DISABILITIES AND THEIR LIFELONG BURDEN IN PEOPLE AFFECTED BY LEPROSY IN INDIA

A LEPRA ÁLTAL OKOZOTT ROKKANTSÁG ÉS ENNEK ÉLETRE SZÓLÓ TERHE INDIÁBAN

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Abstract

Disabilities in persons affected by leprosy pose a life-long disease burden, both for patient and the responsible medical service. The obligate intracellular pathogen *Mycobacterium leprae* affects skin, as well as peripheral nerve cells, and can result in leprosy reactions, which can be intensifications of the host's immune response, or antibody reactions to immune complexes. Leprosy can thus lead to disabilities, that are currently graded in three categories. The proportion of grade-2 disabilities in newly diagnosed leprosy patients (G2D) is one of the main indicators for leprosy monitoring. In total numbers, G2D are declining according to the size of the analyzed populations. The G2D-Rate per 1 Million persons however, shows fluctuations, which correspond to the efforts made in case-finding, and the public awareness concerning early reporting. Furthermore, no global data has been published yet, regarding the development of grade-0 and grade-1 disabilities throughout the course of treatment and beyond. The practical prevention of disabilities, and the exacerbation of those in already impaired persons, poses a great difficulty, especially in India, where historically stigmatization is present, the integration of leprosy services into the public health sector was described as failure, and funding is scarce, due to the fact, that leprosy was officially eliminated on a public health level in 2005.

Key words: Leprosy, Disabilities, Leprosy Reaction, G2D, EHF-Score

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Összefoglalás

A lepra által okozott rokkantság egész életen át tartó betegségteher mind a beteg, mind az egészségügyi ellátó rendszer számára. Az obligát intracelluláris kórokozó, a *Mycobacterium leprae* megtámadja a bőrt, a perifiériás idegsejteket, leprás reakciókat idézhet elő, amik a gazdaszervezet fokozott immunválaszát jelenthetik vagy az immun komplexekkel szembeni ellenanyag reakciókat. A lepra fertőzés így rokkantságot okozhat, amelyet jelenleg három fokozatba sorolunk. A lepra betegség monitorozására az újonnan diagnosztizált leprás betegek körében a 2-es fokozatú rokkantság (G2D) arányát tartják legalkalmasabbnak. Összességében a G2D száma csökken a vizsgált populáció körében. Ezzel szemben a G2D 1 millió főre vonatkoztatott aránya ingadozik, attól függően, mennyire intenzív az eset felkutatás és a lakosság tudatossága a korai esetjelentés tekintetében. Ezen túlmenően nem közöltek még globálisan adatot arról, hogyan súlyosbodik az első fokozatú állapot G2-vé az alkalmazott kezelések függvényében. A rokkantság gyakorlati prevenciója, továbbá a már rokkantak körében a betegség súlyosbodása nagy problémát jelent, különösen Indiában, ahol a stigmatizáció történelmileg jelen van, a leprás betegeket ellátó egészségügyi szervezetek integrációja a közegészségügybe kudarcot vallott, az anyagi támogatás korlátozott, mivel a lepra népegészségügyi szintű felszámolását 2005-ben hivatalosan bejelentették.

Keywords: Lepra, rokkantság, lepra reakciók, G2D, EHF-Score

Introduction

This last publication of our three-fold series on leprosy in India, focuses on disabilities, which in leprosy affected persons represent the life-long burden of a complex yet curable infectious disease. Parts of this three-fold publication series have also been published in the Diploma-thesis of the author "Leprosy Disabilities - Complications of the Poorest?" (2019) (1). The intracellular pathogen *Mycobacterium leprae* grows in macrophages, histiocytes and keratinocytes of the skin (2,3) and Schwann cells in peripheral nerves (4). Its primary diagnosis is based on skin manifestations. People in endemic areas know about the primary signs of leprosy (5), however, through stigmatization and discrimination of the affected persons, delayed diagnostic processes are common (6-8).

The WHO's goal of a Prevalence Rate (PR) of less than 1 per 10.000 persons affected by leprosy, and therefore the elimination of leprosy on a public health level, was achieved globally in 2000 and in India on a national level in 2005. Since then the PR continued to be within the aspired range for 15 years and was set at 0.29 as a point-prevalence in 2015 (9). Thus, the goals over the past years focused on reducing the disease-burden, measured as new cases with visible deformities or new cases with grade-2 disabilities at diagnosis (G2D) (9–11). The WHO's new target is therefore defined as the reduction of the annual G2D-Rate to less than 1 per 1 Million persons, which, as preventive measures are still not available, requires early case detection and

early reporting. At the same time, life-long care for those living with disabilities ought to be continued and a focus be put on the prevention of disability progression.

