Sports Injuries

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2018

CHAPTER 7

CONSIDERATIONS AND INTERPRETATION OF SPORTS INJURY PREVENTION STUDIES

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In preparation

ABSTRACT

Promoting sports participation for health is part of the public health agenda worldwide. The same holds true for preventing sports injuries, an unfavourable consequence of sports. In order to transfer research findings to practice; however, clinicians should consider the particulars of design, outcome measures, and data analyses of studies on the prevention of sports injuries. This paper provides a summary of approaches used to assess the effect of injury prevention strategies in sports. This summary is intended to support clinicians in the decision-making process to apply research findings in the area of sports injury prevention in their practice.

INTRODUCTION

Maintaining a physically active lifestyle is a major contemporary public health issue.[1] Therefore, promoting sport participation is crucial for contemporary society.[2] The paradox is that, on the one hand, sports participation improves health through the well-documented benefits of regular physical exercise.[3] On the other hand, sports participation also increases the risk of unfavourable consequences, such as sports injuries.[4] The negative experience associated with injuries can discourage one to maintain sports participation, which conflicts public health efforts.[2] Moreover, sports injuries negatively influence team's and individuals' athletic success.[5] Given the detrimental impact of sports injuries for the individual and society, preventative efforts are of great importance.[6]

Through the understanding of research methodology, clinicians are better able to assess whether a research finding would be valid and applicable to their context. Accordingly, this paper is meant to be a resource for sports clinicians to understand and interpret (1) study designs, (2) outcome measures and (3) statistics in research on the prevention of sports injuries. This should provide a foundation of knowledge for clinicians on the decision-making process to apply research findings in the area of injury prevention in practice.

STUDY DESIGNS IN INJURY PREVENTION STUDIES

Sports injuries prevention efforts follow, in general, the 'sequence of prevention' (Figure 1).[7] One should first establish the extent of the injury problem (step 1) and, subsequently, investigate the problem's underlying aetiology and mechanisms (step 2). After following these first two steps, one would have enough information to develop and introduce a preventative strategy (step 3) and, finally, assess its (cost-)effectiveness (step 4). This paper focuses on the methodology of step four of the sequence of prevention; i.e. assessing the (cost-)effectiveness of an injury prevention strategy.

It should be noted that there needs to be a clear distinction between efficacy and effectiveness of preventative measures. Efficacy describes the effect of any intervention under fully-controlled and ideal conditions, taking any potential disturbing factors into account, and giving the intervention the best conditions to demonstrate its true effect. This is usually done in explanatory randomised controlled trials (RCTs),[8] and gives an answer to the question 'does the intervention work under ideal circumstances?'.[9] Effectiveness is established under less-controlled and more pragmatic conditions.[10] As such, the outcomes are more influenced by external factors that act in a true sporting context. This type of outcome stems usually from less-controlled study designs and answers the question 'does the intervention work in a real-world context?'.[9] Naturally, one would first establish the efficacy of a developed intervention before moving to effectiveness assessment and implementation.

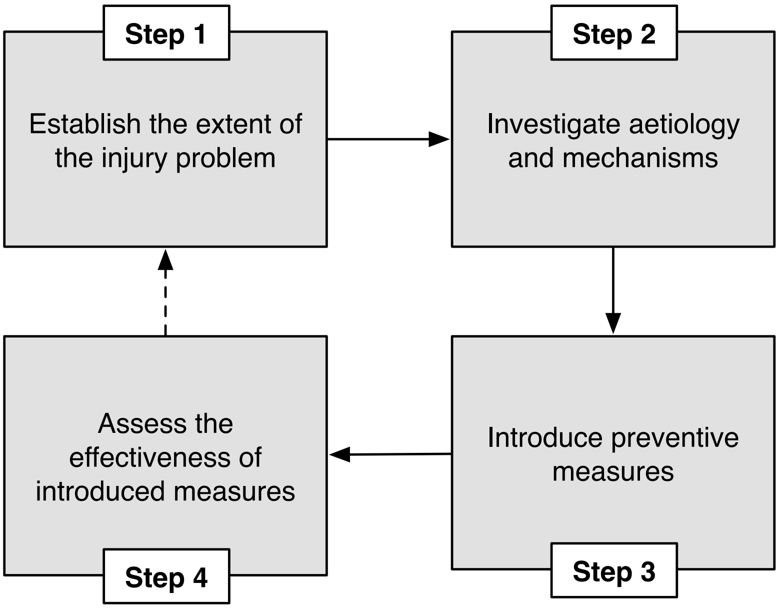

Figure 1. The sequence of prevention of sports injuries. Adapted from van Mechelen et al.[7]

