed patients with primary invasive melanoma in our study sample had moderate-to-high unmet supportive care need(s) particularly in the areas of melanoma-specific information and psychological concerns. Levels of psychological distress were similar to those in other cancer patients (30–50%) [24]. This is the first large study of needs of people with early stage melanoma and demonstrates that supportive care could still be substantially improved to meet specific information and psychological needs of this sizable patient population. On the other hand, our findings indicated that clinical care needs, general health informational needs and physical and sexuality needs were either absent or met, suggesting

Table 2. Top 10 moderate or high unmet supportive care needs amongst 386 newly diagnosed people with primary invasive melanoma

Rank	Items	(%)	Domain
1	More information about the risk of recurrence of melanoma	17	Melanoma specific
2	Fears about the cancer spreading	17	Psychological
3	More information about possible outcomes when melanoma has spread from the skin	16	Melanoma specific
4	To be informed about how and when to check your skin for changes	16	Melanoma specific
5	To be informed about things you can do for skin protection	15	Melanoma specific
6	Uncertainty about the future	14	Psychological
7	To be informed about the need for surgical treatment of melanoma of the skin	14	Melanoma specific
8	Concerns about the worries of those close to you	14	Psychological
9	More information about nonsurgical treatment of melanoma (chemotherapy or immunotherapy)	13	Melanoma specific
10	To be informed about the need for surgical removal of lymph nodes	13	Melanoma specific

that health providers are providing adequate care across these domains.

Provision of information congruent with patients' disease-specific needs has been shown to lower distress and improve quality of life [25,26]. Because specific information about risk of recurrence and possible outcomes if the melanoma spreads were priority unmet needs for this group, it is possible that provision of this information may help reduce distress. This may also be important because psychological stress may be associated with melanoma progression [27–29].

Having more knowledge about the disease can also result in informed decision-making regarding treatment [30]. In regard to undergoing SLNB, the optimal situation is that the decision rests with the patient after discussion with their doctor. In our study sample, patients who underwent SLNB (with negative pathology) were more likely to be younger, less educated and be treated by a specialist. Tumour thickness did not differ between those who underwent SLNB with negative result, and those who did not have SLNB indicate a possible need for systematic

Table 3. Supportive care need domain scores^a and anxiety and depression scores^b amongst people diagnosed with primary invasive melanoma

	Overall (n = 386) (%)	SLNB (n = 72) (%)	No SLNB (n = 159) (%)	Adjusted odds ratio ^c (95% CI)	p-value
Any needs (met or unmet)					
Melanoma specific	86	94	81	2.8(0.9, 8.5)	0.073
Psychological	82	90	77	1.6(0.6, 4.1)	0.307
Health system/information	81	90	79	2.1(0.8, 5.2)	0.111
Patient care	65	74	63	1.4(0.8, 2.8)	0.259
Physical/daily living	63	76	68	1.1(0.5, 2.1)	0.851
Sexuality	25	26	21	1.1(0.6, 2.2)	0.753
Total	94	100	91	—	—
≥1 moderate or high unmet need					
Melanoma specific	32	36	32	1.0(0.5, 1.9)	0.949
Psychological	25	31	20	1.3(0.7, 2.6)	0.399
Health system/information	19	19	17	1.0(0.5, 2.2)	0.959
Patient care	9	8	8	0.9(0.3, 2.6)	0.858
Physical/daily living	17	24	19	1.0(0.5, 2.1)	0.911
Sexuality	4	0	2	—	—
Total	46	51	47	1.0(0.5, 1.8)	0.978
Anxiety					
Normal	69	65	75		
Subclinical	15	14	15		
Clinical	17	21	11		
Depression					
Normal	85	90	86		
Subclinical	10	7	10		
Clinical	5	3	4		
Anxiety (subclinical/clinical versus normal)				1.2(0.6, 2.3)	0.592
Depression (subclinical/clinical versus normal)				0.5(0.2, 1.3)	0.159

SLNB, sentinel lymph node biopsy; CI, confidence interval.

^aSupportive Care Needs Survey–Short Form measure.

^bHospital Anxiety and Depression Scale measure.

^cLogistic regression outcomes of SLNB compared with no SLNB, adjusted for age.

