



Submitted: 17.11.2024
Accepted: 15.12.2024
Early publication date: 04.02.2025

Endokrynologia Polska
DOI: 10.5603/ep.103617
ISSN 0423-104X, e-ISSN 2299-8306
Volume/Tom 76; Number/Numer 1/2025

How to use properly the POL-RISK algorithm developed for 10-year prediction of osteoporotic fractures in daily practice

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Abstract

Introduction: Osteoporosis is one of the most common diseases in elderly subjects. Accurate assessment of fracture risk is essential in the management of osteoporotic patients. The aim of the study was to present the optimal manner of using a method designed for fracture risk prediction, e.g. POL-RISK, in daily practice.

Material and methods: Methods for fracture prediction were presented, especially those which allow easy and quick online assessment. In addition to true medical aspect, e.g. the ability to accurately detect high fracture risk patients who need therapy, the economic aspects were also presented. Due to the enormous number of osteoporotic patients the therapy should be indicated mainly in patients with high fracture risk. The optimal threshold of fracture risk for the initiation of reimbursed therapy should be established as a compromise of prior established medical threshold and economic aspects. The expected endpoint is the reduction of new fractures noted in longitudinal observation.

Conclusion: Implementation of the described scenario should enable the development of the optimal model of care in osteoporotic subjects. Broad use of fracture risk thresholds to initiate reimbursed therapy, encompassing both true medical and economic aspects, should result in the reduction of osteoporotic fractures and decrease overall osteoporosis-related costs to the healthcare system. (*Endokrynol Pol* 2025; 76 (1): 82–85)

Key words: economy; fracture prediction; osteoporosis; therapy

Introduction

Osteoporosis is one of the most common and important diseases in the elderly population. Due to its silent clinical course and the enormous number of affected subjects, osteoporosis is called a “silent epidemic”. Osteoporosis is often not recognised for a long time, and the first clinical symptom is usually low-energy fracture. Fracture of the distal radius is most often the first one, and it is usually not considered as a serious health problem. However, each osteoporotic fracture should be treated as a ‘red flag’ because prior fracture is one of the most important risk factors for subsequent fractures. It should be also taken into account that a subsequent fracture may concern hip or spine, both deleterious for human health and even life threatening. Therefore, the primary aim in the management of osteoporotic subjects is to avoid the first fracture. The number of potential patients is high, and it is not possible to carry out diagnostic procedures and start the treatment in all

of them in daily practice. The most reasonable approach is to identify patients at high fracture risk and implement appropriate therapy in that selected subgroup.

In recent decades several tools have been developed to assess fracture risk, including: FRAX [1], the Garvan algorithm [2, 3], QFracturescores [4], and POL-RISK [5]. Usually the 10-year fracture risk is assessed separately for hip, for any or major osteoporotic (hip, spine, arm, and forearm) fractures. FRAX is a fracture risk assessment tool, designed to estimate the 10-year probability (limited by life expectancy) of hip and major osteoporotic fracture. POL-RISK assesses any fracture risk in postmenopausal women aged over 55 years. This method was based on 10 years of follow-up in the epidemiological, population-based sample of women in the RAC-OST-POL (the city of RACibórz, POLand and OSTeoporosis) study. The basic epidemiological features of this population sample were presented previously [6]. Meanwhile, in this population several analyses were performed [7, 8].



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Table 1. Sensitivity, specificity (with 95% CI), and balanced accuracy (BAcc) for FRAX, Garvan, and POL-RISK calculated for the newly determined cut-offs [13]

Method	Cut-off	Sensitivity	Specificity	BAcc
FRAX major fracture	6.3%	0.5833 (0.4328–0.7207)	0.7213 (0.6746–0.7637)	0.6523
Garvan any fracture	20%	0.5873 (0.4564–0.7076)	0.7284 (0.6811–0.7712)	0.6579
POL-RISK any fracture	18%	0.6984 (0.5682–0.8043)	0.5939 (0.5435–0.6425)	0.6462

After five years of observation, an algorithm for the five-year fracture risk was established [9], and after a decade of observation the final algorithm was presented [5]. POL-RISK is available at www.fracture-risk.pl.

The aim of the current manuscript is to present recommended actions that can help determine the optimal way of using POL-RISK. Medical practitioners expect precise and accurate methods for predicting fractures, and their implementation in daily practice with patients must take into consideration both medical and economic aspects.

Material and methods

Origin of POL-RISK

Details of the development of the original POL-RISK algorithm were presented earlier [5]. Briefly, an epidemiological, population-based sample of postmenopausal women ($n=978$) aged over 55 years was recruited in May 2010 and observed during a 10-year follow-up study. Then, from 2011 to 2020, one author (W.P.) contacted each participant by phone once a year in May for information on new non-traumatic fractures, fall rates, and osteoporosis treatment [10]. Finally, 640 (65.4% of the baseline cohort) women remained at the end of the research project.

