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ORIGINAL ARTICLE - SPINE - OTHER

How good are the outcomes of instrumented debulking operations for symptomatic spinal metastases and how long do they stand? A subgroup analysis in the global spine tumor study group database

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Abstract

Background The benefits of surgery for symptomatic spinal metastases have been demonstrated, largely based on series of patients undergoing debulking and instrumentation operations. However, as cancer treatments improve and overall survival lengths increase, the incidence of recurrent spinal cord compression after debulking may increase. The aim of the current paper is to document the postoperative evolution of neurological function, pain, and quality of life following debulking and instrumentation in the Global Spine Tumor Study Group (GSTSG) database.

Methods The GSTSG database is a prospective multicenter data repository of consecutive patients that underwent surgery for a symptomatic spinal metastasis. For the present analysis, patients were selected from the database that underwent decompressive debulking surgery with instrumentation. Preoperative tumor type, Tomita and Tokuhashi scores, EQ-5D, Frankel, Karnofsky, and postoperative complications, survival, EQ-5D, Frankel, Karnofsky, and pain numeric rating scores (NRS) at 3, 6, 12, and 24 months were analyzed.

Results A total of 914 patients underwent decompressive debulking surgery with instrumentation and had documented follow-up until death or until 2 years post surgery. Median preoperative Karnofsky performance index was 70. A total of 656 patients (71.8%) had visceral metastases and 490 (53.6%) had extraspinal bone metastases. Tomita scores were evenly distributed above (49.1%) and below or equal to 5 (50.9%), and Tokuhashi scores almost evenly distributed below or equal to 8 (46.3%) and above 8 (53.7%). Overall, 12-month survival after surgery was 56.3%. The surgery resulted in EQ-5D health status improvement and NRS pain reduction that was maintained throughout follow-up. Frankel scores improved at first follow-up in 25.0% of patients, but by 12 months neurological deterioration was observed in 18.8%.

Conclusion We found that palliative debulking and instrumentation surgeries were performed throughout all Tomita and Tokuhashi categories. These surgeries reduced pain scores and improved quality of life up to 2 years after surgery. After initial improvement, a proportion of patients experienced neurological deterioration by 1 year, but the majority of patients remained stable.

Keywords Metastasis · Spine · Debulking surgery · Quality of life · Frankel score

Introduction

In the 1990s, regular use of spine stabilization techniques following decompression or debulking surgery for spinal metastatic disease re-established the role for surgery. Previously, laminectomy alone resulted in inferior outcomes [8, 23]. In a landmark randomized controlled trial, the combination of

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surgery and radiotherapy was demonstrated to produce significantly better neurological outcomes compared to radiotherapy alone for solid spinal metastases causing spinal cord compression [15], and reduction of pain and neurological improvement was seen in other studies [7, 9, 10, 14, 24]. In patients selected for surgery, operative management of spinal metastatic disease has been shown to improve and maintain quality of life, proportional to preoperative functional status [4, 7]. In the prospective cohort study of 922 patients from the Global Spine Tumor Study Group (GSTSG), surgery included all techniques and approaches, ranging from percutaneous cementoplasty or pedicle screw fixation to treat instability from a pathological fracture to less or more complete debulking surgery for decompression of the spinal cord (with or without instrumentation) to extralesional en bloc vertebrectomy. Despite the fact that surgery has been recognized as a useful option in the management of symptomatic spinal metastases, there is still little evidence to guide decision-making as to which subtype of surgery is most suitable or beneficial for a particular patient. The more aggressive operations are potentially associated with higher complication rates [22]. One would assume that less invasive options are usually chosen in situations that are "more palliative," i.e., for patients with a perceived shorter life expectancy. Conversely, the more aggressive surgery subtypes might be advised when life expectancy is considered to be longer, and hence local tumor control is deemed necessary for longevity. However, to date, it is not clear whether techniques involving more radical tumor excision result in longer maintenance of neurological function or better survival. In addition, the long-term performance of the less invasive surgical options with respect to reduction of pain, maintenance of function, and quality of life and survival is not entirely clear. The question becomes more and more relevant in view of increasing survival lengths from improving cancer treatments.

