Current Concepts in the Treatment of Sports Concussions

Margot Putukian, MD*
Jeffrey Kutcher, MD‡

*University Health Services, Princeton University, Washington Road, Princeton, New Jersey; ‡University of Michigan Medical School, Ann Arbor, Michigan

Correspondence:
Margot Putukian, MD,
Princeton University,
Robert Wood Johnson UMDNJ,
University Health Services,
Princeton University,
Washington Road,
Princeton, NJ 08540.
E-mail: putukian@princeton.edu

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The management of patients with sports-related concussion (SRC) is comprehensive and includes preseason planning, education, initial evaluation, postinjury assessment, disposition, return-to-play decisions, and consideration of long-term brain health. Several recent publications have addressed sports concussion management using the best available evidence, and we review them here. The diagnosis and management of sports concussion have evolved over the past several decades, and with a greater understanding of the importance of both short- and long-term sequelae, there has been a clear trend toward recognizing and treating these brain injuries more cautiously and developing a proactive approach to management and return-to-play decision making. Although each of these used different methodologies in their review of the literature, their conclusions are fairly consistent, providing basic guidelines for contemporary approaches to management of SRC. Although many questions remain unanswered, there are several areas of agreement including the importance of education, preseason assessment, the benefit and utility of a standardized multimodal assessment on the sidelines, individualized treatment and return-to-play protocols, and the benefit of a multidisciplinary team in managing complicated injuries. This paper reviews these current sports concussion guidelines and the best available evidence that guides current management of SRC.

KEY WORDS: Consensus, Position statement, Return to play, Sport-related concussion, Team physician

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The management of patients with sports-related concussion (SRC) is comprehensive and includes preseason planning, acute injury management, return-to-play decision making, and treatment and consideration of long-term considerations. In the past 5 years, several consensus statements and guidelines have been published specific to SRC, including the Team Physician Consensus Conference (TPCC) statement,[1] the American Medical Society for Sports Medicine (AMSSM) position statement,[2] the American Academy of Neurology (AAN) position review,[3] and the International Concussion in Sport (CIS) consensus statement[4]; the purpose of this review is to discuss how these statements guide current management concepts.

ABBREVIATIONS: AAN, American Academy of Neurology; **AMSSM,** American Medical Society for Sports Medicine; **CIS,** Concussion in Sport; **CISG,** Concussion in Sport Group; **CTE,** chronic traumatic encephalopathy; **NP,** neuropsychological; **PCS,** postconcussion syndrome; **SCAT,** Sideline Concussion Assessment Tool; **SRC,** sports-related concussion; **TPCC,** Team Physician Consensus Conference

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Definition of Injury

Concussion is a challenging injury for the clinician to evaluate in the office setting ands on the sidelines, and much of this is due to confusion regarding the definition of concussion and how to identify severity and track recovery of this often elusive injury.[5] Although there are several consensus statements and guidelines for SRC, this review focuses on those mentioned here. The definition of concussion in all of these documents is similar and most commonly reflects the definition put forth by the international Concussion in Sport Group (CISG). Undergoing subtle modifications over time, the CISG describes concussion as "a brain injury

and is defined as a complex pathophysiological process affecting the brain, induced by biomechanical forces."[4] They expand on the definition to include the mechanism, the clinical and cognitive symptoms that occur, and the typical onset and resolution of these symptoms. The TPCC and the AMSSM both use a very similar definition. The AAN states that "concussion is recognized as a clinical syndrome of biomechanically induced alteration of brain function, typically affecting memory and orientation, which may involve loss of consciousness (LOC)."[3]

Methodologies

Each of the consensus statements and guidelines follow different methodologies in their review. The TPCC is a consensus-driven document with team physician representation from 6 different professional organizations that addresses select medical issues to provide guidelines for team physicians. The AMSSM position statement is an evidence-based best practices summary that uses the strength of a recommendation taxonomy system to grade recommendations based on athlete outcomes[6] and involved a multidisciplinary group of clinicians with expertise in concussion as the writing group. The 3rd International Conference on Concussion in Sport was designed as a formal consensus meeting following the organizational guidelines set forth by the US National Institutes of Health (http://consensus.nih.gov/ABOUTCDP.htm.) For the 4th International Conference on Concussion in Sport, there were specific questions asked in preparation for the conference, and a group of multidisciplinary authors were charged with answering the questions by performing an evidence-based review of the literature and then presenting their summary during the conference. The AAN selected a multidisciplinary panel of experts who performed a comprehensive research of the literature. The evidence was subsequently synthesized using a modified form of the Grading of Recommendations Assessment, Development, and Evaluation process, with the panel then forming recommendations and a clinician level of obligation of recommendations assigned using a modified Delphi process.[7] Despite differences in the methodologies used in each case, the conclusions are, for the most part, consistently similar.

