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Pre-race screening and stratification predicts adverse events—A 4-year study in 29585 ultra-marathon entrants, SAFER X

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Background: Pre-race screening and risk stratification in recreational endurance runners may predict adverse events (AEs) during a race.
Aim: To determine if pre-race screening and risk stratification predict AEs during a race.
Methods: A total of 29 585 participants (Male 71.1%, average age = 42.1 years; Female 28.9%, average age = 40.2 years) at the Two Oceans ultra-marathon races (56 km) completed a pre-race medical screening questionnaire and were risk stratified into four pre-specified groups [very high risk (VHR; existing cardiovascular disease–CVD:3.2%), high risk (HR; risk factors for CVD:10.5%), intermediate risk (IR; existing other chronic disease, medication use or injury:53.3%), and low risk (LR:33.0%)]. Race starters, finishers, and medical encounters (ME) were recorded. Did-not-start (DNS) rate (per 1000 entrants that did-not-start), did-not-finish (DNF) rate (per 1000 starters that did-not-finish), AE rate [per 1000 starters that either DNF or had an ME], and ME rate (per 1000 starters with an ME) were compared across risk categories.
Results: Adverse events were significantly higher (per 1000 starters; 95%CI) in the VHR (68.9; 52.4-89.9:$P = .0407$) compared with the LR (51.3; 46.5-56.7). The DNS rate was significantly different between the IR (190.3; 184.0-196.9) and LR (207.4; 199.2-216.0: $P = .0011$). DNF rates were not different in the VHR (56.4; 41.9-75.9) compared to LR (44.2; 39.7-49.1: $P = .1295$), and ME rate was also not different between risk categories, however, VHR (12.9; 7.0-23.9) was approaching significance compared to LR (6.9; 5.2-9.1: $P = .0662$).
Conclusion: Pre-race medical screening and risk stratification may identify athletes at higher risk of AEs. Further studies should be performed in larger cohorts to clarify the role of pre-race medical screening in reducing AEs in endurance runners.

KEYWORDS
epidemiology, medical screening, pre-race screening, risk stratification, running, SAFER study

1 | INTRODUCTION

Due to increased awareness of the health benefits of physical activity in the prevention and treatment of non-communicable diseases (NCDs),[1-5] current guidelines suggest a minimum of 150 minutes of moderate to vigorous-intensity exercise per week.[1] Therefore, more people than previously participate in moderate to vigorous physical exercise, including mass community-based sports events. In distance running events, particularly, the number of older athletes participating has increased.[6] However, during/after participation in vigorous-intensity exercise there is a higher risk of medical encounters (MEs),[7,8] including acute myocardial infarctions and sudden death.[6,9-11] Recent literature has started to document not only deaths at mass community-based endurance sports events but also moderate and serious life-threatening MEs.[8,11] The incidence rate (IR) (per 100 000 race starters) of sudden death during/after distance running events is 0.4-3.4,[12] with the IR of sudden cardiac arrest at least double (2.18).[11] The IR of serious life-threatening MEs (16.7-155 per 100 000),[8,12] and all MEs (827-4449 per 100 000),[8,12] are considerably higher. These data show that documenting only sudden cardiac arrests or deaths during sporting events and represent only the "tip of the iceberg" of the total medical burden during/after a mass community-based sports event.

Another aspect of distance running events is the "adverse events" occurring at events. An adverse event is defined as the count of any participant who did-not-finish the event (participants withdrawing for reasons other than medical, or withdrawing for medical reasons without consulting the medical team)[13] or had a medical encounter[13] or both. These outcomes place a large burden on the race organizers and medical teams at mass community-based events, as well as on the participant themselves. Therefore, measures should be implemented to reduce adverse events at races, and the data regarding adverse events can be used for better race planning.[12]

The role of pre-exercise screening to identify individuals that may be at higher risk for MEs has recently received more attention. Many sports federations[14,15] and international bodies including the International Olympic Committee (IOC)[16] and the International Paralympic Committee (IPC) either mandate or recommend pre-participation screening.[14] However, currently, these screening programs focus mostly on screening younger elite athletes,[17-19] and concentrate almost exclusively on pre-participation cardiac screening (including a resting electrocardiogram) to reduce the risk of acute cardiovascular complications. Although the American Heart Association (AHA)[20] and the European Association for Cardiovascular Prevention and Rehabilitation (EACPR)[21,22] have developed recommendations for pre-participation screening for master and leisure athletes wanting to engage in moderate to vigorous physical exercise, these recommendations are rarely executed.

