



Spinal tumours: recommendations of the Polish Society of Spine Surgery, the Polish Society of Oncology, the Polish Society of Neurosurgeons, the Polish Society of Oncologic Surgery, the Polish Society of Oncologic Radiotherapy, and the Polish Society of Orthopaedics and Traumatology

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Abstract

Purpose The purpose of these recommendations is to spread the available evidence for evaluating and managing spinal tumours among clinicians who encounter such entities.

Methods The recommendations were developed by members of the Development Recommendations Group representing seven stakeholder scientific societies and organizations of specialists involved in various forms of care for patients with spinal tumours in Poland. The recommendations are based on data yielded from systematic reviews of the literature identified through electronic database searches. The strength of the recommendations was graded according to the North American Spine Society's grades of recommendation for summaries or reviews of studies.

Results The recommendation group developed 89 level A-C recommendations and a supplementary list of institutions able to manage primary malignant spinal tumours, namely, spinal sarcomas, at the expert level. This list, further called an appendix, helps clinicians who encounter spinal tumours refer patients with suspected spinal sarcoma or chordoma for pathological diagnosis, surgery and radiosurgery. The list constitutes a basis of the network of expertise for the management of primary malignant spinal tumours and should be understood as a communication network of specialists involved in the care of primary spinal malignancies.

Conclusion The developed recommendations together with the national network of expertise should optimize the management of patients with spinal tumours, especially rare malignancies, and optimize their referral and allocation within the Polish national health service system.

Keywords Primary malignant spinal tumours · Spinal metastases · Sarcoma · Multidisciplinary management of spinal tumours · Benign primary spinal tumours

Introduction

Initially, the only purpose of our project was to develop recommendations for the evaluation and management of spinal tumours among clinicians caring for such entities. To the best of our knowledge, no comprehensive recommendations

regarding the full spectrum of spinal tumours have been published thus far. Soon after starting the project, we added another goal: the development of a network of expertise at a national level for the management of primary malignant spinal tumours in Poland with a plan to incorporate this network into the existing organizational structure of the Polish national cancer care system. Such a network will follow recommendations of the European Union Joint Action on Cancer and the European Partnership for Action Against Cancer (EPAAC) [1].

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The EPAAC recommends the establishment of networks of expertise in the management of soft tissue and bone sarcomas in regions where it is not possible to establish comprehensive centres for their management. In Poland, similar to the majority of other countries, such centres offering comprehensive expertise under the one roof do not exist or are very rare. Our expertise network seems to be a reasonable alternative given the lack of such centres and a good response to the EPAAC recommendations.

We believe that with the national expertise network, our recommendations have an increased chance to be fully met in everyday clinical practice.

Incorporation of our expertise network into the existing national system of cancer care in Poland should be straightforward. This is because in Poland, interdisciplinarity in the management of cancer is a fundamental principle and a statutory requirement of a Polish national cancer care system. This principle is executed with relative ease for most oncology patients in Poland, but clinicians and patients can experience problems in regard to very rare malignancies, such as spinal sarcomas and chordomas. Access to the expertise network for both patients and clinicians encountering spinal tumours should complement the Polish cancer care system in the management of rare primary spinal malignancies. Currently, specialists with expertise in these tumours are dispersed across the country and, consequently, problems with coordinated referral and interdisciplinary management of these patients exist. In practice, interdisciplinary services for the management of rare spinal tumours are not available under the one roof, even at quaternary or university hospitals. Furthermore, the interdisciplinary management of these tumours may not be available, even within a single broader region of the country. Complex oncologic spine surgery can be performed by a specialist in one corner of the country, molecular histology of sarcomas in another corner, and proton beam therapy or radiosurgery in yet another corner. Similar dispersions of expertise and facilities for the management of rare malignancies can be found worldwide, including in highly developed countries. We believe that a dedicated expertise network for rare spinal tumours at the national level will improve the coordinated interdisciplinary management of patients, despite the dispersion of experts and facilities across the country.

Methods

The recommendations development group

The project to develop such recommendations was an initiative of the Executive Committee of the Polish Society of Spine Surgery. The Committee invited some stakeholder organizations to the project to ensure broad representation

of all specialties involved in the care of patients with spinal tumours. Ultimately, seven organizations, including the Polish Society of Spine Surgery, agreed to participate in the project: the Polish Society of Oncology, the Polish Society of Neurosurgeons, the Polish Society of Oncologic Surgery, the Polish Society of Oncologic Radiotherapy, the Polish Society of Orthopaedics and Traumatology, and the Department of Soft Tissue/Bone Sarcoma and Melanoma at the Maria Skłodowska-Curie National Research Institute of Oncology, Warsaw, Poland. Each one nominated representatives to serve on the Recommendation Development Group. In total, 20 volunteers participated in this effort, including the following specialists: (1) neurosurgeons and orthopaedic surgeons with expertise in the field of spine surgery, (2) radiation oncologists, (3) medical oncologists, and (4) experts in the field of sarcoma from the Department of Soft Tissue, Bone Sarcoma and Melanoma at the Maria Skłodowska-Curie Institute Oncology Center in Poland.

Grading recommendations and level of evidence

The recommendations were based on systematic reviews of the literature identified from searching electronic databases. The strength of the recommendations was graded according to the North American Spine Society's Grades of Recommendation for Summaries or Reviews of Studies (Tables 1 and 2). A: good evidence (level I studies with consistent findings) for or against recommending intervention; B: fair evidence (level II or III studies with consistent findings) for or against recommending intervention; C: poor quality evidence (level IV or V studies) for or against recommending intervention; and I: insufficient or conflicting evidence not allowing for a recommendation for or against intervention [2, 3].

Each identified source of evidence was rated in terms of the strength of yielded evidence with the use of levels of evidence for primary research questions as adopted by the North American Spine Society in January 2005 and other societies and journals, namely, the American Academy of Orthopaedic Surgeons, Pediatric Orthopaedic Society of North America, Clinical, Orthopaedics and Related Research, Journal of Bone and Joint Surgery and Spine (Table 2) [3].

