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ORIGINAL ARTICLE

Ten-year experience of the multidisciplinary Osteoncology Center

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Abstract

Purpose Bone metastases (BMs) are responsible for high morbidity in patients. A multidisciplinary approach involving a team of specialists offers an effective therapeutic strategy based on disease characteristics, medical history, and performance status. We evaluated the impact of our 10-year multidisciplinary experience on the management of patients with BM.

Methods We retrospectively analyzed 2194 medical reports of 1628 patients referred to our Osteoncology Center from 2005 to 2015. Cases were discussed weekly by a multidisciplinary team.

Results Eight hundred thirty-eight (38.2%) of the 2194 visits were requested because of a risk of complications from BM. Antiblastic treatment and bone-targeted therapy were modified in 709 (66.3%) and 309 (31%) of cases, respectively. Radiotherapy was scheduled in 220 (20%) of the 1099 patients for whom information was recorded. Patients completed the Brief Pain Inventory (BPI) during their first visit, 1296 (59.1%) reporting pain (median intensity 4), and 537 (41.4%) experiencing a level that interfered substantially with daily activities. New ortheses and/or antalgic therapy was prescribed accordingly. After 7 days, 208 (16%) patients were re-evaluated and a new BPI administered. A significant improvement in the *worst* ($p < 0.0001$) and *current* pain ($p = 0.03$) was seen, together with a favorable impact on daily activities ($p = 0.02$). Two thousand fifty-one patients completed an anonymous questionnaire on the quality of the service, the majority (69.4%) expressing high satisfaction.

Conclusions Our 10-year osteoncology experience confirms the importance of a multidisciplinary approach to optimize BM management. Further evaluations are needed in relation to quality of life, outcome, and costs.

Keywords Osteoncology · Bone metastases · Multidisciplinary team · Skeletal-related events · Quality of life

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Introduction

The survival of cancer patients has improved dramatically in recent years because of advances made in diagnosis and treatment [1]. Bone is the third most common site of metastasis after the liver and lung. In the USA, about two thirds of patients who die from cancer each year have evidence of bone disease [2, 3]. In addition to pain, reported in 75% of patients, other complications known as skeletal-related events (SREs) can occur, including pathological fractures, spinal cord compression, radiotherapy, surgery to bone, or hypercalcemia [4]. SREs are a further burden on healthcare resources and negatively influence prognosis and quality of life [5].

Bone metastases (BMs) frequently involve the axial skeleton and often lead to SREs that favor the development of lung infections, skin ulcers, and deep vein thromboses, depending on the site and type of lesion (lytic metastases have a higher risk of SREs) and on the preventive treatment administered [6–9].

Given the heterogeneity of the disease, a multidisciplinary approach involving a team of specialists in the areas of oncology, palliative care, radiotherapy, orthopedics, nuclear medicine, radiology, and physiatrics is essential for the effective management of patients with bone cancer, including primary tumors and metastases [10]. Current options are still fragmentary and unsatisfactory and patients are often obliged to see a series of specialists, increasing psychophysical distress and resulting in poor continuity of healthcare. Since 2005, the Osteoncology Center of Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) IRCCS in Meldola has used an organizational approach involving a dedicated team of specialists to offer diagnostic and treatment options aimed at reducing morbidity, hospitalization rates, and overall costs associated with bone disease [11]. The Osteoncology Center also carries out preclinical, clinical, and translational research into bone disease. Specialist training is given to medical professionals, including general practitioners (GPs), psycho-oncologists, and healthcare workers. Interdisciplinary meetings are organized regularly and numerous collaborations have been established with other national and international healthcare institutes working in the area of bone disease. The first BM database was created in 2014 and is the basis for an Italian multicenter prospective observational study using web-based software supported by an open-source package system in which demographic, clinical, and pathological information are recorded and updated every 6 months by the participating centers [12].

The aim of the present study was to describe the activity of our Osteoncology Center and to analyze the impact of the multidisciplinary approach on the management of patients with BM.