We implemented a pre-participation screening questionnaire (based on the EACPR recommendations) in a sample of distance runners[21,22] and showed that 31% of participants would require a medical assessment prior to the event, with 16.8% (of the total sample) identified to have suspected CVD.[23] Recently, we investigated the efficacy of implementing a pre-participation medical screening and an educational intervention, based on risk stratification, during the Two Oceans Marathon races (21.1 and 56 km running distance)[24] and showed that a pre-screening and an educational intervention decreased the incidence of MEs. Specifically, it reduced 29% of all MEs and 64% of serious life-threatening MEs.[24]

Thus, the aim of this study is to determine if pre-race medical screening and risk stratification in recreational endurance runners can identify athletes at higher risk of adverse events. We hypothesize that ultra-marathon runners that are in higher risk stratification categories have a higher incidence of adverse events during/after a 56 km running race.

2 | MATERIALS AND METHODS

2.1 | Study design

We conducted cross-sectional analysis of data that we collected prospectively over a 4-year period (2012-2015).

2.2 | Participants and data collection

This study forms part of the SAFER (**S**trategies to reduce adverse medical events **F**or the **E**xercise**R**) studies. Participants for this study were all from the Two Oceans Ultra-marathon (56km) races, a mass community-based running event in South Africa. Entry for the 56 km race requires a sub-5 hour 42.2 km-qualifying time. Entrants, defined as any runner registering for the races (registration typically opens 3-5 months before the races), over a 4-year period (2012-2015) were considered as participants. In each of the 4 years, the race entrant data (demographics including age, sex, previous participation, and previously completed races) and race-day data (number of starters and finishers) were obtained. Demographic and race data are in the public domain and are available on the race website. We analyzed the anonymized data on MEs in runners who presented to the medical facilities on race day. All entrant, race-day, and ME data were accessed with permission from the race medical team and race organizers. Medical facilities consisted of on-route medical stations and the medical facility at the finish, and the ME definition from the 2019 consensus statement was used, and only MEs of at least moderate severity were included in this study.[13] Race physicians recorded accurate and detailed clinical information of each ME in a standardized format.

The Research Ethics Committee of the University of Cape Town (REC 009/2011 and REC R030/2013) approved the protocol and the Research Ethics Committee of the University of Pretoria (REC 433/2015) approved the ongoing data collection, and subsequent analysis of the data.

2.3 | Online pre-race medical screening, risk stratification, and educational intervention

In this 4-year study period (2012-2015), an intervention was implemented for all 56 km race entrants. The intervention consisted of a compulsory pre-race medical screening questionnaire or "self-assessment of risk" (full details have previously been described).[24] The pre-race medical screening questionnaire was based on the EACPR recommendations and consisted of the following main categories: cardiovascular disease (CVD), symptoms of CVD, risk factors for CVD, other chronic disease, general prescription medication use, medication use during racing, injury and a past history of collapse during racing. Following the screening questionnaire, an athlete's risk was stratified into one of four risk categories ("very high" [VHR], "high" [HR], "intermediate" [IR], and "low" [LR] risk), using an automated algorithm.[24] Athletes completing the screening were given the opportunity to consent to their data being used for research purposes upon completion.

Following risk stratification, if the runner was classified into one of the two highest risk categories (VHR or HR) targeted educational material was delivered to the runner via a personalized email, and they were specifically advised to seek medical clearance prior to the race.[24] Furthermore, a general educational intervention was conducted through weekly posts on the dedicated medical section of the official race website, and all runners were sent regular emails to notify them to visit the website. No runner was prevented from participating in the race by race-organizers or the medical team, and the final decision to run on race day was left up to the athlete and his/her medical practitioner.

