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Validating the three-step return-to-play decision model

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The purpose of this study was to validate a recently proposed return-to-play (RTP) decision model that simplifies the complex process into three underlying constructs: injury type and severity, sport injury risk, and factors unrelated to injury risk (decision modifiers). We used a cross-over design and provided clinical vignettes to clinicians involved in RTP decision making through an online survey. Each vignette included examples changing injury severity, sport risk (e.g. different positions), and non-injury risk factors (e.g. financial considerations). As the three-step model suggests, clinicians increased restrictions as injury severity increased, and also changed RTP decisions when factors related to sport risk and factors unrelated to sport risk were changed. The effect was different for different injury severities and clinical cases, suggesting context dependency. The model was also consistent with recommendations made by subgroups of clinicians: sport medicine physicians, non-sport medicine physicians, and allied health care workers.

Return-to-play (RTP) decisions are made daily by sports medicine clinicians in the clinic or on the field, and guidelines are becoming more frequent for many sportsrelated medical conditions such as concussion (Cohen et al., 2009; Randolph et al., 2009), spinal cord injury (Jeyamohan et al., 2008), and cardiovascular abnormalities (Anderson & Vetter, 2009). However, wellestablished RTP guidelines do not exist for the vast majority of conditions and patients are greatly dependent on their clinician's ability to navigate through an apparent complex web of factors to arrive at an optimal decision.

We recently developed a three-step model for individualized RTP decision making (Creighton et al., 2010), taking into account three key concepts that can be expressed through sociological or biomechanical frameworks. Sociologically, RTP decisions require input from medical science (medical factors: symptoms, function tests), sport (participation risk: contact vs non-contact), and third party issues (decision modifiers: timing and season). From a biomechanical perspective, an injury (or reinjury) occurs when the stress applied to a given tissue is greater than the stress it can absorb. In this context, medical factors reflect the stress the tissue can absorb and sport risk modifiers determine the amount of stress applied to a tissue. Together, these factors determine the risk of injury with activity and the third step involving decision modifiers reflects health factors unrelated to biomechanical injury risk.

The three-step model was developed based on a literature review and knowledge from experienced clinicians (Creighton et al., 2010). In addition to face validity, each of the 19 different factors (Shultz et al., 2013) in the three-step RTP decision-making model was considered relevant by at least 40% of experienced team clinicians making RTP decisions, albeit with a high degree of variability in how they weight the different factors (Shultz et al., 2013). The purpose of this study was to assess the validity of the three-step model by determining how specifically changing individual factors identified in the model might affect RTP decisions made by clinicians.

Methods

Survey distribution

We distributed the survey online using SurveyMonkey (www.surveymonkey.com) to sport medicine clinicians of the American College of Sports Medicine (ACSM) who might be involved in RTP decision making. Although physicians are often responsible for RTP decisions at elite levels, they are not always immediately available, and many different specialties and allied health care clinicians make day-to-day RTP decisions at the amateur and recreational level. We included physicians (primary case and specialists), chiropractors, podiatrists, nurse practitioners, athletic trainers, kinesiotherapists, occupational therapists, physical therapists, physician's assistants, and registered nurses

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(n = 2361). We sent follow-up reminder emails 2, 4, and 6 weeks after the initial email. Data were anonymized and the Research Ethics Committee of the Jewish General Hospital in Montreal, Canada approved the study.

Survey content

During survey development, we were conscious that clinicians might be unlikely to complete surveys requiring more than 15-20 min. Given the detail of information we had to obtain, this limited the number of clinical vignettes we could use and hence the contexts that could be studied. The survey contained four sections and was developed using an iterative approach with feedback from three sport medicine physicians (at least 20 years experience working in clinics and with teams) during pilot testing to ensure the questions were relevant and appropriate. When no further major suggestions were forthcoming, we proceeded to distribute the survey. Section 1 included demographic questions. The subsequent three sections each presented a clinical vignette in the same order [3-week-old acromio-clavicular (AC) sprain in American National Collegiate Athletic Association football linebacker; medial collateral ligament (MCL) knee sprain in a college hockey defenseman with National Hockey League potential; Oligomenorrhea (OLIGO) in a world class cross country female runner] and then asked a series of questions. The reasons for these specific cases were related to the potential for long-term consequences if the athlete returned to activity too soon: the AC sprain is a common injury with a very low probability of long-term consequences; the MCL sprain is a common injury that has potentially severe consequences (anterior cruciate ligament tear); the OLIGO vignette is a medical problem with potentially severe injury consequences (femoral or tibial fracture). The entire survey is available in Appendix S1.

