

Caseload, management and treatment outcomes of patients with hypertension and/or diabetes mellitus in a primary health care programme in an informal setting

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Abstract

OBJECTIVE In three primary health care clinics run by Médecins Sans Frontières in the informal settlement of Kibera, Nairobi, Kenya, we describe the caseload, management and treatment outcomes of patients with hypertension (HT) and/or diabetes mellitus (DM) receiving care from January 2010 to June 2012.

METHOD Descriptive study using prospectively collected routine programme data.

RESULTS Overall, 1465 patients were registered in three clinics during the study period, of whom 87% were hypertensive only and 13% had DM with or without HT. Patients were predominantly female (71%) and the median age was 48 years. On admission, 24% of the patients were obese, with a body mass index (BMI) > 30 kg/m². Overall, 55% of non-diabetic hypertensive patients reached their blood pressure (BP) target at 24 months. Only 28% of diabetic patients reached their BP target at 24 months. For non-diabetic patients, there was a significant decrease in BP between first consultation and 3 months of treatment, maintained over the 18-month period. Only 20% of diabetic patients with or without hypertension achieved glycaemic control. By the end of the study period, 1003 (68%) patients were alive and in care, one (<1%) had died, eight (0.5%) had transferred out and 453 (31%) were lost to follow-up.

CONCLUSION Good management of HT and DM can be achieved in a primary care setting within an informal settlement. This model of intervention appears feasible to address the growing burden of non-communicable diseases in developing countries.

keywords hypertension, diabetes mellitus, primary health care, Kenya, medical management, operational research

Introduction

Hypertension (HT) and diabetes mellitus (DM) are important public health challenges worldwide, and together, contribute significantly to mortality through cardiac, cerebral and renal events (Abegunde *et al.* 2007).

Levels of detection, treatment and control of HT are low in both developed and developing countries, suggesting that complications such as stroke, heart failure and renal failure will continue in years to come (Lopez *et al.* 2006; Addo *et al.* 2007; Messerli *et al.* 2007). In 2011, an estimated 366 million people globally were living with DM, of whom 183 million (50%) were undiagnosed

(International Diabetes Federation 2011). The global prevalence of DM is expected to reach 552 million by 2030. Poorly controlled DM affects both quality of life and life expectancy. In 2010, ischaemic heart disease and stroke collectively killed 12.9 million people, or one in four deaths worldwide, compared with one in five in 1990; 1.3 million deaths were due to diabetes, twice as many as in 1990s (Lozano *et al.* 2012). In 2010, ischaemic heart disease carried the highest disease burden in terms of disability-adjusted life years (DALYs) worldwide (up from fourth rank in 1990, increasing by 29%) and stroke was ranked third (from fifth in 1990; 19% increase). The global disease burden has continued to shift away from communicable to non-communicable

diseases and from premature death to years lived with disability (Murray *et al.* 2012).

In 2005, the World Health Organisation (WHO) emphasised the importance of chronic, non-communicable diseases (NCDs) as a neglected global health issue and recommended offering services for chronic diseases in primary health care settings (WHO 2005). However, the evidence base for provision of care for chronic diseases at primary level, in particular in resource-poor settings, is limited at best. In these settings in particular, the health care needs of HT and DM patients (as two indicator NCDs) remain largely unmet due to lack of NCD services, inadequately trained staff, expensive treatments and difficulties in maintaining follow-up. In addition, there is a lack of well-defined models of care for these diseases. Two prospective studies conducted in hospital-based chronic disease clinics in rural Cambodia showed encouraging results in blood pressure and glycaemic control, but high losses to follow-up remained a challenge (Raguenaud *et al.* 2009; Isaakidis *et al.* 2010). In these studies, the model of care was based on a specialised HIV/Chronic Diseases clinic model and not on a primary care approach. In sub-Saharan Africa, there is limited literature on treatment outcomes of HT and DM patients. Most published studies are cross-sectional surveys and do not report on treatment outcomes.

In 2009, Médecins Sans Frontières (MSF) recognised the importance of addressing NCDs and started a programme caring for patients with HT and DM in three primary health care clinics in the informal settlement of Kibera, Nairobi, Kenya. These clinics were already providing other primary care services as well as treatment for TB and HIV in collaboration with the Kenyan Ministry of Health (MoH). To our knowledge, the integration of NCD care in this programme is unique within existing primary health services in Kenya and East Africa.

Results from studying this programme add to the scarce literature on outcomes for treatment of HT and DM in sub-Saharan Africa and contribute to developing a model of NCD care that is feasible in the primary care setting. This study therefore aims to describe the case-load, management and treatment outcomes of patients with HT and/or DM receiving care in a primary health care programme in Kibera, Nairobi, Kenya.

Methods

Design

This was a descriptive study of prospectively collected routine data.

Setting

Kenya has a population of 41 million with 3.1 million residing in the capital, Nairobi. Kibera is one of the largest informal settlements in Africa, located in the south-western part of Nairobi city, with an estimated population of 200 000–300 000 people. Kibera is characterised by poverty, rudimentary sanitation and lack of health facilities, a very mobile population and high unemployment.