The objective of our study was to review the outcome of decompressive debulking surgery with instrumentation in a prospective cohort of patients that underwent this surgery for a symptomatic spinal metastasis. Debulking and instrumentation followed by radiotherapy is among the most frequently used strategies to manage spinal metastases that cause spinal cord compression. We investigated the indications for such surgery, the patient factors that might influence surgeons to choose this type of surgical option, and the outcomes of surgery. We hypothesized that these "palliative" procedures successfully improved function, reduced pain, and improved quality of life in the majority of patients with spinal metastases but that we would see a deterioration over time in a subset of patients.

Methods

The GSTSG database contains prospectively collected data of consecutive patients that were treated with surgery for symptomatic spinal metastatic disease in 20 specialist spine centers in Belgium, Canada, China, Denmark, France, Germany, Japan, Netherlands, Spain, South Korea, UK, and USA. Patients were excluded if they were younger than 18 years or if they were unable to give informed consent. Data were anonymized and entered in the database by the spine surgeon and their team. The data were kept on secure servers managed by an established data management company (Applied Network Solutions, Basingstoke, UK) with full secure socket layer certificated encryption software. Data forms were locked at 4 weeks following data entry in order to preclude subsequent changes. Local institutional ethical approval was granted for all centers according to national regulations. Patients for this study were recruited between January 1, 2004, and September 1, 2016, and gave informed consent for data collection, analysis, and publication.

Collected data includes preoperative tumor type, Tomita score [19], Tokuhashi score [18], pain numeric rating score (NRS), Frankel score, EQ-5D-3 L quality of life index, Karnofsky Performance Status score (KPS), type of surgery [3], complications, and postoperative pain visual analogue score, Frankel score, EQ-5D-3 L quality of life index, KPS at each follow-up (3 months, 6 months, 1 year, 2 years), as well as date of death. For the current analysis, we specifically looked at the group of patients that underwent partial removal of less than 50% of the tumor in combination with instrumented stabilization of the spine and analyzed the above variables. Patient that underwent piecemeal near complete, piecemeal complete, or en bloc excisions and patients with missing data on the exact surgical procedure were excluded. Also, patients with follow-up less than 2 years and without documented date of death were excluded from the analysis.

Data were analyzed in a descriptive way using summary statistics: means and standard deviations or medians and interquartile ranges for continuous variables depending on their distribution and proportions for binary and categorical variables. Survival data were analyzed using Kaplan-Meier statistics and Cox regression analysis. Statistical analyses were performed in Stata 14 (College Station, Texas, USA). *P* values below 0.05 were considered significant.

Results

A total of 914 patients underwent a decompressive debulking (i.e., partial removal < 50% of the tumor as determined by the operating surgeon) with instrumentation and had documented follow-up until death or until 2 years post surgery. Mean age was 60.7 years (SD 12.3 years). 500 patients (54.7%) were males. Data on the entire GSTSG dataset, including full demographic data, is available in Choi D et al. [4].

Median preoperative KPS was 70 (IQR 50–80), and 32.3% of patients were admitted with a KPS ≥ 80. Mean EQ-5D index was 0.37 (SD ± 0.30), and median NRS was 7 (IQR 4–8). A total of 383 patients were neurologically intact upon admission (41.9%); 299 had Frankel score D (32.7%); 223 had Frankel scores A, B, or C (24.4%); and 9 were not documented (1.0%). With respect to primary tumors, the most frequent tumor types were breast carcinoma (167 patients, 18.3%) and lung carcinoma (133 patients, 14.6%). Visceral metastases were present in 656 patients (71.8%) and extraspinal bone metastases in 490 patients (53.6%). Tomita scores were evenly distributed above (49.1%) and below or equal to 5 (50.9%). Similarly, Tokuhashi scores were almost evenly distributed below or equal to 8 (46.3%) and above 8 (53.7%) (Table 1). Tomita scores of 5 or higher or Tokuhashi scores of 8 or below were considered thresholds beyond which the original publications recommended palliative surgery only [18, 19].