The components of sports concussion management can be broken down into preseason planning and assessment, sidelines assessment, office assessment, return-to-play decision making, and managing complex concussion cases. The remainder of this review reviews what each of the most recent consensus statements have concluded as it relates to these issues. Although each of these consensus statements also discuss the role of prevention, equipment, rules and enforcement, and behavioral modifications, these are not be discussed in detail as they are outside the scope of this review.

Preseason Planning

There is clear agreement that for sports at risk of concussion, an emergency action plan that includes a concussion plan should be provided for each sport and venue.[8-11] The emergency action plan provides a blueprint for how to handle emergencies and should be simple and understandable by coaches, athletes, and other laypeople. The emergency action plan identifies the emergency personnel and chain of command, emergency communication, equipment, transportation, sport-specific venue directions/maps, emergency facilities, and proper documentation. The plan should be written and reviewed by the medical personnel, coaches, and other key stakeholders such as emergency medical technicians, ambulance crews, and emergency department providers. The concussion plan should describe the protocol for assessment and return to play that is to be used and should be shared with the athletes, coaches, parents, and administrators as well as any others considered an integral part of the health care network[12,13] such as athletic trainers and other health care providers. It is extremely important to account for the potential for more significant brain or cervical spine injury, planning for transportation to a facility that can provide emergent consultation. In addition, the concussion plan should identify the common signs and symptoms of concussion and state that any athlete presenting with signs and symptoms of concussion should be removed from play and not allowed to return until evaluated by an appropriate health care provider.[14] This concept has been identified as an essential component of all statements as it relates to the recognition of injury.

Preseason Assessment

The preseason assessment should ideally include a comprehensive history of concussive injury and a history of other modifiers of SRC that have been associated with a delay in recovery from concussion.[4,15] The TPCC identifies modifiers that include a history of concussion (total number, proximity, severity), number and severity of symptoms (intensity and duration), signs (prolonged loss of consciousness), susceptibility (concussions that occur with lower impact magnitude and/or requiring longer recovery), age (younger age), and other pre-existing conditions (migraine, depression or anxiety, attention deficit/hyperactivity disorder, learning disabilities). These same factors are described as being associated with a complicated recovery in the AMSSM position statement, with the exception of a concussion history, which the authors state is a risk factor for increasing the incidence of concussion but not necessarily prolonged recovery. The AMSSM statement also supports the modifiers of age and learning disability as they relate to prolonged recovery, but does not believe that there is evidence of mood disorders as a modifier. The CIS statement also includes dangerous style of play and contact and collision sports as well as a high level of sport as modifiers, although it is unclear whether this increases recovery vs only putting the athlete at greater risk of sustaining a concussion. The AAN identifies as "highly probable" ongoing clinical symptoms, concussion history, and "probable" specific symptoms of headache, fatigue/fogginess, early amnesia, alteration in mental status or disorientation, ands younger age as risk factors for increasing the likelihood of postconcussion impairments.

Another important component of the preseason planning is education, including the education of athletes, coaches, parents, administration, and individuals across the health care network regarding the signs and symptoms of concussion, the importance of having a concussion management plan, reporting signs and symptoms, and the potential consequences of missed or repetitive injury.[16-18] This is particularly true for school-aged athletes in whom academic progress may be affected by their injury. There are several educational modalities to consider, including written print, videos, and other formats that are engaging and informational, although the effectiveness of these modalities has been questioned.[19] It is critical that athletes understand the importance of reporting the symptoms of concussive injury and all medical injuries or illnesses.[20] More recently, additional educational focus has also included the importance of technique as it relates to sports where there is tackling or body checking.[21,22]

The preseason assessment should also ideally include the evaluation that will be used at the time of injury. This evaluation should include a symptom inventory, a brief cognitive evaluation, an assessment of balance, and a comprehensive neurological evaluation to identify pre-existing brain or spine injury. The components of the sidelines assessment are discussed in the following.