Randomised controlled trials

The efficacy of an injury prevention strategy is investigated through a RCT, while this is the most rigorous design to infer a cause-effect relationship between a preventative strategy (i.e. the intervention) and injury occurrence (i.e. the outcome).[11] In a RCT, the randomisation process allocates study participants to at least two groups; an intervention (e.g. the group exposed to the preventative strategy) and a control group (e.g. the group not exposed to the preventative strategy). Both groups are then followed over a pre-set period of time (e.g. one season). The randomisation process accounts for potential differences between participants' characteristics that might influence their response to the intervention and their baseline risk of injury. Therefore, in a well-conducted RCT, researchers can assume that known and unknown participants' characteristics are similar in both the intervention and control groups, and the intervention is virtually the only difference between both groups.[11]

A RCT, as explained above, usually assumes that each individual is an independent 'unit'. In sports, this is not always the case. Many sports are practised in teams, and one is usually confronted with the issue that one needs to randomise entire teams to an intervention or control group. Here one speaks of a cluster RCT. As an example, a cluster RCT investigated the effect of a structured warm-up program on the rate of injuries in young football (soccer) players from different countries, clubs, and teams.[12] Clubs were randomised to an intervention and a control group; i.e. structured warm-up and usual sessions, respectively. Clubs were randomised into the same group in order to minimise the risk of 'contamination' (i.e. participants of the control group knowing about and adopting the intervention). The country, age group, and the number of participating teams per club served as strata for the randomisation.

Beyond randomised controlled trials

It is important to note that there are also a number of limitations to RCTs.[11] In sports injuries prevention research, we argue that the main issue is its validity. Given the well-controlled study design, RCTs have high internal validity – results can be very trustable inside the specific controlled setting in which the study was conducted. However, RCTs often lack external validity also due to the well-controlled study design[13] – an 'efficacious' preventative measure may not work as expected when applied in a setting that differs from the one originally studied. Therefore, non-randomised study designs are also important to evaluate the effectiveness of an efficacious preventative strategy in less-controlled, 'real-life' situations.[14]

Non-randomised studies are considered a group of study designs that lack random allocation of participants to intervention and control group.[15] In sports injuries prevention, those include non-RCTs (i.e. quasi-experiments) and prospective cohort studies, which can be experimental (i.e. with an intervention) or not (i.e. observational).[14] Prospective experimental cohorts, or pretest-posttest designs, enable time-trend analysis to evaluate injury occurrence before and after the implementation of preventative measures. This approach is useful for evaluating the effect of e.g. sporting rule changes aimed at reducing injuries[16] and nationwide injury prevention campaigns.[17] Prospective observational cohort studies may be used to monitor injury occurrence and investigate the effect of preventative strategies already in use. For example, a study monitored ice hockey players who had been wearing full face shields and players wearing half face shields over a season.[18] This study found that ice hockey players wearing full face shields had a lower injury risk of facial and dental injuries and recommended that the sport governing body should consider mandating full facial protective gear.

The lack of random allocation in non-randomised studies potentially leads to systematic differences groups;[11] and therefore, one should consider the non-random allocation 'bias' when inferring a cause-effect relationship between a preventative strategy and injury occurrence in non-randomised studies. For this reason, non-randomised studies would have lower internal validity than a RCT.[15] On the other hand, non-randomised studies have more potential to emulate 'real-world' experiences when applying research findings; and therefore, have increased external validity.[19]

OUTCOME MEASURES IN INJURY PREVENTION STUDIES

When studying the effect of injury preventative efforts, multiple outcomes need to be assessed in order to provide reliable results and meaningful conclusions. Naturally, injury occurrence is the main outcome of interest. However, the constructs 'exposure', 'severity', and 'compliance' or 'adherence' are also key elements to establish the outcome of injury preventative efforts.

