J Cancer Res Clin Oncol
DOI 10.1007/s00432-016-2313-2

ORIGINAL ARTICLE – CLINICAL ONCOLOGY

Preoperative characteristics of the P.R.O.S.T.A.T.E. scores: a novel predictive tool for the risk of positive surgical margin after radical prostatectomy

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Received: 23 July 2016 / Accepted: 28 November 2016

Abstract
Objectives To propose a novel scoring system to predict the risk of positive surgical margin (PSM) after radical prostatectomy (RP) in prostate cancer (PCa) patients.
Materials and methods Eight reproducible variables available from preoperative characteristics of PCa patients were measured: PSA level (*P*), ratio of positive biopsy needles (*R*), obesity (*O*), scores of Gleason (*S*), *T* stage by preoperative MRI scan (*T*), age (*A*), tumor volume (*T*) and experience of the surgeon (*E*). Of the eight components, seven were scored on a 0-, 1- or 2-point scale, with only the "*A*" component on a 0- or 1-point scale. The P.R.O.S.T.A.T.E. scores can range from 0 to 15.
Results A total of 441 patients were included from the Peking University First Hospital between November 2007 and March 2016, among whom 195 patients (44.2%) had a PSM identified by a postoperative pathological examination. The preoperative P.R.O.S.T.A.T.E. scores statistically correlated with the postoperative SM status ($p < 0.001$) when the 441 consecutive patients were divided into three groups (low-risk group: score of 0–4, moderate-risk group: score of 5–9 and high-risk group: score of 10–15). The risk of PSM after RP in the low-risk, moderate-risk and high-risk groups was 21.1, 40.1 and 87.0%, respectively.
Conclusions The novel scoring system of P.R.O.S.T.A.T.E. that we presented was found to predict the risk of PSM after RP. A combination of reproducible, standardized parameters obtained from preoperative characteristics of PCa patients can be used as a tool for predicting PSM, thus assisting in the strategy of performing surgical procedures. More careful manipulation or wider resection may be of utmost importance in the high-risk group.

Keywords Prostate · Positive surgical margin · Prostatectomy · Predictive · Scores

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Introduction

Prostate cancer (PCa) is the most common non-dermatological malignancy, and the vast majority of cases present with localized or locally advanced disease (Orr et al. 1996). A standard treatment option for PCa is radical prostatectomy (RP). However, regardless of the detailed approach, RP can still achieve a positive surgical margin (PSM) situation, reporting a rate of 10–40% (Fontenot and Mansour 2013). A PSM is pathologically defined as the presence of tumor at the inked margin of a prostate specimen (Luke et al. 2016), which is an independent predictor of biochemical recurrence (BCR) and local disease recurrence as well as the need for secondary cancer treatment (Vincenzo et al. 2009). Therefore, the achievement of negative SM (NSM) is of utmost importance in patients with PCa.

To a certain extent, certain preoperative characteristics of PCa patients are related to the risk of PSM. It has been reported that serum PSA level, clinical stage, biopsy Gleason score and individual surgeon's expertise are consistently associated with PSM (Rafael et al. 2010; Liss et al. 2008). Howard et al. (2012) also noted that older patients

Published online: 05 December 2016

were associated with higher levels of PSA and thus an increased risk of PSM, and Fleshner et al. (2010) reported that PSM rates were related to obesity. In addition, Vipul et al. (2011) proposed that increasing prostate volume was associated with a lower risk of PSM, and Zorn et al. (2008) noted that the ratio of positive biopsy cores could be used as a preoperative risk factor.

Although some literature has conversely concluded that the preoperative characteristics mentioned above might not be a statistically independent factor for predicting PSM, we contend that the risk of PSM can be predetermined in many instances before RP, by using multiple involved factors rather than a single factor. To our knowledge, there is currently no scoring system that predicts the risk of PSM after RP in a reproducible, quantifiable manner by analyzing a combination of preoperative characteristics.

In the same way that the R.E.N.A.L. nephrometry score (Kutikov and Uzzo 2009) and the S.T.O.N.E. nephrolithometry score (Zhamshid et al. 2013) have standardized the evaluation of nephron-sparing surgery and percutaneous nephrolithotomy, we propose a novel, quantitative scoring system (P.R.O.S.T.A.T.E. scores) that uses eight preoperative characteristics to predict the risk of PSM after RP. The primary aim of the present study is to introduce the P.R.O.S.T.A.T.E. scoring system for the prediction of PSM after RP and to validate this system with regard to its ability to allow for more reasonable treatment decisions, thus creating a perfect balance between oncological and functional outcomes.

