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Resource Utilization in Cancer Patients with Bisphosphonate-Associated Osteonecrosis of the Jaw

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Abstract

Background and objective—Bisphosphonate-associated osteonecrosis of the jaw (BONJ) is an emerging oral complication that occurs most commonly in the setting of high dose bisphosphonate therapy for cancer. The purpose of this study was to estimate the health care-related costs associated with a diagnosis of BONJ in cancer patients evaluated and managed at one tertiary oral medicine practice.

Methods—This was a retrospective electronic medical record review of cancer patients with BONJ. All health care related resources were abstracted using a structured chart abstraction tool; data captured included medications, imaging studies, laboratory investigations, procedures, and visits. Standardized references were used to assign costs in 2010 US dollars.

Results—Ninety-two cancer patients with BONJ were identified that were followed for a median of 12 months. The median cost of a case of BONJ was \$1,667 (interquartile range from \$976–\$3,350). Medication costs comprised the majority (42%) of the total costs, followed by procedural interventions (22%), clinic visits (19.5%), and imaging studies (13.8%). Patient factors associated with higher median costs included a greater number of involved oral quadrants and more advanced BONJ stage.

Conclusion—There are considerable costs associated with the diagnosis and management of BONJ in cancer patients, with medications accounting for nearly half of resource expenditures.

Keywords

Osteonecrosis; Bisphosphonates; BONJ; Cancer; Cost

Introduction

Bisphosphonate-associated osteonecrosis of the jaw (BONJ) is a well-characterized oral complication that affects approximately 5% of cancer patients who are treated with intravenous bisphosphonates(Lo et al., 2009). BONJ is characterized by exposed necrotic bone in the oral cavity that can develop spontaneously or following dental extractions or other oral surgical procedures(Ruggiero & Woo, 2008). Pain is most commonly the result of

secondary bacterial infection of the local surrounding soft tissue; however other contributing factors include bony sequestra, neuropathy, and pathologic fracture. In addition to a comprehensive clinical examination, the diagnostic work-up frequently includes jaw imaging studies to evaluate the location and extent of bony changes (Chiandussi et al., 2006, Treister et al., 2009).

Medical management of BONJ includes treatment and prevention of infections and symptom management (Ruggiero et al., 2009). Treatment is typically initiated with conservative modalities including the removal of bony sequestrum, debridement, smoothing rough or sharp areas of bone, and medical management of infections and neuropathic symptoms with appropriate pharmacologic agents (Ruggiero et al., 2006, Alons et al., 2009, Thumbigere-Math et al., 2009, Wongchuensoontorn et al., 2009, Williamson, 2010). In cases where teeth become symptomatic or progressively mobile within the field of osteonecrosis, dental extractions may be necessary (Edwards et al., 2008, Khan et al., 2008, Ruggiero & Woo, 2008). In more advanced cases otherwise refractory to conservative measures, and in cases of pathologic fracture, surgical intervention is generally indicated (Ruggiero et al., 2009).

BONJ may become a source of chronic pain, infection, reduced function, and overall increased morbidity (Bamias et al., 2005, Migliorati et al., 2006, Miksad et al., 2011). While a number of reports have characterized BONJ clinically and epidemiologically and provided important information on diagnostic features and treatment outcomes, to date there is a lack of data describing the costs associated with the management of BONJ. The objective of this study was to systematically analyze the health care-related costs associated with BONJ.

Methods

Study Design and Cohort

A retrospective electronic medical record review was conducted of cancer patients with BONJ that were evaluated and managed at the Division of Oral Medicine and Dentistry, Brigham and Women's Hospital, Boston, MA. All patients were clinically evaluated by an expert group of oral medicine specialists. Clinical diagnosis and staging (0–3) was determined according to the guidelines published by the American Association of Oral and Maxillofacial Surgeons (AAOMS) (Ruggiero et al., 2009).

The analysis was limited to cancer patients with BONJ secondary to intravenous aminobisphosphonate therapy who were evaluated and managed from 2002–2010 and had at least one follow-up visit. This study was approved by the Dana-Farber/Harvard Cancer Center's Office for Human Research Subjects.