2.4 | Outcome measures

The primary outcome measures were the did-not-start (DNS), did-not-finish (DNF), medical encounter (ME), and adverse event (AE) rates in each risk category. The outcome measures were defined as follows: did-not-start rate (DNS: runners registering but not starting, per 1000 entrants), did-not-finish rate (DNF: runners starting but not finishing the race, per 1000 starters), medical encounter rate (ME: starters having a medical encounter, per 1000 starters), adverse-event rate (defined as those that DNF or had an ME, per 1000 starters). The objective of the study was to determine if there was an association between the applied risk category (based on the risk stratification) during the Two Oceans Ultra-marathon races (2012-2015) and the above outcome measures.

2.5 | Statistical analysis

All available data were entered into an Excel spreadsheet (Microsoft 2010) and then analyzed using the SAS Enterprise Guide (V7.13) statistical program. For analyses purposes, the data had to be transformed from a wide format to a long format so that when a runner did-not-finish and had a medical encounter it counted for 2 adverse events. All the medical complications data were analyzed with a Poisson regression model, using a robust error estimator (log link function). This cohort consists of correlated data as numerous runners ran these races more than once during the 4-year period. The correlated structure was accounted for by using an exchangeable correlation matrix. This was to estimate the incidence rates (IRs) and CIs. Group comparisons and 95% CIs for these IRs and differences were also obtained. Poisson regression analyses were conducted to determine the risk stratification associated with the development of any medical encounter, any adverse event, not starting the race and also not finishing the race during this 4-year period. The low risk (LR) stratification group was the reference category. In the Poisson context, the ratio of these proportions was recast as a ratio of rates (rate ratio) for each of the outcomes. These regressions were unadjusted as age-group, and gender were already accounted for in the four risk stratification groups. Statistical significance was accepted at $P < .05$.

3 | RESULTS

Over the four years, 29 585 ultra-marathon entrants gave consent for their pre-race medical screening data to be used for research purposes (70.4% of all ultra-marathon entrants). Of the consenting entrants, 71.1% were male, with an average age of 42.1 years, and the 28.9% females had an average age of 40.2 years. Of these, 5589 entrants (18.9%) did-not-start the race and 23 996 entrants (81.1%) started the race. Over the four-year period, 22 964 starters finished the race (95.7% starters), 1032 were non-finishers (4.3% starters), and 179 medical encounters were recorded. The total number of adverse events (number of non-finishers and number of medical encounters) over the 4-year period was 1211, but the total number of runners with AEs were 1191 (some MEs were counted separately as DNFs as well). The consenting entrants, starters, non-starters, finishers, non-finishers, medical encounters, and adverse events (n; %) in each risk category are presented in Table 1.

TABLE 1 The consenting entrants, starters, non-starters, finishers, non-finishers, medical encounters, and adverse events (n; %) in each risk category

Risk category	Consenting entrants (n and % of consenting entrants)	Starters (n and % of starters)	Did-not-start (n and % of non-starters)	Finishers (n and % of finishers)	Did-Not-Finish (n and % of non-finishers)	Medical encounters (n and % of medical encounters)	Adverse events (n and % of adverse events)*
Total	29 585	23 996	5589	22 964	1032	179	1191
Very high risk (VHR)	934 (3.2)	748 (3.1)	186 (3.3)	708 (3.1)	42 (4.1)	10 (5.6)	50 (4.3)
High risk (HR)	3101 (10.5)	2499 (10.4)	602 (10.8)	2382 (10.4)	119 (11.5)	17 (9.5)	134 (11.2)
Intermediate risk (IR)	15 780 (53.3)	12 919 (53.8)	2861 (51.2)	12 390 (53.9)	539 (52.2)	98 (54.8)	627 (52.6)
Low risk (LR)	9770 (33.0)	7830 (32.6)	1940 (34.7)	7504 (32.7)	332 (32.2)	54 (30.2)	380 (31.9)

*Must be noted that Medical Encounters and Did-Not-Finish do not add up to Adverse Events, because some runners were both non-finishers and had an ME.

Among all the race starters (n = 23 996), 3.1% were in the VHR category, 10.4% in the HR category, and 53.8% were classified in the IR category.

3.1 | Did-Not-Start (DNS) per 1000 entrants, Did-Not-Finish (DNF), Medical Encounter (ME), Adverse Event (AE) per 1000 starters

The did-not-start rate (per 1000) of entrants, per risk category over four years, is presented in Table 2. The did-not-finish, medical encounter, and adverse-event rate per 1000 race starters for the four years are also presented in Table 2.