Patients and methods

The multidisciplinary osteoncology team (MDOT) meets once a week to carry out clinical and radiological evaluations of patients and to establish treatment plans for those with BM or primary bone tumors (PS ECOG ≤ 2). As our institute is a tertiary referral center, requests for second opinions are very common. Patients are usually referred to us by specialists from our own institute or from other Italian hospitals, or by GPs. A dedicated osteoncology nurse calls the patient and organizes the appointment, which is divided into 3 phases:

- When the patient arrives, the nurse explains what to expect during the appointment and asks the patient to complete a Brief Pain Inventory (BPI) questionnaire [13]. Demographic data and information on tumor site, histological type, disease extension, radiological stage, and previous treatments are inserted into a centralized database and updated after each appointment by the oncologist.
- The patient is seen by the MDOT which comprises an oncologist (coordinator), palliative care specialist, radiotherapist, orthopedist, nuclear medicine specialist, radiologist, physiatrist, and oncology nurse. All take part in the decision process. At the end of the visit, the patient receives a detailed report with the MDOT's recommendations and indications.
- The patient is asked to complete an anonymous questionnaire on the quality of the service provided. The questionnaire was created ad hoc for the study and comprises 4 satisfaction-related questions (Fig. 1).

BPI

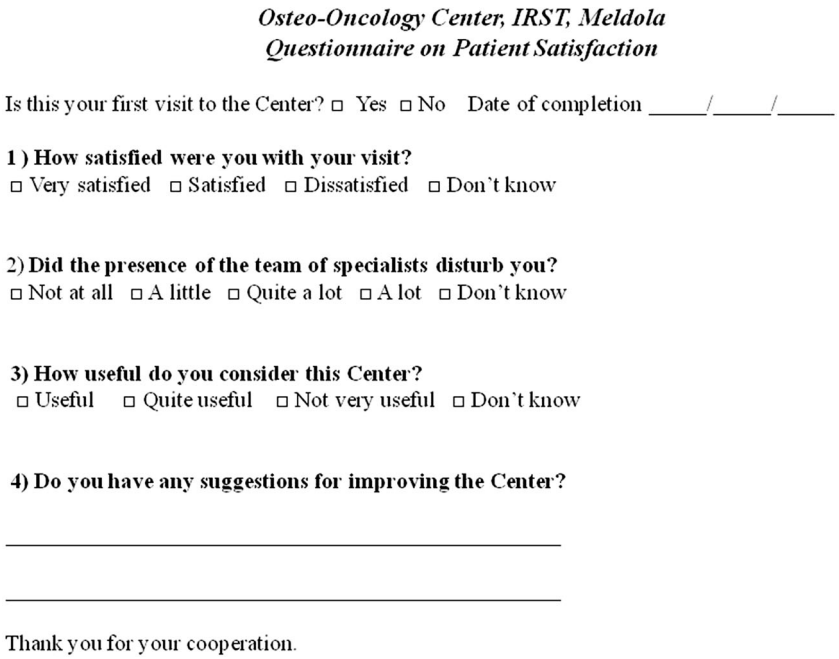
The BPI, a validated multidimensional pain assessment tool providing valuable information on pain severity and the degree to which it interferes with daily activities, enables healthcare professionals to plan appropriate treatments, including interventional therapies [14]. Patients complete the BPI before each multidisciplinary visit. As pain intensity may vary, they are asked to rate the "worst," "least," "average," and "current" levels of pain. Item scores range from 0 (no pain) to 10 (pain as bad as you can imagine). The question on how pain interferes with daily activities is rated from 0 (does not interfere) to 10 (completely interferes). Pain drawing diagrams (painful and most painful areas) help to pinpoint the site of the pain, and a percentage-based scale item on pain relief treatment evaluates the efficacy of the analgesic therapy currently being used.

