Ethical qualms while treating diabetes in low resource areas

GAJANAN PHUTKE, SUSHIL PATIL, YOGESH JAIN

Abstract

Diabetes care in low-resource rural areas is often compromised by access and finance barriers, leading to ethical dilemmas for physicians in diagnosis and treatment. Rural health workers should be educated on how poverty, disproportionate rural health infrastructure, and illiteracy impact diabetes care to facilitate a paradigm shift from blaming patients for poor adherence to improving health systems in order to address underlying structural care seeking barriers of cost, distance and social stigma. With these barriers urban, high resource protocols cannot be implemented and there is need for separate evidence-based protocols for rural, low resource populations. Having such set protocols coupled with continuous training and use of mobile/telemedicine technology could help shifting tasks to nurses and peripheral health workers. The National Programme For Prevention And Control Of Cancer, Diabetes, Cardiovascular Diseases & Stroke may benefit from this communitising care model by setting up PHC-level NCD clinics run by trained nurses and health workers with physician backup using technology as needed. This way of utilising non-physician health workers to treat uncomplicated diabetes patients may not only allow physicians quality time and more resources to treat complicated diabetes patients but also provide good quality, accessible care within everyone's reach.

Introduction

India has the largest number of patients diagnosed with diabetes in the world. An ICMR-INDIAB study estimates that there are 62 million diabetes patients in India (with a prevalence rate of 7.3%), with a higher urban (11.2%) than rural prevalence (5.2%) (1). Community health programmes traditionally used for maternal and child health can also be used to reach this large and dispersed diabetes patients'.

Jan Swasthya Sahyog (JSS), or People's Health Support Group, runs a rural secondary-care hospital and a comprehensive community health programme in 72 hard-to-reach forest villages with village heath workers in rural central India. At JSS Hospital, we see about 20,000 new patients every year who require secondary-level care. Around 450 of these new patients get diagnosed as having diabetes every year. Diabetes Mellitus constitutes 2.5 % of routine new outpatients. 90% of our diabetes patients present during adulthood (type 2 DM), while 10% present symptoms during childhood and adolescence (type 1 DM). The median age for type 2 diabetes is just under 50 years. In contrast to about 45 % obese urban diabetes patients, only a third of type 2 diabetes patients have a BMI greater than 22.5 Kg/M2 – the Indian BMI cutoff for overweight people (2). Further, over a third of the diabetes patients we treated had a BMI lower than 18.5 Kg/M2, a phenomenon often referred to as "lean diabetes"(3).

In a retrospective cohort study of 1,023 patients from 2013 to 2016, 793 patients (78%) in the sample were on oral anti-hyperglycaemic agents (OHA), 230 (22%) required insulin, and 81% were taking metformin (4). In another prospective random cohort study of 250 type 2 diabetes patients between November 2017 and April 2018, 42% patients with a Haemoglobin A1C (HbA1c) level of more than 7 % had uncontrolled diabetes with the following complications prevalence: diabetic foot ulcer – 14.8%; late nephropathy – 14%; and peripheral neuropathy – 50% (5).

Poor glycaemic control, and the high prevalence of complications, in rural areas can be attributed to barriers like poverty, food insecurity, illiteracy, disproportionate allocation of health resources in urban vs rural areas, poor screening and preventive services, non-adherence to diabetes management guidelines, poor availability of counselling, and long travel distances to health services (6). Most of these barriers are structural and cause ethical dilemmas for rural healthcare providers. Basu et al (7) have described the under-recognised nature of ethical dilemmas in low-resource settings focused on drug therapy. We further elaborate on the structures that lead to ethical dilemmas and suggest possible solutions. There is an urgent need to improve our understanding of the barriers and dilemmas faced while administering diabetes care in rural areas to plan and deliver appropriate care for neglected patients.

Diabetes is a deficiency arising from excess glucose production. In the case of lean diabetes, we observe a cruel parallel at the societal and cellular levels. A diabetic's cells are surrounded by abundant glucose, but they are unable to use it. Similarly, our rural poor live in a country with rising incomes and material resources, but they cannot reap these benefits due to rising socio-economic inequity (8). Some dilemmas are not specific to diabetes but are relevant to all chronic illnesses. For example, how does one respect the patient's autonomy and shared decision-making when the patient has uncontrolled diabetes and neglects close follow-up due to

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To cite: Phutke G, Patil S, Jain Y. Ethical qualms while treating diabetes in low-resource areas. *Indian J Med Ethics*. 2020 Jan-Mar;5(1) NS: 49-53. DOI: 10.20529/IJME.2020.019.