For each clinical vignette, we described three related cases. The base case succinctly described a particular injury context. The role of medical factors (the stress a tissue can absorb) is reflected with increasing severity of symptoms/signs across six examples. For each example, participants indicated the type of restrictions they might apply (no restrictions, modified game activity, full practice only, modified practice only, strength & conditioning only, no activity). If participants increased activity restrictions as injury severity increased, this would confirm the applicability of our clinical vignettes to further study the model.

Next, we again described the base case, but altered one sport risk modifier (sport case) resulting in less stress to the injured tissue. For the AC sprain, the line backer was changed to field goal kicker; for the MCL sprain, a brace was provided; for the OLIGO, the athlete only competed locally. Participants then completed the same six examples of increasing injury severity. We expected that participants would decrease restrictions as stress applied to the tissue decreased.

Finally, we again described the base case, but now altered a decision modifier (decision case) unrelated to injury risk but still detrimental to the patient. For the AC sprain, an National Football League team was evaluating the player for a signing bonus; for the MCL sprain, the athlete had minimal pain with 1000 mg of naproxen; for the OLIGO, the athlete was to compete in the Olympics in 8 weeks. We expected participants to decrease restrictions compared with the base case.

Analysis

We describe demographic information using means (SD) for continuous variables and proportions for categorical variables. We analyzed each set of clinical vignettes separately. We first explored our data by describing the proportions of respondents who chose each of the six levels of outcome (no restrictions to no activity) for each of the base cases.

For our principal analyses, we dichotomized the outcome to "no restrictions" vs "any restrictions" in order to present the data in a concise format that reflects competition-day decisions. In brief, for each set of clinical vignettes, we plotted the proportion of respondents allowing activity without restriction across different injury severities for the base case, and again after changing a sport risk modifier or decision modifier. We only included responses if the participant responded to each of the three cases of a particular vignette. We also conducted a multiple logistic regression (independent variables: injury severity, sport risk modifier, decision modifier) that included participant as a random effect to adjust for within-participant correlation. In sensitivity analyses, we repeated the analysis but dichotomized the outcome to "no restrictions or compete with modified role" vs "all others". We hypothesized that each participant would respond qualitatively similarly (applying the same restrictions or change restrictions in the same direction) to changes in sport risk modifiers and decision modifiers.

Finally, we stratified analyses to determine if the effects were present when we restricted the analysis to sport medicine physicians, to other types of physicians, and to non-physicians. We conducted similar analyses among other types of subgroups (e.g. sex, age, country, experience). Because our primary analyses were within-clinician comparisons that minimize the variance (i.e. required sample sizes are small and similar to animal studies), we included any analysis where there was a minimum of 10 respondents in each category.

Results

We distributed the survey to 2361 self-identified clinician members of ACSM. Of the 25% (n = 584) who began the survey, 343 completed at least one series of the three clinical vignette cases (Fig. 1).

Table 1 illustrates the demographics of clinicians completing at least one series of clinical vignette cases and clinicians not completing any clinical vignette series. Those not completing any vignettes were younger with less experience. The median time spent caring for sport medicine patients was 20 h per week in clinic and 8 h per month covering games/competitions.

The median completion time for participants answering only the AC vignette (n = 54) was 12 min but one subject required only 4 min. The median completion time for participants answering only the AC and MCL vignettes (n = 25) was 21 min and the median completion time for participants answering all three vignettes (n = 264) was 18 min.

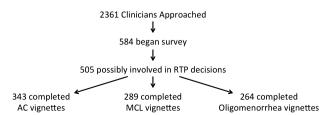


Fig. 1. Subject flow diagram illustrating the number of potential participants approached and those that responded completely to each of the clinical vignette questions.

