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Reliability and validity of a German asthma quality of life questionnaire

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Summary

The Asthma Quality of Life Questionnaire (University of Sydney [AQLQ-Sydney]) is a self-administered questionnaire that has been developed in Australia and validated in different languages in Australia, the USA and Spain. We developed a German translation of this questionnaire by applying a sequential forward and backward translation approach.

The objective of this study was to validate a German translation of the AQLQ-Sydney questionnaire in an outpatient population of asthmatic patients in Switzerland. Outpatients were assessed for a diagnosis of asthma and those who consented were selected for the validation study. All patients had spirometry, methacholine challenge testing, fractional exhaled nitric oxide recorded and answered the German AQLQ-Sydney. A subgroup of 17 patients answered the questionnaire for a second time after receiving asthma treatment with combined steroids and bronchodilators for two months. Test-retest-reliability was tested in 12 stable asthmatic patients without treatment modification.

Of 90 patients assessed, 57 were diagnosed with asthma and participated in the validation study. The total score did not significantly correlate with any of the objective measures of severity of asthma. However, the "Breathlessness" subscale score correlated weakly with PD20 methacholine. Internal consistency was high with Cronbach's alpha of 0.97 for the total score and 0.91–0.97 for the subscale scores. Test-retest reliability was also high for the total score and the subscale scores. The questionnaire detected a significant improvement in total quality of life score and "Breathlessness" and "Mood" subscale scores after a period of combined treatment with inhaled steroids and long acting bronchodilators.

The German translation of the AQLQ-Sydney had a good internal consistency and test-retest-reliability in stable asthmatic patients. It shows responsiveness to treatment. Some correlations with objective markers were detected.

Key words: asthma symptoms; bronchial provocation test; fractional exhaled nitric oxide; methacholine; quality of life

Introduction

Asthma is a chronic inflammatory disorder of the airways that is associated with airway hyperresponsiveness (AHR). Patients report episodes of wheeze, breathlessness, chest tightness and cough. Asthma is usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment [1]. The aim of treating patients suffering from asthma is to achieve and maintain control of symptoms, to prevent exacerbations and to maintain normal activity levels and, therefore, to improve quality of life. Self-reporting of asthma or frequency of bronchodilator use have been recently reported as significant predictors for airway hyperresponsiveness [2]. Determination of health-related quality of life is important for the management of patients in clinical practice and for research [3]. The widely used general quality of life indices do not address the issues that are directly relevant to people with asthma and also do not account for the intermittent nature of the disease. The asthmatic population is often young and otherwise healthy and may avoid certain situations that lead to exacerbation of symptoms [4]. This limits the validity, sensitivity and responsiveness of the generic quality of life questionnaires for use in patients with asthma. For English speaking people, a variety of asthma specific quality of life questionnaires are used in clinical practice and research [5]. These have proved to be of satisfactory construct validity [4, 6–10] and also to be able to detect responses to treatment [4, 10] in adults. The Asthma Quality of Life Ques-

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tionnaire (AQLQ-Sydney) has been shown to have these properties, is short and easy to administer. It has not yet been translated in German. We developed a German translation of the AQLQ-Sydney by applying a sequential forward and backward translation approach [11] and then performed a cross-sectional examination of its validity and assessed its responsiveness to treatment. Selected results from the study have been previously presented in the form of an abstract [12].

Methods

Study design

We conducted a cross sectional study and longitudinal study in an adult outpatient population presenting to our clinics for the assessment of asthma. The relation between AQLQ-Sydney scores and clinical measurements obtained at the baseline examination was investigated. In a sub-sample we tested the test-retest reliability over a one-week interval without change in treatment. We also assessed the ability of the questionnaire to detect responses to treatment with combined inhaled steroids and bronchodilators administered over a period of two months.

The format of the AQLQ-Sydney

The AQLQ-Sydney is a 20-item self-administered questionnaire. The average time needed to complete the questionnaire is five minutes. Each item has five response options ranging from "not at all" (scored 0) and "very severely" (scored 4). The total score is calculated as the mean of the 20 item scores, rescaled to a score out of 10 by multiplying the result by 2.5. Four subscale scores can also be calculated as means of subsets of the items, each multiplied by 2.5. The four subscales are: a) breathlessness and physical restrictions "Breathlessness", b) mood disturbances "Mood", c) social disruption "Social" and d) concerns for health "Concerns" (4). Higher scores represent more severe impairment of quality of life.