Chronic disease clinic

Since 2006, MSF has supported the provision of primary health care together with HIV/AIDS and TB care in three outpatient clinics for the inhabitants of the Kibera slum. From 2010, care for HT and DM was integrated into the existing services. This integration implied that, regardless of the reason for the consultation, the patient was seen by a single clinician managing chronic conditions (NCD and/or HIV and/or TB) and any acute infections. It was a 'one stop service', which avoided patients attending separate clinics (NCD clinic, HIV clinic, TB clinic, primary health care clinic). It allowed a holistic management of the patients, including treatment adherence counselling and management of possible drug interactions.

The clinics were staffed with 10 clinical officers, 12 nurses, four nutritionists, 10 adherence counsellors, three social workers, four health educators and four receptionists. Care protocols for HT and DM were developed and staff was trained in the provision of this care. All health-care was provided free of charge; there were no fees for initial registration, essential drugs, or baseline laboratory tests.

The NCD programme enrolled patients over 14 years diagnosed with HT and/or DM (diagnostic criteria described below). Between January 2010 and May 2011, only patients who committed to coming for regular follow-up for at least the first 6 months after diagnosis were enrolled in the programme. From June 2011 onwards, the commitment to attend follow-up visits was dropped, and all patients with the diagnoses were included.

Upon enrolment, patients were seen by a clinician (clinical officer), a nutritionist and a social worker. The nutritionist assessed the patient and provided dietary advice, with follow-up consultations scheduled as required on a case-by-case basis. The social worker obtained patients' details including phone number and physical address in the event of needing to trace them. Tracing of patients who missed an appointment was, however, not systematically done as was the case for HIV/AIDS patients seen at the same clinics. Instead, this was handled on a

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case-by-case basis, with tracing reserved for patients with more severe clinical conditions and/or requiring treatment adjustment, as judged by the clinician. Examples of this could be abnormal laboratory results coming back that justified a patient being seen at the clinic before their next scheduled appointment, or close follow-up of a very sick patient. Patients were only actively traced (by phone or through a home visit) by a social worker after the request of a clinician.

In terms of health education, patients were encouraged to identify a family member/friend who could become a treatment assistant, but this was not a condition for inclusion. Health talks were held in group sessions with the help of the health educators. Patients were sent for counselling with counsellors on a needs basis.

Patients were initially given scheduled follow-up visits on specific day(s) of the week. However, from October 2011, these visits were scheduled for any weekday to accommodate the growing number of patients being enrolled.

HT care and management

Patients had their vital signs, including blood pressure (BP), recorded systematically by nurses in triage. BP was measured upon patient arrival. No recommendations were given to take the BP in the right or left arm. If the first BP was elevated, it was repeated upon examination by the clinical officer later during the appointment. The lowest blood pressure reading was recorded. For hypertension, two or more high BP ($\geq 140/90$) measurements recorded during two or more clinic visits were necessary for the diagnosis prior to patient enrolment (Box 1). BP values at enrolment were considered as baseline BP.

Patients were educated about the importance of life style modifications including the following: (i) body weight reduction (to attain and maintain a BMI < 25 kg/m²), (ii) dietary salt reduction, (iii) diet changes (diet rich in

fruits, vegetables and low in fat), (iv) a reduction of alcohol consumption, (v) smoking cessation, and (vi) regular exercise.

Drug therapy was started if the life style measures did not control BP (Boxes 2 and 3), if there was concern of target organ damage (increased serum creatinine, evidence of stroke, history of heart disease) or if the blood pressure reading was higher than 160/100 mmHg.

Patients with Grade 3 HT were prescribed a combination therapy of two or three drugs. Patients with very elevated BP were referred to the MoH hospital for admission and BP control. The target blood pressure was $< 140/90$ mmHg for patients with HT only and $< 130/80$ mmHg in patients with DM, proteinuria or chronic kidney disease.

For pre-HT, patients were to follow non-drug measures and return for review in four to 6 months. For Grades 1 and 2 HT, monthly follow-ups were requested until blood pressure was controlled and then follow-ups were scheduled every 3 months. Grade 3 HT patients were followed bi-monthly till blood pressure was controlled, and then monthly.

DM care and management

Patients with a known history of diabetes or those presenting with clinical signs indicative of diabetes were tested with a fasting blood glucose. The diagnostic criterion for DM was fasting plasma glucose ≥ 7.0 mm (126 mg/dl). For blood glucose measurement, a fasting test was performed: patients were requested to come early in the morning on a specific day, at the opening hours of the clinical laboratory, before taking any breakfast. Random blood sugar was only performed if a patient presented at a non-scheduled time with clinical symptoms of glycaemia. HbA1c was not performed at baseline but was taken after 6 months of treatment and 6-monthly thereafter. Patients with Type I and gestational diabetes were systematically referred to the MoH district or central hospitals for management and follow-up.