There was an overall significant difference in DNS rates between risk categories ($P = .008$).

There was no significant overall difference in DNF rates between risk categories ($P = .366$), ME rates between risk categories ($P = .5076$) or AE rates between risk categories ($P = .278$). However, for DNF and AE rates there were significant differences between specific risk categories.

There was no apparent difference between risk categories' relationship to environmental conditions (WBGT) over the years (Figure S1).

4 | DISCUSSION

The main finding of this study was that the AE rate was significantly higher in a VHR category [runners reporting known cardiovascular disease (CVD) or symptoms of CVD] compared with the LR category in ultra-marathon runners who were risk stratified into four risk categories using a pre-screening medical questionnaire and risk stratification process. We also note that DNF and ME rates were highest in the VHR category, although these rates were not statistically different. Furthermore, the DNS rate between groups was also significantly different.

In this study, we show that existing cardiovascular disease (CVD) or symptoms of CVD[23] is associated with a 30% increased risk of an adverse event in ultra-marathon race entrants. To our knowledge, no other study has investigated if pre-race risk stratification, based on a history of pre-existing diseases, is associated with an increased risk for adverse events in distance running events. International pre-participation health screening guidelines and recommendations, with risk stratification, have been developed and are promoted by international organizations.[25-27] However, the implementation of these guidelines and recommendations has not been applied, specifically in mass community-based sports events. Our data illustrate the potential value of pre-race medical screening and risk stratification to identify athletes "at risk" for adverse events. This information will also be of value to medical staff and race organizers to plan for management of

TABLE 2 The did-not-start rate (per 1000 entrants: 95% CI) per risk category of entrants and did-not-finish, medical encounter, and adverse event rate (per 1000 starters: 95% CI) per risk category of starters

Risk category	DNS rate (per 1000 entrants)	95% CI		Rate ratio*	95% CI		P-value*
Very high risk	205.4	180.4	233.8	1.0	0.9	1.1	.888
High risk	205.4	191.1	220.9	1.0	0.9	1.1	.822
Intermediate risk	190.3	184.0	196.9	0.9	0.9	1.0	.001
Low risk	207.4	199.2	216.0	-	-	-	-
Risk category	**DNF rate (per 1000 starters)**	**95% CI**		**Rate ratio***	**95% CI**		***P*-value***
Very high risk	56.4	41.9	75.9	1.3	0.9	1.8	.130
High risk	48.6	40.4	58.5	1.1	0.9	1.4	.377
Intermediate risk	43.3	39.8	47.1	1.0	0.9	1.1	.756
Low risk	44.2	39.7	49.1	-	-	-	-
Risk category	**Medical encounter rate (per 1000 starters)**	**95% CI**		**Rate ratio***	**95% CI**		***P*-value***
Very high risk	12.9	7.0	23.8	1.9	1.0	3.7	.066
High risk	6.8	4.2	10.9	1.0	0.6	1.7	.956
Intermediate risk	7.6	6.2	9.3	1.1	0.8	1.6	.567
Low risk	6.9	5.2	9.1	-	-	-	-
Risk category	**Adverse-event rate (per 1000 starters)**	**95% CI**		**Rate ratio***	**95% CI**		***P*-value***
Very high risk	68.7	52.4	89.9	1.3	1.0	1.8	.047
High risk	55.5	46.7	65.0	1.1	0.9	1.3	.435
Intermediate risk	51.1	47.3	55.3	1.0	0.9	1.1	.956
Low risk	51.3	46.5	56.7	-	-	-	-

Total non-starters: n = 5589.
Total non-finishers: n = 1032.
Total medical encounters: n = 179.
Total runners with adverse events: n = 1191.
*Compared to the Low-Risk group.

adverse events (ie a medical encounter, or participants who do not finish the event) on race day.

