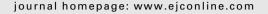


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## Aggressive treatment of non-metastatic osteosarcoma improves health-related quality of life in children and adolescents \*

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#### ABSTRACT

Background: Health-related quality of life (HRQOL) of paediatric patients with osteosarcoma has not been documented longitudinally during treatment. Aims of this prospective study were to assess treatment effects on patients' HRQOL at diagnosis, during therapy and after completion of therapy, to assess sex- and age-related differences in HRQOL ratings and to assess differences between patients' and parents' reports.

Patients and methods: Sixty-six patients (median age, 13.4 years) with newly diagnosed, localised disease completed three HRQOL instruments, and their parents completed two of the same instruments at diagnosis, before surgery (Week 12), at Week 23 and a median of 20 weeks after treatment completion.

Results: Significant improvements in most domains and worsening of nausea were reported by patients and parents from diagnosis to Weeks 12 and 23. Symptom distress decreased from diagnosis to Weeks 12 and 23 in 81% and 64% of patients, respectively. There were no sex- and few age-related differences in scores. Scores from patients and parents achieved good agreement.

Conclusions: The HRQOL of patients improves during aggressive treatment for non-metastatic osteosarcoma, except in the domain of nausea. Clinicians can use these findings to prepare their patients for the distressing symptoms that they will likely experience at certain time points and to provide reassurance that these will significantly improve.

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#### Introduction 1.

Advances in sarcoma treatments have improved disease outcomes, control of treatment-related symptoms and func-

tional mobility. 1-5 The 5-year survival rate for patients with sarcoma in general has improved from 50% for the reporting period of 1975-1984 to 63% for the period of 1985-1994. The current 6-year survival rate for patients with localised osteo-

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sarcoma, the most common malignant bone tumour in children, is approximately 70%.6 These improved survival rates have facilitated the study of outcomes beyond disease response and treatment-induced toxicity to include aspects of the patient's life that have meaning to the patient, i.e. the health-related quality of life (HRQOL). Incorporating HRQOL findings into treatment is theorised to improve patient/family-physician communication and satisfaction with care, to identify hidden morbidities in the treatment of paediatric illnesses and to facilitate treatment decision making.<sup>7,8</sup> Previous HRQOL research reports have not been specific to the illness or treatment experience of paediatric patients with osteosarcoma and have not followed patients through treatment. Instead, they have focused on adults with sarcoma or survivors of childhood sarcoma at a single time point, 5,9-11 combined data from adult and paediatric patients with osteosarcoma<sup>12-16</sup> or summarised HRQOL data from patients with other types of sarcoma.<sup>2,10,17</sup> Only one report included both patients' and parents' proxy HRQOL ratings18 and only two had longitudinal assessments of HRQOL (one based on maternal reports at the time of diagnosis and after completion of therapy, 19 and the other based on patient reporting at the time of surgery and then annually for an average of 3 years<sup>20</sup>). The aims of this prospective study were to assess the effect of treatment on patients' HRQOL at the time of diagnosis, during therapy and after the completion of therapy; to assess whether differences in HRQOL ratings are associated with differences in sex and age and to compare patients' and parents' HRQOL reports.

#### 2. Methods

#### 2.1. Protocol treatment

Patients with newly diagnosed non-metastatic osteosarcoma were treated on our institution's osteosarcoma protocol (OS99) that incorporated polychemotherapy and aggressive surgery. Therapy comprised 12 intensive cycles of chemotherapy administered every 3 weeks with hematopoietic growth factor support for a total of 35 weeks. After 4 cycles of neoadjuvant chemotherapy, surgery for local control was done, mostly by a limb-sparing procedure, followed by eight additional cycles of chemotherapy.

#### 2.2. Sample

Seventy-one of the 72 (98.6%) patients enrolled on OS99 who were older than 5 years, had non-metastatic osteosarcoma, spoke English or Spanish and had parental permission to be in the study were eligible to participate in this HRQOL study. Sixty-six (93%) patients and 67 (94%) parents completed 1–3 of the HRQOL instruments at 1–4 pre-specified times of data collection. Most participants (61/66; 92%) had osteosarcoma of the lower extremity; most of these patients (50/61; 82%) had limb-sparing surgery and eight had amputation on study.

#### 2.3. Setting

The study was approved by the Institutional Review Boards of the participating institutions: St. Jude Children's Research Hospital, a paediatric comprehensive cancer centre in Memphis, TN; Luis Calvo McKenna Hospital, a national centre for paediatric bone tumours in Santiago, Chile; and Washington University in St. Louis, MO. All participants gave written informed consent or assent.

#### 2.4. Study design

We used a descriptive, longitudinal design in which patients' and parents' reports were solicited during face-to-face interviews at each of 4 time points: diagnosis (before or during cycle 1 of chemotherapy), Week 12 (before definitive surgery), Week 23 (cycle 8 of chemotherapy) and after the completion of therapy at a median of 20 weeks after the last cycle of chemotherapy. Patients 5 years of age and older and their parents completed the PedsQL Inventory v. 4.0 and the PedsQL Cancer Module v. 3.0. Patients 8 years of age or older additionally completed the Symptom Distress Scale (SDS).

#### 2.5. Instruments

Because the study aims comprised longitudinal assessments, and score comparisons made by patients' sex and age and by patients' and parents' reports, we needed to select HRQOL instruments that could capture change over time, that were available in age-specific forms and that had matching child and parent versions.

#### 2.5.1. PedsQL Inventory v. 4.0

This 23-item instrument measures the domains of physical, emotional, social and school HRQOL experienced during the past 30 days, which has age-specific forms for patients' reports (5-7 years, 8-12 years and 13 years and older) with matching parent forms. Three domains (social, emotional and cognitive) can be combined to yield a psychosocial health score. The response format for patients 5-7 years is a 3-point Likert-type scale and the format for patients 8 years of age and older is a 5-point Likert-type scale. Ratings indicate the extent of problems in each domain; ratings are reverse-coded and linearly transformed such that higher scores indicated better HRQOL.<sup>21</sup> This instrument has acceptable internal consistency, known groups and construct-validity estimates when used with paediatric samples including well, acutely and chronically ill children. 21-24 The Cronbach alpha values for patients' reports in our study at baseline ranged from 0.45 (social functioning) to 0.88 (physical functioning) and those for parents' reports ranged from 0.58 (social functioning) to 0.90 (physical functioning). Because of the unacceptably low Cronbach alpha values (<0.70) for the social functioning domain for patients' (0.45-0.68) and parents' (0.55-0.62) reports at all 4 data points, we excluded this domain from our analyses.

#### 2.5.2. PedsQL Cancer Module v. 3.0

This 27-item instrument measures the eight domains of pain and hurt, nausea, cognition, procedural anxiety, treatment anxiety, worry, perceived physical appearance and communication and has achieved satisfactory internal consistency, known groups and construct-validity estimates. <sup>25–27</sup> Item formatting and scoring were the same as those for the PedsQL

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