

# Is point of care testing for anaemia (Hb) and microalbumin feasible in people with type 2 diabetes attending diabetes outpatient clinics?

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## Abstract

**Introduction:** Diabetes is the major cause of chronic kidney disease (CKD) in Australia. Anaemia of CKD occurs earlier than in non-diabetics and is often insidious and undetected.

**Aim:** A large, prospective, single-centre study was undertaken to determine the feasibility of point of care testing (POCT) haemoglobin (Hb) and microalbumin in people with type 2 diabetes (T2DM) attending routine outpatient clinic appointments (OPC).

**Method:** Clinic nurses measured Hb and microalbumin using the HemoCue Haemoglobin Capillary Analyser and the HemoCue Urine Albumin Analyser (Medipac Scientific), respectively when they tested blood glucose, weight and blood pressure. The nurses were trained to use the analysers before the study commenced. Standard demographic data, duration of diabetes, treatment mode, and presence of complications, comorbidities, and HbA<sub>1c</sub> were ascertained from patients' medical records.

**Results:** Five hundred and fifty-four (80%) patients were screened. The nurses were able to perform the tests competently but testing, especially microalbumin, was time-consuming. Patients' mean age was 62 years (11 SD): 230 females, mean blood glucose (BG) 10 (3.9 SD) mmol/L, mean haemoglobin 127.2 (16.3 SD) g/L; mean microalbumin 47.8 (58.7 SD) mg/L: 324 were males, mean BG 10.2 (3.9 SD) mmol/L, mean Hb 138.6 (18.8 SD) gm/L, and mean microalbumin 67.9 (73.9 SD) mg/L. 27% of males and 22% of females were anaemic. Of those with anaemia, 27% of females and 29% of males had microalbuminuria.

**Conclusions:** POCT is feasible in routine outpatient clinics but is time-consuming. One in four T2DM attending OPC were anaemic. POCT Hb testing in OPC is feasible and could identify T2DM who need full haematological assessment.

## Keywords

Type 2 diabetes, anaemia, microalbuminuria, point of care testing, screening.

## Introduction

Diabetes is a significant cause of chronic kidney disease (CKD) and there is an increased risk of anaemia in type 2 diabetes (T2DM) with CKD (Thomas *et al.*, 2005; Al-Khoury *et al.*, 2006; National Institute for Clinical Excellence (NICE) 2006; Mostafa *et al.*, 2009). CKD and diabetes are increasing globally. Rates of anaemia associated with diabetes-related CKD range from 11% to 23% (Thomas *et al.*, 2004; Craig, 2005; Cawood *et al.*, 2006) with higher rates in females in some studies (Cawood *et al.*, 2006; Li Vecchi *et al.*, 2007). Other researchers report higher rates in males (Craig *et al.*, 2005) but the reason for the difference between the genders is unclear. CKD occurs in both

type 1 (T1DM) (Thomas *et al.*, 2004) and T2DM diabetes and the pathogenesis is similar in both types (Stanton, 2000).

Erythropoietin (EPO) concentration is predictive of the rate of progression of CKD; however, epidemiological studies do not show lower haemoglobin (Hb) in people with diabetes (PWD) without renal disease (Dikow *et al.*, 2002). However, PWD with anaemia have more severe CKD than those without anaemia, and the anaemia occurs at an earlier stage than in non-diabetics with similar disease severity (Bosman *et al.*, 2002; Li Vecchi *et al.*, 2007; Mostafa *et al.*, 2009). In fact, anaemia is common in the early stages of diabetes-related kidney disease and Hb is lower by an average of 10 g/dL at every level of renal function in PWD compared to non-diabetics (Al-Khoury *et al.*, 2006).

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CKD is primarily microvascular in origin. It frequently occurs with other diabetic vasculopathies and is associated with the duration of diabetes. In addition, pre-existing retinopathy is present in 90% of people with CKD, especially those with T1DM (Thomas *et al.*, 2004). Microalbuminuria is an early clinical manifestation of CKD, and is also a predictor of vascular risk, and an early marker of early death from cardiac disease. If treatment is not instituted, 20%–40% PWD develop overt CKD. The onset and progression of CKD correlates with glycaemic control. Normalising blood glucose slows the onset and progression of CKD (Diabetes Control and Complication Trial (DCCT) 1993; Marks & Raskin, 1998) in addition to improving cardiovascular status by controlling blood pressure and smoking cessation (Locatelli *et al.*, 2004).

Anaemia is defined as Hb < 13 g/dL in males and < 12 g/dL in females (World Health Organization (WHO) 2008). Significantly, anaemia is often symptomless, apart from lethargy, which can be attributed to hyperglycaemia, depression, increasing age and other causes. The symptoms vary with the speed of onset and the Hb level: the lower the Hb the more severe the symptoms. Diabetes-related anaemia is usually normocytic and normochromic and may be due to several interrelated causal mechanisms.