Table 1. Demographic information on study participants	[% (<i>n</i>)] who completed at least one of the clinic vignette cases
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	Participants completing one case $(n = 343)$	Participants not completing any cases ($n = 133$)
Sex (% male)	81% (279)	77% (103)
Age		(),
20–35 years	14% (49)	17% (23)
36–49 years	42% (143)	51% (68)
50+ years	44% (151)	32% (42)
Primary specialty		
Primary care sport medicine physician	39% (135)	35% (46)
Other physician*	49% (168)	48% (64)
Non-physician [†]	12% (40)	17% (23)
Country where training received		
United States	85% (291)	81% (108)
Canada	4% (14)	6% (8)
Other [‡]	11% (38)	13% (17)
Years of experience making RTP decisions		
\leq 5 years	21% (72)	21% (28)
6–10 years	16% (56)	20% (27)
11–20 years	25% (86)	35% (46)
> 20 years	38% (129)	24% (32)
Affiliated with academic medical center		
Full-time	39% (131)	44% (59)
Part-time	20% (70)	19% (25)
No	41% (141)	37% (49)

*Includes the following specialties: Cardiology, Emergency Medicine, Family Medicine/General Practice, General Surgery, Internal Medicine, Orthopedic Surgery, Pediatrics, Physiatry, Podiatry, Psychiatry.

[†]Includes the following professions: Athletic Trainer, Chiropractor, Kinesiotherapist, Occupational Therapist, Physical Therapist, Nurse Practitioner, Registered Nurse.

[‡]Includes: Australia, Brazil, England, Germany, Italy, Mexico, Netherlands, New Zealand, Norway, Philippines, Portugal, Puerto Rico, Trinidad and Tobago, Turkey.

Heterogeneity of recommendations

Figure 2 illustrates the detailed answers that included all levels of restrictions for the first scenario of each case. Fewer clinicians allowed unrestricted or game activity and more clinicians only allowed low levels of activity (strength & conditioning only, no activity) for the injury examples we classified as more severe, suggesting that our categorizations were appropriate and could be used to further validate our three-step model. Of note, responses were quite heterogeneous for each vignette. With the exception of the very lowest injury severity for the base case in the AC sprain vignette, every injury example in every case had some clinicians recommending unrestricted activity and some clinicians recommended no activity at all.

Internal validity of the three-step model

Figure 3 illustrates the results when we dichotomized the RTP decision to "no restrictions" vs "all other answers" (left graphs) and our sensitivity analyses of "no restrictions/modified game activity" vs "all other answers" (right graphs). Each panel shows results for the base case, sport case (changed sport risk modifier), and decision case (changed decision modifier). Similar to Fig. 2, the proportion allowing unrestricted activity decreased as the severity of injury increased for all injury examples. Examining the AC sprain and MCL sprain (upper two rows), changing the sport risk modifier had a greater effect than changing the decision modifier but the effect was context specific. For the AC sprain, changing the sport risk modifier affected RTP decisions at all injury severities, whereas changing the decision modifier only affected RTP decision at middle injury severities. For the MCL sprain, changing either the sport risk modifier or decision modifier only substantially affected decisions at middle injury severity levels.

In the OLIGO vignette, changing the sport risk modifier resulted in more clinicians applying restrictions (opposite direction to other vignettes). Changing the decision modifier had a strong effect on RTP decisions at what we considered high injury severity; approximately 60% of respondents would let the athlete continue training if the Olympics were 8 weeks away compared with only approximately 20% if it were early in the season.

The multiple regression results for the three different scenarios confirm that the relationships shown in Fig. 3 are likely not due to chance. Because of the many possible interactions between injury examples and sport/decision modifiers, assessing exactly where an interaction exists would result in problems with multiple hypothesis testing and therefore we report only the overall interaction. In brief, for the AC vignettes, injury severity and sport risk modifiers independently affected RTP decisions (P < 0.0001) and the effect of the sport/decision modifiers depended on the injury severity (P < 0.0001). For the MCL vignettes, the results were

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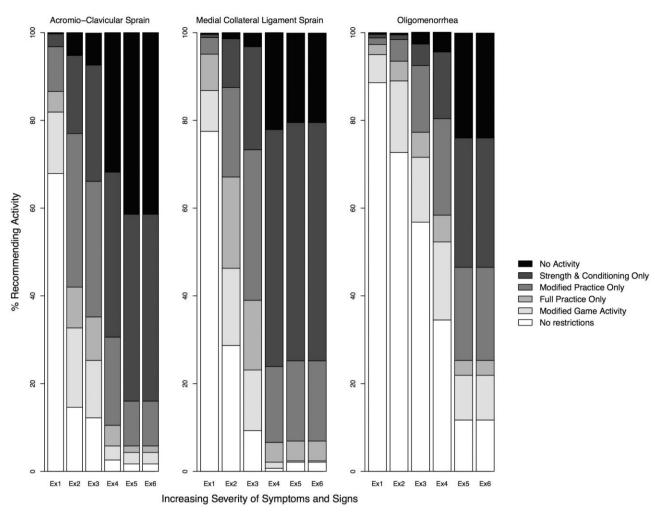