The DNF and ME rates were highest in the VHR category, but these rates were not statistically different across risk categories. This may be because the sample size of medical encounters and DNFs was too small to show significant differences and we acknowledge that as a limitation. Future studies with larger sample sizes are required to address this limitation. The results may have also been affected by the educational intervention. Specifically, all runners in the VHR and HR risk categories received individualized targeted pre-race educational material. This consisted of advice to: (1) undergo a medical assessment and clearance by a medical doctor prior to the race, (2) be aware of possible symptoms of CVD while exercising, and (3) stop exercise if these symptoms occur during running. Runners in all categories also received general education material via the race website. We could not record the reasons why runners did-not-finish the race in this study. Therefore, the results of this study must be interpreted with this limitation in mind. However, we note that, despite the targeted intervention in the VHR and HR categories, the DNF, ME, and AE rates in the VHR was still the highest compared with all the other categories. We can speculate that, if there was no pre-race screening and educational intervention, runners in the VHR, HR, and IR would have even higher DNF, ME, and AE rates, and thus we may have underestimated the effect of pre-race medical screening in the present study. However, to conduct a study where pre-race screening to risk stratify entrants is done but without an educational intervention, would pose a very significant ethical challenge.

It could be argued that the pre-race screening and educational intervention would increase the DNS in the VHR and HR categories, because entrants in these groups were advised to seek medical clearance from their medical practitioner before the race. However, we note that the DNS rate was not higher in the VHR or HR groups, but rather that the DNS rate was highest in the LR group. We acknowledge that we do not present data to show that entrants in the VHR and HR group sought medical clearance from their medical practitioner and if they did, whether they adhered to advice given by the medical practitioner. We interpret these DNS data to show that, over the 4-year period, the pre-race screening and intervention did not result in a significant "self-exclusion" of runners in the VHR and HR categories from starting the race. Rather, we suggest that runners in these two categories chose to start the races, but were equipped with the correct information to make their own decisions about participation in these races. Furthermore, only a selected few of the highest risk (not affecting the overall participation rate) chose not to participate. We suggest that future studies should further investigate these runners that are identified as VHR or HR, and what medical clearance or lack thereof they sought.

The strengths of this study include the large homogenous sample size of 56km race entrants, and that the data were collected prospectively over four years. To our knowledge, this is the largest study of this nature and the first study to identify risk stratification as a possible predictor of adverse events. Medical data were collected by medical doctors. We also had comprehensive information on all participants, regarding entry data and their pre-screening medical questionnaire data for risk stratification. Previous research has not had access to such in depth knowledge of the participants' medical history, and only had access to race-day data and basic entry information.[28-32]

One of the limitations of the study is that it was a prospective cross-sectional study and not a randomized controlled trial. As mentioned, the cohort used in this study had been exposed to an intervention, and the results could have been affected by the advice distributed during the intervention. Therefore, the results of this study must be interpreted with this study limitation in mind. The study is under-powered and would require approximately 41 000 entrants to find a significant effect in all three outcomes. Another limitation is that all the pre-race medical screening data of the participants was self-reported, and there were participants who did not give consent, so there could also be a selection bias of "at risk" individuals not willing to reveal their medical history for research. The specific risk factors responsible for the association between the outcomes (such as adverse events, did-not-finish, and medical encounters) and the risk stratification categories found in this cohort should also be further investigated. We acknowledge that further potential external factors unrelated to health status could influence the AE/ME/DNF rates in risk categories (such as environmental conditions)[33] and should be further explored in future studies.

5 | PERSPECTIVE

In summary, this study shows that risk stratification of ultramarathon runners using a pre-screening medical questionnaire enables identification of a very high risk (VHR) group of runners that has a 30% greater risk of an adverse event during a race. Pre-race screening and risk stratification may aid the medical staff to better prepare for medical care on race day. Future studies (using a larger sample and a follow-up) should investigate which specific risk factors contributed to the risk of adverse events, did-not-finish, and medical encounter rates in distance running events, with the goal of refining pre-exercise medical screening questionnaires.

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CONFLICT OF INTERESTS

The authors declare that there are no competing interests.

AUTHOR CONTRIBUTIONS

Nicola Sewry (NS) involved in data interpretation, manuscript (first draft), and manuscript editing. Martin Schwellnus (MS) involved in responsible for the overall content as guarantor, study concept, study planning, data cleaning, data interpretation, manuscript (first draft), manuscript editing, and facilitating funding. Mats Borjesson (MB) involved in data interpretation, manuscript (first draft), and manuscript editing. Sonja Swanevelder (SS) involved in study planning, data analysis including statistical analysis, data interpretation, and manuscript editing. Esme Jordaan (EJ) involved in study planning, data analysis including statistical analysis, data interpretation, and manuscript editing.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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