During the period of observation 190 osteoporotic fractures were identified in 129 women.

The final analysis led to the establishment of the algorithm for fracture prediction. Among the potential risk factors gathered at baseline, 4 were identified as significant: prior osteoporotic fracture and the number of prior fractures, femoral neck T-score, prior falls in the previous 12 months, and baseline age. The algorithm is available at www.fracture-risk.pl.

The prediction accuracy of the proposed model achieved in the test set, expressed by the area under the ROC curve (AUC), is 0.66 [95% confidence interval (CI): 0.604–0.71].

Validation of POL-RISK

The POL-RISK algorithm was validated in the GO (Gliwice, Osteoporosis) Study cohort, which was used for other previously published analyses [11, 12]. The aim of the study was to establish the optimal threshold of fracture risk for the initiation of pharmacological therapy, and the details were presented in a recent paper [13]. Briefly, the study group consisted of 457 postmenopausal women recruited from the database in Outpatient Medical Care, Gliwice, Poland. Necessary data for clinical factors related to fractures were collected for all participants. Data on the incidence of osteoporotic fractures were collected over the last 10 years following baseline data collection in a longitudinal, retrospective study. During the period of observation, 72 osteoporotic fractures occurred in 63 subjects. Based on ROC curves, the threshold for high risk of fractures was established at 18.0%. Using this threshold, 70% of patients with observed fractures would be accurately identified at baseline.

This threshold was found to provide non-inferior diagnostic accuracy of the POL-RISK calculator compared to the other analysed fracture prediction tools: FRAX and Garvan (Tab. 1, Fig. 1).

Discussion

The data presented earlier in our manuscripts allowed us to establish the first condition, i.e. true medical threshold for the correct use of a diagnostic tool designed to determine the risk of osteoporotic fracture [5, 13]. The POL-RISK study, based on an epidemiological female sample and long-term observation, provided sufficient data to establish a reliable diagnostic tool [5]. Further, validation of POL-RISK in the GO Study cohort determined the optimal threshold of fracture risk assessment [13]. Using the latter analysis, we may accurately identify 70% of patients at high fracture risk among the whole population. It means that 70% of patients will either receive necessary therapy (when fracture risk is equal to or exceeds 18%) or will avoid unnecessary treatment (when the fracture risk is lower than 18%).

In the recommendations of a group of American experts, it was suggested that locally derived fracture risk assessment methods should be used instead of other methods [14]. We believe that POL-RISK meets these recommendations. In a further part of the manuscript, we present a suggested further scenario leading to the establishment of the optimal manner of use of this new diagnostic tool in daily practice.

In addition to medical conditions, the proper use of POL-RISK should depend on economic issues of the health system. Generally, the majority of medications used in the therapy of osteoporosis are reimbursed, and the economic aspect requires the establishment of the acceptable threshold of risk. The excellent example of such an idea is presented in the Garvan algorithm available at www.fracture.risk.calculator [2, 3]. In the Australian model reimbursement therapy is recommended and allowed if any fracture risk exceeds 26%, and when the risk is below 14% reimbursement is not allowed. Patients at fracture risk within the range between 14% and 26% may obtain reimbursed therapy according to additional medical circumstances. Respective thresholds for hip fracture are 3% and 9%.