Table 1 The strength of recommendations was graded according to the North American Spine Society's grades of recommendation for summaries or reviews of studies

A	good evidence (level I studies with consistent finding)
B	fair evidence (level II or III studies with consistent findings)
C	poor quality evidence (level IV or V studies)
I	insufficient or conflicting evidence not allowing a recommendation for or against intervention

Table 2 Levels of evidence for primary research questions as adopted by the North American Spine Society January 2005 and other societies and journals, namely the American Academy of Orthopaedic

Surgeons, Pediatric Orthopaedic Society of North America, clinical, orthopaedics and related research, Journal of Bone and Joint Surgery and Spine

Level I high-quality randomized controlled trial (RCT) with statistically significant differences or no statistically significant differences but narrow confidence intervals, systematic review of level I RCTs (with homogenous study results)

Level II lower-quality RCT (e.g., < 80% follow-up, no blinding, or improper randomization), prospective comparative study, systematic review of level II studies or level I studies with inconsistent results

Level III case control study, retrospective comparative study, systematic review of level III studies

Level IV case series

Level V expert opinion

Organization of the literature search

Members of the Recommendation Development Group were divided into several working teams, each performing a database search for one or more topics allocated to them in accordance with the specialties of the team members. There were 11 core topics: epidemiology of spinal tumours, aetiology and classification of spinal tumours, imaging diagnostics of spinal tumours, clinical diagnosis and grading scales, biopsy and management of biopsy samples, histological diagnosis, chemotherapy and radiotherapy of primary tumours in particular, chemotherapy and radiotherapy of metastatic tumours, surgical treatment of primary malignant spinal tumours, surgical treatment of benign spinal tumours, and surgical treatment of metastatic tumours. Most malignant primary tumours, namely, osteosarcoma, chondrosarcoma, Ewing sarcoma, chordoma, osteoblastoma, and solitary plasmocytoma, and many benign tumours, aneurysmal cysts and giant cell tumours in particular, were searched for separately and reviewed by working teams according to the specialties of the team members. Each team had the freedom to identify papers relevant to the allocated topic. It was a duty of each team to critically assess the quality of the identified studies and downgrade their levels of evidence if any shortcomings were present in the execution of the reviewed study.

Formulation of recommendations

All members of the Recommendation Development Group participated in the recommendation development process. Each team proposed preliminary recommendations in a structured way that included formulating the recommendation and the following: (1) classifying the strength of the formulated recommendation, (2) classifying the quality of the study that the recommendation was based on, (3) referencing the source of the study, and (4) stating the type of the study, e.g., randomized controlled trial, retrospective study, and expert opinion. The preliminary recommendations were summarized in a table by each working team (Table 3). Tables with preliminary recommendations from all working

teams were compiled into one table embedded in a Word file that was available online for all members of the Recommendation Development Group. The teams were asked to review the table and provide written remarks, comments, objections or opinions in the comments panel of the Word file based on their areas of expertise. This process was supervised by four chairs who were members of the development group but were not involved in the literature search and instead chaired all the meetings and voting sessions of the group. Once the preliminary recommendations were reviewed, each single recommendation was separately subjected to voting during a series of meetings of the whole Recommendation Development Group. Every single preliminary recommendation was separately accepted as a final recommendation when at least 75% of members voted positively. Recommendations that did not achieve this result during the first round of voting were returned to the appropriate working team for revision. Based on the revision, the recommendation could be either rejected or reformulated by the working team and subjected to the second review and vote by the whole Development Group during the subsequent meetings. Those preliminary recommendations that were not accepted during a second vote were ultimately rejected or when representing a crucial issue, put on a discrepancy list.

Expertise network for multidisciplinary management of rare primary spinal tumours

Based on internal surveys in the stakeholder societies represented in the development group, we created a list of institutions, hospitals, teams and individual colleagues with expertise in the diagnosis and treatment of rare malignant spinal tumours. Specifically, we inquired about facilities offering in-depth molecular histological diagnostics, stereotactic body radiation therapy of the spine, proton beam therapy, and complex oncologic spine surgery. Each scientific society was asked to provide such a list with regard to its specialties. A survey among the members of the Polish Society of Spine Surgery concerning their experience in complex oncologic spine surgery, namely, en bloc Enneking-appropriate resections, allowed us to create a list of centres and individual

Table 3 Template of the table which was filled in with preliminary recommendations by each working team

Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
Formulated recommendation	To be chosen from four possible options A, B, C, I (see Table 1)	Reference to the source of evidence (journal articles, textbooks, etc.)	To be chosen from five possible options I–V (see Table 2)	To be chosen from the following: RCT, systematic reviews, prospective studies, retrospective studies, case series, expert opinions

colleagues who have expertise in this type of surgery. These experts were also asked about their willingness and readiness to accept patients requiring this type of surgery from other institutions/colleagues on a regular basis.

Results

Eighty-nine recommendations were developed and accepted by the Recommendation Development Group and divided into four sections: (1) diagnostics, (2) primary tumours, (3) metastatic tumours, and (4) discrepancies (Tables 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27 respectively). The list of recommendations will be available on the homepages of stakeholder organizations participating in the development of recommendations and accompanied by an appendix including a list of institutions, teams and individual specialists with expertise in the diagnostics and management of rare primary malignant tumours to optimize patient referral and allocation within the cancer care system of Poland (Table 28).

Discussion

As mentioned above, interdisciplinarity in the management of cancer is a fundamental principle and a statutory requirement of the Polish national cancer care system.

While the principle of interdisciplinarity in the management of most spinal tumours is relatively easy to execute, this is not the case for primary malignant spinal tumours requiring sophisticated molecular diagnostics as well as complex oncologic spine surgery.

No single centre in Poland provides complete management of rare primary malignant spinal tumours from in-depth molecular histological diagnosis through complex oncologic spine surgery to spine radiosurgery and chemotherapy in one institution.