Materials and methods

P.R.O.S.T.A.T.E. scores

We performed a MEDLINE review of English language studies from 2000 to 2016 to identify clinically relevant and reproducible variables that could preoperatively predict the risk of PSM. The inclusion criteria were identified without filters and with the intersection of the following MESH terms: "positive surgical margin," "prostate" versus "predictors" or "predictive factors." Non-English language studies and studies without the specific terms mentioned above in the headline were excluded. After reviewing the relevant literature, the scoring system was established based on 8 reproducible variables available from preoperative characteristics of PCa patients. The 8 variables were abbreviated using the acronym "P.R.O.S.T.A.T.E." The detailed parameters included PSA level (*P*), ratio of positive biopsy needles (*R*), obesity (*O*), scores of Gleason (*S*), *T* stage by preoperative MRI scan (*T*), age (*A*), tumor volume (*T*) and experience of surgeon (*E*).

Table 1 Summary of P.R.O.S.T.A.T.E. scoring system

Variable	Scores		
	0pt	1pt	2pts
(*P*)SA level (ng/ml)	<10	10–20	>20
(*R*)atio of positive biopsy needles	<25%	25–49%	≥50%
(*O*)besity (kg/m^2)	<24	24–30	>30
(*S*)cores of Gleason	≤6	7	≥8
(*T*) stage by preoperative MRI scan	≤*T*2a	*T*2b	≥*T*2c
(*A*)ge	<60	≥60	–
(*T*)umor volume (ml)	≥60	20–59	<20
(*E*)xperience of surgeon (cases)	>100	30–100	<30

To determine the cutoff value of each preoperative factor, we established strict criteria based on routine standards in clinical practice: (1) based on the D'Amico high-risk criteria (D'Amico et al. 1998; Ren et al. 2013), the PSA level (*P*) was divided into categories of <10, 10–20 and >20 ng/ml; scores of Gleason (*S*) were divided into categories of ≤6, 7 (including 3 + 4 and 4 + 3) and ≥8; the *T* stage by preoperative MRI scan (*T*) was divided into ≤*T2a*, *T*2b and ≥*T*2c; (2) the ratio of positive biopsy needles (*R*) was studied as a categorical variable into <25, 25–49 and ≥50% according to Arees D's criteria (Arees et al. 2016); (3) obesity (*O*) was calculated with the parameter of body mass index (BMI) and divided into <24, 24–30 and >30 kg/m^2 (BMIs of 24 and 30 kg/m^2 were selected due to the currently accepted cutoff for normal weight and obesity, respectively) (Zhamshid et al. 2013); (4) the age (*A*) at surgery was categorized into <60 and ≥60, as older age is an important clinical determinant of PCa (Tward et al. 2006); (5) the tumor volume (*T*) was categorized into ≥60, 20–59 and <20 ml based upon Arees D's investigation (Arees et al. 2016); and (6) the experience of the surgeon (*E*) was categorized into <30 cases, 30–100 cases and >100 cases based upon our institution's laparoscopic learning curves. Of the eight components, seven were divided into three groups and then scored on a 0-, 1- or 2-point scale, except for the "*A*" component, which was divided into two groups and thus scored on a 0- or 1-point scale.

As summarized in Table 1, the scores from each variable were summed to determine the total P.R.O.S.T.A.T.E. scores. The scores can vary from a minimum of 0 to a maximum of 15. A score of 0 denotes the least risk of PSM after RP, and a score of 15 denotes the most risk of PSM after RP.

Patient samples

The clinical records of 441 patients who underwent RP for PCa between November 2007 and March 2016 were prospectively collected in the PCa database of the Peking University First Hospital. All patients treated with neoadjuvant hormonal therapy before RP were excluded from this study. The patients had signed an informed written consent form authorizing data collection for scientific purposes. All surgeons involved in our study had independently completed at least 10 cases of laparoscopic RP or at least 30 cases as the assistant holding the laparoscope or aiding in exposing and clamping. The tumor volume was preoperatively calculated using B-ultrasonography with the following formula: volume = $(\pi/6) \times$ width $\times$ length $\times$ height in mm^3. The diagnosis of PCa was made after an ultrasound-guided 13-core prostate biopsy performed with the indication of abnormal digital rectal examination finding and/or higher PSA level.