MDOT visit

The MDOT specialists are involved in the patient's individually tailored diagnostic-therapeutic programs as follows:

1. Radiology and nuclear medicine. Instrumental tests and radiological and nuclear medicine interventions requested by the MDOT are carried out within 10–15 days. Urgent cases are evaluated immediately by the radiologist.
2. Orthopedic surgery and rehabilitation: once assessed by the team, patients enter a facilitated orthopedic and rehabilitation program. If necessary, bone biopsies are performed.
3. Oral surgery and preventive dentistry: patients follow a prevention program, as specified in the osteoncology protocol. All dental problems are dealt within 2 weeks.
4. Oncologist and radiotherapist: the need for systemic and locoregional treatment is evaluated on the basis of the primary tumor and metastatic disease. Priority is given to urgent cases requiring locoregional interventions (i.e., embolization, radiotherapy due to spinal cord compression).

Fig. 1 Anonymous questionnaire on patient satisfaction



Osteo-Oncology Center, IRST, Meldola
Questionnaire on Patient Satisfaction

Is this your first visit to the Center? □ Yes □ No Date of completion _____/_____/_____

1) How satisfied were you with your visit?
□ Very satisfied □ Satisfied □ Dissatisfied □ Don't know

2) Did the presence of the team of specialists disturb you?
□ Not at all □ A little □ Quite a lot □ A lot □ Don't know

3) How useful do you consider this Center?
□ Useful □ Quite useful □ Not very useful □ Don't know

4) Do you have any suggestions for improving the Center?

_____

_____

Thank you for your cooperation.

5. All specialists: patients are enrolled in clinical and translational studies focusing on metastatic bone disease. Patients receiving bone-targeted treatment are also closely monitored for side effects, especially with regard to the potential development of osteonecrosis of the jaw.

Two types of patients are referred for a MDOT visit, i.e., patients with an initial diagnosis of bone lesions and those with previously diagnosed BM. The latter group is further divided into patients at BM first occurrence and those at risk of complications who are selected on the basis of eligibility criteria such as performance status (PS), pain and risk of pathological fracture, or spinal cord compression. PS is evaluated according to the Eastern Cooperative Oncology Group (ECOG) scale. These 2 subgroups are considered eligible when patients have pain of unknown etiopathogenesis or are resistant to conventional treatment (strong opioids or adjuvant drugs), indicating the need for a specialist approach, e.g., opioid rotation or field-specific palliative procedures (orthopedic, physiatric, radiometabolic, radiotherapeutic, and/or invasive antalgic).

The aim of the MDOT visit is to identify lesions at high risk of fracture [15–18] on the basis of the site of metastasis (femur, humerus and cervical, dorsal, and lumbar spine), extension of disease (lesions that exceed half of the bone diameter), and cortical interruption. The risk of spinal cord compression [15–19] is determined by clinical evaluation of the neurological deficit (sensory, motor, and/or autonomic nervous system) and of secondary alterations of the architecture of the spine (kyphosis, lordosis, and scoliosis). Radiological evidence of an initial invasion of the spinal cord canal and/or of conjugate foramen is also assessed.

Statistical considerations

Data on patient characteristics are expressed as median (min, max) values for continuous variables and percentages (%) for categorical variables. The non-parametric McNemar test was used to assess whether a significant change in pain score reported as mild, average, or severe in the first questionnaire had occurred after 7 days in the same population. p values obtained were corrected for multiple comparisons using the false discovery rate method of Benjamini-Hochberg, with $p < 0.05$ considered statistically significant. All statistical analyses were performed using Stata 14.1 for Windows (StataCorp LP, College Station, TX) and R Software (version 3.2.2).