Currently, patients with such tumours and some clinicians involved in the care of such patients may not be aware of the centres offering unique molecular diagnosis or top-level oncologic surgical treatment of the spine. With the dispersion of these highly specialized services across Poland, it may take time and effort to find an institution with the required facilities. A patient may undergo surgical treatment in one place and radiotherapy or chemotherapy in another, while having molecular diagnosis done in yet another place. In everyday practice, such patients and clinicians may both feel lost in regard to deciding which referral centre can offer the most appropriate diagnostics and treatment. Based on internal surveys within scientific societies represented in the development group, we prepared a list of institutions and colleagues with expertise

Table 4 Recommendations. Imaging diagnostics. General rules

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	MRI a method of choice in the detection of neoplastic invasion in the spine The sensitivity of multislice computed tomography is significantly lower in detecting metastases to the spine than that of MRI. For this reason, MRI is the method of choice as the most sensitive tool in the detection of neoplastic invasion in the spine	B	[4]	III	Retrospective
2	MRI and CT to identify patients at high risk for vertebral fracture and spinal cord compression (SCC) The current clinical consensus favours MRI and CT for the investigation of SCC and vertebral fracture	B	[5]	III	Systematic review of literature
3	MRI as a more sensitive imaging technique than skeletal scintigraphy in detecting spinal metastases	B	[6]	II	Prospective
4	Sagittal T1-weighted and/or T2-weighted axial projections as necessary to detect vertebral metastases, epidural tumour masses and the degree of compression of the spinal cord	B/C	[7]	II/III	Randomized prospective study
5	Imaging diagnostics of the spine in patients with prostate cancer even in the absence of neurological deficits A significant proportion of patients with metastasis may harbour overt or occult spinal cord compression in the absence of functional neurological deficits	B/C	[8, 9]	II/III	Prospective and retrospective study
6	T2-weighted images for grading spinal canal compromise with the Epidural Spinal Cord Compression scale (ESCC) T2-weighted images are superior indicators of epidural spinal cord compression to T1-weighted images with and without gadolinium The ESCC scale provides a valid and reliable instrument that may be used to describe the degree of ESCC based on T2-weighted MR images	C	[10]	V	Validation study
7	Spinal instability neoplastic score (SINS) for the assessment of spinal instability due to neoplastic disease SINS demonstrates near-perfect inter- and intraobserver reliability in determining three clinically relevant categories of stability. The sensitivity and specificity of SINS for potentially unstable or unstable lesions are high	C	[11]	III	Validation study
8	Radiology reports should include the spinal instability neoplastic score (SINS) in patients with neoplastic disease of the spine Among radiation oncologists, SINS is a highly reliable, reproducible, and valid assessment tool to address a key question in tumour-related spinal disease: is the spine 'stable' or is there a 'current or possible instability' that warrants surgical assessment?	I	[12]	V	Multicentre validation study

in the diagnosis and treatment of rare malignant spinal tumours, namely sarcomas and chordomas. The list will be available as an appendix to the recommendations on the homepages of the stakeholder organizations. The list aims to give clinicians involved in the care of patients with spinal tumours clues on where to refer patients with rare spinal malignancies for optimal management, especially in regard to complex oncologic spine surgery. The colleagues

experienced in this type of surgery declared they would be ready to accept such cases on a regular basis. The appendix will also include a list of institutions with expertise in performing molecular pathology of sarcomas and a list of places and colleagues providing radiosurgery. Therefore, we recommend referring patients with primary malignant tumours to these centres or colleagues. This approach should not be a problem, as in Poland, allocation and free

Table 5 Recommendations. Imaging diagnostics. Primary benign tumours

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	To further investigate signal intensity measurements on T1-weighted images with and without fat suppression to differentiate spinal haemangiomas from metastases	B	[13]	III	Retrospective
2	MRI as study with a key role in the diagnosis of benign tumours of the spine. In some cases of benign tumours, MRI enables a reliable diagnosis (e.g., stem haemangioma, osteoma, and lipoma). Some tumours may not require contrast examinations due to their characteristic imaging findings but in case of doubt, the examination should be supplemented with contrast, computed tomography, possibly scintigraphy, or even PET	B	[14]	III	Retrospective
3	To take into account the tumour size, preoperative alkaline phosphatase (ALP) and CT images for distinguishing aggressive osteoblastoma from conventional osteoblastoma	B	[15]	III	Retrospective

Table 6 Recommendations. Sarcomas. General diagnostic requirements

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	That medical centres that perform diagnostic and therapeutic procedures on spine sarcomas should have the following organizational possibilities: (1) Staff: oncological surgery specialist/orthopaedist and neurosurgeon with experience in en bloc spine surgery/paediatric surgeon with experience in the treatment of bone sarcomas—on site, clinical oncology specialist—on site, radiotherapy specialist—on site, physiotherapist—on site, psycho-oncologist—at the location (2) Intensive care unit—on site (3) Radiology laboratory (24/7 access)—USG, CT, MRI in a location with the possibility of performing an intraoperative X-ray examination (4) Histopathology laboratory with the possibility of performing an intraoperative examination pathology at the location (5) Possibility of a multidisciplinary consultation (oncologist/orthopaedic surgeon, radiotherapist, clinical oncologist-chemotherapist, pathologist, radiologist) at the centre (6) Possibility of carrying out adjuvant treatment (chemotherapy, radiotherapy with the possibility of IMRT and stereotaxic techniques) at the location or under an agreement with an external centre. Coordination of systemic treatment and radiotherapy must be ensured (7) Possibility to perform cytogenetic and molecular diagnostics—at the location or on the basis of an agreement with an external centre (8) In Poland, it is recommended that patients with bone sarcomas be treated only in specialized reference centres or in units with extensive experience in treating patients with this cancer, where at least 20–25 patients with bone sarcomas are treated annually	C	[1]	V	Expert opinion

referrals to any institution within the Polish national health service system are protected by the patients' right to freely choose primary care doctors, specialists, hospitals, and medical institutions anywhere in the country. Free referrals within the system are by no means restricted, and patients,

regardless of their place of residence in Poland, who are entitled to free services of the national health system (NHS) have the freedom to choose the place and physician for treatment. Additionally, we believe that the allocation of patients with spinal sarcomas and chordomas to