Translation

The AQLQ-Sydney questionnaire was originally developed in English. An established translation protocol was used to develop the German translation of the English AQLQ-Sydney [11]. The original English questionnaire was translated by a bilingual doctor into German. Then it was translated back into English by another bilingual doctor unaware of the original English AQLQ-Sydney and compared to the original questionnaire. A team of respiratory doctors compared the back-translated questionnaire for conceptual discrepancies. For the German translation of the English AQLQ-Sydney see Appendix 1.

Subjects and setting

Ninety consecutive adult patients (M:F, 49:41) referred to the lung function laboratory of the University Hospital of Basel by general practitioners (32 patients) or the University Hospital Departments (58 patients) for assessment of possible asthma were included in the study. Only patients who spoke German as the first or "daily" language and who were steroid-naive were included in the study. All patients underwent measurement of exhaled nitric oxide and spirometry before they were challenged with methacholine. After these tests the patients completed the German AQLQ-Sydney. A detailed clinical history was obtained in all patients. Information about diagnosis and treatment was noted. To validate a questionnaire dealing with quality of life of asthmatics we limited our study population to patients who were diagnosed as having asthma by the same pulmonary physician (57 patients). Asthma severity was classified based on the Global Initiative for Asthma (GINA) guidelines [1].

Test-retest-reliability of the questionnaire was assessed in another twelve patients (mean age 40, M:F 6:6) with stable mild or moderate asthma recruited from the pulmonary medicine outpatient clinics. Patients were asked to fill out the questionnaire at their regular consultation and then were asked one week later to answer the questionnaire again. None of these patients had their treatment changed for at least one month before the control consultation visit or within the investigation period.

To estimate the responsiveness of the questionnaire in patients with asthma, a subgroup of the study patients (n = 17) who were being followed up in our outpatient clinic after the diagnosis was made were asked to complete the German AQLQ-Sydney after being treated with combined inhaled steroids and long acting bronchodilator for two months.

Nitric oxide measurement

Expired nitric oxide (NIOX® Nitric Oxide Analizer by Aerocrine AB, Solna, Sweden), was measured according to American Thoracic Society (ATS) guidelines [13]. The subject exhaled to residual volume took a deep breath over 2–3 s, through the mouthpiece to total lung capacity and exhaled immediately through the mouthpiece over 10 seconds against an oral pressure of between 5 cm H_2O and 20 cm H_2O maintaining a flow between 0,045 l/s and 0,055 l/s. This was archived by a computed biofeedback software installed nitric oxide analyser.

Lung function

Spirometry was performed using either a Jaeger spirometer (Erich Jaeger GmbH, Höchberg, Germany) or Easyone spirometer (ndd Medizintechnik AG, Zürich, Switzerland). Forced vital capacity (FVC) and forced expiratory volume at one second (FEV_1) were recorded according to ATS recommendations [14]. The higher of two values for FEV_1 reproducible to within 100 ml were recorded and the percentage of predicted values [15] were calculated.

Methacholine challenge

Patients who reported a respiratory tract infection in the previous 3 weeks were rescheduled. The questionnaire was administered on the same day the patients underwent the lung function tests. All those whose FEV_1 was at least 70% predicted and >1.5 L were invited to undergo methacholine challenge by using the nebulizer method [16]. Methacholine was delivered using a dosimeter (Mefar, Bovezzo, Italy) set to deliver the aerosol over a period of 1 second. Methacholine solutions of various concentrations, were prepared by the Hospital Pharmacy of the University Hospital of Basel, Switzerland. Patients were asked to expire to functional residual capacity, place their lips around the mouthpiece, inspire to total lung capacity, hold their breath for at least 4 s and then exhale. FEV_1 was recorded 2 minutes later and in the absence of a 20% fall in FEV_1 from baseline the next dose was given. Patients

inhaled until there was a fall in FEV_1 greater than 20% from the control value or until the maximum cumulative dose of 3.20 mg of methacholine was administered. A dose response curve was plotted and from this curve the dose causing a 20% fall in FEV_1 ($PD20FEV_1$) was read by interpolation. The response to methacholine was reported as the provoking dose to cause a 20% fall in FEV_1 (PD20) and the dose-response-ratio (DRR: fall in FEV_1 divided by maximal dose of methacholine). Bronchial hyperresponsiveness was defined as a $PD20FEV_1$ <3.0 mg.