Table 4. Mean quality of life scores^a amongst people diagnosed with primary invasive melanoma

	Overall (n = 386) Mean (SD)	Adjusted ^b		
		SLNB (n = 72) Mean (CI)	No SLNB (n = 159)	
			Mean (CI)	p-value ^c
Quality of life				
Physical well-being	23.9 (4.4)	23.4 (22.4, 24.4)	23.9 (23.2, 24.5)	0.410
Emotional well-being	18.8 (4.2) ^e	19.1 (18.1, 20.1)	19.4 (18.7, 20.0)	0.701
Social/family well-being	22.3 (5.6)	23.5 (22.3, 24.8)	22.3 (21.4, 23.1)	0.104
Functional well-being	21.1 (5.9)	20.2 (18.9, 21.6)	21.5 (20.6, 22.4)	0.131
Melanoma-specific well-being ^d	82.4 (11.2)	79.0 (76.4, 81.7)	82.5 (80.9, 84.2)	0.030
Total FACT-M ^d	168.3 (23.7)	165.4 (160.0, 170.8)	169.3 (165.8, 172.8)	0.238
Total FACT-G	86.0 (14.9)	86.3 (82.9, 89.7)	86.9 (84.7, 89.1)	0.787

SLNB, sentinel lymph node biopsy; FACT-M/G, Functional Assessment of Cancer Therapy–Melanoma/General; SD, standard deviation; CI, confidence interval.

^aFACT-M measure.

^bAdjusted for age.

^cGeneralised linear model indicates significance of SNLB compared with no SLNB.

^dNot comparable with general population.

^eSignificantly lower than Queensland general population norms (Psycho-Oncology 18(6), 606–614).

information provision around the prognostic implications of this procedure.

Another finding was that postdiagnosis, a substantial proportion of patients want to be informed about how and when to check their skin for changes and steps they can take for skin protection. Because skin cancer prevention campaigns have been active in Queensland for over three decades [31,32], it is likely that melanoma patients require more tailored information from support service providers and clinicians who can personalise and reinforce advice about adequate sun protection and skin self-examination.

Whilst the supportive care needs identified in our sample of high-risk primary melanoma patients were fewer on average than those found in other cancer patients [33–37], their emotional well-being was significantly worse than that of their general population counterparts. Thus, although people with this early stage cancer may not be as needy for support as people with poorer prognoses or may be better catered for by experienced Queensland service providers, our results indicate that immediately after their melanoma diagnosis many still require additional emotional support. However, 2 years after diagnosis of primary invasive melanoma, others have found quality of life comparable with the general population [38].

Intervention studies of patients with melanoma have produced evidence that brief psychological interventions incorporating education, psychotherapy, stress reduction and coping techniques can reduce patients' distress and improve immune function [39–41]. Indeed, the Australian melanoma clinical practice guidelines recommend that structured psychosocial interventions and psychoeducation be made available to all patients [10], although such support may not be universally provided. In a review of international melanoma

follow-up guidelines [42], it was noted that only the American Academy of Dermatology recommended patients' psychological needs be accommodated in follow-up care and that further studies were needed. A review also indicated that psychological needs of melanoma patients are often overlooked [11].

Although ours was a large study, it had limitations. Firstly, the cross-sectional design means it is not possible to determine whether supportive care needs and psychosocial issues are being met over time or are truly overlooked. Secondly, it is likely that our sample had slightly more advanced local disease or more difficult-to-treat sites than the source population because our group comprised more patients ascertained through tertiary care centres and specialist surgeons than through primary care. Thus, we may overestimate unmet needs, psychological morbidity and symptoms. Thirdly, as this was an observational study, the characteristics of those who had node-negative SLNB and did not have a SLNB were not evenly distributed. Although we adjusted our models of patient-reported outcomes for confounders, residual selection bias between the groups is likely, and thus, differences in outcomes may not be due to the SLNB procedure itself. However, despite the different characteristics of those not having or having the procedure, this nonrandomised sample provides support personnel and services with a quasipopulation-based understanding of the type and volume of supportive care issues and group characteristics that could be used to provide targeted support within these two groups.

In conclusion, the present study offers a comprehensive snapshot of the psychological and physical morbidity of newly diagnosed primary invasive melanoma patients at high risk of recurrence and of their level of satisfaction with their cancer care. Although the

immediate dissemination of disease-specific information and immediate referral for psychological support could be improved, it seems that in general, clinical care and general information are well provided for. Whether there are fundamental differences in needs between persons who have and do not have a SLNB remains unresolved, but this study flags a possible need to improve provision of care for melanoma patients prior to and after this procedure.

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