Categories of Treatments

Management and follow-up were driven largely by signs and symptoms of BONJ. Interventions included 0.12 % chlorhexidine oral rinse, and/or long-term or intermittent antibiotics and local bone debridement, sequestrectomy and surgery.

Pharmacologic management—Secondary infection was managed with topical antimicrobial rinses and systemic antibiotics, sometimes on an extended basis in cases of recurrent infection. Neuropathic complications, including neuralgias and dysesthesias, were managed with appropriate medications (e.g. anticonvulsants).

Non-surgical sequestrectomy—Sharp edges of bone and mobile fragments of bone were removed, typically without the need for local anesthetic.

Debridement—Cases with refractory infection or persistent pain were managed with localized debridement of the necrotic bone under local anesthesia.

Surgery—Cases that were refractory to the interventions above were managed with segmental resection, with or without titanium plating.

Others—Acrylic protective stents were fabricated in cases when patients continued to have intense focal pain with functional contact of the area of BONJ with food and liquids, despite standard interventions and control of secondary infection.

Medical Record Review

Dental, medical and pharmacy utilization data were abstracted from the patients' electronic medical records. Clinical and demographic information, BONJ features (e.g. staging, number and location of lesions); diagnostic tests/imaging studies, medications prescribed, clinical visits, and type and number of procedures/interventions were collected using a standardized collection form. Data collection was limited to care provided at Brigham and Women's Hospital and there was no attempt to determine if additional BONJ-associated treatment was rendered by providers outside of the hospital..

Medication utilization, including, dose, frequency and duration, was determined based on the written prescriptions. For patients who did not return for further follow-up, the end date was calculated as the middle of the month following the final visit. When medications were prescribed for management of side effects, such as fluconazole for vaginal/oral candidiasis secondary to antibiotics, these prescriptions were also included. Other adjunctive therapies, such as localized corticosteroid therapy (topical and intralesional) for management of traumatic tongue ulcerations and analgesics prescribed for BONJ-related pain, were also included.

Health Care Resource Utilization

Direct medical costs attributed to BONJ included office visit fees, co-pays, laboratory tests, radiologic procedures, surgical procedures, prescriptions, and other treatment-related expenditures (e.g. oral appliances, intralesional steroid injections). When relevant, procedure and professional fees were included. Unit costs were assigned to each health care resource using standard cost references(2008). All costs were estimated in 2010 US dollars (Appendices 1–4). Based on these unit costs the total cost of BONJ care was calculated for each subject.

Statistical Analyses

Descriptive statistics were performed to characterize the cohort demographics, comorbid conditions, and BONJ clinical features. Median costs and interquartile ranges were calculated for the total cohort and relevant subgroups (e.g. medical diagnosis, BONJ stage/severity, clinical outcomes).

RESULTS

Ninety-two cancer patients diagnosed with BONJ with a median follow-up of 12 months met the eligibility criteria and were included in this study (Table 1). At initial visit the median age was 61 and the majority of patients were white, with an equal gender distribution. The most frequent underlying cancer diagnoses were multiple myeloma (65.2%) and breast cancer (19.6%). The median duration of bisphosphonate therapy was 36 months, with the majority (82.6%) treated with zoledronic acid alone or following pamidronate therapy. Nearly Half of the patients presented with Stage 2 BONJ at the initial

visit, with the next most frequent being Stage 1 (40.2%); Stage 0 (8.7%) and Stage 3 (2.2%) disease was infrequent. The majority (72.8%) presented with a single quadrant of involvement. Overall clinical outcomes at the end of the study period were improved (from Stage 3 to Stage 2 or less, or from Stage 2 to Stage 1 or less) and/or healed in 76% of patients, with 3.3% demonstrating progressive/worsening BONJ.