Education on life style modifications was offered, including (i) individualised diet counselling, (ii) total number of daily calories tailored according to the target BMI, (iii) the need for regular exercise, (iv) smoking cessation, and (v) reduction of alcohol intake.

If life style measures did not provide adequate glycaemic control, drug therapy was started (Boxes 4 and 5).

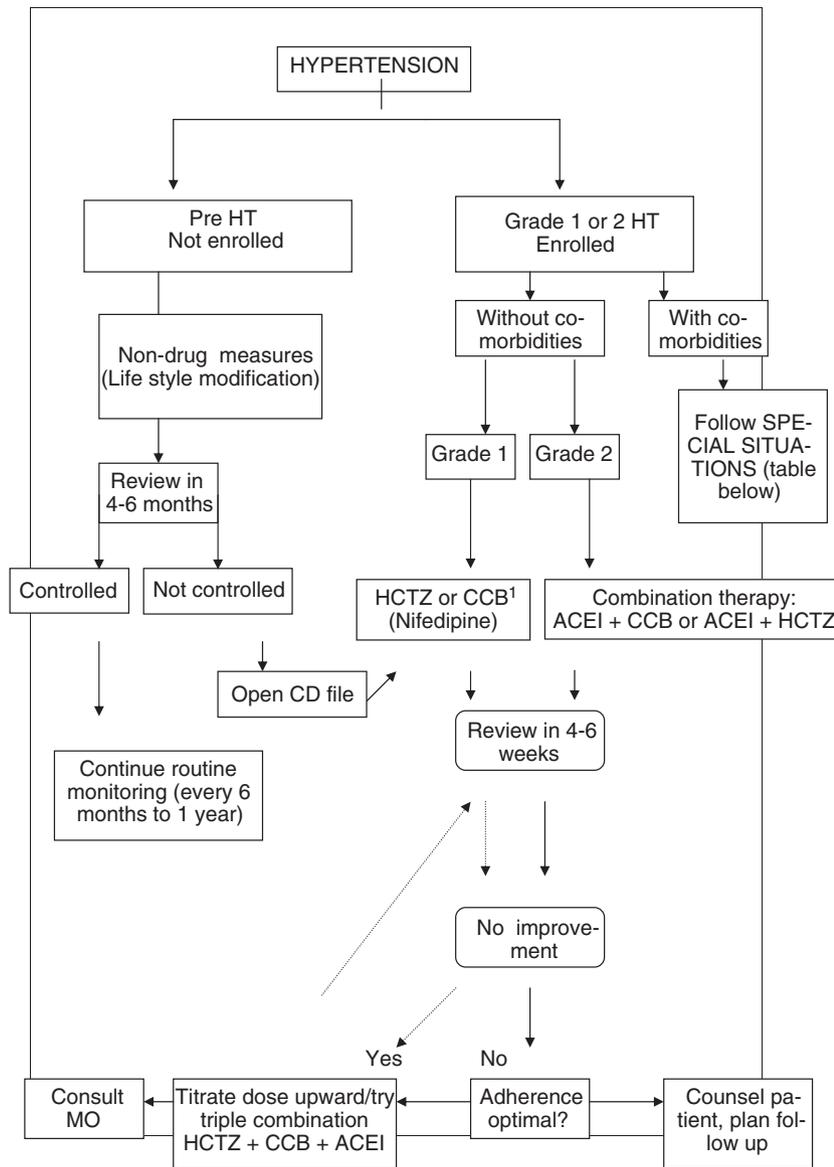
Study population

The study included all patients aged 15 years or older diagnosed with HT and/or DM, enrolled from January

Box 1 Grading of hypertension

Category	Systolic BP (mmHg)		Diastolic BP (mmHg)
Optimal	<120	AND	<80
Normal	<130	AND	<85
Pre-hypertension	130–139	OR	85–89
Grade 1 HT (mild)	140–159	OR	90–99
Grade 2 HT (moderate)	160–179	OR	100–109
Grade 3 HT (severe)	≥ 180	OR	≥ 110
Isolated systolic HT	≥ 140	AND	<90

Box 2 Algorithm for treatment of hypertension



¹HCTZ, hydrochlorothiazide; CCB, calcium channel blockers, ACEI, ACE inhibitors.

2010 to June 2012 in the primary health care programme in Kibera, Nairobi, Kenya.

