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DEFORMITY

Best Practice Guidelines for Assessment and Management of Osteoporosis in Adult Patients Undergoing Elective Spinal Reconstruction

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Study Design. Expert consensus study.

Objective. This expert panel was created to establish best practice guidelines to identify and treat patients with poor bone health prior to elective spinal reconstruction.

Summary of Background Data. Currently, no guidelines exist for the management of osteoporosis and osteopenia in patients undergoing spinal reconstructive surgery. Untreated osteoporosis in spine reconstruction surgery is associated with higher complications and worse outcomes.

Methods. A multidisciplinary panel with 18 experts was assembled including orthopedic and neurological surgeons, endocrinologists, and rheumatologists. Surveys and discussions regarding the current literature were held according to Delphi method until a final set of guidelines was created with over 70% consensus.

Results. Panelists agreed that bone health should be considered in every patient prior to elective spinal reconstruction. All patients above 65 and those under 65 with particular risk factors (chronic glucocorticoid use, high fracture risk or previous fracture, limited mobility, and eight other key factors) should have a formal bone health evaluation prior to undergoing surgery. DXA scans of the hip are preferable due to their wide availability. Opportunistic CT Hounsfield Units of the vertebrae can be useful in identifying poor bone health. In the absence of contraindications, anabolic agents are considered first line therapy due to their bone building properties as compared with antiresorptive medications. Medications should be administered preoperatively for at least 2 months and postoperatively for minimum 8 months.

Conclusion. Based on the consensus of a multidisciplinary panel of experts, we propose best practice guidelines for assessment and treatment of poor bone health prior to elective spinal reconstructive surgery. Patients above age 65 and those with particular risk factors under 65 should undergo formal bone health evaluation. We also established guidelines on perioperative optimization, utility of various diagnostic modalities, and the optimal medical management of bone health in this population.

Key words: abaloparatide, best practice, consensus guidelines, CT Hounsfield units, osteoporosis, reconstructive spine surgery, teriparatide.

Level of Evidence: 5

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Undiagnosed osteopenia and osteoporosis can have devastating consequences on patients undergoing reconstructive spine surgery. Patients with poor bone health are at an increased risk of pedicle screw loosening,[1,2] instrumentation failure,[1,2] pseudarthrosis,[3–5] vertebral compression fractures,[2,4] proximal junctional kyphosis

(PJK),[2,4,6,7] and revision surgery.[5,8,9] These complications can potentially be decreased by preoperatively identifying and treating osteoporosis.[10–15]

Poor bone health is frequently underdiagnosed and undertreated in spine surgery populations. A survey of 349 spine surgeons found only 19.6% screened their patients for osteoporosis prior to surgery.[16] Kadri *et al*[17] found out of 124 patients undergoing arthroplasty or thoracolumbar surgery, 91% met at least one criterion for receiving osteoporosis medications according to the US National Osteoporosis Foundation (NOF) guidelines. Jain *et al*[10] found in 849 patients diagnosed with osteoporosis undergoing three or more level spinal fusion, only 14.3% were on osteoporosis treatment prior to surgery and 43% for 1 year after surgery.

Despite osteoporosis and osteopenia being common and associated with adverse outcomes in spine surgery, currently, no guidelines or consensus exists on how to evaluate and treat patients with poor bone health prior to and after spinal reconstructive surgery. The purpose of this study was to form a multidisciplinary panel of experts to create best practice guidelines for the optimal management of osteoporosis in patients undergoing reconstructive spine surgery.

METHODS

The Panel

Panelists selected included 18 physicians: 10 orthopedic spine surgeons, two rheumatologists specialized in osteoporosis, two neurosurgery spine surgeons, one family medicine bone health expert, one endocrinologist, one orthopedic traumatologist, and one pediatric orthopedic surgeon with extensive previous osteoporosis research. Experts were from different regions of the United States, including 12 different states. Panelists were invited based on their expertise in osteoporosis, previous research, or experience in spinal reconstructive surgery. The surgeon panelist members practiced on average 24 years (standard deviation = 9 yr) since completing residency. The medical experts practiced on average 32 years (SD = 6 yr). Eighteen physicians participated in all rounds of consensus, two were excluded for not completing all rounds of consensus surveys.