Statistics

Cronbach's alpha was calculated to assess the internal consistency of the total questionnaire and each subscale. Cronbach's alpha is a numerical coefficient for reliability. The coefficient range in value from 0 to 1. The higher the score, the more reliable is the generated scale. Test-retest reliability was assessed by calculating intraclass correlation coefficients. Spearman rank correlation coefficients were calculated to measure the relationships between clinical data and questionnaire scores. As our sample was not randomly selected from all those with asthma referred to our laboratory and it is not known what fraction our sample is of this population, we present descriptive statistics without statistical inference [17].

Results

The AQLQ-Sydney was delivered to 90 patients at the first visit. Asthma was diagnosed in 57 patients. The final diagnosis in the remaining 33 patients were: post-nasal drip (7), gastro-oesophageal reflux (8), atopy without asthma (4), chronic bronchitis (3), cystic fibrosis (1), pulmonary hypertension (1), congestive heart failure (2), drug induced cough (ACE-Inhibitor) (1), hyperventilation (1) and unknown cause of respiratory disturbance (5). The characteristics of the study population are presented in table 1.

Of the 57 asthmatic patients, 22 patients (38.6%) had intermittent, 20 patients (35.1%) mild, 13 patients (22.8%) moderate and 2 patients (3.5%) severe asthma according to GINA guideline criteria (1). The mean (±SD) scores in these patients were as follows: AQLQ-Sydney total score was 2.5 (1.8), "Breathlessness" 3.4 (2.2), "Mood" 3.4 (2.1), "Social" 1.6 (1.7) and "Concerns" 1.7 (1.9).

The clinical markers were not significantly correlated with the German AQLQ-Sydney at baseline (table 2). Airway hyperresponsiveness, measured as log PD20 methacholine and log DRR methacholine was significantly correlated with the "Breathlessness" subscale score (figure 1).

There was good test-retest-reliability with intraclass correlation coefficients of 0.94 for the total score and 0.83–0.94 for the subscale scores in 12 patients who completed the questionnaire on two occasions, one week apart (figure 2).

Internal consistency was high with Cronbach's

Table 1

Sample characteristics and descriptive statistics of the asthmatic patients (n = 57, male/female = 32/25).

Variable	Mean	Min	Max	SD
Age (yrs)	38	18	76	12
BMI (kg/m^2)	25	17	53	6
FEV_1 %predicted	93	60	125	16
FVC %predicted	100	76	135	13
PD20 (µg) methacholine	485	24	3200	743
DRR methacholine	0.04	<0.01	1.77	0.25
FE_{NO} (ppb)	33.4	3.4	300	57.7

Mean values of PD20 (µg) methacholine, DRR methacholine and FE_{NO} are expressed as geometric mean
SD = standard deviation; BMI = body mass index; FEV_1 = forced expiratory volume in 1 second; PD20 = provocative dose that causes a fall in FEV_1 of 20%; DRR = dose response ratio; FVC = forced vital capacity; FE_{NO} = fractional exhaled nitric oxide

Table 2

Correlation between AQLQ-Sydney scores and clinical data (n = 57).

Clinical variables	total score	"Breathlessness"	"Mood"	"Social"	"Concerns"
Age (yrs)	0.03	0.03	0.05	–0.07	0.06
Asthma severity (GINA)	0.10	0.18	–0.01	0.02	0.07
FEV_1 %predicted	–0.20	–0.23	–0.04	-0.17	–0.12
FEV_1/VC	0.06	0.07	–0.03	0.11	0.04
PD20 (µg) methacholine	–0.21	–0.32	–0.08	–0.18	–0.14
DRR methacholine	0.19	0.32	0.10	0.08	0.08
TLCO	0.22	–0.13	–0.22	–0.23	–0.25
FE_{NO} (ppb)	–0.17	0.06	–0.15	–0.01	0.03

GINA = The Global Initiative for Asthma (1); FEV_1 = forced expiratory volume in 1 second;
VC = vital capacity; PD20 = provocative dose that causes a fall in FEV_1 of 20%; DRR = dose response ratio;
TLCO = single-breath transfer factor