Manuscript Editor: Vijayaprasad Gopichandran

underlying structural, financial, and geographical constraints. Should one deny care to those unable to adhere to treatment recommendations or continue treatment while accepting long-term micro and macro vascular complications? Should we recommend limiting carbohydrate intake despite knowing that protein and fat are often unaffordable for patients, and that 80% of the calories consumed by patients with a body mass index (BMI) of 16 Kg/M2 or lower are carbohydrates?

Ethical problems in diagnosis

Ethical dilemmas faced can be sub classified at the time of diagnosis and during treatment for better understanding.

At diagnosis

Is lean diabetes a separate class?

Classifying diabetes types clinically is challenging in the presence of under-nutrition. Often, lean diabetes is misclassified as either type 1 or type 2 due to difficulties in concluding whether the patient's low BMI is a cause or effect. This leads not only to the underestimation of the actual burden of lean diabetes, but also to delays in the initiation of insulin. Some authors propose that lean diabetes presents a different patho-physiological process than classic type 1 and type 2 diabetes, while others believe that it is a variant of type 2 diabetes (9). Should we consider lean diabetes as a separate category, different from Maturity Onset Diabetes of the Young (MODY), when the World Health Organisation (WHO) has removed it from the current classification (3)? Should all lean diabetes patients be investigated for chronic calcific pancreatitis? Classification is important as early administration of insulin preserves beta cell function for a longer duration. Various reports estimate population prevalence of fibrocalculous pancreatic diabetes (FCPD) to be 0.09%, and diabetes clinic prevalence ranges between 1% and 29% with most studies from south India. Reported FCPD prevalence in Kerala in 1964 was 29% of all diabetes patients, in Chennai 1% of all patients and 4 % among young diabetes patients. It is not clear whether decline in prevalence is due to a true decline in the incidence of FCPD or merely represents a change in the diagnosis and admission protocols at these centres over a period of time (10). Further studies are needed to assess causation and mortality reduction in lean diabetes patients (11–13).

In treatment

Dilemmas during treatment are a real challenge faced by care providers. With no separate protocols' for rural low resource populations, on one side the provider has to negotiate skillfully between patient autonomy and dissatisfaction at providing substandard care.

Balancing intensive hyperglycaemic control and risk of hypoglycaemia

A large majority of rural adults with diabetes have to perform heavy manual work seasonally and cannot control their meal content or timings (due to their job profile and the expenses involved). These uncontrolled meals leads to swings in blood glucose levels, from life-threatening hypoglycaemia to hyperglycaemia. Should different glucose or HbA1c targets be set for these patients compared to those in areas with better access to healthcare? Fear of hypoglycaemia is an important factor given the high glycaemic index of rice-based diets (leading to rapid blood glucose swings), frequency of skipping meals, religious fasts, livelihood work demanding intense physical activity, mistakes in OHA or insulin dosage, and higher infection rates in these populations. Often, we err on the side of caution, risking long-term micro- and macro vascular complications rather than hypoglycaemia, based on the principle of non-malfeasance – the latter can kill and cause major clinical problems immediately, while the former will show up gradually in months and years, making it the lesser threat. Such decisions deny equitable treatment and, consequently, subvert the principle of justice for the poor since it is these long-term complications which will determine quality of life and longevity. Perhaps well-kept registries of patients prospectively may help us make balanced ethical decisions regarding the aggressiveness with which we pursue glycaemic control in diabetes treatment.

Frequency of follow-ups

It is difficult to achieve the desired glucose control as patients do not attend regular monthly follow-ups due to financial and geographic constraints. The situation compels us to make a difficult choice between accepting the patient's autonomy and robust sugar control without any clarity on the unintended consequences of each decision. We wonder about shared decision-making guidelines when patients often seem to have a poor understanding of consequences or are forced to adopt a less than ideal follow-up frequency owing to structural factors like poor socio-economic status and accessibility of services. We find community-based peer support groups very useful in reducing follow-up distance and supplementing decision-making, as published previously by us (14).