Injury

The issue of defining what is a recordable sports injury in epidemiological studies has been investigated comprehensively.[20] There are strict as well as broad injury definitions that have been used in research. Basically, definitions of injury can be summarised to injuries that lead to 'sport time-loss', require 'medical attention', or 'all complaints' reported by athletes.[20] The 'sport time-loss' definition will, by default, concentrate on more severe injuries since athletes may continue participation in training and competition despite having a minor injury.[21] A time-loss injury does not necessarily receive medical attention since this is highly dependent on medical staff availability. In some cases, injured athletes may not consult health professionals. For example, a field hockey player could sustain a contusion in the thigh during a collision with another player. This contusion could lead to one or more days of time-loss, without the player considering medical care. The 'medical attention' definition, however, enables capturing injuries regardless of sport time-loss. The 'all complaints' definition enables capturing injuries beyond medical attention and time-loss (Figure 2), and also allows for more frequent monitoring of health status. Obviously, there are also studies focusing on the prevention of specific injuries (e.g. anterior cruciate ligament or hamstring injuries), which will, by default, have a very specific definition of a recordable injury and its appropriate diagnosis.

While standardised definitions of sports injuries facilitate comparability between different studies and data pooling for meta-analyses, the chosen definition should reflect the goals of the study and the context of the surveillance. Clinicians should consider the strengths and limitations of each approach while interpreting research findings on the prevention of sports injuries.[20]

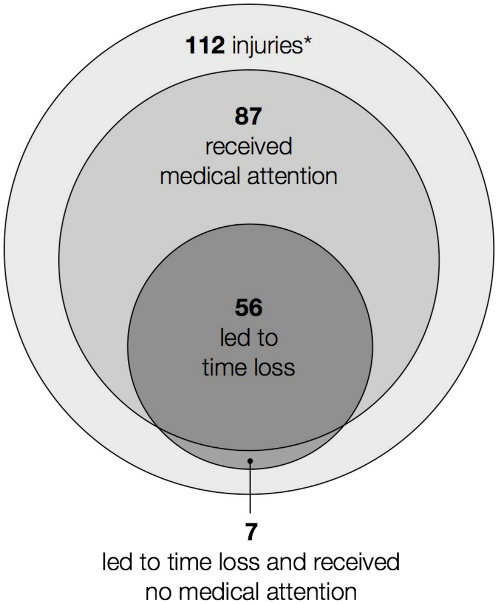

Figure 2. The number of injuries registered in a one-season cohort of elite field hockey players[22] (adapted from Clarsen and Bahr[20]). This example shows how different injury definitions (i.e. all athlete self-reported injuries, injuries receiving medical attention, and injuries leading to training/match time-loss) would impact the observed magnitude of the injury problem within a study. *An injury was defined as disorders of the musculoskeletal system or concussion.

Sport exposure

Measuring the number of injuries is obviously fundamental in studies on the prevention of sports injuries. However, data on the exposure to the sport is also essential in order to provide some context to the actual risk of sustaining an injury while participating in sports.[23] If one is investigating the effectiveness of an injury prevention strategy in two groups of athletes – intervention and control – and both have the same number of injuries, one could prematurely conclude that there was no preventative effect in the intervention group. However, what if the athletes in the intervention group had played 5,000 hours, and those in the control group only 2,500? The intervention group would have been more exposed to the risk of sustaining injuries than the control group, and yet had the same number of injuries.

Combining the number of injuries with exposure data brings the concept of what is generally called injury rate.[23] Injury rates are usually described as the number of injuries per 1,000 athlete-hours, which is calculated by dividing the total number of injuries by the total number of hours that athletes were exposed to the sport and multiplied by 1,000. Injury rates can also be expressed by the number of injuries per 1,000 athlete-exposures (i.e. sessions of exposure), albeit hours is preferred in order to take into account potential differences in length of training and match sessions.[23] Following the previous example, if both groups had 30 injuries, the injury rates in the intervention and control group would be 6 and 12 injuries per 1,000 athlete-hours of exposure, respectively. Although the number of injuries was the same in both groups, the injury rate in the intervention group was half compared to the control group. Therefore, measuring exposure data in injury prevention studies is highly recommended to enable the reporting of injury rates.[23]

Severity of injury

When it comes to the prevention of sports injuries, one is interested in reducing both the number and severity of injuries.[7] An injury prevention strategy could also be considered successful when reducing the severity of injuries, even without a reduction in the absolute number of injuries.[24] Therefore, injury severity is an important outcome when assessing preventative strategies. Different measures of severity have been described for sports injuries in the literature, such as nature of injury, recovery time (i.e. injury duration), received medical attention, sport time-loss, work/school time-loss, permanent damage, and the economic cost to treat the injury.[25] The impact of an injury on athletes' performance is also an important measure of injury severity.[26]