The number of levels instrumented was 1 to 3 in 187 patients (20.5%), 4 to 6 levels in 489 patients (53.5%), and 7 or more levels in 104 patients (11.4%), with missing data in 134 (14.7%). The incidence of intraoperative and postoperative complications is shown in Table 2. The most frequent complications were wound complications, with a rate of 4.6%. 30-day mortality was 3.8%. 6-month survival was 71.2%, 12-month survival 56.3%, and 24-month survival 32.5% (Fig. 1).

Debulking surgery with instrumentation in general resulted in substantial EQ-5D health status improvement that was maintained above 0.70 throughout follow-up (Fig. 2). Pain intensity was reduced, and the reduction was maintained over 24 months with a stable median NRS of 2 (Fig. 3). KPS scores started from a median of 70 preoperatively and slightly increased postoperatively (Fig. 4).

Table 1. Distribution of preoperative Karnofsky Performance Index, Tomita and Tokuhashi scores.

Karnofsky Performance Index (n=894)	
20	13 (1.4%)
30	68 (7.6%)
40	86 (9.6%)
50	145 (16.2%)
60	128 (14.3%)
70	165 (18.4%)
80	175 (19.6%)
90	89 (9.9%)
100	25 (3.0%)
Tomita score (n=909)	
No of pts with 2-3 (%)	291 (32.0%)
No of pts with 4-5 (%)	172 (18.9%)
No of pts with 6-7 (%)	218 (24.0%)
No of pts with 8-10 (%)	228 (25.1%)
Tokuhashi score (n=777)	
No of pts with 0-8 (%)	360 (46.3%)
No of pts with 9-11 (%)	295 (38.0%)
No of pts with 12-15 (%)	122 (15.7%)

Table 2. Distribution of intra- and postoperative complications (n=914).

Intraoperative complications	
Vascular	17 (1.9%)
Neurological	12 (1.3%)
Visceral	4 (0.4%)
Postoperative complications	
None	710 (77.8%)
Medical	32 (3.5%)
Neurological deterioration	17 (1.9%)
Wound complications	42 (4.6%)
Implant failure	7 (0.8%)
Other	64 (7.0%)
30 day mortality	35 (3.8%)
Revision surgery within 30 days	27 (2.9%)

Frankel scores were improved at first follow-up in 106 out of 423 patients (25.0%). At 6 months, patients with Frankel A-C were reduced to less than 1% (Fig. 5), partially explained by patients further improving (14.9% between 3 and 6 months) and by a proportion of patients dying. At 12 months, however, an increase in patients with Frankel A-C was observed, due to a proportion of patients of 18.8% that deteriorated between 6 and 12 months (Fig. 6).

Discussion

In the present retrospective analysis of prospectively collected data from the GSTSG, we specifically focused on the patients that underwent debulking surgery with the addition of instrumentation for reconstruction, in a consecutive cohort of 914 patients. In the consensus statement of the GSTSG, in which surgery types for spinal metastases were classified into five categories [3], this surgery falls under category 2, i.e., palliative debulking. We found that these procedures were able to produce an improvement in health status and a reduction of pain that was maintained throughout follow-up to 2 years or death. Palliative debulking surgery was able to improve the Frankel scores at first follow-up in a quarter of patients. A

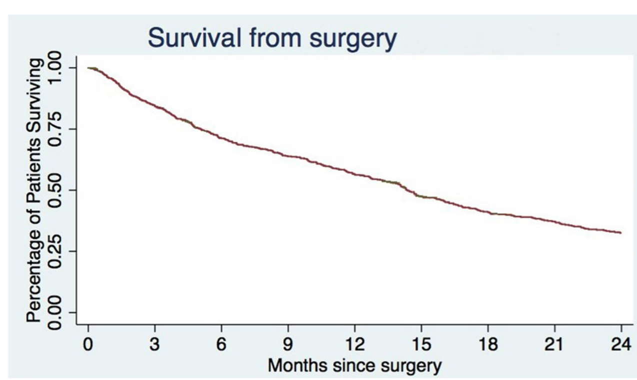

Fig. 1 Kaplan-Meier survival curve (n = 914)