Results

During the 10-year period of the Osteoncology Center's activity (January 2005 to December 2015), 2194 multidisciplinary team visits took place. A total of 1628 patients (724 males, 1470 females) were seen, 85 (3.9%) of whom were found not to have neoplastic disease. Patient characteristics are reported in Table 1. Breast (39.7%) and lung (11.2%) were the most frequent primary tumor sites, followed by the prostate (6.5%). Three hundred seventy-nine (17.3%) patients had more than one primary cancer. Of the 2194 multidisciplinary visits carried out, 39.7% were for patients at risk of complications from BM, 7.1% for those at first diagnosis of BM with no risk of complications, and 21.0% for patients with suspected BMs. 32.1% of visits involved patients who did not fulfill any of the above criteria. This information was missing for 120 patients.

Table 1 Patient characteristics

	No. of cases (2194)	%
Median age, years (range)	63 (14–92)	
Gender		
Female	1470	67.0
Male	724	33.0
Period		
2005–2008	584	26.6
2009–2012	755	34.4
2013–2015	855	39.0
Site of disease		
Breast	871	39.7
Lung, pleura, mesothelium	246	11.2
Prostate	142	6.5
Gastrointestinal tract	133	6.1
Genitourinary system	119	5.4
Hematological tumors	68	3.1
Head and neck	37	1.7
Neuroendocrine neoplasia	16	0.7
Bone (sarcoma and osteosarcoma)	29	1.3
Multiple sites	379	17.3
Other	20	0.9
Unknown primary site	49	2.2
Non cancer patients	85	3.9
Brief Pain Inventory questionnaire		
First	1628	74.2
Additional	566	25.8
Pain in the last week		
Yes	1312	59.8
No	882	40.2
Most painful areas		
Trunk	916	71.8
Arms	108	8.5
Trunk + arms	252	19.7

MDOT interventions are summarized in Table 2. Following MDOT evaluation, specific antiblastic and bone-targeted therapy was changed in 709 (66.3%) and 580 (68.5%) patients, respectively, with no need for additional diagnostic investigations. Radiotherapy was indicated in 220 (20%) out of 1099 patients for the following reasons: pain in 76 (33.6%), spinal cord compression in 31 (14.1%), pathological fracture in 62 (28.1%), and post-surgery in 4 (0.2%). This information was missing in 49 (22.3%) patients. Orthotics were prescribed in 197 (18.4%) patients to prevent pathological fractures and devices were changed in 308 (28.9%). A limited number (32.3%) of surgical interventions were performed. BM embolization was indicated in 93 (8.7%) patients.One thousand three hundred twelve (59.8%) patients reported experiencing pain (median intensity, 4) in the week prior to their visit. The main areas of pain were trunk (71%), limbs (16%), and both (19.7%). Somatic nociceptive pain was prevalent, followed by mixed pain, whereas pure neuropathic

Table 2 Multidisciplinary team intervention in patients with bone metastases referred to our Osteoncology Center

Type of intervention	No. (%)
Change in antiblastic therapy	
Yes	709 (66.3)
No	361 (33.7)
Change in bone-targeted therapy	
Yes	580 (68.5)
No	266 (31.4)
Change in antalgic therapy	
Yes	438 (58.7)
No	308 (41.3)
New antalgic therapy	
Yes	230 (37.0)
No	391 (63.0)
Radiotherapy	
Yes	220 (20.0)
No	879 (80.0)
Site of radiotherapy	
Spine	142 (61.4)
Trunk	17 (7.5)
Limbs + pelvis	72 (31.1)
Total	231
Indication for radiotherapy	
Cord compression	31 (17.2)
Pain	74 (41.1)
Pathological fracture	62 (20.0)
Post-surgery	4 (2.2)
Rehabilitation program	
Yes	33 (3.0)
No	1033 (97.0)
Orthesis	
Yes	197 (28.3)
No	499 (71.7)
Change in previous orthesis	
Yes	482 (61.0)
No	308 (39.0)
Orthopedic Surgery	
Yes	32 (3.0)
No	1034 (97.0)
Radiological intervention	
Yes	93 (8.7)
No	973 (91.3)
Radiometabolic treatment	
Yes	23 (2.1)
No	993 (93.2)