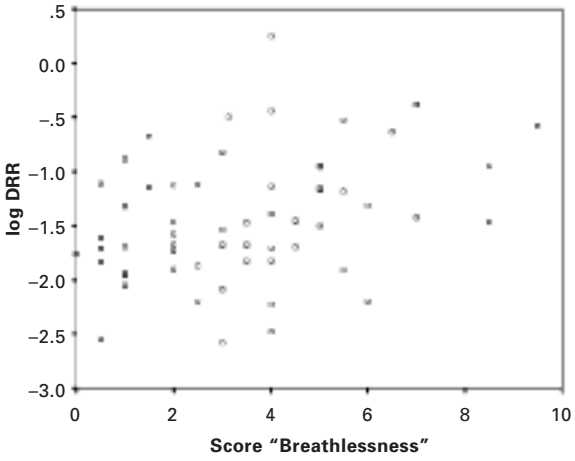

Figure 1

Correlation between the clinical variable dose response ratio methacholine (log-DRR) and the AQLQ-Sydney score "Breathlessness" (n = 57, rho = 0.32).

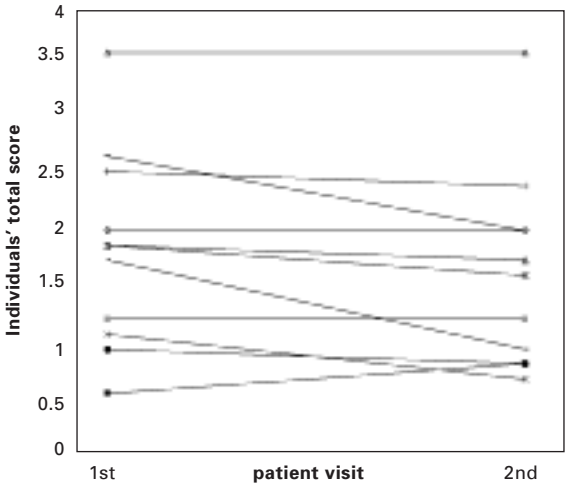

Figure 2

Change in individuals' total scores when questionnaire is given to the patients one week later without modification of treatment indicating a good test-retest-reliability (n = 12).
The second lowest line (starting with a total score of 1) represents the observations of two different patients.

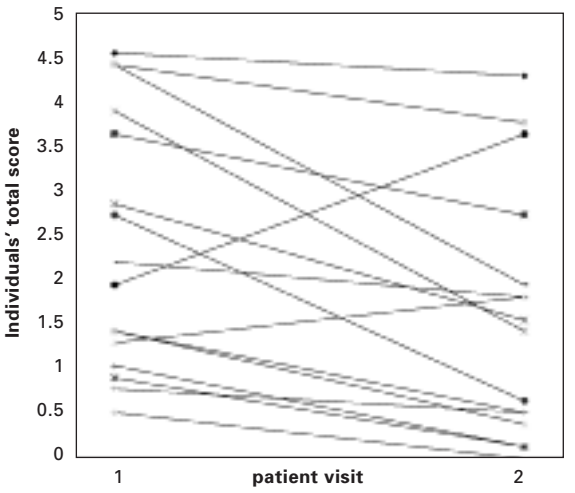

Figure 3

AQLQ-Sydney scores responsiveness to anti-asthmatic treatment for two months (n = 17).
The fifth line from top (starting with a total score of 3.5) represents the observation of two different patients.

alpha of 0.97 for the total score and 0.91–0.97 for the subscale scores. Results are presented in table 3.

Seventeen patients with asthma from the study population were reviewed at the University Hospital of Basel for follow up after 2 months of treatment with inhaled long acting bronchodilator and inhaled corticosteroids. The questionnaire detected an improvement in quality of life after the treatment period. This was reflected in total score (mean change 0.77), the subscale score "Breathlessness" (mean change 1.47) and "Mood" (mean change 0.97). (See figure 3 and table 4).

Table 3

Internal Consistency and Test-Retest-Reliability of the AQLQ-Sydney (n = 12).

Score	Cronbach's α	Intraclass Correlation Coefficent
total score	0.97	0.94
"Breathlessness"	0.91	0.83
"Mood"	0.97	0.94
"Social"	0.95	0.91
"Concerns"	0.96	0.92

Cronbach's α is a numerical coefficient for reliability.
Intraclass Correlation Coefficient is used to demonstrate test-retest reliability.

Table 4

Change of the questionnaire scores in asthmatic patients under treatment with combined inhaled steroids and long acting bronchodilators for two months (n = 17)[a].