PWD are twice as likely to be anaemic than non-diabetics with renal disease from other causes: at least one in five DM attending outpatient clinics is anaemic (Thomas *et al.*, 2006). Li Vecchi *et al.* (2007) found higher anaemia rates in PWD with stages four and five CKD (16%) than non-diabetics, and females had lower Hb levels than males. Likewise, in the KEEPS study (Obrador *et al.*, 2010) 27% of 5380 participants had diabetes: 11.6% were anaemic compared to 6.35% of non-diabetics. In addition, anaemia is prevalent in residents in aged care facilities for various reasons including nutritional deficiencies, hypertension and multiple comorbidities, diabetes and renal and vascular disease (Resnick, 2009).

Anaemia affects physical performance, possibly due to reduced red cell oxygen carrying capacity leading to tissue hypoxia, which puts the individual at risk of reduced muscle strength and falls. Mood and quality of life are also affected. It is possible that early detection and instituting preventative management strategies such as optimising iron levels, excluding and correcting reasons for blood loss and education could improve patient outcomes. Improved quality of life, increased exercise capacity and reduced ventricular hypertrophy have been demonstrated in patients with cardiovascular disease when anaemia is treated (MacDougall, 2000). Other benefits include improved cognitive function (Lawrence *et al.* 1997) and wellbeing, which could be partly due to attending to underlying pathologic processes early and throughout the person's life (van Ypersele de Strihou, 1999).

Recognising renal anaemia early could improve all these issues. However, anaemia screening is not routinely performed as part of diabetes complication screening, although such screening may occur during acute illnesses such as myocardial infarction and infection (Al-Khoury *et al.*, 2006). Point of care testing (POCT) makes routine screening more achievable and is an alternative to laboratory investigations for a number of health parameters such as HbA<sub>1c</sub>, microalbuminuria, International Normalised Ratio (INR) and anaemia. POCT refers to analytical tests performed

outside the laboratory (Kost, 2002). POCT is equivalent to laboratory testing for HbA<sub>1c</sub>, urine albumin, albumin-creatinine ratio, total cholesterol and triglycerides (Bubner *et al.*, 2009).

POCT enables clinicians to have access to key information at the time of the consultation, which helps them detect risk parameters early. It is particularly useful for non- and irregular health care attendees, and can be used to involve patients in their care. Thus, POCT can facilitate proactive disease monitoring, clinical decision-making, and timeliness of interventions, which can improve outcomes (Bubner *et al.*, 2009). However, routine POCT Hb testing might not be feasible in diabetic outpatient clinics. Currently, clinic nurses routinely weigh patients and measure their blood glucose and blood pressure and record the results in the medical record before the diabetologist and/or diabetes educator and dietitian assess the patient. The impact of the extra screening on clinic nurses' workload is not clear.

### Aim of the study

The aim of the study was to explore the feasibility of POCT Hb and microalbumin in people with T2DM attending routine outpatient clinic appointments (OPC).

### Method

#### Clinic nurse role and training

The three regular clinic nurses participated in the prospective, single-centre study. The nurses were all female and had worked in the diabetes clinic for at least four years. Their regular role includes weighing each patient, testing capillary blood glucose, testing blood ketones if the individual is hyperglycaemic (especially T1DM) and measuring the blood pressure before the clinicians assess the patient. In order to address the study aim, the clinic nurses tested Hb and microalbumin in diabetic clinic attendees using the HemoCue Haemoglobin Capillary Analyser and the HemoCue Urine Albumin Analyser (Medipac Scientific), respectively, over three months (April to June 2009).

The analysers are photometric devices with established sensitivity and specificity in a range of populations and conditions (Sari *et al.*, 2001; Nuefield *et al.*, 2002). The analysers were subject to routine quality assurance testing by the hospital laboratory staff during the current study to ensure they read within the recommended reference range. The test protocol was based on the Australian Government Department of Health and Aging (DOHA) (2004) POCT standards. However, sensitivity and specificity testing was considered unnecessary.

The three nurses were trained to obtain blood and urine samples and to measure Hb and urine using the HemoCue analysers, prior to commencing the study. Training consisted of the HemoCue representative demonstrating the correct technique for each test; each nurse then independently performed Hb and microalbumin tests until they accurately performed six consecutive Hb and six consecutive microalbumin tests correctly. The HemoCue representative attended the clinic for the first week of the study to provide advice and support, if required.