The overall median treatment cost was \$1,667 (interquartile range from \$976–\$3,350; Figure 1). Treatment costs were less than or equal to \$2,000 in more than 60% of patients, and 25% had associated costs between \$2–4,000, while in the remaining 15% of patients there was a gradual increase in costs to a maximum of \$25,097. One patient had costs of \$21,546 due to prolonged usage of medication and an extended follow-up period (64 months). The maximum cost of \$25,097 occurred in a patient that developed a pathological fracture of the mandible and required surgical resection and reconstruction, with \$20,714 in total associated surgical costs. The median cost of treatment increased with more advanced baseline BONJ stage, ranging from \$1,053 in patients with Stage 0 disease to \$4,031 in patients with Stage 3 disease, with a median of \$1,675 difference by stage (Table 2). The number of involved quadrants did not affect cost. There was no association between clinical outcome and overall cost, with a total median cost of \$1,751 for improved/healed cases and \$1,733 for progressive cases.

The two most costly aspects of BONJ management in the vast majority of cases were medications (35%) and clinic visits (31%; Figure 2). With respect to medications, prescriptions for amoxicillin/clavulanate potassium accounted for approximately two-thirds of all medication-associated costs. Procedure-based interventions accounted for 16% of total median costs with nearly 40% of these costs attributed to non-surgical sequestrectomy and debridement (Table 3). Imaging studies accounted for 18% of total median costs, with intraoral and panoramic radiographs being the most frequently ordered imaging studies (88.4%) that accounted for approximately 60% of all imaging-associated costs (Table 4). Microbiological and histopathological investigations each accounted for no more than 1% of total median costs.

DISCUSSION

We systematically analyzed the health care-related costs associated with BONJ in cancer patients managed at a single academic oral medicine practice. The primary driving factors that affect the cost of BONJ treatment were long term medication use and follow-up visits. Approximately two thirds of the medication costs were due to the prescription of amoxicillin/clavulanate potassium. Since medications consumed almost half of the necessary resources for treating BONJ and amoxicillin/clavulanate was a large portion of these costs, alternative and less expensive antibiotics such as penicillin, amoxicillin or clindamycin should be considered (Marx et al., 2005, Bagan et al., 2006, Lam et al., 2007, Weitzman et al., 2007, Tubiana-Hulin et al., 2009). Penicillin may also be used as a first-line antibiotic therapy and appears to have similar efficacy as amoxicillin/clavulanate in controlling BONJ-associated infection.

The main limitation of this analysis was that visits outside of our hospital were not taken into consideration so that there is likely an under-estimation of the costs for some patients. Furthermore, since this study was conducted at one academic medical center, our results may not be generalizable to other centers. For example, antibiotic prescribing patterns and surgical treatment planning could differ significantly and this could have a profound effect on costs. Furthermore, all cost estimates were based on Medicare allowed reimbursement levels and did not take into account actual individual insurance plans. Collectively, these factors may have resulted in both under- and over-estimation of costs.

This study has several strengths. We had a large cohort with BONJ who presented with a range of severity and extent of disease. All patients were managed in a fairly uniform manner by a small group of experienced oral medicine clinicians. Furthermore, follow up of patients was performed within a single center, and all clinical data was abstracted from a single longitudinal electronic medical record system.

This is the first report characterizing costs associated with the management of BONJ in cancer patients. We found that as BONJ progresses according to stage, the median cost of treatment increases, and the primary drivers of costs are medications and clinic visits. Based on these findings, strategies to reduce costs associated with BONJ might be directed at prevention, use of cost-effective medical therapies, and when feasible limiting the number of clinical visits. Multicenter analyses should be conducted to account for any center-specific management biases, and prospective studies evaluating various therapies for BONJ should be assessed for relative cost effectiveness.

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Abbreviations and acronyms

AAOMS	American Association of Oral and Maxillofacial Surgeons
ONJ	osteonecrosis of the jaw
BONJ	bisphosphonate associated osteonecrosis of the jaw

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Figure 1.
The distribution of individual treatment costs. Q1 = 25th percentile cost. Q3 = 75th percentile cost. Costs exceeded \$20,000 in two patients.

Figure 2. Median cost per patient based on category of cost. Histopathological and microbiological investigations accounted for less than 1% of median per patient costs and are not included.

Table 1

Patient demographics.