Consensus Determination

The consensus panel was structured according to the Delphi method (Figure 1).[18] Survey data were collected using REDCap electronic data capture tools hosted at Columbia University.[19,20] An initial survey collected information on

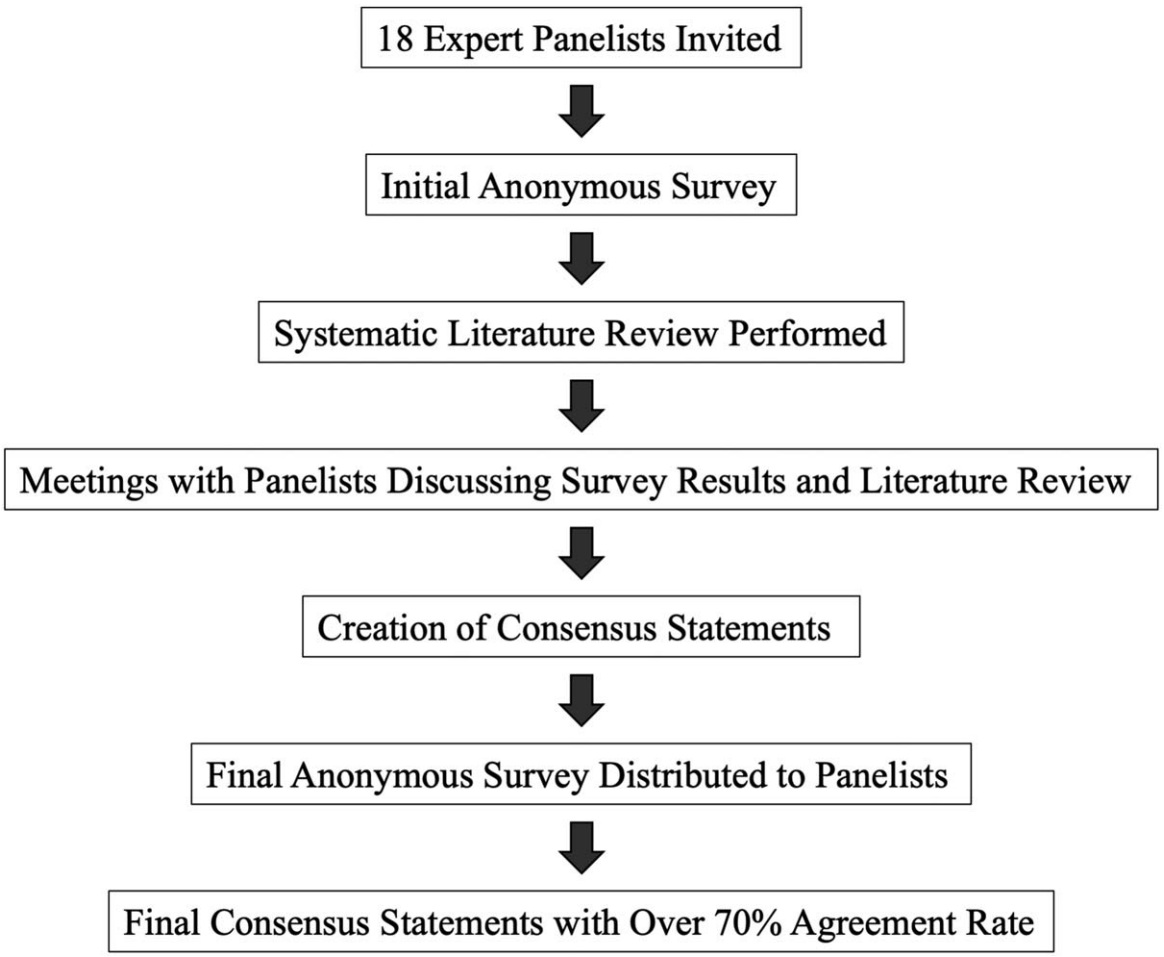

Figure 1. Consensus study methodology structured according to Delphi method.

the physician's current bone health practices and perceptions prior to reconstructive spine surgery involving instrumentation and fusion. A full list of questions can be seen in Appendix A. A literature review was performed according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines by the primary authors regarding each surveyed topic and 64 studies were identified. Literature review was not constrained by dates, it was performed on PubMed, Medline, and Cochrane databases. A series of meetings were held where the initial survey results and literature review was presented. Panelists discussed what guidelines would be appropriate. After the meetings, a final survey was distributed with potential consensus statements. Panelists were given the option to strongly agree, agree, disagree, and strongly disagree. They were not given the opportunity to edit their answers. A 70% agreement rate including strongly agree and agree was used as a threshold for consensus.