Complications of Leprosy

Primarily, *M. leprae* affects Schwann cells in peripheral nerves (4), which in turn leads to dedifferentiation of these into immature cells (12), and furthermore, to axonal dysfunction and demyelination causing sensory impairment (4,13). Keratinocytes, macrophages and histiocytes are the cell types affected in the skin (2,3) accounting for the dermatological manifestation.

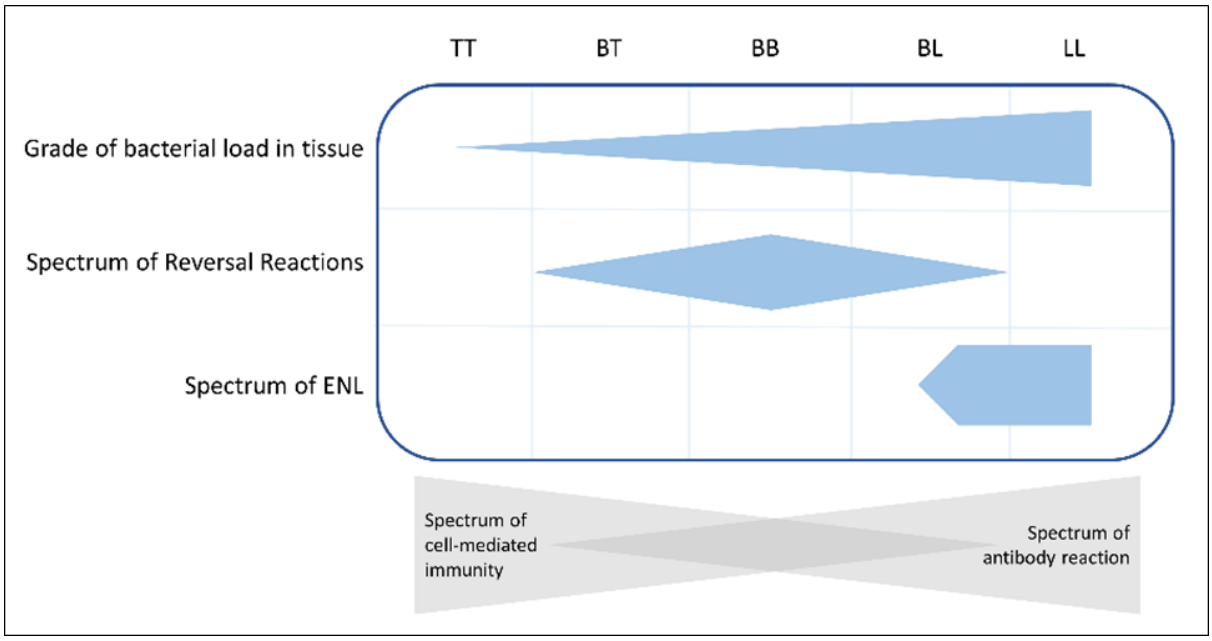
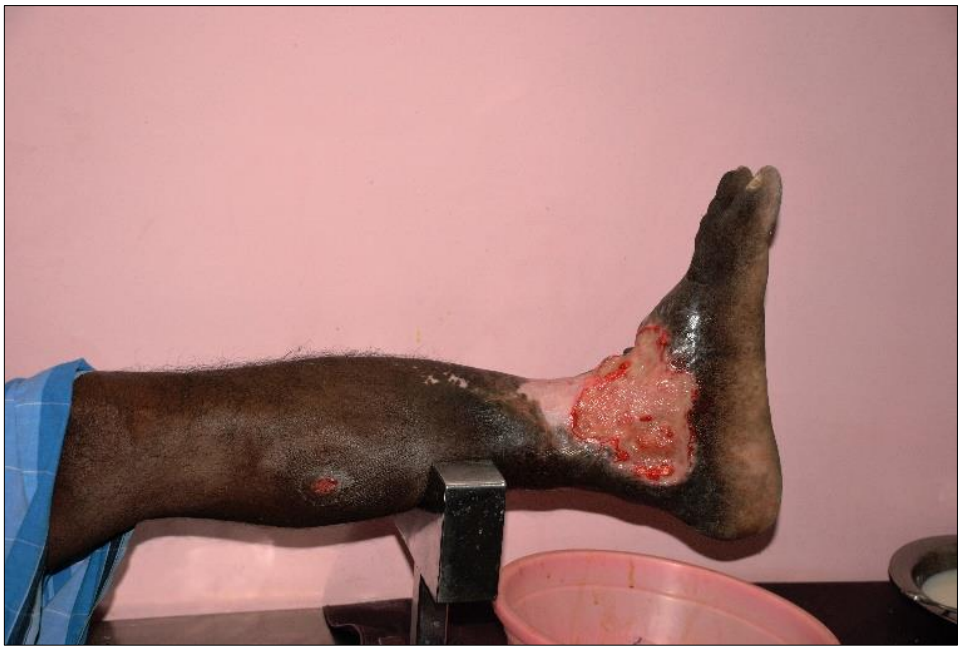