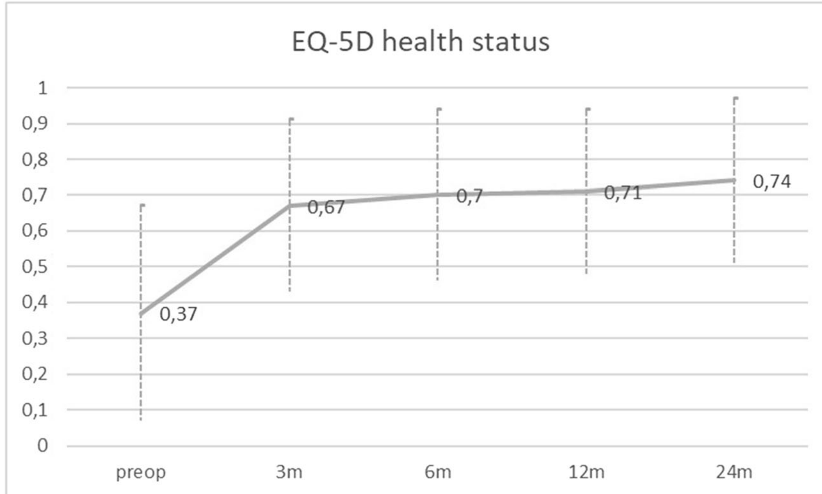

Fig. 2 Evolution of EQ-5D health status over time (mean values ± standard deviation)(pre-op n = 765, 3 m n = 426, 6 m n = 293, 12 m n = 218, 24 m n = 122)

subsequent worsening of the neurological status was observed between 6 and 12 months in 18.8% of patients. The complication rate was acceptable, with intraoperative complications in less than 2% and overall postoperative complications in up to 22.2%. The overall 1 year survival was 56.3%.

The Tomita and Tokuhashi prognostic scores have been proposed as guides to decide when palliative surgery should be performed, based on predicted prognosis. Tomita et al. advocated to perform en bloc or complete excisions in patients with a Tomita score between 2 and 5, palliative surgeries in patients with a 6–7 score, and conservative supportive care in higher scores [19]. Surprisingly, in our present cohort, palliative surgeries were performed throughout all Tomita and Tokuhashi categories. Surgeons did not appear to choose palliative operations based on overall metastatic disease load or prognostic scoring systems. Although this may reflect a certain degree of pragmatism in surgeons' decision-making, it is more likely that it particularly reflects that the available scoring systems are not sufficiently accurate in their prediction of survival to support decision-making in individual patients. It has been found by Choi et al. in a GSTSG analysis that none of the predictive scoring systems had good predictive value [5].

In previous GSTSG publications, a strong overall association between preoperative KPS and subsequent survival has been demonstrated [4, 20]. Although this association to some extent may reflect an effect of treatment decisions, also in multivariate analyses, KPS was an independent predictor of survival, suggesting that to some extent KPS may be a good clinical guide. In order to further help personalized management, the GSTSG developed a risk calculation tool based on a prediction model build on its database that visualizes the patient's expected survival in relation to the average survival of patients with spinal metastases [6].

Several small- to medium-sized series in the literature report on palliative surgery for symptomatic spinal metastases with outcomes comparable to our series. Bouras et al. looked at 88 patients that underwent decompression/debulking with or without fixation and that had a Tokuhashi score ≤ 8 [2]. About 55.3% of their patients improved, with reduced pain and restored or