Table 7 Recommendations. Biopsy

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Spine biopsy should be planned based on at least two out of following three imaging studies: CT, NMR, PET	B	[16]	II	Systematic review of the literature
2	Biopsy be performed in a centre where definite Enneking-appropriate surgical treatment can be performed if a primary tumour is suspected	B	[17]	II	Systematic review of the literature
3	Percutaneous is preferred over open biopsy of neoplastic lesions of the spine Percutaneous biopsy is safer than open biopsy and equally effective	A	[18]	I	Retrospective
4	The diameter of the collected bone cylinder on the percutaneous biopsy of the vertebral lesion should be greater than 2 mm This size ensures the preservation of the bone architecture crucial for histological diagnosis The diagnostic value of percutaneous vertebral biopsy is very high	B	[19, 20]	II/III	Retrospective, prospective
5	Percutaneous biopsy should be performed under the guidance of a CT scan or ideally under navigation CT allows for more accurate and safer biopsy compared to C-arm navigated biopsy	B	[20]	III	Retrospective
6	Percutaneous biopsy should be performed, especially for lesions in the anterior column of the spine	B	[20]	III	Retrospective
7	Biopsy be performed in a centre with full surgical and pathomorphological facilities The accuracy of the biopsy is influenced by the experience of the surgeon performing the procedure and the pathologist assessing the bone tissue, therefore the biopsy should be performed in a centre with full surgical and pathomorphological facilities. Errors, complications, and changes in the course and outcome are two to twelve times greater when the biopsy is done in a referring institution instead of in a treatment centre	B	[20, 21]	III	Retrospective

Table 8 Recommendations. Sarcomas. General requirements of histological diagnostics

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	The pathomorphological examination report should be based on the classification of the World Health Organization In the differential diagnosis of small cell neoplasms	B	[35, 36]	II	Systematic review
2	The differential diagnosis be performed in centres with access to immunohistochemical and cytogenetic tests A differential histological diagnosis is necessary to assess the characteristic translocations	B	[35, 36]	II	Systematic review

Table 9 Recommendations. Primary tumours. Surgical treatment. General principles

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	En bloc resection in cases of benign aggressive tumours considered Enneking stage 3 (i.e., osteblastomas and giant cell tumours) and low-grade malignant tumours considered Enneking stage I A and B, such as chordomas and chondrosarcomas	C	[25]	V	Expert opinion
2	The Weinstein Boriani Biagnini staging system is a helpful tool in planning of en bloc surgical resection	C	[26, 27]	V	Expert opinion

Table 10 Recommendations. Sarcomas. Treatment. General principles

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Combination therapy within established therapeutic protocols for all of the Ewing group's sarcomas and bone sarcomas These tumours are highly malignant neoplasms. The results of surgical treatment alone are poor, with 5-year survival rates less than 20%	A	[37–50]	I	Randomized control study
2	Surgical treatment of Ewing sarcoma should be preceded by chemotherapy	A	[37–50]	I	Randomized control study
3	High-dose adjuvant photon/proton radiotherapy of chordomas, chondrosarcomas, and other sarcomas should be used This kind of radiotherapy provides high local control while the late morbidity appears to be acceptable	B	[51]	III	Prospective
4	Surgical treatment should aim for a cure rather than palliation whenever possible	C	[52]	III	Retrospective comparative study
5	Periosteal osteosarcoma is the only exception to the use of perioperative chemotherapy	C	[53]	IV	Retrospective

the recommended centres will not burden colleagues with expertise in oncologic spine surgery, and it is unlikely that these surgeons will be swamped by these additional cases, as these tumours are extremely rare. With the incidence of spinal sarcomas being 0.19–0.38 per 1,000,000 people, only approximately 7–15 new cases can be expected in Poland per year. The slightly higher incidence of spinal chordoma, 1 per 1,000,000 population, means approximately 38 new cases can be expected in Poland [22–24].

The list is not intended to mandate referrals to the recommended places and specialists, especially in regard to surgical management. Additionally, these specialists will not be obliged to accept such referrals. The estimated number of yearly referrals for spinal sarcomas and chordomas

should not exceed 50. Thus, even if only a dozen colleagues have expertise in oncologic spine surgery, each one would potentially accept no more than 3–5 cases if the allocation is evenly distributed across the country. These colleagues declared that they are happy to accept such referrals. Conversely, colleagues who did not declare expertise in complex oncologic spine surgery but will eventually gain such skills with increasing experience should not feel an obligation to refer spinal sarcoma/chordoma patients to colleagues renowned for their expertise in oncologic spine surgery. We understand that complex oncologic spine surgery follows the principles of the Weinstein–Boriani–Biagini (WBB) surgical system used for planning en bloc resections of spinal tumours [25–27]. The WBB systems were developed based

Table 11 Recommendations. Primary malignant tumours. Surgical management

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Enneking marginal and wide resections (Enneking appropriate resections) over intralesional resection Enneking marginal and wide resections result in a lower risk of recurrence at the surgical site and longer survival than “intralesional” excision according to Enneking. Favourable oncological outcomes after en bloc resection may be achieved in terms of recurrence and survival. “Intralesional” procedures (when the surgeon incidentally or intentionally violates the margins of the tumour) worsen the prognosis and recurrence rate	B/C	[54–56]	II/III	Multicentre ambispective cohort analysis, prospective cohort study, retrospective review
2	Multilevel en bloc spondylectomy performed by experienced surgeons Oncologic resections achieved by multilevel en bloc spondylectomy in experienced hands can lead to an acceptable survival rate with reasonable local control	C	[57]	IV	Case series