All surgical procedures were performed using a transperitoneal or retroperitoneal three-/four-port laparoscopic technique. The primary outcome measure was the status of SM, which was evaluated by uropathologists. Every patient was assessed for the eight preoperative characteristics of the P.R.O.S.T.A.T.E. scoring system according to their SM status.

Statistical analysis

The baseline differences in patient characteristics between the PSM and NSM groups were analyzed using the *t* test for continuous variables and the Chi-square test for categorical variables. The association of each score component with postoperative SM status was evaluated using a Chi-square or Fisher's exact test when appropriate. The analysis of the final score with preoperative characteristics was performed using logistic regression. The diagnostic accuracy, sensitivity and specificity of the final score and its individual components were analyzed using receiver operating characteristic curves. All statistical analyses were performed using SPSS 19.0 software, and a *p* value of 0.05 was considered statistically significant.

Results

A total of 441 patients were included from Peking University First Hospital between November 2007 and March 2016, of whom 195 cases (44.2%) had a PSM as identified by postoperative pathological examination. The preoperative characteristics of the PCa patients were compared between the PSM and NSM groups, as listed in Table 2. Among them, the PSA level ($p < 0.001$), ratio of positive biopsy needles ($p < 0.001$), scores of Gleason ($p < 0.001$) and T stage by preoperative MRI scan ($p < 0.001$) were independent predictors of PSM after RP, without any significant discrepancies detected in the other four characteristics. Moreover, the P.R.O.S.T.A.T.E. scores were statistically different between the PSM and NSM groups using logistic regression ($p < 0.001$). Overall, the P.R.O.S.T.A.T.E. scores predicted the risk of PSM after RP with an accuracy of 71.1% (95% CI 0.664–0.761), as shown in Fig. 1. Subsequently, the area-under-curve (AUC) values of the score and its constituent parts were compared and evidently suggest that the AUC value of the P.R.O.S.T.A.T.E. scores was significantly higher than that of any of its components ("*P*": $p = 0.0033$, "*R*": $p = 0.0437$, "*O*": $p < 0.0001$, "*S*": $p = 0.0001$, "*T*": $p < 0.0001$, "*A*": $p < 0.0001$, "*T*": $p < 0.0001$ and "*E*": $p < 0.0001$).

The preoperative P.R.O.S.T.A.T.E. scores statistically correlated with the postoperative SM status ($p < 0.001$) when the 441 consecutive patients were divided into three groups (low-risk group: 0–4, moderate-risk group: 5–9 and high-risk group: 10–15). Figure 2 demonstrates the number of patients by P.R.O.S.T.A.T.E. scores according to the different risk groups. The risk of PSM after RP in the low-risk, moderate-risk and high-risk groups was 21.1, 40.1 and 87.0%, respectively. It could be detected that the P.R.O.S.T.A.T.E. scores reflected a close correlation with the SM status, with a greater score resulting in a higher risk of PSM after RP. Evidently, the patients with postoperative PSM had significantly greater P.R.O.S.T.A.T.E. scores than the NSM patients.

Table 2 A comparison of patients' preoperative characteristics between different SM status

Variable	PSM	NSM	*p* value
(*P*)SA level (ng/ml)	18.1 ± 14.7	12.5 ± 10.7	<0.001
(*R*)atio of positive biopsy needles (%)	0.47 ± 0.28	0.31 ± 0.20	<0.001
(*O*)besity (Kg/m^2)	24.5 ± 2.6	24.2 ± 2.8	0.336
(*S*)cores of Gleason			<0.001
≤6	33 (16.9%)	88 (35.8%)	
7	131 (67.2%)	137 (55.7%)	
≥8	31 (15.9%)	21 (8.5%)	
(*T*) stage by preoperative MRI scan			<0.001
≤*T*2a	53 (27.2%)	95 (38.6%)	
*T*2b	79 (40.5%)	110 (44.7%)	
≥*T*2c	63 (32.3%)	41 (16.7%)	
(*A*)ge	66.3 ± 6.7	66.0 ± 7.0	0.641
(*T*)umor volume (ml)	42.2 ± 22.0	42.2 ± 25.4	0.991
(*E*)xperience of surgeon (cases)			0.189
<30	75 (38.5%)	76 (30.9%)	
30–100	103 (52.8%)	151 (62.4%)	
>100	17 (8.7%)	19 (7.7%)	
P.R.O.S.T.A.T.E. scores	7.96 ± 1.99	6.46 ± 1.68	<0.001