Basically, severity measures relate to the consequences of injuries that can be measured at various levels, as described above. It should be noted, however, that these severity measures are strongly correlated.[25] Arguably, the most commonly employed severity measure of sports injuries is days of sport time-loss. Although important, some injuries do not lead to time-loss, and therefore, require other severity measures (e.g. injury impact on athlete performance). Similarly to the injury definition, the severity measure within a study is based on the context of the surveillance and research question; however, uniform measures between studies would improve comparability of research data.[25]

Compliance and adherence

The extent to which study participants 'uptake' and use an intervention as prescribed is a critical and yet often overlooked outcome measure in injury prevention studies.[27] Although the importance of compliance and adherence is evident, the way compliance is dealt with in preventative studies is subject to a large degree of heterogeneity.[28] Valid and reliable tools to measure and report compliance and adherence are needed and should be matched to uniform definitions of both constructs. In studies investigating efficacy (i.e. explanatory RCTs), intervention uptake is defined as 'compliance', referring to the act of a participant conforming to recommendations with regard to prescribed dosage, timing and frequency of an intervention.[29] In studies investigating effectiveness (e.g. pragmatic RCTs or quasi-experiments), intervention uptake regards to 'adherence', which refers to a process influenced by the environment, and recognizes that user behaviour is determined by social contexts and personal lifestyle.[30]

There is substantial heterogeneity in the way that studies on sports injury prevention have defined, measured and reported the extent to which participants actually 'uptake' preventative interventions.[27] These measurements are often derived from a supervisor (e.g. coach), or by the athletes in case of a non-supervised intervention (e.g. home-based exercises). This information can be collected via paper sheets or online reports and can also be supplemented with random (unannounced) visits or phone calls by investigators/researchers. Similarly to the definition and severity of injuries, definitions and measurements of compliance and adherence are diverse, and uniformity would facilitate interpretation and comparison of studies on the prevention of sports.[27]

COMMON STATISTICS IN INJURY PREVENTION STUDIES

Difference and ratio of injury rates

As mentioned, injury rates are usually described as the number of injuries per 1,000 athlete-hours or athlete-exposures. A simplistic method to estimate the effect of an injury prevention strategy is to calculate the arithmetic difference or ratio between injury rates in an intervention and control group. The reasoning of a difference and a ratio calculation is that, if there is no difference between groups, the results are zero and one, respectively. Thus, if the 95% confidence interval (95% CI) of the injury rate difference or injury rate ratio include zero and one, respectively, one can conclude there was no statistically significant difference between groups.[31] The 95% CI states that the 'real' difference or ratio lies somewhere inside the given range with a 95% certainty. For example, in Table 1 we see an injury rate ratio of an intervention and control group of 0.64. This point estimate indicates that the intervention group had a 36% lower injury rate. The corresponding 95% CI (0.52–0.79) shows that the observed intervention effect was statistically significant. Now let us assume that the sample size of this study was not large enough to investigate the intervention effect with sufficient accuracy. Consequently, the observed point estimate of the rate ratio could still be the same (i.e. 0.64), but due to the smaller sample size, the 95% CI would be wider and might include the number one (e.g. 0.30–1.20). In this scenario, one could not draw firm conclusions on the effect of the intervention due to the non-statistically significant effect.

Cox regression analysis

The Cox regression analysis has advantages over the injury rate difference or ratio since it takes into account athlete's individual time 'at risk' of sustaining an injury (i.e. athlete-specific sport exposure data), and not only the summarised injury rate of a group. The outcome of a Cox regression analysis is the hazard ratio, which is a combination of two measures – the difference in the proportion of injured athletes in the intervention and control group, and the difference in the time-to-injury (i.e. sport exposure data) between groups. In addition, a Cox regression analysis permits adjustment for confounders and the investigation of potential effect modifiers.[32] An example of a Cox regression analysis to assess the efficacy of a preventative strategy is shown in Table 1. In this example, the hazard ratio was 0.59, which means that the risk of sustaining an injury in the intervention group was 41% lower compared to the control group. However, a limitation of the original Cox regression analysis is that it is only able to handle data until the first event (i.e. the first injury sustained by an athlete), ignoring all potential exposure and subsequent injury data after the first injury.[32] Further, it cannot handle clustered data (e.g. players nested in teams).