Fig. 2. The proportion of respondents who would restrict the athlete's return to play on a 6-point scale (from "no restrictions" to "no activity") depending on increasing injury severity (Ex1: lowest severity, Ex6 highest severity) of the different examples provided in the clinical vignettes (described in detail in the Appendix S1).

qualitatively similar. For the OLIGO vignettes, sport risk modifiers did not appear to affect RTP decisions (main effect *P* value = 0.09, interaction term *P* values > 0.4) and the effect of decision modifiers was dependent on the injury severity (P < 0.0001 for the interaction term).

Similar patterns across different types of professionals

Figure 4 shows the same results as the left column graphs in Fig. 3, but stratified on primary care sport medicine physicians, other physicians, and non-physicians. The patterns are similar regardless of the clinician training. Primary care sport medicine physicians and other physicians responded similarly [odds ratio (OR) ranged from 1.0 (95% confidence interval; CI: 0.5 to 2.0) to 1.3 (95% CI: 0.5 to 3.5)]. Although there were wide 95% CIs, sport medicine physicians tended to more likely recommend no restrictions compared with non-physicians for the AC [OR = 1.6 (95% CI: 0.6 to 4.3)] and MCL sprain vignettes [OR = 1.5 (95% CI: 0.3

to 6.9)]. For OLIGO, physicians were more likely to allow activity than non-physicians [OR = 12.5 (95% CI: 2.2 to 66.7)].

Exploratory analyses: Comparisons between subgroups

Finally, we explored RTP decisions across other clinician subgroups (see Table 1 for subgroup "n"). The following summarizes overall patterns observed when plotting the data (Appendix S2) and the regression analyses (reported as OR, and therefore overestimates relative risk; CIs are not reported because these estimates are only exploratory in nature and there are too many comparisons to provide details succinctly).

- The patterns observed in Fig. 2 for the entire population were also observed in each of the subgroups of each of the variables (sex, age, region of training, academic status, and years of experience making RTP decisions).
- Men tended to be more likely (OR ≈ 2–3) to recommend no restrictions.

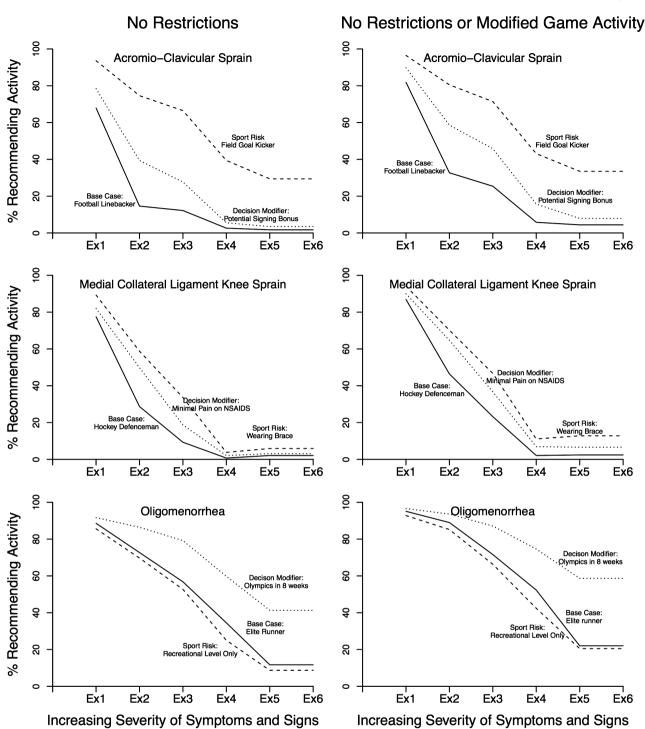


Fig. 3. Proportion of respondents who would allow activity without restriction (left column) or competition with restrictions (right column) for the different injury severity levels for the three clinical vignettes (AC sprain, MCL sprain, Oligomenorrhea). For each graph, the solid line presents the results for the base case, the dashed line presents the results when we changed the sport risk modifier, and the dotted line presents the results when we changed a decision modifier. Data include all participants who answered all the questions for the three cases of each particular vignette (n = 343 for AC sprain, n = 289 for MCL sprain, n = 264 for Oligomenorrhea). The results were unchanged when we included only those who answered all the questions for all the vignettes (n = 264 for AC sprain, MCL sprain and Oligomenorrhea; data not shown).