PSM Positive surgical margin, *NSM* negative surgical margin

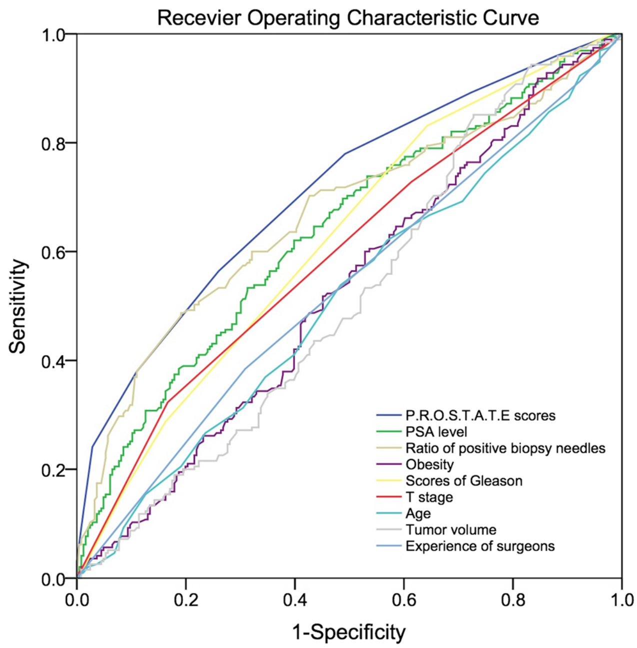

Fig. 1 Preoperative characteristic curves for P.R.O.S.T.A.T.E. scores and individual components for PSM patients

Discussion

The presence of a PSM after RP is uniformly considered an adverse outcome as well as a quality indicator of RP (Nazareno et al. 2016). Surgeons are often faced with the dilemma of how to interpret a PSM. In general, PSM after RP has several implications: It has been associated with higher rates of BCR and shorter time to progression, which could also lead to significant fear in the PCa patients and a negative impact on quality of life (D'Amico et al. 1998). Knowing these facts, the associated factors that could predict the risk of PSM after RP must be identified (Caroline et al. 2015).

To more accurately predict the risk of PSM after RP and thus provide a more reasonable surgical procedure regarding whether the nerve is reserved or not, we propose a novel scoring system that is best recalled using the acronym P.R.O.S.T.A.T.E. In a multivariate regression analysis, the P.R.O.S.T.A.T.E. scoring system was found to be highly predictive of PSM, with a projected accuracy of 71.1%, which is greater than any of the individual variables alone. In our trial, a "low-risk" group (score of 0–4) demonstrated a PSM of 21.1%, a "moderate-risk" group (score of 5–9) reported a PSM of 40.1% and a "high-risk" group (score of 10–15) revealed a PSM of 87.0%. The differences among the different risk of groups reached statistical significance ($p < 0.001$). In considering these results as indexes of a predictive scoring system, the significant observations in these characteristics support the utility of the P.R.O.S.T.A.T.E. scores in preoperative patient counseling.

Three important issues must be highlighted when interpreting our results. First, why focus on a predictive tool? It is well known that the nerve-sparing RP has been increasingly introduced into practice instead of a wide resection of the prostate to help preserve postoperative potency, and the decision of whether to preserve the neurovascular bundle has traditionally been the individual responsibility of the operating surgeon (Sultan et al. 2010) without a standard and reproducible procedure being performed. Boehm and Graefen (2015) mentioned that nerve sparing was associated with an increased risk of a PSM in organ-confined PCa. Preston MA also reported that bilateral nerve sparing during RP was associated with increased risk of PSM in patients with organ-confined PCa (Preston et al. 2015). Therefore, the nerve-sparing procedure must be carefully considered preoperatively when analyzing the incidence of PSM after RP. Fortunately, this P.R.O.S.T.A.T.E. scoring system can help accurately divide PCa patients into the appropriate risk groups preoperatively and provide information on the risk of PSM after RP, thus reducing the incidence of PSM using more careful manipulation or wider resection. For instance, if the sum scores range from 0 to 4, a more aggressive nerve-sparing surgical technique should be performed to preserve erectile function and urinary continence; if the sum scores range from 5 to 9, the nerve-sparing surgical technique should be carefully selected only when a surgeon with excellent surgical technique has sufficient experience in handling these situations (Williams et al. 2010); and if the sum scores range from 10 to 15, a standardized wide resection technique instead of a nerve-sparing procedure might be referred due to the dramatic increase in risk of PSM after RP. Therefore, in clinical practice, low-risk (0–4 scores) and moderate-risk (6–9 scores) groups could receive the nerve-sparing surgical procedure more often, whereas the high-risk (11–15 scores) group would be more likely to undergo a wide resection of the prostate.