Cox regression with subsequent events and/or nested data

The above-mentioned limitations of the original Cox regression analysis are important as athletes might sustain multiple injuries during a study as well as in real-life situations. Extensions of the Cox regression analysis allow analysis of more than one injury of individual athletes. Additionally, these extended Cox models take into account that subjects who sustained an injury are probably at a higher risk to sustain another injury. Further, it is possible to account for a hierarchical data structure; e.g. multiple injuries in an athlete, athletes nested in teams, and teams nested in clubs.[32] For these reasons, extended Cox models can be seen as more realistic than the traditional Cox regression analysis.[33] In our example in Table 1, the hazard ratio of an extended Cox regression was 0.52. As this extended Cox model considered what happened with athletes after their first injury, in contrast with the original Cox regression, we can conclude that at any point in time, the risk of sustaining an injury in the intervention group was 48% lower than in the control group.

Considering adherence in the analysis

The examples provided above had so far illustrated comparisons between two groups – the intervention (i.e. using a preventative strategy under investigation) and control (i.e. not using the preventative strategy under investigation). Analysing outcomes according to the participants' original group allocation characterizes an intention-to-treat analysis. This approach dismisses any potential deviations from the intervention protocol.[34] However, in real-life situations, protocols may not happen exactly as planned a priori. This is also the case in preventative strategies for sports injuries, where participants' intervention 'uptake' may deviate from the original plan.

Studies that accounted for compliance and adherence to preventative strategies demonstrated that it significantly affects outcomes.[27] Naturally, preventative strategies will not work if they are not used. This is illustrated by Verhagen et al.,[35] who showed a strong dose-response relationship between adherence to a prescribed injury prevention program and its effects (Table 2). As shown in this study, and which most likely is also the case in other preventative measures, the actual effects found are due to a relatively small subpopulation who adhered sufficiently to the prescribed intervention. The actual preventative effect in the intervention can be, as such, greater than shown in the outcomes that are derived in an intention-to-treat analysis.

Table 1. Different statistical outcomes comparing the use of a structured exercise-based injury prevention program (i.e. '11+ Kids' intervention group) for children's football (soccer) players and the non-use of the program but the teams' regular warm-up program (i.e. control group).[12]

	Intervention		Control		
Statistical comparison	Number of injuries	Injury rate[a] (95% CI)	Number of injuries	Injury rate[a] (95% CI)	**Outcome (95% CI)**
Injury rate difference (IRD)	139	0.99 (0.84–1.17)	235	1.55 (1.36–1.76)	IRD 0.56 (0.30–0.81)
Injury rate ratio (IRR)	139	0.99 (0.84–1.17)	235	1.55 (1.36–1.76)	IRR 0.64 (0.52–0.79)
Cox regression[b]	123	0.88 (0.74–1.05)	178	1.20 (1.03–1.38)	HR 0.59 (0.47–0.74)
Cox mixed effects model[c]	139	0.99 (0.84–1.17)	235	1.55 (1.36–1.76)	HR 0.52 (0.32–0.86)

95% CI: 95% confidence interval; HR: Hazard ratio.
[a] Number of injuries per 1,000 athlete-hours of exposure to football (soccer).
[b] Adjusted for adjusted for age, age-independent body height, and match-training ratio. This analysis considers player's data until first injury only.
[c] Adjusted for adjusted for team clustering, age, age-independent body height, and match-training-ratio, and taking into account multiple injuries of players.

Table 2. Number and rate of ankle sprain recurrences for various adherence categories. Adapted from Verhagen et al.[35]

	Participants (% of total)	Ankle sprain recurrences	Injury rate[a] (95% confidence interval)
Intervention group[b]	**256**	**56**	**1.86 (1.37–2.35)**
Full adherence	58 (23%)	4	0.52 (0.01–1.04)
Partial adherence	75 (29%)	21	2.02 (1.16–2.89)
No adherence	89 (35%)	30	3.04 (1.95–4.13)
Control group	**266**	**89**	**2.90 (2.30–3.50)**

[a] Number of injuries per 1,000 participant-hours of sports exposure.
[b] Participants rated a five-point scale twice during the study: 'I performed the exercises of the program as prescribed'. Participants rating four or five twice were considered fully adherent. Participants who scored a four or a five in only one out of the two occasions were termed partially adherent. Participants who gave scores of three or lower on both occasions were considered not to have adhered to the prescribed intervention.