Score	Before	After	Change
total score	2.4 (1.4)	1.6 (1.3)	0.8 (1.0)
"Breathlessness"	3.4 (2.1)	1.9 (1.8)	1.5 (1.5)
"Mood"	2.9 (1.9)	1.9 (1.9)	1.0 (1.5)
"Social"	1.3 (1.4)	1.1 (1.7)	0.2 (1.5)
"Concerns"	1.6 (1.3)	1.4 (1.3)	0.2 (1.2)

[a] Mean (SD) SD = standard deviation

Discussion

In this study we have successfully translated the AQLQ-Sydney into German and revalidated the translated version in a sample of asthmatic outpatients in Switzerland.

Sample characteristics and descriptive data

Compared with another validation study by Perpina and coworkers [11] the mean age of our patients is slightly lower. According to the asthma severity based on the Global Initiative for Asthma (GINA) guidelines [1] there were more patients with intermittent asthma but less patients with persistent severe asthma in our study group compared to the group investigated by Perpina and coworkers. The mean FEV_1 % predicted was higher in our study reflecting the difference in distribution of disease severity. These differences might be due to the fact that our patients were re-

ferred to our department for a bronchial challenge test to establish the diagnosis of asthma and therefore had milder symptoms than the population studied by Perpina and coworkers with an already established diagnosis of asthma.

Construct validity

A weak negative correlation was found between PD20 methacholine with the subscale score "Breathlessness" and between DRR methacholine with the subscale score "Breathlessness". This association was also observed in a previous cross-sectional study [4]. As we have examined a selected population of asthmatics presenting for methacholine challenge testing all the patients had a FEV_1/VC of greater than 70 and an FEV_1 % predicted of 80% and higher. This might be one reason why we could not show a correlation between AQLQ scores and FEV_1 % predicted as in other studies [4, 9, 11]. The findings are consistent with the hypothesis that quality of life is a dimension of the impact of asthma that is distinct from the traditional clinical dimensions.

Internal consistency

Cronbach's alpha, a widely used measure of internal consistency was >0.9 for the total score and the four subscale scores "Breathlessness", "Mood", "Social" and "Concerns". For scales used to compare groups Cronbach's alpha >0.8 is regarded as satisfactory [18]. Similar values were obtained in a sample of asthmatic patients in Australia [4] in the United States [19] and in Spain [11]. Therefore we found a comparable level of internal consistency of the German translation of the AQLQ-Sydney in a sample of Swiss asthmatics.

Responsiveness to treatment

Based on the GINA guidelines, inhaled corticosteroids are an effective and evidence based treatment for asthma and leads to improvement in QOL [1]. We, therefore, investigated if such a response to treatment could be measured with the German translation of the questionnaire, as all the patients participating in the study were treatment naive. Accordingly, in our study, significant changes in the subscales "Breathlessness", "Mood" and in the total score were demonstrated after 2 months of treatment with inhaled long acting bronchodilator and inhaled corticosteroids. Ideally this could be better confirmed by using a control group. It is not clear if the German translation of the AQLQ-Sydney can also detect deterioration in quality of life for example when treatment is withheld. We cannot exclude that the improvement of the questionnaire score is an effect of regression to the mean. Past investigations [10, 11] suggest that the English version of the questionnaire can detect deterioration or improvement in quality of life.

Test-retest-reliability

Intraclass correlation coefficients (ICC) were high for the total score as well as for the four subscale scores. The values of the ICC were in the same range as in other studies validating the AQLQ-Sydney [10, 11]. This indicates that the questionnaire is reproducible over a short period in stable asthmatic patients. The small decline in questionnaire score in 8 out of 12 patients might be as well due to the effect of regression to the mean.

As a limitation of our study he sample size was relatively small compared to the original validation study by Marks et al. [4, 10]. AQLQ-Sydney has been used in cross sectional studies [20–22], a cohort study [231] and intervention studies [24, 25] in English speaking people as well as in an intervention study in Japan [26]. Therefore, we propose that this German language translation of the AQLQ-Sydney is suitable for use in studies investigating German-speaking patients with asthma.

Conclusion

As previously shown in studies in Spain, United States and Australia the AQLQ-Sydney seems to have appropriate properties in a German speaking outpatient population of asthmatics in Switzerland. The German translation of the questionnaire provides data that seem to have good internal consistency, to be reproducible in stable asthmatics and might be responsive to treatment. Some correlations with clinical markers were detected, indicating construct validity. The questionnaire seems to be a useful tool for research purposes to measure the state and the change of quality of life in asthmatics. To further validate the questionnaire more patients with more diverse disease stage should be studied.