Figure 1. Grade of *M. leprae* in tissue and spectrum of leprosy reactions within the classification of Ridley-Jopling.
Figure adjusted according to Walker, Lockwood 2007; see also Heidinger 2019 (1)

Leprosy reactions are immunological reactions, which can occur any time before, during or after the initiation of Multidrug therapy (MDT), consisting of rifampicin, clofazimine and dapsone. The inflammation affects peripheral nerves and can thus lead to loss of sensibility, paralysis and deformities (14-16). To determine the risk of such reactions, classification according to WHO's therapeutical approach of paucibacillary (PB) versus multibacillary infections (MB) is not ideal (17,18). The classification according to Ridley-

Jopling (19,20) represents a physiopathologically more accurate system based on the host's disease-response shown as the clinical signs, histopathological features as well as the bacterial index. It offers an estimate of the immune-competency and therefore risk of leprosy reactions for each patient (14,21). The classification-systems have been presented in detail as part of the first publication in this series "Leprosy in Southern India". Borderline types of leprosy are the most prone to reactions, as their status can be described as immunologically unstable. "Upgrading" reactions thereby refer to an increase in cell-mediated immunity and a move towards the tuberculoid spectrum of the infection, whilst "downgrading" means a loss of cell-mediated immunocompetency as visualised in **Figure 1**.

Furthermore, leprosy reactions can be distinguished into Type 1 and Type 2 reactions. Type 1 reactions, also called reversal reactions, solely affect skin and nerves and present as erythema and edema of skin lesions, tender and painful peripheral nerves and loss of nerve function (22-25). Around 30% of individuals with borderline infections are at risk for such reactions (18). These reactions can affect patients with all types of leprosy during all periods of the disease. They mainly occur in the first two months of MDT treatment. This reaction is understood to be an "upgrading" immune response to *M. leprae* (22-25).



Picture 1. Tethered ankle joint through *M. leprae* and its complications, subsequently leading to skin-cracks and open ulcers.

Type 2 reactions, also called Erythema Nodosum Leprosum (ENL), can occur in all different tissues and organs other than the central nervous system. The lepromatous form of

leprosy, a high bacterial index (>4+), and the grade of skin infiltration, represent an increased risk for type-2 reactions. Of borderline and lepromatous leprosy cases, 19% suffer from this type (26). Additional risk factors include hormonal changes in women (puberty, pregnancy, lactation), and possibly stress (27). Reduced risk was found in persons older than 40 years (26). Even though the onset is mainly acute, a high chance to turn into a chronic reaction exists (27,28). ENL is caused by deposition of immune complexes, clinically presenting as fever, malaise, lymphadenitis, uveitis, arthritis, dactylitis and/or orchitis (14,22). Skin manifestations can range from painful and tender papules or nodules occurring in crops, to bullous ENL, with lesions that can ulcerate. Joint tethering and fixation may occur through subcutaneous tissue involvement and affection of the autonomous nervous system, as presented in **Picture 1** (14).

Complications of leprosy pose significant causes of disability and deformity, and therefore visibility of the disease, which creates branding and stigma, higher vulnerability for further complications associated with it and obligatory life-long care, which patients, as well as caregivers, have to approach comprehensively(6).