Second, does the situation listed above suggest that nerve-sparing RP should be performed less often (or not all) due to an increased risk of PSM after RP? Unexpectedly, nerve sparing should be performed more often and encouraged in men with acceptable risks of extraprostatic extension (Partin et al. 1993). Applying the novel scoring system of P.R.O.S.T.A.T.E. could assist in the selection of the nerve handling technique, especially in developing countries such as China, where intraoperative frozen sectioning of the prostate to ensure a safe nerve-sparing procedure (Christian et al. 2013) cannot be currently realized. In place of this sophisticated intraoperative method, preoperatively calculating the detailed P.R.O.S.T.A.T.E. scores can

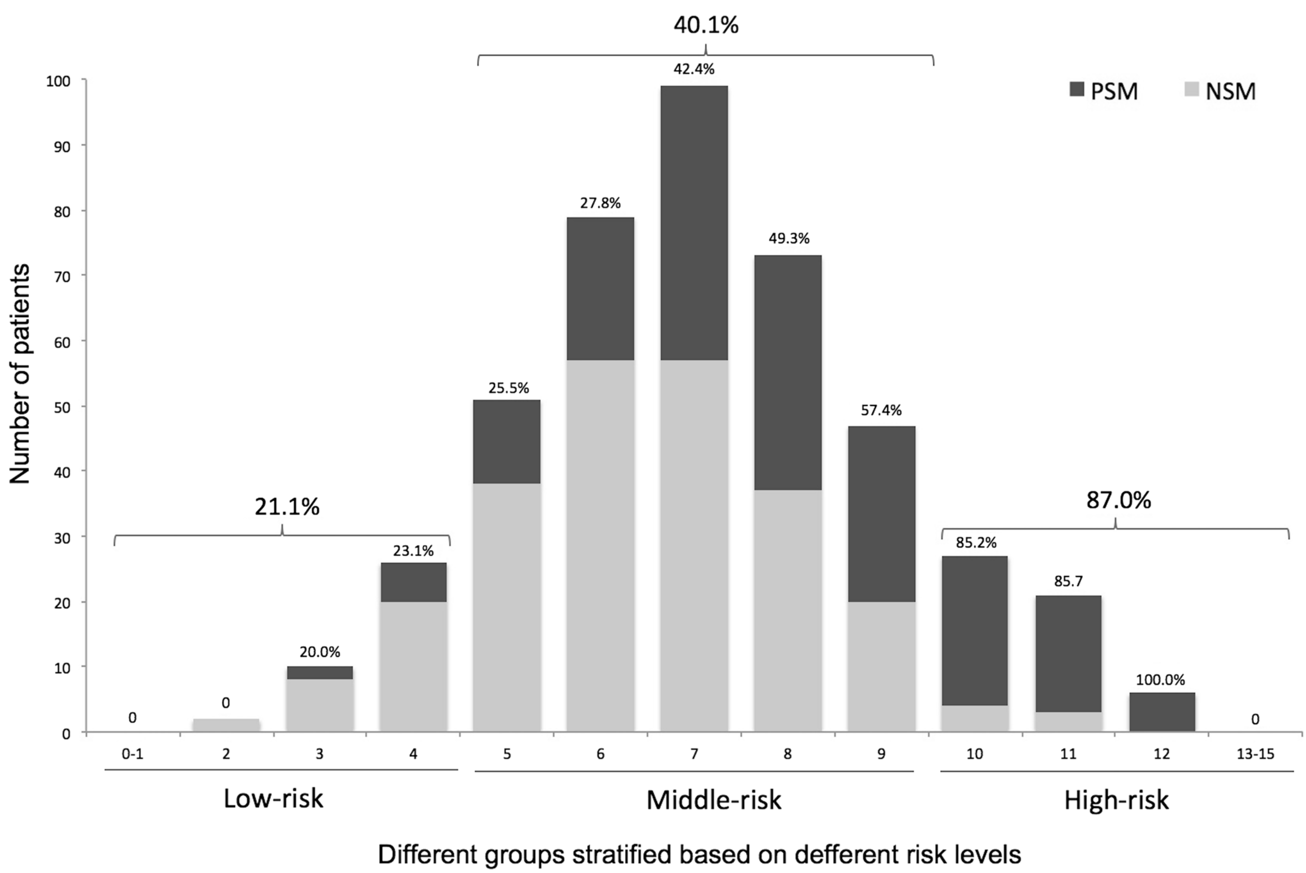

Fig. 2 Percentage of PSM patients stratified by low-risk, moderate-risk, and high-risk groups

have similar implications on operative planning for patients where nerve resection may be most appropriate.

Finally, surgeons should note that patients with lower or higher P.R.O.S.T.A.T.E. scores may not necessarily be treated solely via RP with or without nerve-sparing techniques. In fact, alternative approaches may be more appropriate for those whose scores are exactly located at both sides of the "0–15 score" range, which is a potential advantage of the P.R.O.S.T.A.T.E. scores, i.e., to filter the most suitable patients for RP. For example, for some patients scoring 0, 1 or 2, active surveillance instead of instant RP could be considered and implemented after adequate communication with the patient. Similarly, for certain patients scoring 12, 13, 14 or 15, radical external beam radiotherapy or hormonal therapy with less risk of perioperative complications may be more practical and effective than RP. In specific circumstances, the P.R.O.S.T.A.T.E. scores systems could even assist in case selection by providing alternative approaches in place of RP for those patients with a particularly optimistic or relatively unsatisfactory score. In speculating from Fig. 2, patients scoring from 3 to 11 may be better suited for RP, with patients scoring from 0 to 2 or 12 to 15 referred to other noninvasive therapies; however, more related statistics and investigations are still urgently required to confirm these findings in the long term.