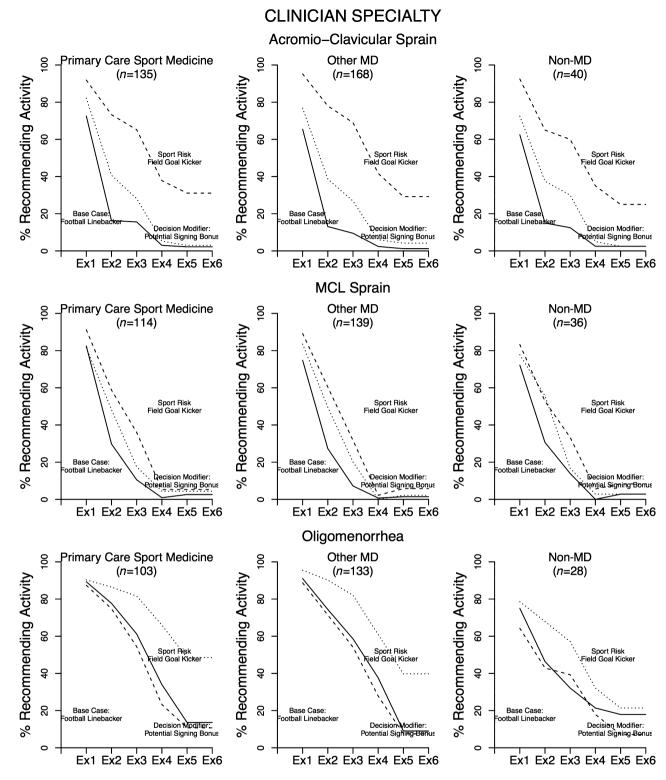


Fig. 4. Proportion of primary care sport medicine physicians (left column), other physicians (middle column), and other clinicians (right column) who would allow activity without restriction for the different injury severity levels for the three clinical vignettes (AC sprain, MCL sprain, Oligomenorrhea). For each graph, the solid line presents the results for the base case, the dashed line presents the results when we changed the sport risk modifier, and the dotted line presents the results when we changed a decision modifier.

- Respondents ≥ 36 years old tended to be more likely (OR ≈ 1.5–3) to recommend no restrictions compared with respondents 20–35 years old.
- Respondents from Canada and the Untied States generally responded similarly, but were more likely (OR: 14.2 for AC sprain, 50 for MCL sprain and 1.8 for OLIGO) to recommend no restrictions compared with respondents from other countries.
- Respondents with 6–20+ years experience responded similarly, but tended to be more likely (OR \approx 1.3 to 2.5) to recommend no restrictions than less experienced respondents.
- Academic respondents (both full time and part time) tended to be more likely (OR ≈ 1.2–2.5) to recommend no restrictions than non-academic respondents.

Discussion

Our findings that clinicians generally increased restrictions as injury severity increased (Step 1: Medical factors indicating tissue ability to absorb stress) supports the appropriateness of the clinical vignettes to further validate our three-step model. Our findings suggest that the three-step model is consistent with the RTP decisionmaking process in the contexts presented: Clinicians involved in RTP decisions generally changed restrictions when the specific sport risk modifier was changed (Step 2: Sport factors that alter stress applied to tissue) or specific decision modifier was changed (Step 3: Noninjury risk factors related to overall patient well-being). Both sport risk modifiers and decision modifiers were dependent on injury severity and clinical context for the entire group of respondents, as well as for primary care sport medicine physicians, other physicians, and non-physicians.

There was considerable heterogeneity in the recommended restrictions, with at least one participant choosing each of the six category restrictions for every injury severity example across every clinical case except one (Fig. 2). Theoretically, these differences could be due to (a) assessment of risk (which is due to a combination of injury severity and sport risk context); or (b) value judgment of what is an acceptable risk.