Table 3 Brief Pain Inventory: pain intensity and interference with daily activities for 1296 patients with questionnaire completed

	No. of patients (%)		
	Pain intensity		
	Mild (0–4)	Moderate (5–6)	Severe (7–10)
Worst pain ($n = 1296$)	304 (23.5)	316 (24.4)	676 (52.2)
Least pain ($n = 1292$)	1157 (89.6)	89 (6.9)	46 (3.6)
Average pain ($n = 1283$)	788 (61.4)	324 (25.3)	171 (13.3)
Median of worst pain within average pain category (interquartile range) ($n = 1282$)	5 (4–7)	8 (7–9)	9 (8–10)
Current pain ($n = 1278$)	950 (74.3)	172 (13.5)	156 (12.2)
Median relief (%) within average pain category (interquartile range) ($n = 975$)	80.0 (70.0–90.0)	80.0 (60.0–90.0)	70.0 (50.0–80.0)
Interference with general activity ($n = 1254$)	494 (39.4)	223 (17.8)	537 (42.8)
Interference with mood ($n = 1255$)	747 (59.5)	166 (13.2)	342 (27.3)
Interference with walking ability ($n = 1259$)	674 (53.5)	190 (15.1)	395 (31.4)
Interference with normal work ($n = 1246$)	521 (41.8)	221 (17.7)	504 (40.4)
Interference with relations with other people ($n = 1238$)	978 (79.0)	109 (8.8)	151 (12.2)
Interference with sleep ($n = 1256$)	933 (74.3)	116 (9.2)	207 (16.5)
Interference with enjoyment of life (1187)	753 (63.4)	148 (12.5)	286 (24.1)

pain was rare. One thousand two hundred ninety-six (98.7%) patients completed the BPI (Table 3). A score 0–4 was indicative of mild pain, 5–6 moderate pain, and 7–10 severe pain. Severe pain was present in 52.5% of patients as maximum intensity and in 3.6% as minimum intensity. The majority reported their average pain intensity as mild. Pain-related interference in everyday life involved mainly general and physical activities, but also relational skills (Table 3).

Of the 1312 patients who reported pain at their first visit, 207 (15.8%) were clinically evaluated after 7 days and a new BPI administered. A comparison of the 2 questionnaires showed that patients experienced an improvement in the worst pain, with 13 (27.1%) reporting a reduction in pain from moderate to mild, 27 (21.6%) from severe to mild, and 27 (21.6%) from severe to moderate after 1 week, resulting in a favorable impact on general activity. No differences were seen in the least and average pain scores. Relational skills and enjoyment of life worsened (Table 4). Data on current pain and interference with general activity were also significant using the Benjamini-Hochberg correction for multiple testing (a corrected p value of 0.013 was considered). No differences were seen in relation to age using 65 years as cut-off (data not shown).

The results of the analysis of 2051 anonymous questionnaires on patient satisfaction are shown in Table 5. Seventy percent of patients were very satisfied with their visit, 28% were satisfied, 1% did not answer, and only 1% expressed dissatisfaction but did not provide feedback in a comment box provided. The majority (70%) were not disturbed by the presence of the team of specialists, 6.2% felt fairly uneasy, and 3.5% felt very uncomfortable. 56.1% of patients considered the Center as very useful, 34.7% as useful, and 8.6% as quite useful. Only a very small number (0.1%) did not acknowledge its usefulness (0.1%). No further information was obtainable due to the anonymous nature of the questionnaires.

Discussion

A multidisciplinary team approach is now advocated as the standard of care in modern oncology, even though a direct benefit in terms of improved patient outcome has only been demonstrated in a few studies to date [20]. Some authors have reported that multidisciplinary discussion leads to substantial improvements in interdisciplinary therapy and adherence to guidelines [21].