Table 12 Recommendations. Sarcomas. Surgical treatment. General principles

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	En bloc resection rather than piecemeal resection even if both have negative margins En bloc resection with tumour-free margins has a lower rate of recurrence than piecemeal resection with negative margins	C	[52]	III	Retrospective comparative study

on the Enneking principles of four types of surgical margins for musculoskeletal sarcoma [28]. Some may confuse true extralesional en bloc resection according to the WBB/Enneking principles with Tomita’s en bloc spondylectomy, which is excision of the whole vertebra in two pieces from the spine, with the cut line dividing the vertebra into two pieces running through the pedicles [29]. An increasing number of colleagues performing spine surgery are skilled in these techniques and apply them for nonneoplastic pathologies of the spine, such as spinal deformities or infections

[30, 31]. These skills do not necessarily translate into expertise in truly extralesional resections because the latter may require different combinations of surgical strategies, including combinations of two, three or even more separate routes of surgical access. Only a few colleagues among spine surgeons have expertise in this type of spine surgery due to the extreme rarity of primary malignant spinal tumours. The chance that an average spine surgeon will encounter a patient with spinal sarcoma or chordoma during his or her career is minimal. The majority of excellent spine surgeons will never

Table 13 Recommendations. Chondrosarcoma. Adjuvant and Standalone radiotherapy

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Adjuvant radiotherapy after complete resection of the tumour Although complete surgical resection is paramount in the management of chondrosarcoma, RT is a useful adjuvant treatment and appears to offer excellent and durable local control when wide surgical resection is difficult to accomplish	B	[58]	III	Retrospective
2	High-dose proton irradiation rather conventional radiotherapy after maximum resection of the tumour, whenever possible Maximum surgical resection followed by high-dose proton irradiation results in superior results to conventional X-ray treatment of chondrosarcomas of the skull base	B	[59–61]	III	Retrospective
3	Irradiation in cases of inoperable tumours Evidence suggests that chondrosarcoma is not radioresistant and that irradiation should be considered when surgery would cause major unacceptable morbidity or be technically impossible. Early evidence suggests there may be a role for chemotherapy to supplement the effects of irradiation	B	[62, 63]	III	Retrospective

Table 14 Recommendations. Osteosarcoma

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Enneking-appropriate en bloc (EA) resection rather than Enneking-inappropriate (EI) intralesional resection of the tumour There is a significant decrease in recurrence, an increase in survival duration and a decrease in metastasis rate with EA en bloc resection when compared with EI intralesional resection	B/C	[64, 65]	III	Ambispective cohort studies, systematic review with meta-analysis
2	High-dose proton therapy doses for some patients with unresectable or incompletely resected osteosarcomas Proton therapy delivering high-dose radiotherapy provides locally curative treatment for some patients with inoperable tumours or partially resected tumours	B	[66–68]	III	Retrospective, case control study
3	Radiotherapy or proton therapy after surgical treatment with positive margins Radiotherapy can help provide local control of osteosarcoma for patients in whom surgical resection with wide, negative margins is not possible. Radiotherapy appears to be more effective in situations in which microscopic or minimal residual disease is being treated		[69]	III	Retrospective
4	Discussion with medical oncologist about adjuvant or neoadjuvant chemotherapy The effect of adjuvant and neoadjuvant chemotherapeutics requires further exploration	B	[64]	III	Ambispective cohort studies

Table 15 Recommendations. Ewing Sarcoma

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Neoadjuvant chemotherapy Preoperative chemotherapy allows for satisfactory results in terms of relapse-free survival (RFS). Patients with resectable tumours after initial chemotherapy have a low local failure rate. Some studies show however that with preoperative radiotherapy, the local control rate is comparable to that with preoperative (neoadjuvant) chemotherapy. The treatment results are comparable between axial tumours and appendicular tumours	A	[45, 50, 70]	I	Randomized control study, retrospective analysis of randomized control studies
2	Surgical resection whenever possible and appropriate Compared to stand-alone radiotherapy for locally advanced disease, a surgical procedure allows for better results in terms of local control (LC), but with no difference in overall survival (OS). The risk of local failure is greater for stand-alone radiation than for surgery	A	[49]	I	Retrospective analysis of randomized control studies
3	Postoperative radiotherapy after intral- esional or marginal resections and after wide resection with a poor histologic response Postoperative radiotherapy may improve local control after resections with positive margins or even Enneking wide resec- tions in patients with poor histologic response	A	[45, 71, 72]	I	Retrospective analysis of randomized control studies
4	Radiotherapy in inoperable cases	A	[50]	I	Retrospective analysis of randomized control studies

operate on such spinal tumours, except of a few colleagues specializing in complex oncological spine surgery. Our recommendation for Enneking's wide and marginal excision of spinal sarcomas and chordomas implies that surgical treatment should ideally be performed by surgeons with expertise in oncological spine surgery. This in turn imposes that a biopsy be performed by the surgeon operating on the tumour because the biopsy must be performed with the surgery plan in mind, as the biopsy tract will have to be removed en bloc with the tumour. Similarly, we recommend that the histopathological diagnostics of spine lesions suspected to be a primary malignancy be performed in recommended centres with expertise in malignant bone tumours. The list of such centres where a sample can be sent for evaluation as well as

instructions on how to maintain and fix the biopsied sample will be included in the appendix to our recommendations.

Malignant spinal tumours, in particular sarcomas, provide a particular diagnostic dilemma due to their variety, with more than 100 histological subtypes that often correspond to different biological behaviours and eventually respond differently to chemotherapeutic agents as well as targeted therapy and immunotherapy [32]. This heterogeneity in classification is accompanied by a broad spectrum of biological behaviour, from locally aggressive and nonmetastatic tumours to tumours that behave relatively indolently in the metastatic state to those that are highly aggressive and rapidly metastasise. Histological evaluations of sarcomas require advanced molecular diagnostics [32, 33].

