



STUDY OF THE USE OF QUALITY OF LIFE QUESTIONNAIRES IN CARDIAC DISEASES IN POLAND



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OBJECTIVE

The aim of this study was to assess the use of quality of life questionnaires in Polish cardiac patients, as well as research methods used by Polish authors in terms of international quality of life research guidelines.

METHODS

Systematic literature review was performed in order to collect publications assessing quality of life in cardiac patients in Poland. Medical databases and the most important health agencies websites were searched for HRQoL assessment guidelines.

Inclusion criteria:

- Studies carried in the Republic of Poland;
- Studies in which authors were using HRQoL questionnaires in cardiac patients.

Exclusion criteria:

- Studies carried outside of Poland;
- Studies estimating HRQoL among patients with vascular diseases;
- Case reports;
- Researches and review papers without HRQoL assessment.

Based on the international guidelines, „checklist” (Table 1) consisting of 19 statements and questions was created as a basis for data extraction from accessed publications.

Table 1. „Checklist” based on the international quality of life research guidelines.

1. Ordinal number	The numbering of subsequent publications included in the analysis
2. Authors, Title, Bibliography	Basic information about the publication
3. Population (description)	Short characteristics of patients enrolled in the study among which quality of life was assessed
4. Population (N)	Number of patients among which quality of life was assessed
5. Intervention	Description of the study intervention(s)
6. Number of questionnaires used	Number of questionnaires used in the study to assess HRQoL
7. Questionnaire used	Name and abbreviation of the used questionnaire(s)
8. Detailed description of the questionnaire	Yes/No/Not applicable/No data
9. Generic/Specific	In this bracket, nature of the questionnaires used was described. Answers: Generic/specific/no data
10. Does it measure physical, mental and social functioning?	Yes/No/No data
11. Was it primary objective to measure HRQoL?	Yes/No
12. Was the questionnaire used properly?	Yes/No/No data
13. Were all the results of HRQoL components listed?	Yes/No/No data
14. Was the official key used?	Yes/No/Not applicable/No data
15. Method of HRQoL assessment	Self-administration/Interviewer/No data
16. Questions timeframe	Range of days/weeks/months in which used questionnaire assessed HRQoL
17. Study design	Description of the HRQoL questionnaire application intervals
18. HRQoL tool validation	Yes/No/Not applicable/No data
19. HRQoL measurement within other domains	Description of other measurements made by researchers

RESULTS

As a result of systematic literature review and inclusion criteria application, 131 Polish studies were included in this analysis. Only one in six studies were published in international journals.

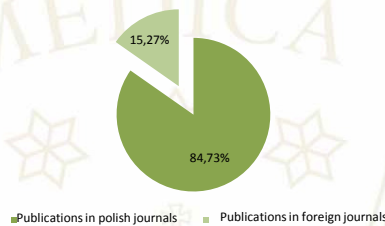


Figure 1. Distribution of studies among domestic and foreign journals.

Most commonly, Polish authors assessed patients' HRQoL in observational studies, which means no intervention was applied (53 studies, 41%). The most rarely evaluated HRQoL was after rehabilitational and pharmacological interventions (15 studies, 11%; 16 studies, 12%; respectively).

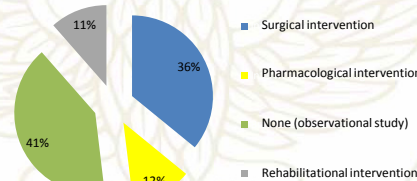


Figure 2. Percentage of studies conducted in terms of type of intervention

Out of the 131 studies, the primary objective in 83 studies (63%) was to evaluate HRQoL. For 37%, it was secondary or higher grade objective.

Most often, Polish authors were using 1 questionnaire (56.5% studies) to assess HRQoL, as well as 2 questionnaires (26.0% studies) and 3 questionnaires (7.6%). The way in which questionnaires were filled is shown on Figure 3.

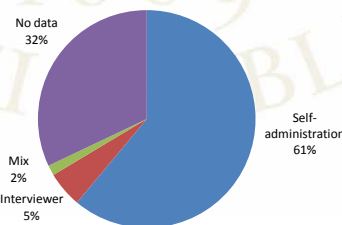


Figure 3. The manner of filling questionnaires

The most popular tool to assess HRQoL in Polish cardiac patients was SF-36 (Short-Form 36 questionnaire, 17% of studies) and EQ-5D (EuroQoL 5D, 5% of studies).

Official keys to calculate the results were used in 43% of studies, 31% contained no information about keys used, and in 15% no information about keys used were available.

Almost in 26% of studies authors used their own questionnaires, out of which 71% were never validated, 27% lacked data of validation and only for 2% attempts of validation were made.

For questionnaires created by authors, HRQoL assessment among 3 basic domains (physical, mental and social functioning) is shown on Figure 4.

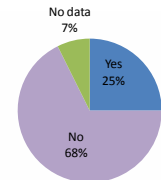


Figure 4. Percentage of questionnaires developed by the authors measuring HRQoL among 3 basic domains.

For studies assessing HRQoL in which tools developed by the authors were used, as much as 76% did not contain any description of the tool.

Level of reporting for all domains measured by the questionnaires created by authors is shown on Figure 5.

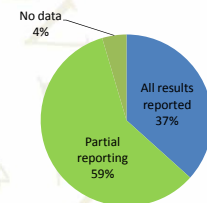


Figure 5. Percentage of studies with tools developed by authors in terms of level of data reporting

Schedules in which authors used questionnaires created for their own needs is shown on Figure 6.

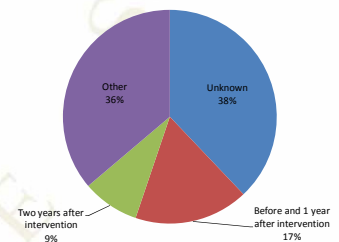


Figure 6. Schedule of authors' own questionnaire application in studies

LIMITATIONS

- Complexity of HRQoL assessment guidelines - subjective choice of the most important - not all aspects of HRQoL analysis have been addressed in this analysis;
- Analysis performed for the last 16 years.

CONCLUSIONS

- Polish studies assessing HRQoL in cardiac patients usually do not meet international criteria issued by EMA, FDA, ISPOR or Oxford University;
- Significant differences on the methodology and HRQoL results reporting; need to harmonize practices related to HRQoL assessment by creating Polish guidelines;
- Polish authors most often use tools developed by their own and usually not validated;
- Lack of HRQoL assessment among 3 basic domains as well as „under-reporting” are two basic mistakes of Polish investigators.