BMs represent an important clinical-epidemiological issue in oncology. Patients are usually referred to single specialists and the fragmentary information obtained on the disease is often reflected in the diagnostic-therapeutic strategies used. A multidisciplinary team for the management of BM has been operating in the Osteoncology Center of our institute for the last 10 years, during which time 1628 patients have been referred to our Center and a total of 2194 multidisciplinary visits carried out. There is evidence that multidisciplinary healthcare has the potential to significantly increase survival in cancer patients, but no data are available as yet on patients with BM [21, 22]. A study performed by Chang et al. reported that the initial treatment recommendations for a group of women with breast cancer were changed in 43% of cases following the second opinion of a multidisciplinary panel [23]. In our study, specific antiblastic and bone-targeted

Table 4 Change in pain 7 days after MDOT visit

	First evaluation (*n*)	No. of patients after 7 days (%)			*p* value
		Mild	Moderate	Severe	
Worst pain (*n* = 207)	Mild (34)	19 (55.9)	12 (35.3)	3 (8.8)	< 0.0001
	Moderate (48)	13 (27.1)	20 (41.7)	15 (31.2)	
	Severe (125)	27 (21.6)	27 (21.6)	71 (56.8)	
Least pain (*n* = 206)	Mild (177)	147 (83.1)	22 (12.4)	8 (4.5)	0.2027
	Moderate (23)	15 (65.2)	5 (21.7)	3 (13.1)	
	Severe (6)	6 (100.0)	0 (0.0)	0 (0.0)	
Average pain (*n* = 201)	Mild (104)	70 (67.3)	26 (25.0)	8 (7.7)	0.9818
	Moderate (63)	25 (39.7)	26 (41.3)	12 (19.0)	
	Severe (34)	8 (23.5)	14 (41.2)	12 (35.3)	
Current pain (*n* = 198)	Mild (127)	91 (71.6)	19 (15.0)	17 (13.4)	0.0323
	Moderate (44)	14 (31.8)	15 (34.1)	15 (34.1)	
	Severe (27)	7 (25.9)	6 (22.2)	14 (51.9)	
Interference with general activity (*n* = 193)	Mild (62)	43 (69.4)	11 (17.7)	8 (12.9)	0.0254
	Moderate (44)	20 (45.5)	11 (25.0)	13 (29.5)	
	Severe (87)	22 (25.3)	11 (12.6)	54 (62.1)	
Interference with mood (*n* = 197)	Mild (89)	57 (64.0)	18 (20.2)	14 (15.8)	0.4617
	Moderate (34)	10 (29.4)	6 (17.6)	18 (53.0)	
	Severe (74)	17 (23.0)	18 (24.3)	39 (52.7)	
Interference with walking ability (*n* = 199)	Mild (85)	58 (68.2)	11 (13.0)	16 (18.8)	0.2587
	Moderate (34)	16 (47.0)	9 (26.5)	9 (26.5)	
	Severe (80)	24 (30.0)	15 (18.8)	41 (51.2)	
Interference with normal work (*n* = 189)	Mild (69)	43 (62.3)	14 (20.3)	12 (17.4)	0.1297
	Moderate (42)	16 (38.1)	10 (23.8)	16 (38.1)	
	Severe (78)	20 (25.6)	7 (8.9)	51 (65.5)	
Interference with relations with other people (*n* = 195)	Mild (147)	101 (68.7)	19 (12.9)	27 (18.4)	0.001
	Moderate (21)	10 (47.6)	5 (23.8)	6 (28.6)	
	Severe (27)	6 (22.2)	3 (11.1)	18 (66.7)	
Interference with sleep (*n* = 198)	Mild (128)	89 (69.5)	17 (13.3)	22 (17.2)	0.3308
	Moderate (22)	11 (50.0)	3 (13.6)	8 (36.4)	
	Severe (48)	16 (33.3)	13 (27.1)	19 (39.6)	
Interference with enjoyment of life (*n* = 189)	Mild (113)	60 (53.1)	18 (15.9)	35 (31.0)	0.0019
	Moderate (20)	6 (30.0)	3 (15.0)	11 (55.0)	
	Severe (56)	15 (26.8)	7 (12.5)	34 (60.7)	

therapy was modified in 709 (66.3%) and 580 (68.5%) patients, respectively, and orthotic devices were changed in 308 (28.9%). A limited number of surgical interventions were performed, indicative of the usefulness of a multidisciplinary approach to reduce BM complications.