RESULTS

Indications to Assess Bone Health

Eighteen panelists assessed each final survey statement (Table 1). Panelists agreed (94.4%) it is important to assess bone health in patients prior to spine reconstruction surgery, including also non-surgical patients (83.3%). The panel concluded that all patients over 65 years-old, independent of risk factors, should have a formal bone health evaluation using bone mineral density (BMD) test prior to surgery (88.9%).

For patients between the ages of 50 and 64, BMD testing should be performed if any of the following 12 risk factors are present: chronic glucocorticoid use defined as over 3 months of prednisone use, minimum 5 mg per day (88.9%), personal history of previous low energy fracture of the hip or spine (83.3%), personal history of metabolic bone disease (83.3%), chronic kidney disease more than or equal to stage 3 (GFR $<$ 60 mL/min) (77.8%), high fracture risk as calculated by FRAX (fracture risk assessment tool) without BMD (77.8%), prior failed spine surgery, including fracture, pseudarthrosis, instrumentation failure (77.8%), alcohol use (three or more units/d) (77.8%), Vitamin D deficiency (72.2%), current smoking (72.2%), limited mobility, wheelchair based (72.2%), on cancer treatment (known to impact bone health) (72.2%), and diabetes mellitus ($>$10 yrs and poor control) (72.2%) (Supplement Table 1, http://links.lww.com/BRS/B810).

For patients under 50 years of age, BMD testing should be performed if any of the following five risk factors are present: chronic glucocorticoid use (88.9%), previous low energy fracture (77.8%), metabolic bone disease (77.8%), cancer treatment (77.8%), or chronic kidney disease (72.2%) as defined above (Supplement Table 1, http://links.lww.com/BRS/B810).

Assessment Tools and Techniques

Panelists agreed that first line BMD assessment should be performed with hip and spine DXA scan, unless physically or technically precluded (94.4%). The agreed upon alternative if hip or spine sites are unavailable or unreliable is the distal 1/2 radius (94.4%). The lowest available score of the three should be used in adults more than or equal to 50 (94.4%). Z-scores should be used for patients between 20 and 50 years old (94.4%). Lastly, trabecular bone score (TBS) should be obtained as part of DXA (88.9%).

Panelists agreed that the vertebral fracture assessment (VFA) as part of the BMD scan is recommended to identify occult fractures (94.4%). If the VFA is unavailable, lateral imaging of the thoracic and lumbar spine in a plain x-ray is recommended to screen for fractures (94.4%).

Lumbar CT-based Hounsfield Units (CTHU) were agreed upon as a useful opportunistic assessment of bone health in patients (100.0%). If the Lumbar CTHU is less than or equal to 150, a DXA scan was recommended for further evaluation (88.9%). CTHU were not agreed upon as an alternative to a DXA.

In addition to osteoporosis screening with imaging, panelists agreed that it is important to measure serum 25-hydroxyvitamin D levels prior to surgery in patients undergoing spine reconstructive surgery (88.9%).

Panelists agreed that a surgeon's intraoperative subjective sense of poor bone quality should prompt a formal bone health evaluation if one was not previously performed (72.2%). All panelists agreed that patients determined to have poor bone health should be evaluated and treated prior to elective spine reconstructive surgery by an experienced bone health provider (100.0%). Most panelists agreed that surgical spine reconstruction should not be withheld based on an arbitrary low BMD alone if appropriate medical treatment has been performed prior to surgery as no agreement on lower limits exists (72.2%). Spine reconstruction practices and centers are suggested to strongly consider creating or affiliating with a Bone Health Clinic/Service (94.4%).

Treatment

All patients found to have poor bone health should have further assessment for secondary causes (100%). Medical treatment of osteoporosis, defined as T-score below −2.5 is recommended for elective spine reconstruction patients prior to surgery (88.9%).