The context-specific effect of injury severity, sport risk modifiers, and decision modifiers observed in Fig. 3 for AC and MCL clinical vignettes, and supported by the multiple regression analysis, should not be surprising. When the injury risk is low or the consequences of a reinjury is minor, one might expect clinicians to allow activity with little restriction, and our sport and decision case modifications would have no effect. Had we been able to include additional clinical vignettes where the sport case increased risk substantially, or the decision case was harmful even though injury risk was slight, we may have also observed that these factors play a role even at low injury severity. When the injury severity is such that the reinjury risk is very high or the consequences are very serious, one would expect sport risk modifiers and decision modifiers to have much less of an effect.

The results of the OLIGO clinical vignette were somewhat surprising. For the sport risk modifier, we thought that changing the competitive level of the athlete from elite to recreational level would be interpreted as a decrease in training intensity. Given the observed result, it remains possible that some participants interpreted the change to mean a difference only in the importance of training. In addition, the pattern of responses for the decision case was different, with the greatest effect occurring at highest injury severity. We consider four possible reasons:

- Baseline risk assessment. The absolute injury risk for OLIGO examples 5 and 6 may have been considered only low or moderate, even though they had much higher relative risk compared with examples 1 and 2. If true, the range of absolute injury risk in the OLIGO vignette between examples 1 and 6 might only cover the absolute risk range of examples 1–3/4 in AC and MCL vignettes, which means the actual pattern across injury severity might not be different across clinical vignettes.
- 2. Consequences of injury: RTP decisions are based both on injury risk and consequences of injury. In the OLIGO vignette, the consequences of a femoral stress fracture are generally considered very serious, making this explanation unlikely.
- 3. Strength of decision modifier: In the OLIGO vignette, the Olympics may be a once-in-a-lifetime opportunity following 10–15 years of complete devotion. Because the risk of mental health problems is increased in competitive athletes who are unable to participate (Young et al., 1994), some clinicians may have concluded that the overall well-being of the athlete was best served by allowing participation. This concern would be less likely in either the AC or MCL vignettes decision cases.
- 4. Non-existing RTP guidelines: RTP guidelines in young athletes with low bone mineral density do not yet exist, although there is some current ongoing research in this area (De Souza et al., 2013; Nattiv et al., 2013). Clinicians may be wary of imposing restrictions in a context of elite or professional sport where there are no official guidelines to support them.

In every subgroup analysis, the pattern of changing restrictions with changes in injury severity, sport case, and decision case results were qualitatively similar to the patterns observed in the total study population. Because our analysis examines changes within participants, the results provide strong evidence that the three-step RTP decision-making model is generalizable for primary care sport medicine physicians, non-sport medicine physicians, and other clinicians, as well as across sex, age,

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region of training, academic status, and years of experience making RTP decisions. That said, our regression analyses that compare responses across levels of subgroups (e.g. male vs female) should be considered hypothesis generating and interpreted with caution because participation rates and reasons for participation may not have been equivalent across subgroups. One unanticipated finding was that the US and Canadian respondents were more likely to recommend no restrictions compared with non-North American respondents. This was unanticipated because there is often a perspective that the legal liability associated with allowing full activity in North America creates an incentive to treat conservatively. Whether this is due to bias for the reasons stated immediately above, or a chance occurrence due to the few non-North American respondents, or in fact true, should be explored in future research.

Limitations

Our 25% participation rate among clinicians making RTP decisions is consistent with recent surveys into current practice for transfusion, pain management, and health practice (response rates ranging from 25% to 40%). Although high response rates are always desired, the reality is that response rates for life-threatening outcomes or those conducted by the Food and Drug Administration only achieve 50-75% participation rates (Kempe et al., 2008; Chen et al., 2009; Harris et al., 2009; Scales et al., 2009), and therefore expectations of high response rates for surveys related to less dramatic clinical questions should be correspondingly lower. Most importantly, our repeated-measures cross-over study design and main analyses examine changes within participants and are therefore internally valid for assessing the foundation of the three-step RTP model; the model was consistent with the responses for these participants. Whether it is also applicable in nonrespondents is a question of generalizability (e.g. is the model consistent for 20%, 60%, or 90% of clinicians) that cannot be answered from our data. For example, some of these non-responders may not have felt competent to answer the survey, even though we did have an option for them to indicate that they do not make RTP decisions. Because of the low response rate, subgroup analyses that require comparison between participants remain exploratory and interpreted with caution. It was not possible to compare demographic data of responders and non-responders because we did not have data on the latter group.