Today's Indicator: Grade-2 Disabilities

Disabilities in leprosy can be graded by WHO's leprosy disability grading system, resulting in the Eyes-Hands-Feet score (EHF), with a range from 0 to 12 (29), posing a potentially more sensitive tool to monitor disability-changes and hidden disabilities compared to WHO's maximum grading (30,31). However, the classification into grade 0,1 and 2 disabilities still prevails as standard in public health terms. Therefore, the WHO's Expert Committee on Leprosy in its eighth report defined and gathered monitoring indicators in three categories concerning leprosy. Main indicators are the Annual New Case Detection (ANCD) Rate per 100.000 persons, G2D per 1 Million persons as mentioned above, and the treatment completion as well as the cure rate for MB and PB cases. Other indicators for monitoring purposes include amongst others the proportion of G2D as well as the rate of MB cases amongst new cases. Furthermore, indicators for the evaluation of quality in existing services are defined as the prevalence of grade-2 disabilities in those who develop them throughout the course of MDT, the proportion of new cases diagnosed correctly, the prevalence-detection-ratio, the number of persons assessed at completion of treatment, and the number of relapses amongst those who completed MDT (23).

Only rough estimates exist regarding the global burden of disabilities due to leprosy, which suggest numbers as high as 3 Million persons (32). Globally, 210.758 new leprosy cases were detected during 2015, setting the ANCD at 3.2 per 100.000 persons. The number of G2D was at 14.059 globally, and therefore a proportion of 6.7% of all newly detected cases and at a rate of 2.5 per 1 Million persons, which over the past 8 years has globally been stagnant (8,20). However, for the SEAR G2D over the same period has risen by almost one-quarter from 6.891 persons annually, to 8.572, resulting in a G2D-Rate of 4.4 per 1 Million in 2015. In India, this rise has been even more drastic, by 55%, from 3.763 to 5.851 people in 2015, which results in a G2D-Rate of 4.46 per 1 Million (9). Moreover, this is striking, as ANCD rates have shown a decline globally, and a stagnant national trend in India, for the same timeframe (6,21). Focusing on Tamil Nadu, as home state of our cooperation-partner Doctor Typhagne Memorial Charitable Trust in Salem, from 2011 to 2015 all key-indicators but G2D have decreased. The latter shows that patients are still reporting late and are diagnosed at a late stage of the disease. The G2D-Rate in Tamil Nadu lies at 2.45 per 1 Million, and is therefore, with according adjustment to the specific population, lower than at all other levels of analyzation. Salem itself, a central district of Tamil Nadu, shows the highest G2D-Rate of all, with 5.38 per Million (33–36.) In Figure 2 absolute numbers of G2D in 2015 are compared to G2D-Rates adjusted to the respective populations.

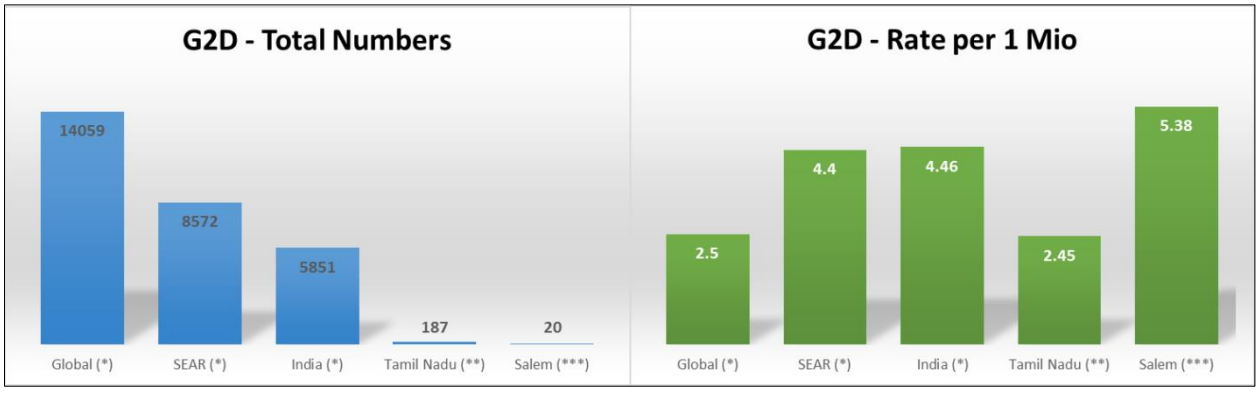


Figure 2. Total numbers of persons with grade-2 disabilities due to leprosy at diagnosis, at all levels of analysis can be seen on the left side, in blue, which consecutively decrease as population-numbers reduce. On the right side, in green, the respective G2D-Rate per 1 Million accordingly adjusted to the specific population, showing variable results.