Vitamin D deficiency was defined as below 30 nmol/L 25(OH)D level and insufficiency as 30 to 50 nmol/L. For patients with Vitamin D insufficiency or deficiency, Oral Vitamin D3 supplement is recommended for treatment prior to surgery (94.4%). The agreed upon initial daily dose is between 1000 and 2000 IU of Vitamin D3 (100.0%) and may be adjusted based on the degree of deficiency and response to the initial dose. A total of 1000 to 1200 mg per day of calcium from either dietary intake or supplements is recommended for all patients undergoing spinal surgery, except those with a contraindication such as history of hypercalcemia or tumors associated with hypercalcemia (*e.g.*, breast, renal, and multiple myeloma) (88.9%).

After optimization of other causes of osteoporosis and osteopenia, anabolic or bone building agents, such as

TABLE 1. Final Recommendations and Consensus Percentage

Consensus Statement	Percentage Strongly Agree or Agree
Bone health should be considered in all patients prior to elective spine reconstruction surgery.	100%
Spine surgeons should recommend routine bone health screening for non-surgical patients as well, according to published guidelines.	72%
Bone mineral density testing (either DXA scan or CT - Hounsfield Units) are recommended for: >65 years old all patients independent of risk factors or gender. <65 years old with certain risk factors	89%
Patients ages 50 to 64 with the following 12 risk factors should be screened for poor bone health:	
Chronic corticosteroid use (≥5 mg/d for ≥90 days)	89%
Personal history of previous low trauma fracture of the hip or spine	83%
Personal history of metabolic bone disease	83%
Chronic kidney disease ≥ stage 3 (GFR <60 mL/min)	78%
High fracture risk as calculated by FRAX without BMD	78%
Prior failed surgery (fracture, pseudarthrosis, instrumentation failure)	78%
Alcohol use (three or more units/day)	78%
Vitamin D deficiency	72%
Current smoking	72%
Limited mobility-wheelchair based	72%
Cancer treatment (chemotherapy or hormone treatment known to impact bone health)	72%
Diabetes mellitus (>10 yrs and poor control)	72%
Patients under 50 with the following five risk factors should be screened for poor bone health:	
Chronic corticosteroid use (≥5 mg/d for ≥90 days)	89%
Personal history of previous low trauma fracture of the hip or spine	78%
Personal history of metabolic bone disease	78%
Cancer treatment (chemotherapy or hormone treatment known to impact bone health)	78%
Chronic kidney disease ≥ stage 3 (GFR <60 mL/min)	72%
When available the vertebral fracture assessment (VFA) is recommended to identify occult fractures of the spine prior to elective spine reconstructive surgery. If not available, lateral imaging of the thoracic and lumbar spine in a plain x-ray is recommended to identify fractures of the spine.	94%
Hip and spine DXA scan should be used for BMD assessment, unless physically or technically precluded, then 1/3 radius. The lowest available score of the three should be used in adults ≥50 for assessment of BMD.	94%
When using DXA for assessment of BMD, Z-scores should be used for patients ≥20 but <50 years old	94%
Trabecular bone score (TBS) should be obtained as part of DXA where available	89%
CT-based Hounsfield Units (CTHU) area a useful initial assessment of bone health in patients without a DXA scan. If the Lumbar CT based Hounsfield units (HU) is ≤150, a DXA scan is recommended for further evaluation.	100%
Serum 25-hydroxyvitamin D levels should be measured prior to surgery, supplementation with 1000 to 2000 IU of Vitamin D3 is recommended for those with insufficiency or deficiency.	94%
All patients unless precluded should have a total of 1000 to 1200 mg per day of calcium from either dietary intake or supplements	89%
Surgeon's intraoperative subjective sense of altered or poor bone quality should be communicated to the bone health provider and prompt formal bone health evaluation	72%
Patients determined to have poor bone health should be further evaluated and treated prior to elective spine reconstructive surgery by an experienced bone health provider	100%
Spine reconstruction should not be withheld based on low BMD alone	72%
Spine reconstruction practices should strongly consider creating or affiliating with a Bone Health Clinic/Service.	94%
All patients found during assessment to have poor bone health shoulder have further work up to investigate and treat possible secondary causes.	100%
Medical treatment of poor bone health is recommended for elective spine reconstruction patients, according to published guidelines for osteoporosis and osteopenia treatment (88.9%, 16/18).	89%
Anabolic or bone building agents, such as TP 20 mcg daily or abaloparatide 80 mcg daily, are recommended as first line treatment for management of poor bone health prior to elective spine reconstructive surgery if no contraindications are present.	89%
When treatment with anabolic agents is contraindicated or not affordable, treatment with zoledronic acid, denosumab, or other antiresorptive agents can be recommended as a second line option.	89%
The recommended duration of medical treatment with anabolic agents is at least 2 months preoperatively or up to 6 months preoperatively for elective spine reconstructive surgery involving multiple levels. The recommended postoperative duration is at least 8 months.	100%
There is no consensus regarding the need for or duration of withholding medical treatment for bone health, either anabolic or antiresorptive agents, in the immediate perioperative period.	89%
After completion of treatment with anabolic agents, treatment can be followed by the use of antiresorptive medications.	94%