Sidelines Assessment

Sidelines assessment should include tools appropriate for the environment and injury management and disposition decision making.[14,23] The first component of sidelines assessment is evaluating for the possibility of cervical spine and/or more serious brain injury and then initiating the emergency action plan in these cases. All of the guidelines and statements agree on this initial component of the sidelines assessment. Once more serious injury is excluded, the diagnosis of concussion is often made using a multifactorial approach combining symptom report,[24] cognitive evaluation,[25-27] and a focused neurological assessment that includes balance and postural stability.[28] This multimodal assessment has been supported and recommended by all of the current consensus statements based on the available evidence. Although each of these components is useful in evaluating concussion, their use together has been shown to be more powerful.[29,30]

For the clinician evaluating an athlete after the initial presentation, an accurate history is essential in determining whether it is possible or likely that a concussion has occurred. In both situations, having a standardized assessment can be useful. The Sideline Concussion Assessment Tool (SCAT)-3 was developed as part of the CISG consensus statement as a modification to the SCAT-2 developed during the third CIS meeting in Zurich.[31,32] The SCAT-3 incorporates a symptom checklist, a brief cognitive evaluation, and a modified balance assessment. The SCAT-3 is very similar to the SCAT-2 with modifications made for assessing more serious brain injury, similar to the "go no-go" questions incorporated in the National Football League Sidelines Assessment (Table),[33] as well as an improvement in the scoring of the assessment. The SCAT-3 has been recommended as a standardized sidelines assessment tool that can be used at baseline as well as post-injury by the TPCC, AAN, and AMSSM documents (see **Figure, Supplemental Digital Content**, http://links.lww.com/NEU/A662). A recent prospective study demonstrated the utility of the SCAT-2, and thus the SCAT-3, in collegiate male and female athletes.[30]

All of the recent guidelines/statements recognize the limitations of the sidelines assessment and the need for serial evaluations and understanding that signs and symptoms of SRC can be delayed and present several minutes to hours to even days later. The sidelines assessment is often limited, and the cognitive evaluation is not as comprehensive as other more sophisticated testing.[34] There is also an understanding that the sidelines assessment may indeed be "normal" in an athlete with concussion and that any athlete suspected of having a concussion should be removed from play and evaluated by a health care provider comfortable with and experienced in managing SRC.[35] They all agree that any athlete in whom a concussion is diagnosed should not return to play the same day, which differs from previous guidelines[32,36,37] that allowed for same-day return to play in certain situations.

The initial presentation of SRC may be vague, and concern for more serious brain injury must be considered. The athletic trainer or team physician on the sidelines must make disposition decisions based on the clinical presentation and rely on his or her judgment and experience. Once more serious brain and cervical spine injury has been excluded, treatment of sports-related concussion includes removing the athlete from play, serial assessments, and disposition decision making. Once more serious injury is excluded, the acute treatment of the athlete is a period of physical and cognitive rest. The utility of serial examinations is to observe for worsening or deterioration and therefore the need for emergent transportation as well as documenting improvement. The most appropriate timing of these evaluations is less clear, and most of the guidelines use "a few hours" as the time frame during which serial observation

TABLE. "Go No-Go" Questions From National Football League Sideline Assessment

Any of the following are obvious signs of disqualification (ie, "No Go"):
1. Loss of consciousness or unresponsiveness? (for any period of time) If so, how long? _____
2. Confusion? (any disorientation or inability to respond appropriately to questions)
3. Amnesia (retrograde/anterograde)? If so, how long? _____
4. New and/or persistent symptoms: see checklist? (eg headache, nausea, dizziness)
5. Abnormal neurological finding? (any motor, sensory, cranial nerve, balance issues, seizures)
6. Progressive, persistent, or worsening symptoms? If so, consider cervical spine and/or a more serious brain injury

Modified From NFL Sideline Assessment. http://www.nflevolution.com/article/sideline-assessment-tool?ref=0ap11000000224868.

should occur. It may be useful on the sidelines to remove the player from the field and evaluate him or her in a setting that is quiet without as many outside stimuli. The athlete whose condition is worsening should be transported to a facility with emergent capabilities, whereas for the athlete who shows improvement, it may be reasonable to have them watched in an infirmary with a capable adult and/or provide take-home instructions and allow the athlete to go home on his or her own. Disposition decisions are challenging, rely on clinical judgment, and should be individualized. The take-home instructions should explain what a concussion is, when they should seek emergent care, provide information on avoiding alcohol and medications, and proper recovery. A specific follow-up plan should be made, with the athlete avoiding significant physical and cognitive activities in the interim. All statements agree that a period of physical and cognitive rest is the cornerstone of acute treatment, although there is no clear description of what the appropriate degree or duration of rest should be.