Table 16 Recommendations. Chordoma

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Enneking-appropriate resection Enneking-appropriate resection plays a major role in decreasing the risk for local recurrence in patients with chordoma of the mobile spine	B	[73]	II	Multi-institutional retrospective study
2	Postoperative proton therapy over conventional therapy Postoperative proton therapy has better overall survival results than postoperative conventional photon radiotherapy. The 10-year overall survival rate is also higher for proton therapy than for stereotactic radiotherapy	B	[74, 75]	II	Meta-analysis, retrospective
3	Aggressive therapy combining resection as radical as possible with postoperative proton or radiotherapy A combination of aggressive surgery and radiotherapy seems to improve the prognoses of suboccipital and cervical chordomas when applied at the patient's first presentation of the disease. Postoperative radiotherapy yields better survival results than salvage radiotherapy in terms of local recurrence	B	[76]	III	Retrospective
4	High-dose definitive radiation therapy in inoperable cases In certain circumstances where resection of the mobile spine or sacral chordoma may result in significant neurologic or organ dysfunction, patients can be treated definitively with the use of high-dose definitive radiation therapy	B	[77]	III	Retrospective

Table 17 Recommendations. Osteblastoma

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Total excision whenever possible	B	[15]	III	Retrospective
2	En bloc resection of stage 3 tumours, with intralesional excision allowed for stage 2 lesions Total resection is important as local recurrence was found to be strongly associated with mortality. Subtotal excision together with higher preoperative alkaline phosphatase, and tumour size greater than 3 cm results in a higher relapse rate	B	[15, 78–80]	III	Retrospective
3	Adjuvant radiotherapy when en bloc or total resection is not feasible or requires unacceptable functional sacrifices Radiotherapy seems to be an effective adjuvant treatment when total resection is not feasible	B	[78]	III	Retrospective

Table 18 Recommendations. Solitary plasmocytoma

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Definite radiotherapy as the treatment of choice Stand-alone radiotherapy achieves very good results in terms of local control. Chemotherapy and/or novel therapies should be investigated for bone or bulky extramedullary tumours	B	[81–83]	III	Retrospective

Table 19 Recommendations. Giant cell tumour

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Surgical treatment (curettage or en bloc resection) as the mainstay of therapy	B	[84]	III	Case control study
2	Denosumab as the treatment of choice for locally advanced tumours	B	[85–88]	III	Prospective comparative study
3	Considering neoadjuvant therapy with denosumab to achieve radical surgical treatment	B	[86–88]	III	Prospective comparative study

Table 20 Recommendations. Haemangioma with clinical manifestations

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Vertebroplasty for the treatment of tumours with clinical manifestations	C	[89]	IV	Case series
2	Considering radiotherapy in some cases Radiotherapy is safe and effective for pain relief in the treatment of spinal haemangioma. Total doses of at least 34 Gy achieve the best symptomatic response	B	[90]	III	Retrospective
3	Radical surgical resection for haemangiomas with an extraosseous extension causing neurological symptoms Local recurrence of the tumour after subtotal resection has been reported, and adjuvant radiotherapy makes a second surgery difficult	C	[91]	IV	Retrospective short case series

Table 21 Recommendations. Osteoid osteoma

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Conservative treatment Osteoid osteoma can be treated conservatively. Surgical excision (curettage) was considered the gold standard in the past but is no longer attractive today due to its invasiveness. Surgical resection should be taken into consideration as an option when the results of conservative treatment are poor	A	[92]	I	Systematic review
2	Surgical resection, radiofrequency ablation, percutaneous laser, and cryoablation in patients harbouring painful spinal osteoid osteoma or when the results of conservative treatment are poor	B	[93–96]	III	Case series

Table 22 Recommendations. Osteochondroma

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Complete resection of the cartilaginous cap of the tumour	B	[97]	III	Case control, systematic review

Advanced molecular diagnostics of rare musculoskeletal tumours, especially sarcomas, are available in very few places dispersed across Poland. This is also the case in other European countries, as documented by the EPAAC through an assessment of the quality of cancer care in Europe [1]. That is why in many countries, there is a trend to concentrate expertise for certain tumour types, including sarcomas, in dedicated centres or units [1].

In Poland, there is a Department of Soft Tissue, Bone Sarcoma and Melanoma at the Maria Skłodowska-Curie Institute Oncology Centre in Warsaw dedicated to the complex management of sarcomas. This department covers the majority of sarcoma cases in regard to molecular diagnostics and surgical treatment in Poland. However, the department mostly encounters only appendicular sarcomas, while spinal sarcomas are randomly operated on elsewhere across the country, often without a preceding biopsy or even radiological diagnosis or radiological suspicion of sarcoma. Therefore, most if not all spinal sarcomas are not operated on compliantly with the WBB/Enneking principles of extralaminar excision. Once the preliminary histology of the operated spinal tumour confirms or suggests sarcoma, the sample

may be sent for further in-depth diagnosis to another institution with better facilities and expertise in molecular pathology. Sometimes the sample may circulate from institution to institution before it reaches one that eventually establishes a thorough molecular diagnosis. To ensure a timely histological diagnosis and prevent patients from receiving an incomplete diagnosis of sarcoma, we identified all institutions and colleagues in Poland with expertise in molecular pathology techniques for sarcomas. These institutions will be listed in the appendix to the recommendations. Although few exist in the country, these institutions are able to cover the histological diagnostics of all spinal and appendicular sarcomas occurring in Poland. The EPAAC expert group recommends that for an institution to be considered a sarcoma centre, it should treat at least 100 new sarcoma patients (both soft tissue and bone) per year [1]. Similarly, guidance from the National Institute for Health and Care Excellence (NICE) in England and Wales states that multidisciplinary teams (MDTs) managing either soft tissue sarcoma or bone sarcoma should manage the care of at least 100 new patients per year (100 soft tissue and 50 bone sarcomas if the MDT manages both types) [34].