* Data for global, SEAR and Indian analyzation as per 31.12.2015; ** Data for Tamil Nadu as per 31.03.2015; *** Data for Salem as per 31.03.2016

Source: see also Heidinger 2019 (1)

No global data is available regarding the rate of grade-1 disabilities at diagnosis in leprosy, and the development of impairments during the lifespan of affected persons. This could be a parameter to determine whether follow-up care is fully functioning, or if grade-0 as well as grade-1 disabilities subsequently progress into grade-2. The Bangladesh Acute Nerve Damage Study showed, that the prevalence of nerve function impairments (NFI), defined as "clinically detectable impairment of motor, sensory or autonomic nerve function" (37), lies at 4.4% within PB patients, and 36% for MB cases from registration to 2 years of follow-up. Two-thirds of acute NFI occurred after registration (38). De Oliveira et al. showed that amongst patients without impairments at diagnosis, 5% of PB and 20% of MB cases developed disabilities throughout the course of treatment. Within those showing either grade-1 or grade-2 disabilities at diagnosis, around one-third improved during treatment, whilst 6% of PB and 12% of MB deteriorated (17).

Disabilities in Leprosy Affected Persons

The best cure for disabilities is to prevent them first-hand. Therefore, early diagnosis of leprosy, as well as prevention, and early treatment of reactions are key, as preventive measures for leprosy are not available to date. Furthermore, already existing disabilities should be preserved from exacerbating, requiring regular follow-ups, prompt treatment if necessary, and a high patient compliance. Therefore, all patients must be instructed and educated towards the prevention of secondary disabilities, resulting out of anaesthetic hands and feet, and preventive measures made available, especially as reactive states may continue even after completion of treatment and possibly outside of regular follow-up timeframes (39). Realistically and practically however, the prevention of disabilities demands the highest compliance of patients affected by leprosy and a proper and timely surveillance by health professionals. This in turn requires manpower, that is based on sufficient funding, which, due to the fact that leprosy is regarded as eliminated on a public health scale, is scarce (40).

Measures to prevent injuries out of anaesthetic limbs include wearing of proper shoes, with a hard and an impenetrable sole and a soft foot-bed (like Micro-cellular rubber). At the same time, they should be in line with local fashion trends, in order to reduce branding and increase the person's compliance in wearing them. Today, persons who are disabled through leprosy are taught to daily inspect all affected extremities, soak them in salt-water, scrap the callus, oil all affected extremities and dress wounds and ulcers. Additionally, affected persons

should cook and drink with sheets covering hot surfaces and cover their eyes in case of lagophthalmos with sunglasses during the day and a wet towel at night (41). All of them being necessary measures, yet highly unpractical according to affected persons, and possibly visible and therefore stigmatizing (42). Reconstructive surgery poses the ultima ration for deformed acrae, which should include physiotherapy prior and after the intervention, as well as proper post-surgical care in terms of bleeding, infection and the correct treatment of these.

Different to solely infected patients, disabled and deformed persons need lifelong care and measures of social equality and integration, which for leprosy as a disease of the poor is striking doubly. Most endemic countries can not deliver these measures due to a general lack of medical, psychological, social and rehabilitative care for disabled and deformed, and through the continuing stigma of the disease and the discrimination of affected persons, they as well have very limited means of self-care. In India, the integration of leprosy into public health services has been declared a failure (40), leaving leprosy on the bifocal verge, with affected persons on the one side facing massive stigmatization and discrimination with solid historical foundations (6), whilst the medical service faces diminishing attention and funds (40) as well as stagnant ANCD and even rising G2D-Rates.

Conclusion

Disabilities in leprosy are preventable collateral outcomes of a curable disease. Therefore, the WHO has included the grade-2 disabilities at diagnosis into their core-set of indicators and spotlight of public health monitoring. The lifelong disease burden at diagnosis, efforts and possibly knowledge within the population concerning early reporting, and endeavors of medical services regarding early case-detection ought to be analyzed with it. Including the indicator of grade-2 development during MDT treatment is a step into the right direction, measuring progression of collateral-effects. As has been shown, progression of disabilities is common, which requires tight observations, high compliance and a reason to do so from a patient's perspective. This could be the re-integration into socio-economic structures which is dependent on stigma reduction and general knowledge regarding leprosy. India faces difficult times, both from patients' and medical perspective concerning a disease of relatively small magnitude, yet probably the longest history known to mankind, with strongly adjoined prejudice. Therapy is simple, and to date has been spared by antibiotic-resistance. The life-

long disease burden is not even identified in its total extent, shows limited therapeutical options and poses the risk of occurrence and progression even after regular follow-up periods.

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