The nurses collected capillary blood for Hb tests at the same time they collected blood for glucose testing, usually from the same finger-prick site. Patients were provided with a labelled sterile urine container and asked to collect a urine sample, which they gave to the clinic nurse for microalbumin analysis.

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The results of all tests were recorded in the study database and the patient's medical record and were available to the clinicians during the consultation.

At the end of the three months' data collection period, all three clinic nurses participated in brief, individual, open interviews to explore their perceptions of the usability of the devices and the feasibility of continuing routine Hb and microalbumin testing in the clinic, in addition to routine blood glucose, weight and blood pressure monitoring. One researcher, experienced in interview techniques, conducted the interviews. The interviews were audio-taped and transcribed verbatim before being de-identified and analysed. Each interview took approximately 15 minutes (longer time was not available in the busy clinic setting).

### Patient sampling population and sample

The patient sample consisted of T2DM attending their routine diabetic outpatient clinic appointments during the study period. The majority is over 40 years and has a range of durations of diabetes and multiple diabetes complications (vascular disease, retinopathy, nephropathy and neuropathy). A range of cultures attends, predominantly Greek, Italian, Vietnamese, Turkish and Australian. Diabetes is treated according to individual needs with diet and exercise, oral hypoglycaemic agents (OHA), insulin or a combination of these treatments.

Between 50 and 60 patients attend each clinic and clinics are held weekly. A convenience sample was recruited. The clinic nurses invited patients to participate when they presented for routine pre clinic screening. If necessary, an interpreter explained the study to the patient. Standard demographic and biochemical data were collected from the patient's medical record and included: age, gender, duration of diabetes, complications present, blood pressure, HBA<sub>1c</sub>, lipids, microalbuminuria, proteinuria and GFR by creatine clearance.

### Data analysis

The nurse interview data were analysed using the framework method (Ritchie & Spencer, 1994). This method consists of a five-step process that involves reading and rereading each transcript line-by-line to become familiar with the data and to identify frequently occurring words and possible themes. The emerging themes were then indexed and grouped into key themes. Two researchers independently analysed the transcripts by hand, identified themes and then met to discuss their findings and reach consensus.

Patient data were entered into a Statistical Package for the Social Sciences (SPSS) 15.0 software (SPSS Inc., Chicago, IL) for analysis. Descriptive statistics including percentages range, mean and standard deviation were calculated. Relationships between demographic and biochemical variables were assessed using Pearson's correlations, t-tests, and Chi square tests. The significance level was set at  $p < 0.05$ . Mean and standard deviation (SD) are shown in the results,

### Ethical considerations

The hospital Human Research Ethics Committee deemed the study to be a quality improvement process added to usual practice. The clinic nurses invited people to participate and contained their verbal consent before they tested Hb and microalbumin.

## Results

### Clinic nurse interviews

Three main themes emerged from the clinic nurse interview data: it takes time; we can do it, and training is essential at the beginning.

#### It takes time

All three nurses indicated they had no difficulty operating the analysers after training but the additional tests took extra time during the already busy clinic screening time, which the nurses felt would make routine Hb screening difficult to sustain in the long term, unless extra resources were available. One nurse said:

*We can do the tests, no worries, but it takes time and the doctors will be asking why the patients are not ready. If we have to keep doing it [Hb and microalbumin testing] we need more staff.*

Another nurse explained that testing Hb was not such a problem because the nurses routinely pricked the patient's finger to obtain a drop of blood to test glucose, but described testing microalbumin as a "nuisance".

*It's more a problem with the microalbumin because you have to explain how to collect the urine, [to the patient] then they go to the toilet and come back and that takes time because they are not used to it [urine testing].*

Having to explain the extra tests to patients who were not proficient in English also took time, and compromised interpreter time; for example:

*A lot of them [patients] can't speak English so it is difficult making them understand the new test. So you have to call the interpreter and they are busy too.*

Despite these limitations, the nurses felt they were able to accurately undertake the tests.

#### We can do it

The three nurses were very confident in their ability to accurately perform Hb and microalbumin tests after the initial training. All three indicated they could continue to undertake the tests in addition to the usual tests, if resources were available, for example:

*We can do it, [perform the tests] and we are accurate, but we need more resources, more time, more staff if we have to do it all the time.*

#### Training is essential in the beginning

The three nurses indicated that training was essential to their ability to accurately perform the tests. As indicated, two of the three nurses felt microalbumin testing was more difficult than Hb testing until you "get the hang of it", for example:

*It looks pretty easy really and the Hb is I suppose, but the microalbumin is not so easy. It took me a while, more goes than the Hb, to get the hang of it and get six tests in a row correct.*

### Patient data

Six hundred and eighty people attended the clinic during the study period, all had T2DM: 544 were (80%) were screened. Of the 544 people screened, 230 were females; average blood glucose 10 (3.9 SD) mmol/L, Hb 127.2 (16.3 SD) g/L, microalbumin 47.8 (58 SD) mg/L: 324 were males average

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blood glucose 10.2 (3.9 SD) mmol/L, Hb 138.6 (18.8 SD) g/L and microalbumin 67.9 (3.9 SD) mg/L. The mean age was 62 years (11.1 SD). Mean duration of diabetes 13.4 years, range new diagnosis to 30 years.