Pain affects quality of life, especially in terms of general and physical activities. In our experience, patients had a reduction in bone pain and a consequent benefit in general activity only 7 days after the MDOT visit. The majority of patients were not disturbed by the presence of a team of specialists and were also highly satisfied with the quality of the service provided. Because of its retrospective nature, our study has some limitations including a lack of data on patient outcome and no cost saving analysis. Another limitation is that quality of life information was only recorded in patients who, experiencing pain, completed the BPI. In recent years, new tools such as European Organisation for Research and Treatment of Cancer (EORTC) questionnaires EORTC QLQ-BM22 and EORTC QLQ-C30 have been validated to assess quality of life in patients with BMs, and these could ultimately provide more complete clinical information than the BPI in this population [24, 25]. We felt that it was important to report our preliminary data because they highlight the usefulness of a multidisciplinary approach and its potentially positive impact on the clinical course of BM. Our organizational model eliminates the need for patient referral to a series of specialists, often with long waiting lists, which creates substantial stress, especially for those traveling long distances to their healthcare center. In addition, the model appears cost-effective as the cost of an MDOT visit is similar to a single-

Table 5 Data on patient satisfaction

	No.	%
New patients		
Yes	1282	67.1
No	628	32.9
Satisfaction		
Dissatisfied	13	0.6
Unanswered	17	0.8
Do not know	19	0.9
Satisfied	577	28.2
Very satisfied	1421	69.4
Total	2047	100.0
Discomfort in the presence of the members of the multidisciplinary team		
Uncomfortable	72	3.5
Quite uneasy	127	6.2
Quite comfortable	72	16.2
Comfortable	1434	70
Usefulness of Center		
Very useful	1145	56.1
Useful	709	34.7
Quite useful	175	8.6
Not useful	3	0.1
Total	2048	100

specialist visit. Severe pain, which inevitably bears a heavy toll on daily activities and interpersonal relationships, is successfully managed by the MDOT, which tailors treatments to fit the specific needs of each patient.

In our experience, innovative organizational models adopting an interdisciplinary approach towards diagnosis, therapy, and rehabilitation have proven to be highly effective, and osteoncology training courses (including those at the university level) have been shown to favor the cultural and scientific growth of medical professionals in this field.

Following along the lines of our innovative model, similar osteoncology centers have been established in other Italian regions; their core aims to decrease the high morbidity of bone disease, reduce complications, minimize psychophysical distress, and improve quality of life. We are currently working towards creating a national osteoncology network to promote multidisciplinary research and training in this specific area.

Conclusion

In conclusion, we believe that it is now time to adopt a multidisciplinary approach as the standard of care for BM management in major tertiary healthcare centers. Given the documented evidence of improvements in the use of guideline-directed approaches, reduced time-to-treatments, and patient outcomes resulting from MDOT interventions, the implementation of such an approach has the capacity to positively impact the lives of patients with BM. Another advantage of the multidisciplinary decision-making process is that it greatly reduces the wide variations in decisions made by professionals acting independently. Prospective studies are needed to validate these findings and to better evaluate patient outcome and cost savings in relation to the use of a MDOT strategy in a clinical setting.

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Author contributions AB, GM, and TI conceived the idea for this study. CL, ADV, GM, and VF performed the literature search. MC provided the images and a detailed description. FF performed the statistical analysis. AB, LM, and FR co-drafted the manuscript. TI and DA critically evaluated the manuscript for important intellectual content. All authors read and approved the final version of the paper.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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