Characteristics	N (%)	
Gender		
Male	49 (53.2)	
Female	43 (46.8)	
Race/ethnicity		
White	89 (96.7)	
Black	2 (2.2)	
Asian	1 (1.1)	
Median age at initial visit (years, range)	61.4 (38.0–80.5)	
Cancerdiagnosis		
Multiple myeloma	60 (65.2)	
Breast cancer	18 (19.6)	
Prostate cancer	4 (4.3)	
Lung cancer	3 (3.3)	
Others	7 (7.6)	
Bisphosphonate		
Pamidronate	11 (12.0)	
Zoledronic acid	47 (51.1)	
Pamidronate and zoledronic acid	29 (31.5)	
Not available	5 (5.4)	
Median duration of bisphosphonate therapy (months, range)	36 (5.0–156)	
Median duration of follow-up (months, range)	12 (0.2–64.0)	
Quadrants involved		
1 quadrant	67 (72.8)	
2 quadrants	20 (21.7)	
3 quadrants	3 (3.3)	
4 quadrants	2 (2.2)	
BONJ Stage	Initial Visit	Highest Stage
Stage 0	8 (8.7)	2(2.2)
Stage 1	37 (40.2)	32 (34.8)
Stage 2	45 (48.9)	53 (57.6)
Stage 3	2 (2.2)	5 (5.4)
Clinical outcome		
Improved/healed	70 (76.0)	
Stable	19 (20.7)	
Progressive	3(3.3)	

Table 2

Cost of care associated with various clinical features.

Classification Categories	No. of patients	Median	25 th percentile	75 th percentile
		<i>US dollars</i>		
All Patients	92	\$1,667	\$976	\$3,350
Multiple myeloma	60	\$1,248	\$871	\$3,004
Breast cancer	18	\$2,007	\$1,312	\$3,459
Prostate cancer	4	\$3,314	\$2,068	\$5,877
Lungcancer	3	\$1,601	\$1,219	\$3,154
Others	7	\$2,408	\$1,525	\$3,119
BONJ Stage				
Stage 0	8	\$1,053	\$741	\$1,772
Stage 1	37	\$1,161	\$948	\$2,832
Stage 2	45	\$2,188	\$1,083	\$3,688
Stage 3	2	\$4,031	\$2,963	\$5,100
Quadrants involved				
One	67	\$1,491	\$869	\$2,361
Two	20	\$3,493	\$1,272	\$4,428
Three	3	\$2,871	\$1,928	\$5,999
Four	2	\$3,323	\$3,231	\$3,416
Clinical Outcome				
Healed/Improved	70	\$1,751	\$958	\$3,610
Stable	19	\$1,194	\$1000	\$2,479
Progressive	3	\$1,733	\$1,241	\$2,018

Table 3

Interventions for management of BONJ and associated costs.

Intervention	Cost	Percentage of intervention costs
Sequestrectomy/debridement	\$22,419.54	40.86%
Surgical resection and reconstruction	\$20,714.00	37.75%
Dental extractions	\$5,280.00	9.62%
Root canal treatment (one root)	\$2,652.00	4.83%
Appliances	\$2,592.00	4.72%
Soft tissue excision (biopsy)	\$649.65	1.20%
Steroid injections	\$318.15	0.58%
Simple incision and drainage	\$240.48	0.44%

Table 4

Costs associated with utilization of imaging studies in the BONJ patient cohort.

Type of imaging tests	No. of imaging tests	Cost	Percentage of imaging costs
Panoramic radiograph	137	\$15,939.95	45%
Periapical radiograph	305	\$5,197.20	15%
CT scan (no contrast then contrast)	11	\$5,120.83	15%
CT scan (no contrast)	16	\$4,817.28	14%
Full mouth series	12	\$1,452.00	4%
CBCT	4	\$1,000.00	3%
MRI	1	\$627.37	2%
Bite wing radiographs	8	\$361.60	1%
Occlusal radiograph	6	\$318.00	1%

CBCT = cone beam computed tomography. CT = computed tomography. MRI = magnetic resonance imaging.

Appendix 1

Categories of costs.