teriparatide or abaloparatide, are recommended as first line treatment prior to elective spine reconstructive surgery if no contraindications are present (88.9%). When treatment with anabolic agents is contraindicated or not affordable, treatment with antiresorptive agents such as denosumab or bisphosphonates (BPs) like zoledronic acid can be recommended as a second line option (88.9%).

The recommended duration of medical treatment with anabolic agents is at least 2-months preoperatively (88.9%) or up to 6-months preoperatively for elective spine reconstructive surgery (100.0%). The recommended postoperative duration of medical treatment with anabolic agents is at least 8-months (72.2%). After completion of treatment with anabolic agents, treatment can be followed by antiresorptive medications (94.4%). No duration of withholding medical treatment for bone health, neither anabolic nor antiresorptive agents, is needed in the immediate perioperative period (88.9%).

DISCUSSION

Spine surgeons should consider a patient's bone health prior to surgery and assess whether further work up is needed based on the screening criteria discussed in these guidelines (Supplement Table 1, http://links.lww.com/BRS/B810). The risk factors selected in this consensus are easy to identify with available screening tools such as the NOF criteria, FRAX, and the 2019 International Society for Clinical Densitometry (ISCD) Official Positions.[21–23] All patients over 65 years old, independent of risk factors or sex, should have a DXA prior to spine reconstructive surgery. Though conversely the ICSD 2019 positions and NOF criteria suggest more than 70 for men and over more than 65 for women,[21] this expert panel concluded that a difference in the minimum age based on sex can lead to a missed diagnoses of poor bone health in male patients as general criteria for osteoporosis screening may not be completely applicable to patients undergoing spine surgery. Kuprys *et al*[24] analyzed patients referred by spine surgeons for bone health screening and found that male patients were under-screened as compared with women. Kadri *et al*[17] as well found no significant difference in T-scores between men and women referred for a DXA prior to spine surgery.

Patients with risk factors should be referred for a DXA scan, specifically hip and lumbar spine akin to the ISCD 2019 positions.[21] DXA is currently considered the gold standard for evaluation of bone health due to its widespread availability, familiarity to physicians, and low cost. In the case of patients with osteoarthritis, fracture, calcified vessels, or other radiopaque material, correction should be performed by removing artifacts or DXA of another region, such as the distal radius.[25] CTHU has been increasingly discussed as an opportunistic method for assessing bone health as surgeons frequently refer patients for a CT preoperatively. The technique was initially described by Schreiber *et al*[26] in 2011 and L1–L4 were found to strongly correlate with DXA results. Compared with the DXA T-score, CTHU had a sensitivity of 0.73, specificity of 0.71, positive predictive value of 0.85, and negative predictive value of 0.56 at the following cut offs: normal (>-1.0): 133.0 ± 37.6, osteopenia (-1.0 to 2.5): 100.8 ± 24.5, and osteoporosis (<-2.5): 78.5 ± 32.4.[26] Ten studies found a statistically significant correlation between CTHU and DXA scan results.[3,7,26–33] The panelists on this study and the ISCD 2019 guidelines both concluded that opportunistic CTHU can be used to estimate the likelihood of osteoporosis, but not as an alternative to a DXA due to the lack of standardized criteria for diagnosing osteoporosis/osteopenia by HU, difficulty defining treatment based by HU, and challenges in widely implementing such a technique.[21] Prior to surgery it is also important to identify vertebral fractures either by VFA if available along with the DXA, careful evaluation of a lateral spine radiograph, or other available imaging, for example, CT or MRI. Lastly in terms of diagnosis, if an intraoperative diagnosis of poor bone quality is made, it should prompt a formal bone health evaluation if not already performed.[21]