Data collection

Data pertaining to this study were sourced from initial consultation and follow-up forms, and patient files kept

in the MSF clinics. Variables collected comprised date and diagnosis at enrolment, age, sex, grade of HT, type of DM, total cholesterol, BP, BS at enrolment and over time, and date of outcome. Trained data technicians entered these data into a dedicated database (EpiData Entry version 3.1; EpiData Association, Odense, Denmark) daily, and missing data was recovered from case

Box 3 Special situations			
Co-morbidity	First choice	Second choice(s)	Comments
Ischaemic heart disease	Beta-blockers	ACEI, CCB	Evaluate for and treat other risk factors
Heart failure	ACEI	Aldosterone antagonists, thiazides, loop diuretics	Anti-failure therapy, refer to medical officer (MO)
Diabetes mellitus	ACEI	Loop diuretic, Thiazide diuretics	Target BP strictly <130/80 mmHg
Chronic renal disease	ACEI + loop diuretic		ACEI may worsen renal function, so monitor creatinine and electrolytes carefully ACEI contraindicated in renovascular disease
Stroke			Too rapid reduction of BP may worsen the condition. Refer patient to MO.
Elderly	CCB	Thiazide diuretic/ACEI	
Isolated systolic hypertension	Thiazide diuretic/CCB	ACEI/Beta blocker	Do not treat patients with postural hypotension.
Accelerated hypertension/ malignant hypertension	Beta blocker/CCB		Refer patient immediately to MO. Do not use sublingual Nifedipine to lower blood pressure at the clinic.

file reviews. Regular quality checks for data accuracy were performed by the project data manager.

Analysis and statistics

Data outcomes were censored in June 2012. Comparison of sequential measurements of BP and BS was done using the paired *t*-test. Cumulative probability of lost to follow-up was determined with the Kaplan Meier method and expressed graphically. The level of significance was set at $P < 0.05$ and 95% Confidence Intervals were used. Data were analysed using EpiData Analysis version 2.2.

Ethics

This study met the Médecins Sans Frontières' Ethics Review Board criteria for analysis of routinely collected programme data.

Results

Patient characteristics

A total of 1465 patients were registered in the three clinics between January 2010 and June 2012, of whom 87% were hypertensive only and 13% had DM with or without HT. Enrolment over time is shown in Figure 1. Enrolment for HT has been much greater than for DM and shows no sign of levelling off.

Patient characteristics at enrolment are shown in Table 1. Patients were predominantly female ($n = 1046$, 71%), the median age was 48 years [interquartile range (IQR): 40–55], 353 (24%) were obese (BMI > 30 kg/m²), and mean systolic blood pressure (SBP) and diastolic blood pressure (DBP) were 157.8 mmHg and 98.4 mmHg respectively. Of the 1279 hypertensive patients, 31% had severe hypertension (Grade 3). Among the 180 patients with diabetes, 44% were diagnosed with hypertension. The mean fasting plasma glucose for DM with or without hypertension was 10 mm.