CLINICAL VISITS	Initial visit Follow-up visits
DIAGNOSTIC STUDIES	Periapical radiograph Panoramic radiograph Occlusal radiograph Bite-wing radiograph Full mouth series of intraoral radiographs Cone beam CT (maxillofacial) CT scan, maxillofacial (without contrast) CT scan, maxillofacial (with and without contrast) MRI, maxillofacial
PROCEDURES	Sequestrectomy/debridement Surgical resection and reconstruction Dental extractions Simple incision and drainage Soft tissue excision (biopsy) Steroid injections Root canal treatment Appliances
MEDICATIONS	Antimicrobial rinses Antibiotics Analgesics Anticonvulsants
LABORATORY STUDIES	Culture bacteria any source Culture bacteria any source aerobic Culture bacteria anaerobic isolate Susceptibility studies Histopathology

Appendix 2

Procedure costs.

CPT Code	Description	Cost (\$)
70300	Periapical radiograph	17.04
D0330	Panoramic radiograph	116.35
00240	Occlusal radiograph	53.00
70310	Bite wing radiograph	45.20
00210	Full mouth series of intraoral radiographs	121.00
	Cone beam CT (maxillofacial)	250.00
70486	CT scan, maxillofacial (without contrast)	301.08
70488	CT scan, maxillofacial (with and without contrast)	465.53
70542	MRI, maxillofacial	627.37
87075	Bacterial culture any source	95.00
87070	Bacterial culture any source aerobic	86.00
87076	Bacterial culture anaerobic isolate	58.00
87181	Susceptibility studies	47.00
88305	Histopathology	125.39
11044	Sequestrectomy/ debridement	226.46
21470	Open treatment of complicated mandibular fracture	1281.34
21047-22	Excision of benign tumor requiring extraoral osteotomy and partial mandibulectomy	1377.14
21014	Soft tissue excision 2.0 cm	1377.14
15732	Muscle, myocutaneous, or fasciocutaneous flap; head and neck	1218.89
D7140	Dental extractions	165.00
40800	Simple incision and drainage	240.48
40808	Soft tissue excision (biopsy)	216.55
D5982	Appliances: Splint or Surgical stent	648.00
D3310	Root canal treatment (one root)	1326.00
11900	Steroid injections	63.63

Appendix 3

Visit costs.

Code	Description	Cost (\$)
99244	Initial visit	193.01
99214	Follow up visits	81.17

Appendix 4

Medication costs.

Medication	Dose	Cost (\$)
Chlorhexidine gluconate	0.12% (480 ml)	5.23
Nystatin elixir	100,000 u/ml (60 ml)	12.37
Amoxicillin	500 mg	0.12
Cephalexin	500 mg	0.27
Azithromycin	250 mg	3.19
Clindamycin hydrochloride	150 mg	0.22
Clindamycin hydrochloride	300 mg	1.2
Amoxicillin/clavulanate potassium	875 mg	5.06
Amoxicillin/clavulanate potassium	500 mg	3.62
Amoxicillin/clavulanate potassium	250 mg	4.53
Penicillin v potassium	250 mg	0.21
Penicillin v potassium	500 mg	0.36
Ciprofloxacin hydrochloride	250 mg	0.38
Ciprofloxacin hydrochloride	500 mg	0.45
Levofloxacin	250 mg	11.33
Levofloxacin	500 mg	11.7
Moxifloxacin hydrochloride	400 mg	13.92
Clarithromycin	500 mg	0.86
Metronidazole	500 mg	0.22
Gabapentin	100 mg	0.08
Gabapentin	300 mg	0.12
Gabapentin	400 mg	0.15
Gabapentin	600 mg	0.97
Gabapentin	800 mg	1.18
Carbamazepine	100 mg	0.20
Carbamazepine	200 mg	0.08
Clonazepam	0.5 mg	0.06
Acetaminophen	500 mg	0.04
Oxycodone hydrochloride	5 mg	0.24
Acetaminophen/hydrocodone bitartrate	500-5 mg	0.34
Ibuprofen	800 mg	0.06
Hydromorphone hydrochloride	4 mg	0.39
Fluconazole	100 mg	0.88
Oxcarbazepine	300 mg	1.71
Capsaicin	0.025% (60 g)	12.44
Clobetasol gel	0.05% (60 g)	27.84
Lidocaine hydrochloride	2% (100 ml)	5.13