It is important to measure serum 25-hydroxyvitamin D levels prior to surgery and supplement if appropriate. Vitamin D deficiency is frequently undiagnosed prior to spinal surgery.[16,34–36] The effect of vitamin D deficiency on spinal fusion is not completed defined in the literature. Ravindra *et al*[36] found a significant association between vitamin D deficiency, nonunion, and longer time to fusion. On the other hand, Donnally *et al*[37] found no significant difference. Clinical outcomes in several studies demonstrated that higher vitamin D levels have been associated with improved ODI scores and decreased pain after spine surgery.[34,38–40] Calcium intake should be the recommended daily amount per clinical guidelines, 700 to 1200 mg per day.[41] Supplementation beyond that has not been proven to be helpful, and above 2000 mg per day is potentially harmful.[41]

Patients determined to have poor bone health should be treated by an experienced bone health provider such as an endocrinologists or rheumatologist. Pantoja and Molina[16] found that 81% of spine surgeons do in fact refer patients to other providers for management of osteoporosis and osteopenia, most frequently to endocrinologists (56.3%). It would be helpful for surgery centers to have an established association with a Bone Health Clinic.

Anabolic or bone building agents, such as teriparatide 20 mcg daily or abaloparatide 80 mcg daily are recommended as first line treatment for osteoporosis and osteopenia. Teriparatide is a synthetic form of parathyroid hormone and the first anabolic, bone building medication approved. Teriparatide can enhance fusion after spine surgery given its bone building mechanism of action as compared with BPs which maintain bone mass. The efficacy of teriparatide has been well demonstrated in the literature (Supplement Table 2, http://links.lww.com/BRS/B811). A meta-analysis by Buerba *et al*[42] identified nine studies covering 536 osteoporosis patients undergoing spinal fusion and found a decreased risk of complications (screw loosening, 10% with teriparatide *vs.* 27.3% control) and higher fusion rates (69% *vs.* 35.1% control).[43] Other studies have

identified a shorter time to union,[11,44–46] higher overall rate of union,[11,13,14,44] reduced pedicle screw loosening,[12,13,15,47] reduced rod breakage,[13] higher insertional torque,[48] and less adjacent segment disease[13,49] as compared with BPs or no treatment. The studies that found no benefit of teriparatide were all dosed for less than 2 months preoperatively or less than 8 months postoperatively, which appears to be insufficient dosing.[50,51] Currently there is no literature in spine surgery for abaloparatide, however it has a similar mechanism of action to teriparatide, a synthetic analog of human parathyroid hormone-related protein that is also an anabolic.[52–55]

The primary limitation of anabolic medications is their high cost.[16,56] The literature trends towards teriparatide being a superior treatment in spine surgery. In seven of the nine studies that compared teriparatide to BP directly, teriparatide demonstrated a significant benefit comparatively (Supplement Table 3, http://links.lww.com/BRS/B812). Both alendronate and zoledronate have been well studied and demonstrated mix efficacy in improving fusion and decrease complications compared with no treatment.[15,45,56–64] Denosumab and romosozumab are two other antiresorptive medications that are monoclonal antibodies. Denosumab was studied once specifically in spine surgery where it is combined with teriparatide and found to be more effective than teriparatide alone.[65] Both of these medications can be seen as alternative antiresorptive medications given their mechanism of action and efficacy in osteoporosis generally.[54,66]

The primary limitation of this study is the nature of the study as a consensus panel. Conclusions were made based on expert opinion and previous studies. Experts were included from multiple fields and geographic areas in hopes to improve the applicability of the study. Otherwise this consensus panel is limited by the breadth of primary research available for systematic review.

CONCLUSION

This expert panel analyzed the current literature and their practice to reach a consensus on guidelines for the screening, assessment, and treatment of osteoporosis and osteopenia in reconstructive spine surgery (Figure 2). All patients above 65 and those with particular risk factors under 65 should undergo formal bone health evaluation prior to surgery. DXA scan of the lumbar spine and hip are recommended as the standard for evaluation. CTHU if available can provide a preliminary assessment of bone health. Vitamin D deficiency screening should be included in routine preoperative laboratory evaluation and supplemented if deficient. The literature most strongly supports anabolic agents in spine surgery as decreasing the time to fusion, increasing overall fusion rates, and decreasing postoperative complications. Based on previous studies in spine surgery, anabolic agents should be administered preoperatively for at least 2 months and postoperatively for at minimum 8 months. Antiresorptive medications such as BPs, denosumab, and romosozumab are acceptable alternatives if contraindications anabolic agents. Surgeons should have a partnership with