Considering severity measures in the analysis

Injury burden on athletes' sport participation

As mentioned, injury prevention studies are interested in reducing the occurrence and severity of injuries.[7] These two outcomes are usually reported separately, such as the number of injuries per 1,000 athletes-hours (i.e. injury rate) and days of sport time-loss due to injury, for example. However, it also possible to account for both constructs in one measure and describe the cumulative days of sport time-loss per 1,000 athlete-hours of sport exposure. This measure is a cross-product of injury rate and severity – days of sport time-loss, in this case – and is referred to as injury burden in sports medicine literature.[36–38] In Figure 3, we illustrate, based on original data from a quasi-experiment on a preventative warm-up intervention in youth field hockey,[39] the value of taking injury burden into account. If the injury burden would not have been taken into account, one could have concluded, based on the descriptive statistics, that the intervention did not lead to a significant reduction in injury rates given the overlap of the confidence intervals of the intervention and control group. However, the injury burden was significantly lower in the intervention group given the non-overlapping confidence intervals of the groups (Figure 3). Alternatively, one can calculate the difference or ratio between the intervention and control group in regard to the injury burden, following the same reasoning of the difference or ratio of injury rates described above. By calculating the difference in the Figure 3 example, one can conclude that the intervention group had 8.42 (95% CI 4.37–12.47) less days of field hockey time-loss per 1,000 athlete-hours.

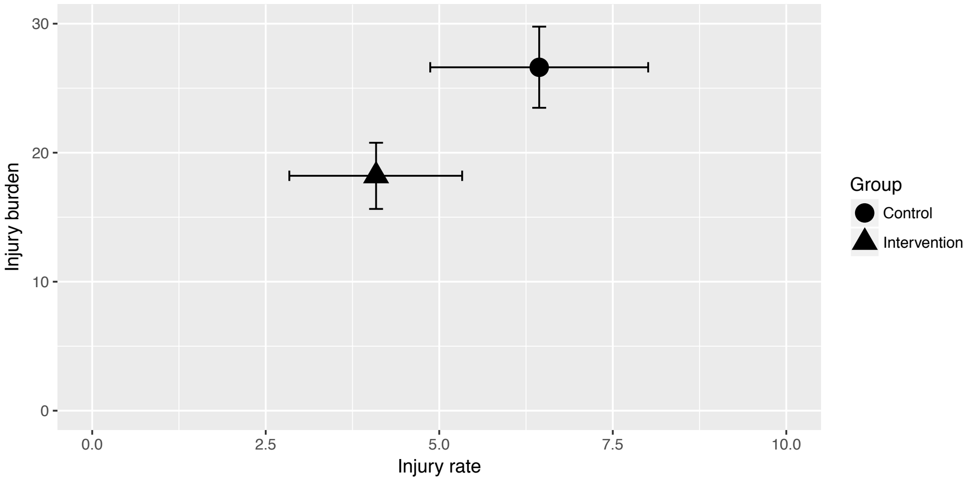

Figure 3. An illustrative comparison between injury rate (i.e. the number of injuries per 1,000 player-hours of exposure to sport) and injury burden (i.e. the number of sessions lost due to injury per 1,000 player-hours of exposure to sport) when assessing the effectiveness of a preventative strategy in youth field hockey.[39]

Economic evaluations

A cost-effectiveness analysis is one form of economic evaluations that determines the efficiency of an intervention by comparing the costs and effects of two or more interventions.[40] As cost data are positively skewed – most athletes will have no injury and no costs, and most injuries will lead to minimal costs – non-parametric bootstrapping is considered the most appropriate method to analyse differences in injury-related costs in sports. The outcomes of bootstrapped cost and effectiveness comparisons can then be graphically depicted in a so-called cost-effectiveness plane. For each intervention, the effect is plotted against the costs of the intervention and compared to a control group (e.g. usual care). The cost-effectiveness plane provides an illustration of the relationship between competing interventions or intervention versus controlled condition in a scatter plot. Figure 4 presents such a plane from a previous study comparing the preventative effect of braces, neuromuscular training, and a combination of both on ankle sprains recurrences.[41] This plane shows that a brace is more cost-effective (i.e. more effective and with lower costs) when compared to neuromuscular training or a combination of bracing and neuromuscular training.