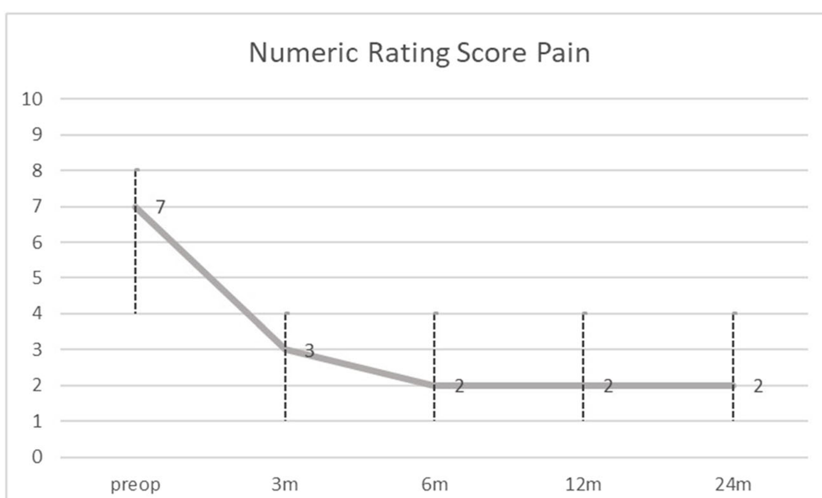

Fig. 3 Evolution of Numeric Rating Score pain intensity over time (median values, IQR)(pre-op n = 776, 3 m n = 427, 6 m n = 291, 12 m n = 213, 24 m n = 117)

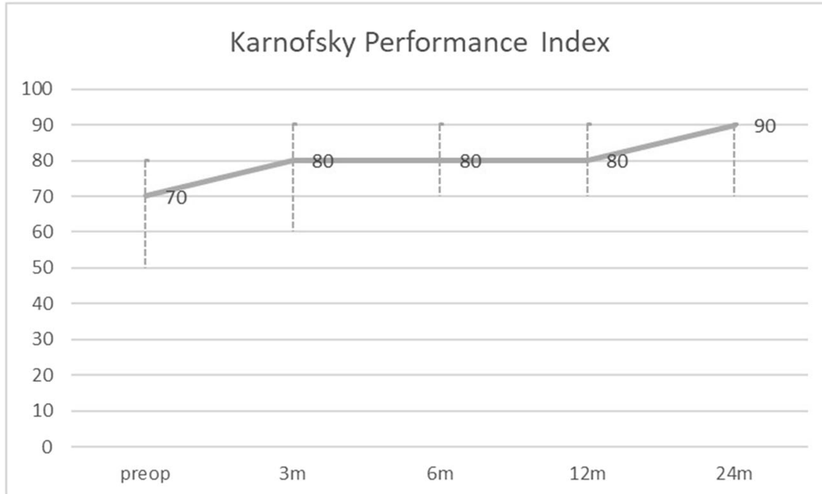

Fig. 4 Evolution of Karnofsky Performance Status scores over time (median values, IQR)(preo-p $n = 902$, 3 m $n = 415$, 6 m $n = 360$, 12 m $n = 209$, 24 m $n = 116$)

maintained ambulation without severe complications at 2 months. The rate of intraoperative complications was 4.5% and 23.9% for postoperative complications, which is similar to our findings. Ha et al. studied 43 patients that underwent either posterior decompression and fusion or a combined anterior-posterior reconstruction [8]. About 20.9% experienced Frankel score improvement at 3 months, and 12 month survival was 31.5% in the posterior only group and 38.7% in the anteroposterior group. In a systematic review of palliative decompressive surgeries, it was found that there was no difference in immediate outcome between anterior and posterior techniques nor between open and minimally invasive techniques [1]. In the prospective multicenter AOSpine study, which included 142 patients and of whom 94.4% underwent instrumentation surgery, the proportion of patients who were able to walk four steps independently postoperatively was higher than the preoperative proportion at all follow-up times up to 12 months. About 29.6% of patients experienced a complication within 30 days, 3-month mortality was 28.2%, and 12-month mortality was 62.0% [7]. Longer follow-up was available in the study of North et al., who modeled ability to walk in a series of 61 patients that underwent palliative surgery for spinal metastases [14]. Twelve patients lost the ability to walk postoperatively over the course of 1.6 years. To the best of our knowledge, the present study is the only analysis on palliative surgeries with the current order of sample size that looked at clinical outcome over 2 years.