Table 23 Recommendations. Aneurysmal bone cysts

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Selective arterial embolization as the first treatment option for spine aneurysmal bone cyst without neurologic deficit, pathological fracture or spinal instability This can be followed by surgery in case of recurrence/ineffective treatment	B	[98]	III	Retrospective study
2	Complete intralesional excision as the therapy of choice in cases of neurologic involvement, pathologic fracture, or local recurrence or when embolization is technically impossible after embolization procedures Remark: radical surgical excision or en bloc resection are correlated with better prognosis for local tumour control with significantly lower recurrence rates, especially when combined with adjunctive therapies such as cryotherapy, phenol, or adjuvant radiotherapy. The resulting recurrence rates are as follows, ranked from highest to lowest: isolated Surgiflo injection into the lesion, decompression/laminectomy, partial excision/resection, and curettage alone. Primary or adjuvant radiotherapy may be an effective and safe treatment option for persistent or recurrent aneurysmal bone cysts	B	[98–102]	III	Retrospective systematic review

Table 24 Recommendations. Giant cell tumours

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Complete surgical resection whenever possible, particularly if neurologic impairment is present En bloc resection with wide/marginal margins should be performed when technically feasible because it is associated with decreased local recurrence rates. Intralesional resection is associated with increased local recurrence rates, and mortality correlates with local recurrence	B	[103, 104]	III	Ambispective observational study
2	Denosumab as neoadjuvant or adjuvant therapy when Enneking-appropriate resection is not possible Denosumab alone is effective in relieving pain, increasing ossification and sometimes reducing the tumour volume. This treatment can be considered when radical surgical treatment is not possible due to associated unacceptable morbidity or loss of function	B	[105]	III	Prospective study

Table 25 Recommendations. Fibrous dysplasia

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Treatment with conventional surgical procedures including internal fixation	B	[106]	III	Literature review

Table 26 Recommendations. Langerhans cell histiocytosis

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>We recommend</i>					
1	Individualised approaches when establishing therapeutic management The spectrum of therapeutic possibilities is wide and, after the exclusion of a malignant lesion, extends from nonsurgical treatment to alternative administrations of corticosteroids, curettage, replacement of the defect with bone grafts, and even en bloc surgical removal	C	[107–109]	IV	Case series, review of case series

Therefore, we recommend sending biopsied and intra-operative samples suspected of being spinal sarcoma to the institutions listed in the appendix. This is in accordance with the recommendation of the European Cancer Organization (ECCO) expert group, who stresses that a diagnosis must only be made in dedicated sarcoma centres [1]. In addition, we added instructions to the appendix on how samples from tumours suspected to be a sarcoma should be fixed immediately after harvesting in the operating room.

Only two recommendations were placed on the discrepancy list (Table 28). These recommendations refer to emergency/urgent decompression of the spinal canal to counteract irreversible neurologic deficits in cases where no histological diagnosis was obtained. As everyday practice proves, emergency decompression surgeries are not uncommon in spinal tumours. Urgent or emergency decompression does not conflict with the principles of treatment of spinal tumours as long as the tumour is a metastasis. However, such decompression may conflict with the treatment principles when a tumour appears to be a primary tumour, especially haematopoietic tumours. Surgical treatment of

haematopoietic tumours has no proven benefit compared with medical treatment, which usually provides excellent long-term outcomes. The view of some medical colleagues in the group clashed with the views of surgical colleagues. The first view stressed that surgery on haematopoietic malignancies of the spine can reduce or even deprive patients of a chance for a complete cure, even if adequate medical treatment is continued after the operation. The second view noted the impact of permanent complete or severe neurological deficits on quality of life, even if the patient receives state-of-the-art medical treatment. Whether patients with spinal tumours and a risk of permanent neurological deficit should undergo surgery without a biopsy should be discussed with the patient.

The majority of recommendations developed were graded as B and C, while the levels of the identified sources of evidence received grades of II–III, especially in regard to primary malignant spinal tumours. The rarity of these tumours is responsible for the paucity of data regarding their management and lack of higher levels of evidence usually achieved through high-quality therapeutic studies including larger numbers of analysed patients.

Table 27 Recommendations. Metastases

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
<i>Scoring systems and diagnostics</i>					
<i>We recommend</i>					
1	The final decision for treating patients with spinal metastases should be made based on the prognostic scales and individual assessment results in each case All widespread scoring systems to estimate both overall survival and tumour-specific survival for patients undergoing surgical treatment for metastatic spine disease have similar efficacy. There is no clear evidence of the superiority of one system	B/C	[110, 111]	III	Literature review, retrospective
2	The spinal instability neoplastic score (SINS) should be used to assess spinal instability in cases with neoplastic involvement of the spine SINS gives reliable indications for spinal instability surgery in patients with metastatic disease of the spine	B	[112]	III	Retrospective
3	The national outcomes measurement system (NOMS) should be used to facilitate decision-making and can optimize patient care	C	[113]	V	Expert opinion
4	Complete radiological diagnostics (skull radiographs, computed tomography of the chest, abdomen and pelvis) should be performed, with a panel of oncological and haematological markers before bone biopsy in patients with suspected metastatic lesions of an unknown starting point	B	[114]	III	Retrospective
<i>Metastases. Use of steroids in spinal cord compression</i>					
<i>We recommend</i>					
1	Short-term salvage use of steroids in metastatic spinal cord compression (MSCC) before surgery in cases with rapid worsening or severe neurological deficits The optimal steroid dose is unknown, with one small trial demonstrating no significant difference in efficacy between high and low doses of dexamethasone. High-dose regimens may have a higher risk of steroid-related adverse effects and thus, whether the risks of high-dose dexamethasone regimens outweigh the benefits should be considered	A/B	[115, 116]	II	Randomized control study, literature review
2	Chronic steroid therapy is not recommended to improve neurological function or reduce pain	B	[117]	II	Literature review
<i>Metastases. Surgical treatment</i>					
<i>We recommend</i>					
1	The least invasive procedures with the use of minimally invasive techniques sufficient to provide patients with pain reduction, decompression of nerve structures and restoration of stability	B	[118–120]	III	Retrospective
2	Minimally invasive fixation or augmentation of the vertebral body in the event of a pathological fracture associated with radiotherapy	B	[121]	III	Retrospective
3	En bloc resection only for carefully selected metastatic lesions such as hormone-secreting tumours and solitary radioresistant tumours, but these procedures must be considered in the context of the patient's systemic disease status and the morbidity of the surgery Total en bloc resection may have narrow indications for carefully selected cases of types 3, 4, and 5 lesions and relative indications for type 1, 2, and 6 lesions according to Tomita's surgical classification of spinal tumour	B	[122–124]	III	Literature review, retrospective
4	Cement augmentation of pathologically fractured vertebral bodies in the course of haematological neoplasms	B	[125, 126]	III	Literature review
5	Decompression of the spinal cord in cases of increasing neurological deficits within 48 h	B	[127]	III	Retrospective
6	Cautious use of surgical treatment for patients with complete paralysis and dysfunction of the sphincters	B	[128]	III	Retrospective