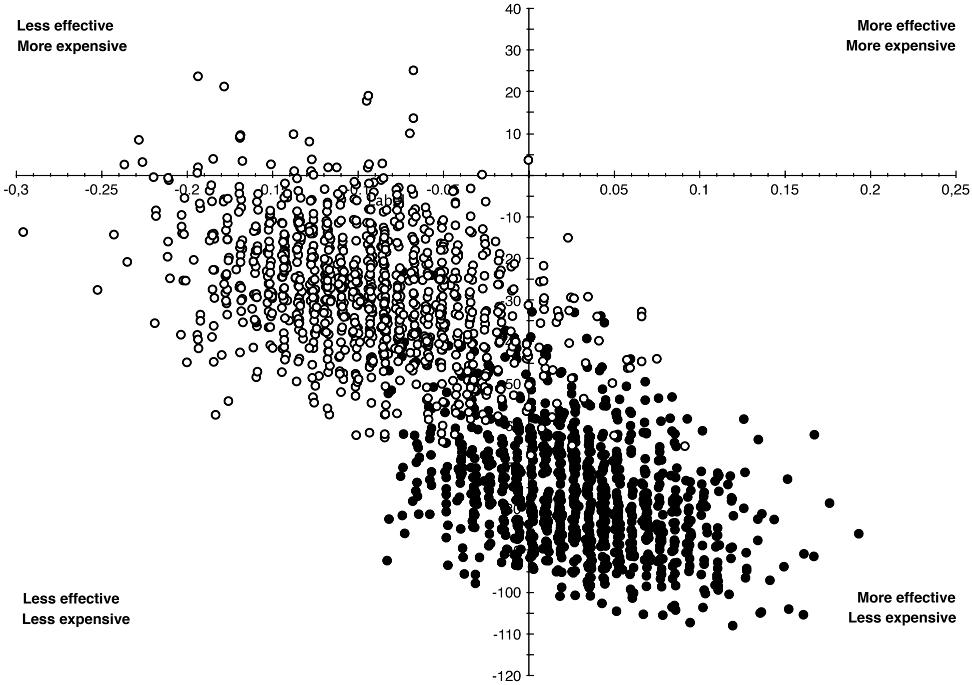

Figure 4. Cost-effect pairs estimated through non-parametric bootstrap (1,000 samples) from a previous study on the prevention of ankle sprains comparing the preventative effect of braces, neuromuscular training and a combination of both. The open dots show the cost-effect pairs for the neuromuscular training group. The closed dots show the bootstrapped cost-effect pairs for the brace group. Both groups are compared to the control group, who received a combination of both interventions. Redrawn from original data of Janssen et al.[41]

The so-called incremental cost-effectiveness ratio (ICER) describes how much additional benefit and at what additional cost an intervention program provides. The ICER is calculated by dividing the net costs of the program minus the net costs of standard care divided by the effectiveness of the program minus the effectiveness of the standard care. Typically, the ICER is given by units of currency per effectiveness gained.[42] For the example in Figure 4, the ICER was 2828. This means that preventing one ankle sprain recurrence in the brace group was associated with €2828 cost savings in comparison to the combination group.

One should be careful when interpreting such results since, in a cost-effectiveness analysis, the comparator should always be usual care treatment. When it concerns prevention, the usual care treatment may be no preventative intervention. This could be regarded as a full control group. However, this is not always the case. The comparator group in the example in Figure 4, for instance, was also provided with an effective preventative intervention; i.e. neuromuscular training combined with bracing as advised in the Dutch ankle sprain guidelines.[43] A cost-effectiveness analysis and the resulting ICER are only to be interpreted in relation to this comparator, and as such may say nothing about the actual preventative and cost-benefit of an intervention as a standalone preventative measure.

CONCLUSION

This chapter provides a summary of the study designs, outcome measures, and common types of data analysis of sports injury prevention studies. There is no single approach which should always be followed to ensure valid assessment of the effect of preventative strategies in sports. The study design and methods will follow the research question and the context of the investigation. However, sports injury prevention studies should provide a clear definition and valid assessment of injury, sport exposure, injury severity, and compliance/adherence to preventative measures. Given the different definitions and methodologies pursued to assess the effect of preventative strategies in sports, clinicians should consider the context of research findings before applying preventative measures in their own setting.

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