The exact role of the more aggressive surgeries for spinal metastases is subject to debate. It has become clear from Tomita's and others' series that en bloc excisions do not preclude recurrence, [13, 16, 19]. Since time to recurrence in these series of solitary thyroid, renal cell carcinoma, or breast metastases was up to 8 years, it seems that the value of the more aggressive surgeries in the context of metastatic disease lies in buying time. Our study of debulking surgeries shows

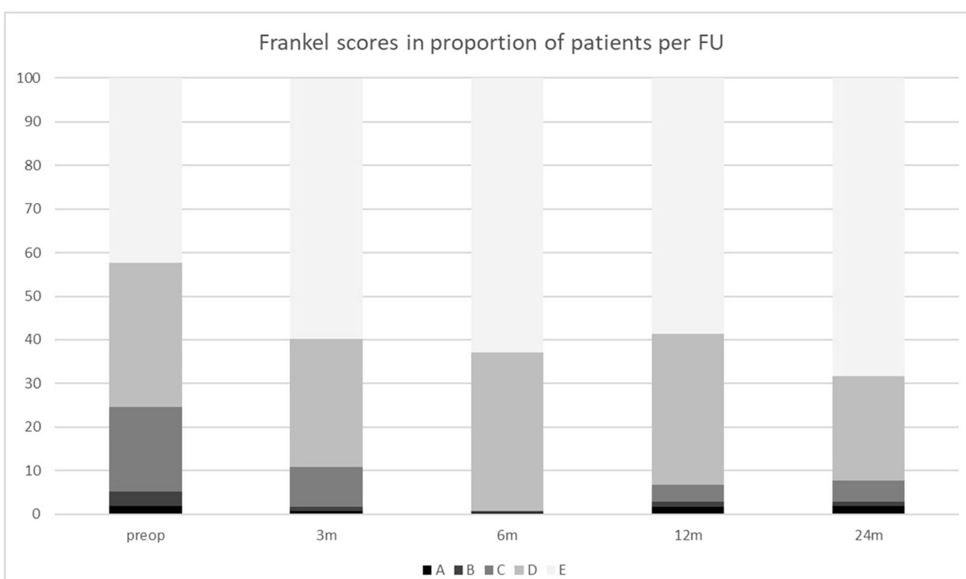

Fig. 5 Preoperative and postoperative Frankel scores expressed in percentage of patients in each follow-up moment (pre-op $n = 905$, 3 m $n = 423$, 6 m $n = 262$, 12 m $n = 179$, 24 m $n = 104$)

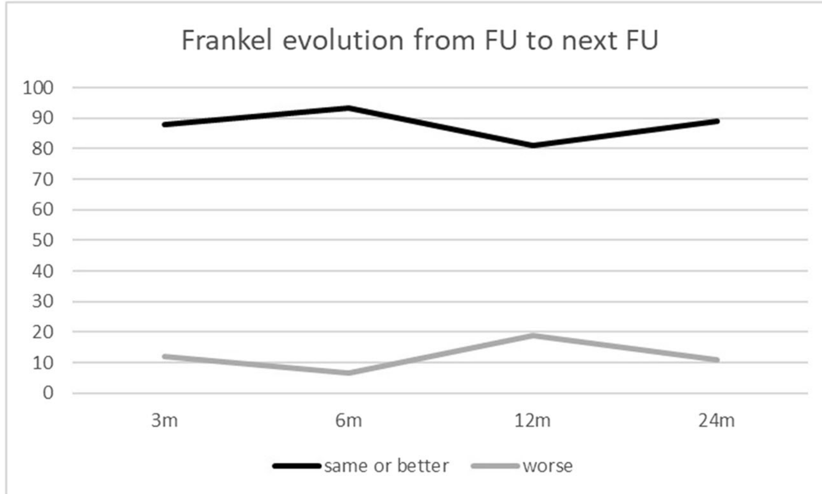

Fig. 6 Proportion of patients experiencing Frankel score worsening from one follow-up moment to the next versus proportion of patients improving or being stable (3 m n = 423, 6 m n = 262, 12 m n = 179, 24 m n = 104)