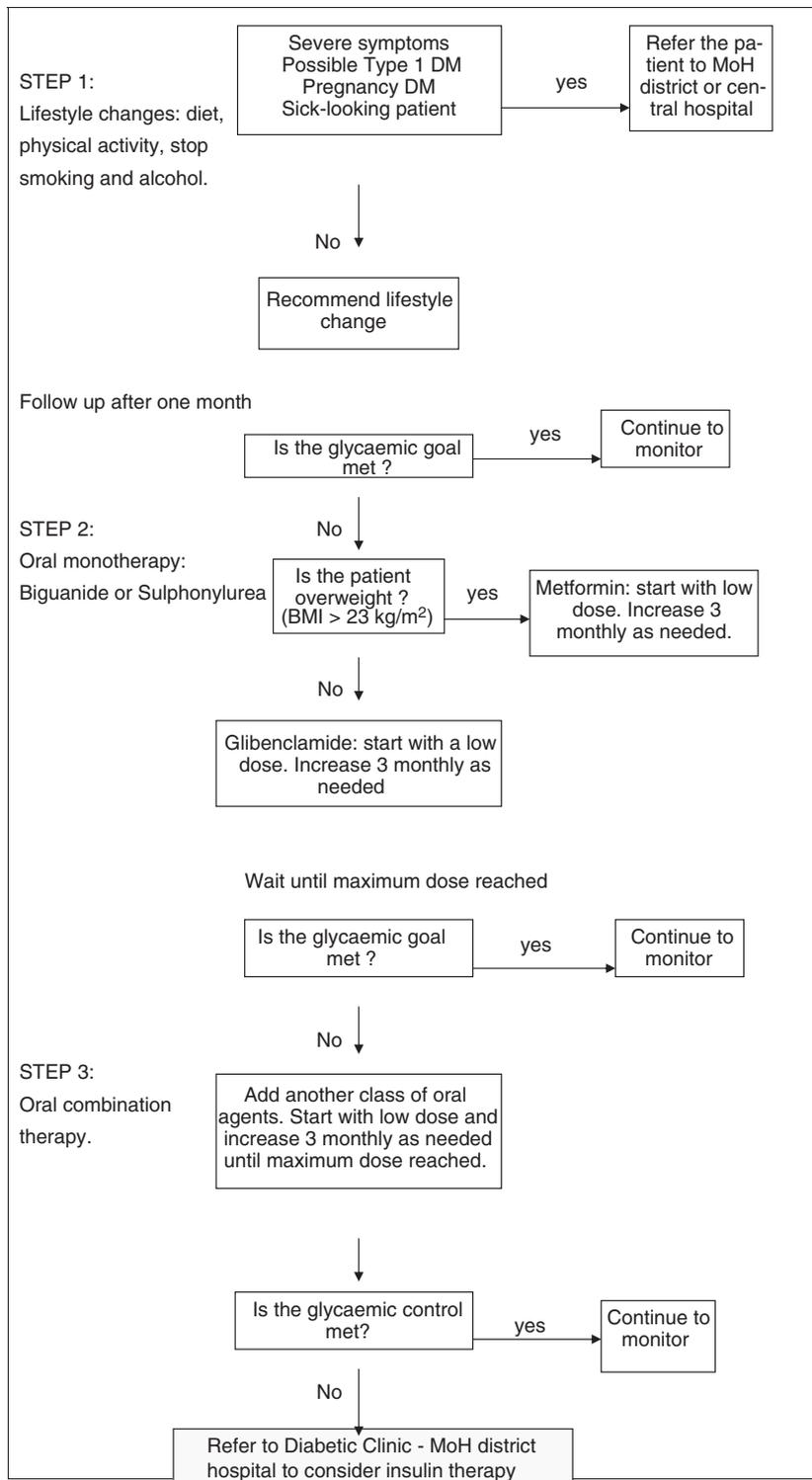
BP control

Regarding BP control, 55% of the 213 non-diabetic hypertensive patients followed up for 24 months reached their BP target, while 28% of the 29 diabetic patients (with or without hypertension) followed up for 24 months reached their target (Figure 2a). Among non-diabetic patients, there was a significant reduction in mean SBP and DBP after the first 3 months of treatment ($P < 0.001$) and this reduction was maintained over the next 18 months of follow-up (Figure 2b).

Blood glucose control

Overall, 20% of diabetic patients with or without hypertension reached their blood glucose target

Box 4 Algorithm for treating diabetes mellitus



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(4.4 < FBG < 6.7 mm) and did so by 3–12 months of follow-up, without changes thereafter. By 18 months, three out of 20 patients (15%) had reached their target (Figure 3).

Very few patients had a HbA1c done and even fewer results were recorded in patients' files. Of the 10 results entered in the database for the patients who had a follow-up at the defined period, none reached their target. The monitoring of the mean values for fasting blood glucose (FBG) over time showed only a minimal improvement and a reduction from 10 mm at baseline (95 patients) to 9 mm by 18 months (20 patients) and 7 mm by 24 months. The improvement observed at 24 months only included three patients.

Cohort outcomes

By the end of the observation period (June 2012), 1003 (68%) patients were alive and in care, one (<1%) had

Box 5 Optimal control indicators for management of DM

Control indicator	Target
Fasting plasma glucose (mm)	4.4–6.7
Blood pressure (mmHg)	<130/80
BMI (kg/m ²)	<25.0 male <24.0 female
HbA _{1c} (%)	<7.0
Total cholesterol (mm)	<5.2

died but the cause of death was not established, eight (0.5%) had transferred out and 453 (31%) were lost to follow-up (LTFU). The treatment outcomes of the whole cohort over time are represented in Figure 4. Most cases LTFU (90%) occurred within the first year after enrolment.

Discussion

To our knowledge, this is among the first reports of the treatment outcomes over time of a cohort of patients with HT and DM treated in a primary care setting in sub-Saharan Africa. It is unique in its integration of these chronic diseases into a system that was already providing routine primary care as well as long-term management of HIV (including anti-retroviral treatment), and TB (including Multi-Drug Resistant TB). The Kibera clinics were dedicated to bringing access to free care close to residents of a large informal settlement and it appears that it was feasible to add these non-communicable diseases to the clinical load.

The treatment outcomes of this large cohort of patients receiving standardised care in primary health care centres in the informal settlement of Kibera are encouraging, in particular for the patients diagnosed with hypertension only. Just over half of the non-diabetic hypertensive patients reached their BP target at 24 months and, overall, there was a significant decrease in BP after the first 3 months of treatment, which was maintained up till 24 months for those still in care. Even if they did not reach targets, it is likely that patients with a decreased