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Appendix 1

German translation of the AQLQ-Sydney

Asthma-Fragebogen

Wir danken Ihnen, dass Sie sich mit diesem Fragebogen befassen. Er ist Bestandteil eines Forschungsprojektes, bei dem man herausfinden möchte, wie Asthma das Leben der betroffenen Personen beeinträchtigt. Alle Ihre Antworten werden vertraulich behandelt.

Es folgt eine Reihe von Aussagen, in denen beschrieben wird, wie Asthma selbst oder die Behandlung von Asthma in das Leben der betroffenen Personen eingreift. Wir bitten Sie, bei jeder Aussage diejenige Antwort anzukreuzen, die für die letzten 4 Wochen am ehesten zutrifft.

- ☐ Es kommt vor, dass ich vorübergehend unter Kurzatmigkeit leide
- ☐ Es kommt vor, dass es beim Atmen plötzlich stark pfeift
- ☐ Es kommt vor, dass ich unter Engegefühl im Brustkorb leide
- ☐ Ich werde durch Asthmabeschwerden oder Kurzatmigkeit eingeschränkt, wenn ich draussen geradeaus gehe oder im Haushalt leichte Arbeit verrichte
- ☐ Ich werde durch Asthmabeschwerden oder Kurzatmigkeit eingeschränkt, wenn ich bergauf gehe oder im Haushalt schwere Arbeit verrichte
- ☐ Ich fühle mich müde oder allgemein kraftlos
- ☐ Ich kann nachts nicht schlafen
- ☐ Ich bin traurig oder deprimiert
- ☐ Ich bin unzufrieden mit mir selbst
- ☐ Ich fühle mich ängstlich, angespannt oder belastet
- ☐ Ich habe das Gefühl, Asthmabeschwerden oder Kurzatmigkeit hindern mich daran, das zu erreichen, was ich im Leben erwarte
- ☐ Asthmabeschwerden oder Kurzatmigkeit beeinträchtigen meinen Kontakt zu anderen Menschen
- ☐ Ich vermeide es, an bestimmte Orte zu gehen, weil sich dort mein Asthma verschlechtert
- ☐ Ich vermeide es, an bestimmte Orte zu gehen, weil ich fürchte, dass dort ein Asthmaanfall ausgelöst und mir nicht geholfen werden kann
- ☐ Beim Sporttreiben, bei meinen Hobbies oder bei anderen Freizeitbeschäftigungen werde ich durch Asthmabeschwerden oder Kurzatmigkeit eingeschränkt
- ☐ Ich fühle mich allgemein eingeschränkt
- ☐ Ich habe das Gefühl, dass das Asthma in meinem Leben die führende Rolle spielt
- ☐ Ich mache mir wegen des Asthmas Sorgen über meinen jetzigen oder zukünftigen Gesundheitszustand
- ☐ Ich mache mir Sorgen darüber, dass das Asthma meine Lebenserwartung verkürzen könnte
- ☐ Ich fühle mich abhängig von den Asthmamitteln, die ich inhaliere

Antworten:	Nie	Selten	Manchmal	Häufig	Sehr häufig
Punkte:	0	1	2	3	4

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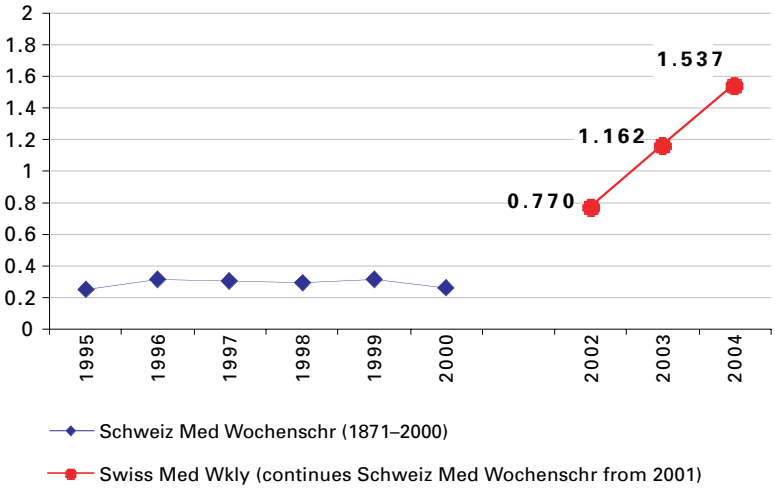

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