that clinical improvements were achieved for a reasonable duration but with an 18.8% of patients experiencing neurological deterioration by 1 year. Although this could theoretically have been caused by newly developed different spinal metastases, this figure is in agreement with reported rates of symptomatic loss of local control of 20% [11] and 22% [21] at 1 year in smaller series. Hence, based on the present data, a choice for debulking comes with risk of approximately one fifth that the patient may suffer recurrent spinal cord compression if he/she survives for more than 1 year. From the perspective of the many unknown variables during the course of cancer, this choice seems very justifiable to date. As medical treatments and survival continue to improve over the years, also radiotherapy techniques have advanced. The advent of spinal stereotactic radiosurgery has led to changing management philosophies, with the focus being more on early surgery for maintaining stability and on radiotherapy/radiosurgery for local control of the spinal metastasis and less reliance on debulking surgery. In the NOMS algorithm, separation surgery – i.e., debulking to create a tumor-free margin surrounding the spinal cord – is only advocated when the tumor extends to the epidural space or causes spinal cord compression, and the tumor histology is not or intermediately radioresponsive [17]. However, it is still too early to fully assess the merits of this newer strategy. In an outcome study by Laufer et al. on 186 patients in whom separation surgery and spinal radiosurgery were used, the authors reported that 18.3% of patients had local progression on imaging at a median of 4.8 months, 55.4% died at a median of 5.6 months, and 26.3% were alive and without progression at a median of 7.1 months [12]. Although the GSTSG database includes patients from centers that have adopted the NOMS principles, it is of note that the results in terms of survival of our current study – that also includes debulkings more extensive than separation – are better than those reported by Laufer et al.

Limitations of our current study relate to the standardized data collection inherent to prospective databases that may not capture the subtleties of the rationale for certain management decisions and all associated variables. This includes surgeons' preferences and centers' philosophies as to which procedure to select in which exact situation. In addition, the classification of "debulking" as less than 50% of the tumor being removed was based on an estimation of the surgeon and not on a comparison of pre- and postoperative imaging. We do not expect, however, that the rough nature of this estimation has had a real influence on the results of the current analysis. Also, although data capture was prospective, some bias may result from incomplete entries or missing data. Since patients were recruited to the GSTSG database after referral for spinal surgery, there may be a bias toward patients who are perceived by referring oncologists as potentially having a better prognosis. Also, the beneficial effects of systemic therapies and radiotherapy on patient outcomes in terms of performance and survival cannot be isolated. Although the majority of patients received pre- or postoperative radiotherapy for the spinal metastasis, there were too many missing data on timing, type and dose of radiotherapy to enable the inclusion of radiotherapy outcomes in our analysis.

Nevertheless, the GSTSG database represents the largest prospective database on patients with spinal metastases managed surgically that includes systematic capture of quality of life, pain, functional, and neurological outcomes. Based on the current analysis of 914 patients that underwent debulking and instrumentation surgery for symptomatic spinal metastases, we strongly recommend the consideration of this type of surgery for patients in whom estimated survival is deemed sufficiently long to benefit from decreased pain, improved or maintained neurological function, and improved quality of life. However, patients should be counseled that this is associated with a risk of approximately one fifth of recurrent spinal cord compression if he/she survives for more than 1 year. In view of improving cancer treatments and longer survivals, this is a relevant observation. It is unsure how this should be dealt with, and an important clue may be in improved survival prediction and customized strategies.

Conclusion

In a prospective cohort of debulking and intrumentation surgeries for symptomatic spinal metastases taken from the GSTSG database, we found that these surgeries were safe and were able to produce and maintain reduction in pain and improvement in quality of life for at least 2 years after surgery. Frankel neurological status improved after surgery in one quarter of patients, but a fifth of patients experienced neurological deterioration by 1 year. Palliative procedures offer benefits to patients with symptomatic spinal metastases and have an important place in treatment algorithms.

Compliance with ethical standards

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Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements) or nonfinancial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the local institutional research committees according to national regulations and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Statement of informed consent Informed consent was obtained from all individual participants included in the study.

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