Glucose monitoring test and quality control

Blood glucose can be tested either by finger prick glucometers or venous blood colorimetry. Glucometric checks are easier to administer, producing rapid results and being point-of-care tests, but they also require regular calibration. They may erroneously show low sugar results if strips are stored above 30°C (15). Glucometers are recommended in temperate climates only if quality control results are within an acceptable range, and have an individualised equipment quality control plan suggested by manufacturers. HbA1c testing can estimate sugar levels for the last 90 days, but it is expensive, is a more difficult technique, and requires a high level of quality control. High prevalence of iron deficiency — which falsely increases HbA1c (16) — and haemolytic anaemia, like sickle cell disease — which falsely reduces HbA1c (17) — is common in rural India, making the interpretation of HbA1c results difficult. Where patients pay for their own healthcare, physicians have

to ensure affordable care or expect high default rates and consequently face a dilemma while choosing monitoring tools for sugar control. We worry about escalating therapy based on glucometric sugar control results done without regular calibration or HbA1C results given the high prevalence (54%) of anaemia (18).

Challenges around insulin

OHAs are the mainstay treatment for type 2 diabetes. However, a large proportion of type 2 and lean diabetes patients require insulin in doses that sometimes reach 100 international units (IUs) a day. We have not been able to find a single satisfactory method for determining insulin dosage. Since the overwhelming majority consume more than 80% of their daily intake of calories as carbohydrates, much higher than the published 65% (19), normal glucose values become difficult to target. The decision to start insulin in addition to OHAs requires careful deliberation because of problems related to insulin costs, injection technique, dosing and insulin storage, and poor access. In Chhattisgarh and Madhya Pradesh, NPH (Neutral protamine Hagedorn) insulin or combination (70/30) insulin are rarely available in health facilities other than district hospitals. Maintaining insulin potency in rural settings without electricity and refrigerators is difficult. Earthen pot storage is a poor option in tropical situations, with room temperatures rising beyond 30°C for some hours each day. Ensuring patients' understanding of injectable devices, dosage, and reusing and disposing of syringes demands extraordinary nursing and counselling skills.

Lean diabetes

The pathogenesis of lean diabetes is multi-factorial, and the standard type 2 diabetes management guidelines are inappropriate in this case. Studies from the West (20) report that diabetes patients with a normal BMI have a higher mortality risk than their obese counterparts with non-cardiac causes. A hospital-based Indian study (21) reports that ischaemic heart disease, infections, nephropathy, stroke, and coma are the leading causes of mortality and should be further investigated by community-based studies in low-resource areas. There is no definite answer regarding whether weight reduction is beneficial in lean diabetes (11). Guidelines about prescribing statins need to be redefined in the case of non-obese (lean) diabetes and higher-than-normal cardiovascular risk in South Asians, as compared to the rest of the world, coupled with limited access to lipid testing. Research on lean diabetes has been almost static since 1991, like that on many other diseases contracted by poor people (22, 23).

Dietary and lifestyle advice

We find this the most difficult aspect of diabetes management. It is ironical to advise a low carbohydrate diet when carbs constitute more than 80% of the dietary intake of the rural poor, and the public distribution system (PDS) provides food items mainly containing carbohydrates, and proteins and vegetables remain unaffordable for poor patients. We are unsure if physicians should advocate for changing PDS food content, given that a diet heavy in carbohydrates is known to increase the risk of diabetes and other non-communicable diseases among the general population as well. The nature of farmers' and farm labourers' work does not allow them to have frequent and small meals. Also, guidelines are required for modifying exercises and optimising weights for hard-working labour populations so as to allow them to perform physical labour without adverse effects.

Type 1 diabetes

Teaching self–glucose monitoring with carbohydrate counting is difficult given the poor literacy levels of patients, the cost of glucose strips, and risk of hypoglycaemia. In our view, just free or subsidised insulin is not enough for their care. The health system should also think of the psychological trauma (of abandonment by spouse/family often due to patients inability to do heavy, longtime strenuous work, care expenses) and physical disability (like cataract, neuropathy reduces earning ability) of patients and invest money to make them self-sufficient by providing educational scholarships and opportunities for professional skill-building. Similarly, our system needs to engage young rural patients requiring chronic care through consistent health systems monitoring, patient-based advocacy, and peer support just like the revised national tuberculosis programme's "TB Survivors to Champions" initiative (24).

Underlying structures leading to dilemmas

Rural health workers should be educated on how poverty, disproportionate rural health infrastructure, illiteracy, and rural culture impact diabetes. We need a paradigm shift from blaming patients for poor adherence to a conscious effort to improve health systems.

Cost of care

Often, people with diabetes spend more than 40% of their total household income on care (25). The chronicity of the disease pushes people below the poverty line. Thus far, there is no insurance coverage for outpatient level diabetes care. The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) promises affordable care, but medicines are not available below the level of community health centres (CHCs), and are prescribed for one or two weeks per visit, resulting in almost equivalent expenditure on travel and opportunity cost. The NPCDCS has not yet been implemented at the primary health centre (PHC) level (26). Equipping PHCs for follow-up care with free investigations and medicines would help resolve distance and cost barriers to care.