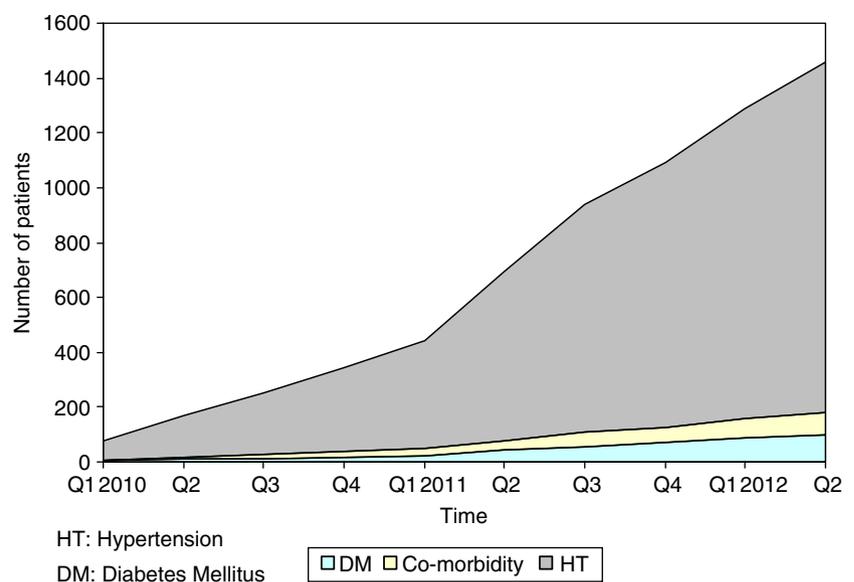


Figure 1 Cumulative number of patients with HT, DM or combined HT and DM enrolled over time, Kibera, Nairobi, Kenya. HT, Hypertension; DM, diabetes mellitus.

A. Sobry *et al.* Hypertension and diabetes mellitus in Kenya**Table 1** Characteristics of patients with HT, DM or combined HT and DM at enrolment in Kibera, Nairobi

Characteristic	Hypertension <i>n</i> (%)	Diabetes <i>n</i> (%)	Hypertension + diabetes <i>n</i> (%)	Total <i>n</i> (%)
Total	1279	100	80	1465
Age (years)				
15–24	29 (2)	2 (2)	0	31 (2)
25–44	495 (39)	33 (33)	14 (18)	545 (37)
45–65	673 (53)	58 (58)	55 (68)	789 (54)
>65	82 (6)	7 (7)	11 (14)	100 (7)
Median (IQR)	47 (40–54)	49 (42–52)	55 (50–62)	48 (40–55)
Sex				
Male	347 (27)	45 (45)	24 (30)	419 (29)
Female	932 (73)	55 (55)	56 (70)	1046 (71)
BMI (kg/m ²)				
<25	534 (42)	54 (54)	24 (30)	618 (42)
2.5–30	378 (30)	20 (20)	28 (35)	426 (29)
>30	311 (24)	16 (16)	26 (32)	353 (24)
Unknown	56 (4)	10 (10)	2 (3)	68 (5)
Median (IQR)	25.8 (22.1–30.1)	23.9 (19.8–28.4)	27.9 (23.7–32)	25.8 (22–30.1)
Total cholesterol (mm)				
<4.5	152 (12)	15 (15)	10 (12)	178 (12)
4.5–6.1	297 (23)	12 (12)	21 (26)	330 (22)
>6.1	112 (9)	1 (1)	14 (18)	127 (9)
Unknown	718 (56)	72 (72)	35 (44)	830 (57)
Median (IQR)	5.2 (4.4–5.9)	4.3 (3.5–5.2)	5.5 (4.6–6.8)	5.2 (4.4–5.9)
Blood pressure (mmHg)				
Systolic, mean (SD)	160.5 (144–175)	127.9 (114–138)	155.1 (137–170)	157.8 (140–173)
Diastolic, mean (SD)	100.4 (91–110)	80.1 (74–85)	91 (83–98)	98.4 (89–108)
Hypertension				
Pre-hypertension	7 (0.5)	NA	0	7 (1)
Grade 1 HT	420 (33)	NA	36 (45)	420 (29)
Grade 2 HT	405 (31.5)	NA	18 (23)	405 (28)
Grade 3 HT	394 (31)	NA	13 (16)	394 (27)
Isolated Systolic HT	53 (4)	NA	13 (16)	53 (4)
Random plasma glucose				
Median (IQR)	4.9 (3.3–5.4)	11.1 (6.7–16)	9.0 (6.2–11)	5.0 (4–7.5)
Type of diabetes				
Type 1	NA	15 (15)	8 (10)	23 (2)
Type 2	NA	83 (83)	71 (89)	154 (11)
Gestational diabetes	NA	2 (2)	1 (1)	3 (0.2)

BMI, body mass index; DM, diabetes mellitus; HT, hypertension; IQR, interquartile range.

BP gained some clinical benefit, with reduced risks for cardiovascular disease and mortality (Mancia *et al.* 2007; Messerli *et al.* 2007). BP control among diabetic patients (with or without hypertension) was not as positive when compared with hypertensive patients only. Stricter BP targets (130/80 *vs.* 140/90) may partially explain the difference, in addition to the fact that effective BP control can be more difficult to achieve in with diabetes as a co-morbidity. The reasons for less-than-optimal blood pressure outcomes are multi-factorial and probably include difficulties to adhere to lifestyle modifications, including

weight control, lack of adherence to medications and lack of treatment optimisation by the clinicians.