Table 27 (continued)

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
7	Composite instrumentation of the spine In contrast to metal implants, composite implants eliminate artefacts and therefore allow for precise planning with radiotherapy, making imaging more effective	B	[129–135]	III	Retrospective
8	No bone grafting in patients who have undergone resection of metastatic tumours	B	[136]	III	Retrospective
9	Preoperative embolization of highly vascularized tumours (kidney cancer, thyroid cancer, pheochromocytoma)	B	[137]	III	Retrospective
<i>Radiotherapy. Metastases</i>					
<i>We recommend</i>					
1	Radiosurgery when available rather than classic radiotherapy as radiation therapy for spinal metastases, regardless of if used stand-alone or in combination with surgery Radiosurgery is safe and does not increase the risk of complications in relation to palliative radiotherapy. Radiosurgery has a longer analgesic effect than conventional palliative radiotherapy	A	[138–143]	I	Randomized control study
2	Stand-alone radiosurgery as the method of choice in diagnosing up to 3 metastatic lesions of the spine without signs of instability or neurological deficits in patients with a survival prognosis of > 3 months Radiosurgery of several metastatic lesions prolongs the survival of patients in relation to palliative treatment	B A	[144] [145]	II I	Systematic review of level II and III studies Randomized control study
3	Repeat radiosurgery as a treatment option in the event of local recurrence after radiosurgery or palliative radiotherapy in patients disqualified from surgery Radiosurgery has a very good therapeutic effect and is understood to stop the growth of the treated focus, both when used alone and in combination with surgical treatment	B	[146]	II	Systematic review of level III studies, case series
4	Radiotherapy of the spine as a treatment option in patients with spine metastases when radiosurgery is not available or patients disqualified from radiosurgery and/or surgical decompression and recommended to abandon EBRT by a radiotherapist A single dose of 10 Gy is not associated with a greater risk of loss of mobility than a 20 Gy regimen administered in 5 fractions in the group of patients not qualified for decompression	B A	[147] [148]	II I	Systematic review of level II and III studies Randomized control study
5	Combination of surgical decompression/separation surgery with radiosurgery, or classic radiotherapy (EBRT) when the former is not available Radiotherapy in combination with surgical decompression improves local control in patients treated for compression of the spine. Radiosurgery allows for less invasive surgical procedures and improves the quality of life of patients with spinal cord compression. Radiosurgery is a safer therapeutic option than conventional radiotherapy in regard to postoperative wound healing The operation performed after radiosurgery is not associated with more frequent complications Performing the procedure in a short time after radiosurgery (less than 7 days) is safe and does not increase the rate of complications Radiosurgery can increase the safety of the subsequent surgery by reducing tumour bleeding	B C	[149–155] [156–158]	I/II III	Randomized control study, systematic reviews, systematic review of level II and III studies, prospective study Systematic review of level III studies Retrospective comparative study, Expert opinion Prospective study Large retrospective study Prospective study

Table 27 (continued)

NR	Recommendation	Strength of the recommendation	Source of data supporting the recommendation	Study level of the source	Study type of the source
6	Conventional radiotherapy should be used optimally, after a min of 2 weeks after the surgery to ensure wound healing Using this method too early may result in the necessity to remove the implants due to inflammation. Radiosurgery can shorten this time	C	[153, 159, 160]	III	Systematic review of level III studies
7	Carbon instrumentation if surgical treatment was performed before radiosurgery The use of carbon implants enables the precise and more effective application of radiation treatment techniques and the planning of radiosurgery	C	[161]	III	Case series

Table 28 Discrepancies

1	Indications for emergency or urgent surgical decompression to counteract irreversible neurologic deficits in patients with confirmed haematopoietic tumours should be established individually after a discussion with the patient and with the opinion that haematopoietic tumours should undergo radiotherapy and/or systemic treatment kept in mind	No evidence were yielded from the literature regarding survival and curability after surgical decompression of haematopoietic tumours with adjuvant therapy verses primarily systemic therapy
2	Decompression of the spinal canal in patients with tumours of unknown origin that threaten severe neurological deficits without biopsy should be individually discussed with the patient Patients may have a reduced chance for being cured if the histological examination finds that the tumour is the primary tumour	See treatment recommendation for primary tumours in Table 2

Conclusions

The developed recommendations together with the national network of expertise should optimize the management of patients with spinal tumours, especially those with rare malignancies, and optimize their referral and allocation within the Polish NHS.

Authors' contribution MA wrote the manuscript, MA, GR, KD, RP were chairs of the Recommendation Development Group, formulated recommendations, supervised voting, AK, DM, DK, GR, GL, GG, MH, JW, JP, ŁD, MA, MT, PT, RM, TŁ, ZR: literature search, formulation of recommendations.

Declarations

Conflict of interest The authors have no financial interests that are directly or indirectly related to the work submitted for publication.

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