Distance

We find distance from health facilities to be a common reason for patients stopping treatment. Almost all diabetes defaulters require costly emergency and/or inpatient care for complications. Should we have active follow-ups by VHWs (village health workers) for such patients, in a manner similar

to tuberculosis? Costing studies may help us understand the cost-effectiveness of active follow-up approaches for health systems.

Social stigma and discrimination

We observed that there is social discrimination and stigma associated with diabetes, leading to cessation of treatment. Children with type 1 diabetes often drop out of schools and hostels for fear of hypoglycaemic seizures. Incidents of young women developing diabetic ketoacidosis (DK) due to discontinued insulin after marriage are not uncommon. Patients often skip their insulin doses to avoid stigma when they have to travel outside their homes to stay with relatives. A health system should prevent social discrimination, especially for patients with type 1 diabetes, in cases of marriage, domestic violence attributed to pregnancy-related complications, and the inability to perform heavy physical labour.

The way forward

Diabetes control programme

We need further studies to determine how far communitisation of diabetes care should reach – the VHW, PHC, or CHC level – for better compliance without harm. Can we task-share care of diabetes patients with mid-level health workers or nurses and patient support groups on ethical principles? With the onset of diabetes at an earlier age, what age group cut-offs should be used for population screening, in addition to opportunistic screening? How should we handle pre-diabetes when follow-up is not guaranteed? Which method should be used for mass screening? Should we investigate all pregnant women in non-obese environments for gestational diabetes screening?

Diabetes education and support groups

Good patient education material is not available in most vernacular languages. Running peer support groups is one effective strategy in diabetes care (27). However, they are difficult to organise and get ignored in a resource-poor setting. People with counselling skills are not available where they are needed the most, and the task of counselling is left to already burdened doctors and nurses. The NPCDCS is currently using mDiabetes (28) with only text messages, the scope of which can be expanded to voice-interactive applications for uneducated diabetes patients and caregivers. Mobile technology can also help in forming peer support groups.

The nurse-led model of multidisciplinary integrated care

Technically, diabetes management is a complex process, especially so in the case of complications. It requires a multidisciplinary approach with physicians, nurses, counsellors, dermatologists, ophthalmologists, dieticians, and often, a surgeon. Some people with diabetes and certain diabetes syndromes may require consultation with an endocrinologist. In the current national programme, NPCDCS, specialist care is available at the district level and above. We need to have well-tested protocols, continued rather than just one-time training, and continuous guidance for peripheral health workers using mobile technology and referral services for surgical needs in diabetes cases to compensate for lack of multidisciplinary teams. We need to learn from countries like Rwanda and South Africa (29, 30) to implement nurse-led models of noncommunicable disease (NCD) care.

Conclusions

Diabetes care in low-resource rural areas is often compromised by access and finance barriers, leading to ethical dilemmas for physicians. Rural health workers should be educated on how poverty, disproportionate rural health infrastructure, illiteracy, and rural impact diabetes care to facilitate a paradigm shift from blaming patients for poor adherence to improving health systems. The NPCDCS may benefit from communitising care by setting up PHC-level NCD clinics, shifting tasks to nurses and health workers according to set protocols, and continuous training and use of telemedicine and mobile technology. They may allow physicians more time and resources to research for complicated cases. In this way, non-physician health workers can be utilised to better handle the diabetes epidemic.

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Ethical issues in expanding latent TB management in high burden countries

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To cite: Basu S, Sharma N, Mase S, Sachdeva KS. Ethical issues in expanding latent TB management in high burden countries. *Indian J Med Ethics*. 2020 Jan-Mar; 5(1) NS:53-6. DOI:10.20529/IJME.2020.020.

Manuscript Editor: Vijayaprasad Gopichandran

Peer Reviewers: Two anonymous reviewers

Abstract

Global efforts are being made to eliminate tuberculosis (TB) as a public health problem by 2030. These efforts are being thwarted by the challenge of effective management to minimise the progression of latent TB infection (LTBI) to TB, thereby interrupting the chain of transmission. Approximately 5%–10% LTBI cases eventually develop TB in their lifetime with the risk being higher in children, people living with HIV/AIDS (PLHIV), undernourished people, and patients with diabetes, chronic kidney disease, silicosis, and other comorbid conditions. Apart from operational barriers, complex ethical issues govern decision-making processes in either retaining current LTBI management practices or advocating implementation of the latest World Health