A smaller proportion of diabetic patients reached their blood glucose targets (20%) and it remained unchanged even after 12 months of follow-up. There was only a minimal improvement in mean fasting blood glucose throughout the 18-month follow-up period. Although monitoring of diabetic patients with glycosylated haemoglobin levels was theoretically part of the protocol, it was rarely done and needs to be encouraged by the programme in future. Possible reasons for the poor control

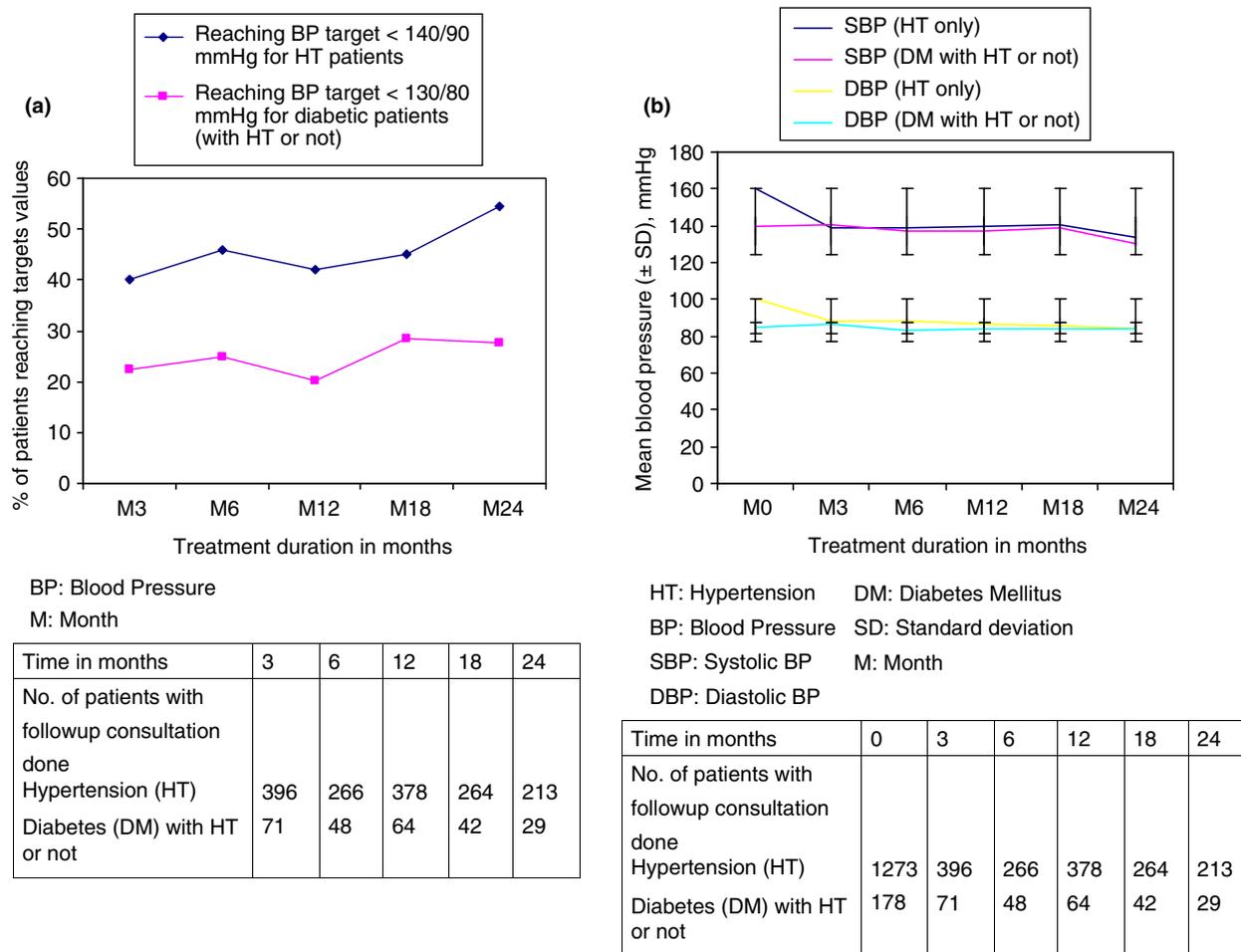


Figure 2 (a) Proportion of patients reaching their blood pressure targets at specific time points after starting treatment, Kibera, Nairobi. (b) Evolution of mean blood pressure (with standard deviation) of patients under treatment, Kibera, Nairobi. HT, hypertension; BP, blood pressure; SBP, systolic BP; DBP, diastolic BP; DM, diabetes mellitus; SD, standard deviation; M, month.

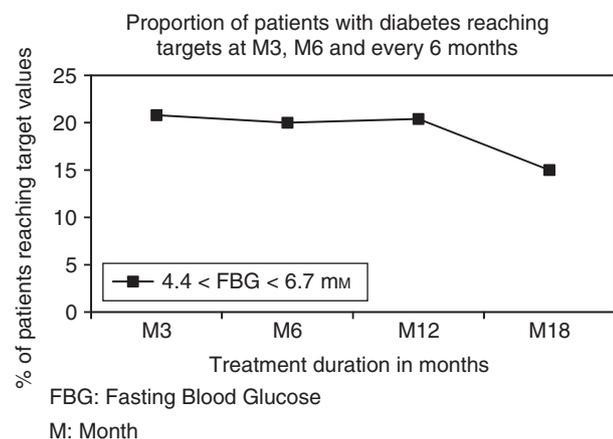
of diabetes among patients in Kibera are multifactorial and may include the following: late detection of diabetes, difficulties adhering to lifestyle modifications, especially weight control, poor adherence to medications (even when provided free), difficulties in accessing insulin when indicated and less than optimal treatment by clinicians.