Office Assessment

The office assessment of SRC is similar to that on the sidelines with the benefit of often having more time for an assessment and the limitations of not always being able to identify the mechanism of injury and the possibility that many acute signs and symptoms as well as deficits after SRC may have resolved. For example, although it may be easier to go through an expanded history, symptom checklist, and a more comprehensive cognitive and/or balance assessment, many of the abnormalities seen within the first few hours of SRC may have resolved. Overall, symptoms of the majority of concussions will resolve within 7 days.[38-41] Cognitive dysfunction can persist in some cases, however, despite the resolution of other symptoms,[34,42] and balance deficits often normalize within 3 to 7 days. The interaction of all of these variables has been evaluated in several studies[43-45] demonstrating that the athlete may be back to normal by the time he or she is evaluated in the office setting. Ultimately, the same tools used to evaluate the athlete on the sidelines are used to evaluate the athlete in the office, with the ability to expand the comprehensiveness of the evaluation in the latter setting, particularly as it relates to a comprehensive neurological evaluation.

The use of neuropsychological (NP) testing, which assesses brain function objectively either through standard paper-and-pencil or computerized tests, as a component of the management of SRC has been an area of significant research. NP testing may demonstrate deficits in athletes who deny symptoms, and the first CISG considered NP testing as the "cornerstone of management,"[46] and although the idea of baseline testing followed by postinjury assessments has been considered by many to be an important component of any concussion plan, more recent guidelines have described the limitations of relying on NP testing solely and instead have recommended their use as 1 component of the assessment. Although previously accepted methods of comparing postinjury test results with baseline test results can have merit, more recent reviews have raised some concern that this approach is not necessarily essential.[47] Several factors can affect the performance on these tests, and it is important to understand the limitations of NP testing.[48,49] In addition, if group-based norms exist, it may be more cost-effective and equally helpful to use only postinjury NP testing.[50] In addition, although the administration of these tests can be performed by non-neuropsychologists, their interpretation is ideally performed by neuropsychologists trained in evaluating the psychometric properties of each test.[51,52] In the TPCC, it is considered essential that the team physician understand that NP testing is recommended as an aid to clinical decision making but not required for the management of SRC and that NP testing is 1 component of the evaluation that should not be used as a stand-alone tool to diagnose, manage, or make return-to-play decisions. Similarly in the AMSSM position statement, although NP tests are considered more sensitive in evaluating subtle cognitive impairment than a clinical examination, they are not considered essential for the management of SRC and should not be used in isolation, and concern is raised regarding who interprets the test. It is stated in the AAN that NP testing should be interpreted by neuropsychologists, although they also state that NP tests can be administered by non-neuropsychologists. The AAN also supports the utility of NP testing, specifically those tests that evaluate memory, reaction time, and cognitive processing as useful in identifying the presence of concussion with a sensitivity of 71% to 88% and states that abnormal NP testing results are associated with a risk of prolonged recovery. The AAN statement also raises concern regarding the use of NP testing in preadolescents, citing a lack of evidence.

Return-to-Play Decision Making

Once an athlete has received a diagnosis of a concussion and assuming that he or she is able to return home and not be hospitalized, follow-up care is the next step in the management, with relative physical and cognitive rest the cornerstone of acute treatment. The recent statements all endorse the concept of individualized treatment as well as an incremental and progressive return to play progression. The CISG endorsed this concept in their statements,[4,32,46] and the other statements concur. The majority of SRCs are considered mild on the spectrum of brain injury and resolve within 10 to 14 days.[1-4,27] The period of time required for resolution will vary depending on the nature, burden, and duration of symptoms, the degree of neurological dysfunction (cranial nerves, cognitive function, and balance), as well as the presence of other modifying conditions. There is no specific template or "cookbook" approach to managing concussive injury, and instead an individualized decision-making process is important, taking into account several factors. The statements all agree that before an athlete can return to contact activities, they should be back to their baseline level of neurological function in terms of symptoms, cognitive function, and balance.