Our study population included clinicians from the ACSM, where most clinicians come from North America (only 38 non-North American clinicians responded to our survey). That said, our exploratory analyses showed that the three-step model is consistent with the patterns of responses for clinicians from each of the different regions. With respect to interclinician

comparisons (e.g. male vs female), our results are only hypothesis generating and we caution against overinterpretation of the results because our study was not powered for these subgroup analyses, there are important potential biases as previously noted, and all results included considerable uncertainty.

We limited ourselves to three vignettes because we were concerned that a longer survey would not be completed. Because mean completion time was 15–20 min for participants regardless of how much of the survey they completed, the results appear to suggest clinicians may lose interest when the time required surpasses 15–20 min.

We provided the vignettes in the same order to all respondents. Randomizing the order of vignettes would have provided more information on OLIGO and reduced any "learning effect," but would have resulted in less information on the other vignettes. Because our pilot testing suggested the questionnaire could be completed in 15–20 min and because our analyses were intraclinician comparisons, we felt that randomization would create a level of complexity with little added value given our particular objectives. Future studies should consider randomizing the order where it would add value to the research questions posed.

Deciding if a particular change in scenario represents a medical factor, sport risk modifier, or decision modifier requires judgment. These represent latent constructs and exact classification is likely context dependent. That said, once the context is defined, our three-step model provides a simplified framework to organize thoughts and decision-making processes.

Finally, for every change in injury severity, sport risk modifiers, and decision modifiers, some clinicians changed their recommendations and some did not, and this was often context dependent. We do not mean to infer that any factor would always affect an RTP decision and one would expect that the effect of any one factor would depend on related personal (both clinician and patient) and societal values.

In conclusion, our results provide preliminary support for the three-step RTP decision-making model as a framework for understanding how clinicians arrive at RTP decisions. Although injury severity is important, clinicians also consider factors related to sport that affect the stress applied to tissue and factors not associated with injury risk that affect the patient's overall wellbeing in other domains.

Perspectives

This is the first study to provide evidence supporting the validity of a three-step model for RTP decision making. Future work on the underlying reasons for heterogeneity of recommendations would help clarify if the differences are due to knowledge, risk assessment, or value judgments (either based on sport or decision

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modifiers). If the differences are due to knowledge, then disagreements and conflict between clinicians could be reduced through algorithms predicting injury risk based on history, physical examination, laboratory tests, and type of activity. If, however, disagreements are due mostly to value judgments, then predictive algorithms might be helpful for some clinicians but would not reduce conflicting recommendations between clinicians. Other areas to explore include differences in our results for OLIGO vs injury (i.e. is this because of the scale for risk is different or some other reason), confirmatory studies of our subgroup analyses. how the model is actually implemented in practice (as opposed to the vignettes used in the current study), and specific contexts that we could not address in our study because of survey length (e.g. pediatrics where parental consent is required).

When processing information for RTP decisions, clinicians across a wide variety of backgrounds consider not only injury severity, but also factors that alter risk associated with sport and factors that may affect other important non-injury related aspects of the patient's life. This is consistent with the three-step model which groups the large number of factors affecting RTP decision making into specific domains, thereby simplifying the process for (a) making RTP decisions; and (b) teaching young sport medicine clinicians how to approach complex issues. Our findings that sport risk and decision modifying factors are context dependent will support clinicians' decisions to individualize recommendations within the simplified process described. Finally, recognition that non-injury risk factors are part of the RTP decision-making process may lead to improved shared decision making in sport.

Key words: Return to play, decision making, reinjury.

Author contribution

Ian Shrier contributed to the conception and design of the study, the analysis and interpretation of the data, and writing of the manuscript. Gordon Matheson contributed to the conception and design of the study, the interpretation of the data, and writing of the manuscript. Mathieu Boudier-Revéret contributed to study design, data management, and writing of the manuscript. Russell Steele contributed to data analysis and writing of the manuscript.

Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Survey questions.

Appendix S2. Subgroup analyses.

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