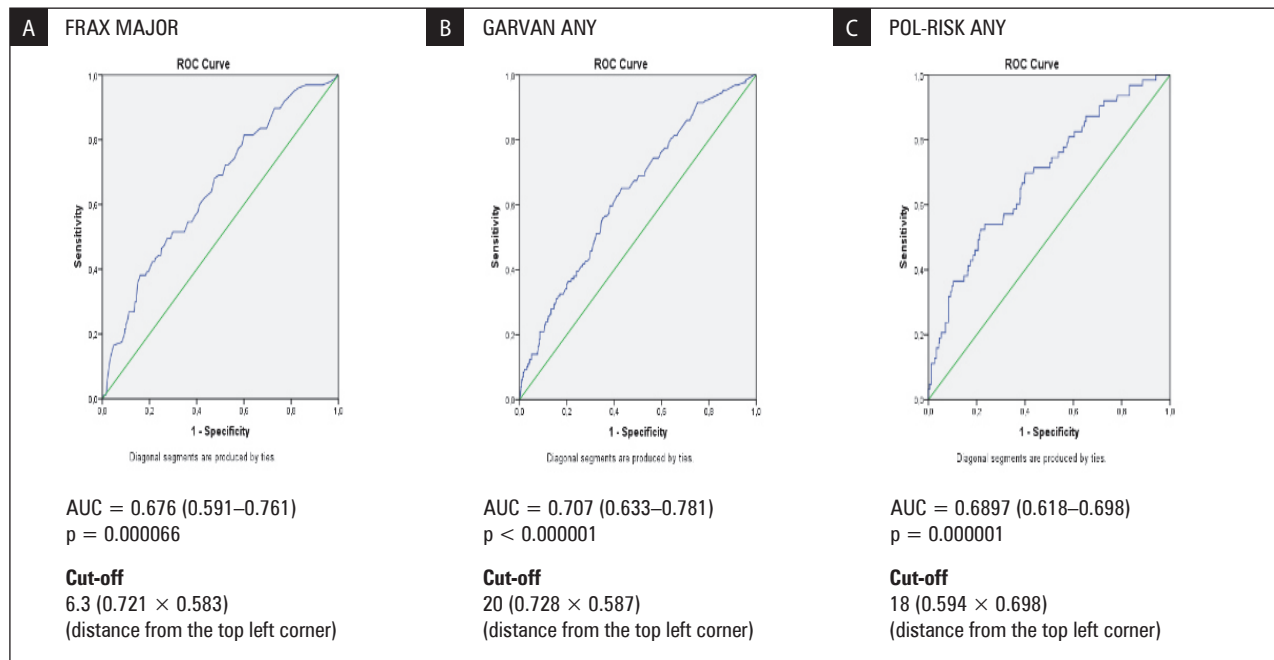


Figure 1. Analysis of receiver operator characteristic (ROC) curves for FRAX, Garvan, and POL-RISK; Null hypothesis: true area = 0.5; The numbers in parentheses indicate specificity and sensitivity values for the proposed cut-off [13]. AUC — area under the curve

Such an interpretation of fracture risk thresholds is a compromise between true medical conditions and economic aspects of the health system. One should also note that besides the thresholds of 14% and 26% for any fractures and 3% and 9% for hip fractures, a wide range between those border values are proposed in order to individualise therapeutic decision-making.

Below we present current suggestions of the expected, necessary scenario to create an original model of treatment recommendations in Polish postmenopausal osteoporotic women.

First (medical) step

First step would be a pilot study using a previously established threshold based on medical conditions with the expected endpoint defined as the reduction of new fractures noted in a longitudinal observation. In patients in the selected region of Poland, the calculated threshold of 18% should be used as the indication for initiation of therapy. The preliminary postulated duration of observation is one year (the final duration is dependent on the decrease of the number of new fractures and studied sample size). An analysis of the efficacy of the applied threshold should be established as a relative reduction of fracture incidence.

This recommendation does not take into account economic factors, e.g. total costs for the health system generated by osteoporosis, and should be interpreted as a pure medical decision. A range of risks such as the proposed by Garvan method (14–26%) is not yet

available for the POL-RISK tool, so the threshold of 18% should be used with caution and individualisation must always be implemented if needed.

Second (economic) step.

This step concerns the analysis of costs to the health system. Data on the costs of osteoporosis treatment for the health system were previously published and may be easily applied [15].

In this stage of the project, an analysis of fracture incidence noted in a longitudinal observation in regard to economic costs for health system would be performed.

Both steps, medical and economic, should allow the establishment of an accepted range for therapy initiation similar to the one proposed in the Australian model. Such a solution is important to individualise therapy according to medical circumstances in each patient. The threshold of 18% should be used only before the final model is ready for implementation to daily practice.

Our study has some limitations: due to the small number of hip fractures (15 fractures in 14 subjects), separate assessment for hip fracture risk is not available in POL-RISK, and the method has been for women only. However, POL-RISK was based on an epidemiologic female sample, observed for 10 years, and its validation also concerned the same duration of observation.

According to the data included in the report of the National Health Service [15], in Poland in 2018, osteoporosis therapy was received by only 6.3% of all

patients with osteoporosis. We assumed that the correct use of POL-RISK would double the number of treated patients. The average efficacy of anti-osteoporosis drugs is about 50%, so in an additional 6.3% of patients undergoing therapy, a 50% reduction in the incidence of fractures can be expected [16]. Considering the number of fractures in 2018 (120,000) given in the cited report, it can be hypothesised that 3780 new fractures could be avoided.

Conclusion

Implementation of the described scenario should enable the development of the optimal model of care for osteoporotic subjects. The threshold of fracture risk determined for initiation of reimbursed therapy, based on both true medical and economic aspects, should result in the reduction of osteoporotic fractures and decrease the total costs to the healthcare system related to osteoporosis management. We believe that the use of the established fracture threshold in daily work in osteoporotic patients will result in a significant reduction of new fracture incidence.

Conflict of interest

The authors declare no conflict of interest.

Funding

The study received no funding.

Authors contribution

W.P.: study design, preparation of the manuscript; P.A.: data analysis, preparation of the manuscript; B.D.: preparation of the manuscript.

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