Our study cohort had 71% female patients, which is higher than reported in studies from other developing countries (Addo *et al.* 2007). The main reasons for this in Kibera is likely due to the fact that more women than men attend health facilities on account of the fact that they are usually the ones accompanying sick children or are coming to access reproductive health services.

A significant finding was that the cumulative enrolment of patients over 30 months was quite rapid and showed

no signs of levelling off at the conclusion of the study. The effect of a growing cohort of NCD patients on workload has important implications for future planning of human resources, clinic space and supplies.

The high LTFU rate (30%) observed at the end of the study period is close to the one documented for the HIV/AIDS patients treated in the same primary health care setting despite free medical care. Although disappointing, this is better than that reported from two Cambodian studies of HT and DM in a specialised clinic setting (Raguenaud *et al.* 2009; Isaakidis *et al.* 2010). While we do not have data to substantiate our speculation, the high rate of LTFU in Kibera is likely to be a reflection of (i) the highly transient population of Kibera and the competing interests of work and survival in such a setting, and



Time in months	3	6	12	18
No. of patients with FBG recorded	48	25	49	20

Figure 3 Proportion of patients with diabetes reaching their blood glucose targets at specific time points after starting treatment, Kibera, Nairobi. FBG, fasting blood glucose; M, month.

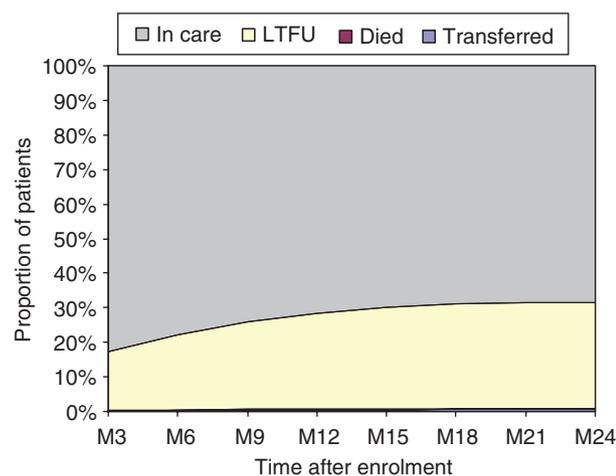


Figure 4 Treatment outcomes of the whole cohort over the study period (January 2010-June 2012), Kibera, Nairobi.

(ii) lack of awareness of the disease(s) coupled with lack of adherence to treatment in the long run. However, the provision of free medications probably helped to sustain the cohort over time.

This study had a number of strengths. The sample size was quite large for HT patients, data were prospectively collected and verified, and specific monitoring tools were

developed. Moreover, this study demonstrated a feasible model for managing NCD in a primary care setting. Standardised, treatment protocols were developed, staff were trained, patient flow was addressed, counselling was available and medications were provided for free. Improvement of documentation in the programme might be achieved using techniques recently described that relied on DOT-based monitoring and electronic records (Khader *et al.* 2012a,b).

This study had certain limitations. Although specialised monitoring tools were implemented (EpiData-based), it was clear that not all clinicians used them conscientiously and since they were paper-based, there was some loss of data. Monitoring of complications at baseline and during follow-up was poorly documented and did not allow interpretation. High rates of LTFU, aside from their programmatic implications, precluded accurate assessment of all patient outcomes. Furthermore, the short-term 30 months monitoring did not permit us to assess if there has been a reduction in morbidity (occurrence of complications) and mortality.

We acknowledge that we mainly used biological measurements as surrogate markers for DM and HT treatment outcomes. We also acknowledge that regression to the mean and habituation to repeated BP measurements could have had an effect on the decrease in BP observed during follow-up. Without control groups, the specific effect of pharmacological treatment cannot be fully assessed. Lastly, deaths were likely underestimated in our cohort and misclassified as LTFU, as we were not able, due to limited resources, to trace defaulters.

For both types of patients, information, education and empowerment are important for improving follow-up and outcomes, and for helping to manage the growing cohort. To cope with the ever-growing cohort, a simplification of the medical management should be planned and community self-support groups, as for HIV patients, should be developed. For hypertensive patients in particular, a greater focus on higher risk groups (Grade 3 HT) could help to reduce morbidity and mortality.

In conclusion, our findings demonstrated that HT and DM can be effectively managed in a primary care setting in sub-Saharan Africa. In view of the growing burden of NCDs in the developing world, this model of care delivery may provide a way forward in similar settings.

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