Above all, an ideal classification system should be simple in its application and reflect current practices. The R.E.N.A.L. nephrometry scores (Kutikov and Uzzo 2009) and the S.T.O.N.E. nephrolithometry scores (Zhamshid et al. 2013) have both demonstrated that such a scoring system must fulfill three requirements to be successfully incorporated into clinical practice and academic reporting: (1) The scores must be "easy" to obtain from available preoperative characteristics; (2) the variables involved must provide "detailed" information of the individual case; and (3) the scoring system should reflect and predict postoperative outcomes using an "objective" parameter, such as the PSM in the P.R.O.S.T.A.T.E. scoring system. Taken together, we strongly believe that the P.R.O.S.T.A.T.E. scoring system fulfills these requirements and that it can be readily applied in clinical settings where RP will be performed.

Unfortunately, we acknowledge the limitations in the present study. First, the data were retrospectively collected in a relatively small cohort; consequently, the statistical analyses could be underpowered. Also, not every 1- or 2-point difference in the parameters of this system reflects a similarly meaningful significance in the predictive risk of PSM. In addition, we did not have sufficient follow-up time to assess BCR or cancer-specific mortality. Finally, other factors may exist that could influence the risk of PSM that were not included in this P.R.O.S.T.A.T.E. scoring system. In summation, the reproducibility of this scoring system must be validated in future studies.

Conclusions

The novel scoring system of P.R.O.S.T.A.T.E. we presented was found to predict the risk of PSM after RP. A combination of reproducible, standardized parameters obtained from the preoperative characteristics of PCa patients could be used as a tool for predicting PSM after RP, thus assisting in the strategy of performing a proper surgical procedure—a reasonable balance between preserving potency and achieving disease control. More careful manipulation or wider resection may be of utmost importance in high-risk groups, but more robust studies are still required.

Author's contribution XB was involved in project development and manuscript writing; LC performed data collection and data analysis; ZQ performed data collection; and JJ reviewed the key points of this manuscript.

Compliance with ethical standards

Conflict of interest There is no conflict of interest involved in this manuscript.

Ethical standards All authors have made a significant contribution to the findings and methods in the paper. All authors have read and approved the final draft. There are no financial interests. The work has not already been published and has not been submitted simultaneously to any other journal. The corresponding author takes on these responsibilities with his signature.

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