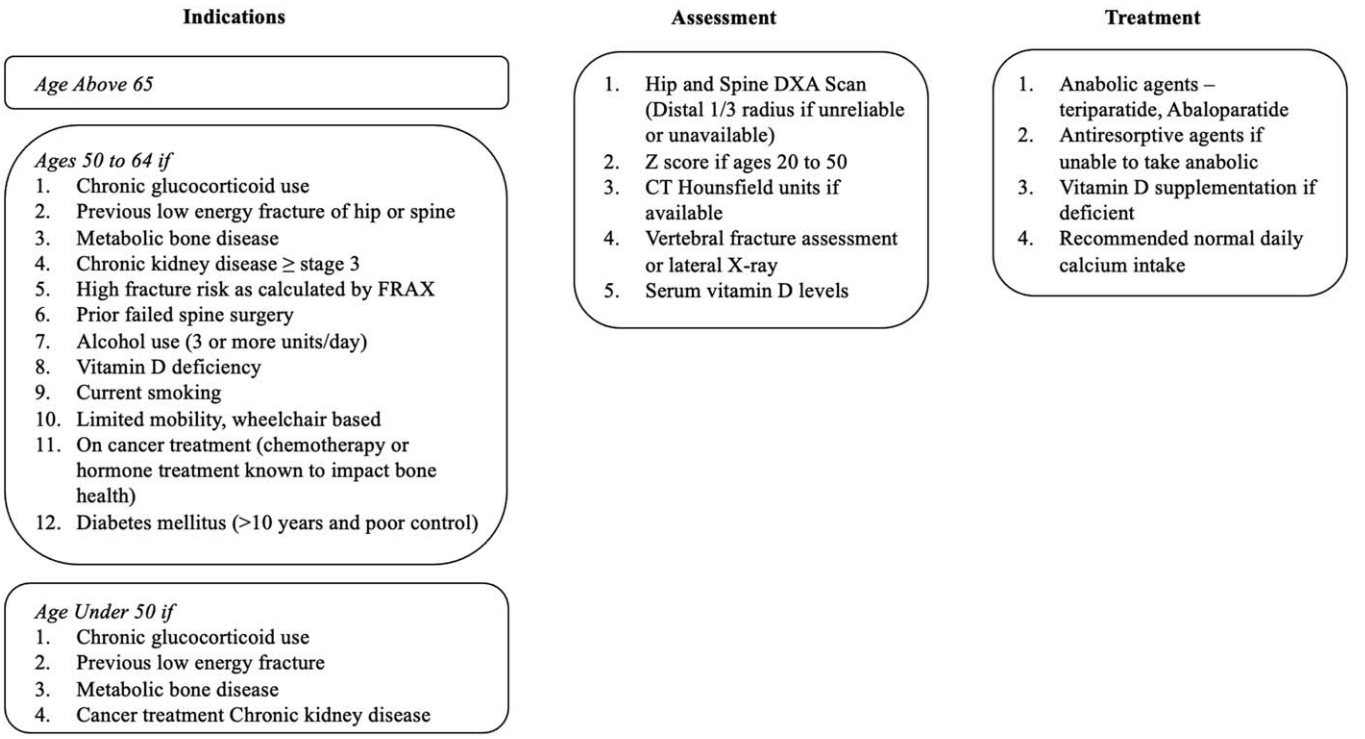

Figure 2. Diagram of the indications for screening, assessment tools, and treatment for poor bone health prior to spinal reconstruction surgery.

a bone health physician or practice to collaborate in managing osteoporosis. Following these guidelines and increasing awareness of poor bone health can improve outcomes and prevent complications for patients undergoing reconstructive spine surgery.

➢ Key Points

- ❑ No guidelines exist for the screening and management of osteoporosis in reconstructive spine surgery.
- ❑ All patients should be assessed for poor bone health and undergo DXA scan if older than age 65 or under 65 and have key risk factors.
- ❑ Anabolic agents are preferred treatment for osteoporosis in spine surgery due to their bone building properties.

Supplemental digital content is available for this article. Direct URL citations appearing in the printed text are provided in the HTML and PDF version of this article on the journal's Web site (www.spinejournal.com).

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