All of the statements discuss the need for cognitive and physical rest, and this includes decision making as it relates to time off from

school or other academic accommodations for symptomatic student athletes and a discussion with parents/guardians, caregivers, and school officials as needed. This also includes limiting activities such as computer use, texting, and video games to minimize overstimulation. It is challenging to determine the specific amount of time needed away from school and/or the extent of academic accommodations necessary, and individual decisions should be made taking into account the athlete's symptomatology, level of functioning, and academic demands with input from others including parents/guardians, caregivers, and school officials.

The initial step in the return-to-play progression is to initiate a carefully prescribed low level of physical exertion, whereby the heart rate is increased slowly and the athlete is monitored for recurrence of symptoms. If the athlete can tolerate this low level of exertion, it is reasonable to increase the duration as well as the intensity and eventually add sport-specific activities that do not include the risk of recurrent contact. Finally, contact activities are introduced and return to competitive practice and then play. Although all the statements agree on the concepts of this gradual incremental progression, the timeline for this is less clear, with little evidence to guide the clinician. It has been suggested that for the "elite" adult athlete with significant resources and where no significant modifiers for prolonged recovery exist, return to play may occur more quickly and that in the young athlete or in the case where there are modifiers, consideration of a more prolonged progression should occur. In addition, if an athlete has a significant nature, burden, and/or duration of symptoms; has cognitive or other balance dysfunction; and/or if he or she has modifiers, a more conservative approach is likely useful. This is, however, based not on evidence but on consensus and opinion, using clinical and neurocognitive markers for tracking recovery. In fact, in 1 study, a symptom-free interval was not associated with earlier return to play.[53] Whether more sophisticated neuroimaging techniques[54,55] or other biomarkers can be used to assess SRC or track recovery remains unclear. There is clearly more research that is needed in this area.

Managing Complex Concussion Cases

Each of the 4 documents describes a framework for routine concussion management, while also acknowledging many of the potential complicating factors or comorbidities commonly seen. Given the different scopes, methodologies, and intended audiences of each effort, however, the documents differ somewhat in the extent to which they provide recommendations for the management of complex concussion cases, an approach to postconcussion syndrome (PCS), discussion of long-term sequelae such as chronic traumatic encephalopathy, the use of medications, and the role of advanced neuroimaging.

Complex Concussion Case Management and Consultation

Although the majority of concussion cases involve symptoms lasting 10 days or less, all 4 documents do mention the presence of more complex or longer lasting clinical syndromes. The AAN guideline suggests the use of cognitive restructuring as an effective mechanism for diminishing the risk of the development of PCS after concussion. It also suggests using "formal neurological/cognitive assessment" to aid in retirement-from-play decisions as well as for patients with a history of concussion and subjective persistent neurobehavioral impairments. The TPCC, in contrast, does not provide specific recommendations regarding the treatment of complex cases or mention the need for consultation, but does state that the team physician should "coordinate assessment and treatment of complications." The CISG consensus statement simply states that cases of concussion with symptoms lasting longer than typical (ie, $\geq$10 days) should be "managed in a multi-disciplinary manner by healthcare providers with experience in sports-related concussion." Furthermore, the CISG does support the idea that psychological approaches to care may have a potential role in complex cases. The position statement from the AMSSM does not specifically address complex concussions, but does offer a framework for retirement decisions, stating that an evidence-based approach is not available due to lack of data. Considerations such as a concurrent structural abnormality, multiple lifetime concussions, persistent diminished brain function, prolonged recovery times, and a reduction in injury threshold are suggested as variables that should be considered in an individualized approach.

Postconcussion Syndrome

PCS is a diagnostic construct without a clearly accepted definition. The AAN guideline does refer to PCS specifically, but also to "chronic neurobehavioral impairment" and "persistent neurocognitive problems," citing a potential risk factor of preinjury difficulty with headache. As noted previously, the AAN concluded that cognitive restructuring might be an effective mechanism for decreasing the risk of the development of PCS after concussion. The AMSSM also discusses PCS, pointing out that no clear cause of the syndrome is widely accepted. The authors further report identification in the literature of several potential risk factors for the development of PCS, including increasing age, female sex, and non–sports-related concussion. The AMSSM authors further suggest that the "foundation of PCS management is time," but do not give specific information on the amount of time typically needed for recovery. The specific therapeutic mechanisms of cognitive therapy, integrated rehabilitation, and supervised exercise are suggested as potentially improving recovery. The TPCC statement describes it as "essential" that the team physician recognizes the possibility of the development of PCS after concussion, but provides no further specific information. The international consensus work produced by the CISG does not address PCS specifically.

Chronic Traumatic Encephalopathy

Chronic traumatic encephalopathy (CTE) is a diagnosis clearly garnering greater attention both in the lay media and the medical literature as the result of increased awareness and concern over the potential of long-term brain dysfunction from head trauma. There

are significant limitations in describing CTE given the lack of evidence-based research regarding the pathophysiology and natural history of CTE, and it is not an emphasis of discussion in any of the definitions of CTE. The definition of CTE can be considered twofold, having both clinical and pathological constructs that are both currently being more clearly developed in the literature. In 2012, the CISG addressed CTE specifically, stating that it "represents a distinct tauopathy" with an unknown incidence and no clearly defined causal relationship with trauma. CTE is defined in the AMSSM statement as a "neurodegenerative disease associated with repetitive brain trauma." The AMSSM authors go on to note that CTE is not a continuation of PCS or acute concussion and is likely due in part to a certain genetic predisposition. The TPCC describes CTE as "a progressive neurodegenerative disease (tauopathy) caused by total brain trauma, and is not limited to athletes who have reported concussions" with an unknown incidence and prevalence. The TPCC also states that CTE is diagnosed only after death and provides typical signs and symptoms as well as the age (40-50 years old) at which these signs and symptoms typically develop. CTE was not discussed specifically in the AAN guideline. This was due to the fact that the AAN effort relied on a level of evidence more than that of case report or a case series for inclusion in their analysis of the literature.

Medication Use

The role of medications in the management of concussion, PCS, and long-term neurobehavioral conditions is evolving. Nonetheless, very few data have been published that suggest that any specific pharmacological therapy is useful. The AAN guideline effort did not identify any medication that could be recommended by the author panel. The AMSSM authors likewise state that "there is no convincing evidence that any particular medication is effective in treating the acute symptoms of sports concussion specifically." They further point out that certain medications should be avoided acutely, such as analgesics and antiemetics that might cloud the ability of the clinician to accurately assess the natural history of the injury. The AMSSM statement discusses the use of medications for sleep disturbance, headaches, and mood dysfunction when these symptoms are prolonged and persistent. The CISG group also cautions against the presence of a medication effect while assessing a patient for injury resolution, while concurrently stating that a pharmacological approach "should only be considered by clinicians experienced in concussion management." The TPCC only addresses the use of avoiding certain medications (eg, aspirin and nonsteroidal anti-inflammatory drugs) acutely and also states that athletes "should no longer be taking medications that mask or modify concussion symptoms" before returning to play.

Neuroimaging, Genetic, Serum, and Cerebrospinal Fluid Biomarkers

The role of advanced neuroimaging, genetic, serum, and cerebral spinal fluid (CSF) biomarkers in the assessment or management of concussion is unclear, and the consensus statements consider these investigational and areas where further research is needed. The role of neuroimaging continues to change as newer technologies become available that may provide some diagnostic and management value. To date, however, there remains no clear neuroradiological study that is clinically useful in a wide setting. All 4 documents clearly state the lack of clinical utility represented by computed tomography or magnetic resonance imaging in the evaluation of acute concussion. Further, the AAN did not find any modality that clearly provides the clinician with a clinically useful tool for the diagnosis or management of concussion, chronic neurological syndromes, or persistent/degenerative diseases related to head trauma. The CISG and AMSSM both describe the potential for functional magnetic resonance imaging and other measures of neuronal physiology to be helpful in the future. The TPCC describes the limited role of plain skull radiographs and emphasizes the need for the team physician to understand the use of computed tomography and magnetic resonance imaging to evaluate for potential concurrent injuries such as "intracranial bleed, cerebral edema, diffuse axonal injury, and/or skull fracture."

SUMMARY

The management of patients with SRC is a comprehensive one that continues to evolve as research efforts address the many unanswered questions. The recent publications discussed in this review and the CISG, TPCC, AMSSM, and AAN statements, although representing slightly different methodologies in how the literature was reviewed, provide similar conclusions as it relates to preseason assessment, initial management, and return-to-play decision making, as well as an understanding of both short- and long-term complications of SRC. In addition, although many questions remain, the importance of treating these brain injuries more cautiously and the need for further research are consistently addressed.

Disclosure

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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