All participants had at least one diabetes-related complication: most had more than three. Medicines included oral hypoglycaemic agents, insulin and a combination of oral hypoglycaemic agents and insulin as well as lipid lowering and antihypertensive agents. The total proportion of the sample that was anaemic was 0.27: 95% CI (range 0.23 to 0.30).

Overall, 25% were anaemic: 22% of females and 27% of males. Of these, 29% of females and 27% of males had microalbuminuria. There was no significant association between age, duration of diabetes, treatment mode and Hb or microalbuminuria ( $p > 0.05$ ). The total proportion of the sample with microalbuminuria was 0.29: 95% CI (range 0.25 to 0.32).

### Discussion

This large prospective study indicates that POCT testing for anaemia and microalbumin is feasible in outpatient clinic settings. Our study shows outpatient clinic nursing staff can be trained to accurately operate the analysers and perform Hb and microalbumin tests in addition to their usual clinic role. However, the extra tests, especially microalbumin, were time-consuming to perform and extra time and resources may be needed to achieve optimal screening in OPC settings. For example, 136 people attending the OPC during the study period were not screened, mostly because of time constraints. Alternatively, existing clinic routines could be reorganised. For example, blood pressure could be measured by the doctors during the consultation, rather than the clinic nurses. Likewise, time-related problems may not be such an issue in clinics that do not have a high proportion of non-English speaking patients.

POCT testing for a number of clinical indicators has increased rapidly in the past decade and is now routinely undertaken in health services and by patients at home as part of diabetes self-management, for example blood glucose. Unreliable POCT results that could put patients at risk have been reported and are largely due to inadequate quality testing and equipment maintenance (Jahn & Van Aken, 2003). The HemoCue Hb meter used in our study is reliable compared with direct cyanmethaemoglobin in venous blood, allowing for the slightly lower red cell volume in capillary blood (1–3% lower) (Sari *et al.*, 2001).

Other researchers confirm Hb measured using the HemoCue analyser provides an adequate estimation of the prevalence of anaemia, providing the population and site conditions are considered (Neufield *et al.*, 2002). Analyser reliability and specificity testing were outside the scope of the current study. However, routine quality control testing was performed on the analysers by the laboratory staff during the study in line with quality management practices in the hospital, for example blood glucose meter maintenance procedures. In addition, training the nurses to perform the tests accurately before the study commenced was important to achieve reliable results. A further study to confirm the accuracy of the clinic nurses' testing technique by comparing POCT values with laboratory values is required.

Twenty-seven per cent of females and 22% of males in our clinic were anaemic, which is consistent with rates reported by Li Vecchi *et al.* (2007) and Al-Khoury *et al.* (2006). However, it is higher than 16% Mostafa *et al.* (2009) reported. None of these studies used POCT. The differences in anaemia rates could be due to unknown differences in the sampling populations and/or differences between laboratory and POCT values.

Anaemia screening is not usually undertaken as part of established diabetes complication screening procedures in the clinic, even when the patient has declining kidney function, POCT Hb and microalbumin testing does not occur in most other Australian diabetes OPCs. However, diabetes complication screening and management guidelines, including those for diabetic renal disease, do not include screening for anaemia, which could influence clinical practice. For example, Hb is not mentioned in *Diabetes Management in General Practice* (RACGP and Diabetes Australia 2011–12), which most Australian general practitioners refer to. Likewise, the Joslin Diabetes Centre *Screening and Treatment Recommendations for Micro- and Macroproteinuria* (Korenman & Khan, 1999) does not recommend Hb screening. Laboratory albumin, but not POCT albumin testing is recommended in these guidelines.

Mild anaemia, like microalbuminuria and retinopathy, is usually symptomless. Proactively screening to detect microvascular disease is standard practice. It could also be useful to routinely screen for anaemia to enable haematological investigations such as iron, vitamin B12, folate, and most importantly, infection to aid treatment decisions at the point of care. Our study suggests Hb and microalbumin POCT testing is feasible if staff members are trained and adequate time is available. This is an important finding, given the Australian Government focus on managing T2DM in primary care and the important role practice nurses play in educating people to self-manage their diabetes, including complication screening.

The growing knowledge about the biological basis of diabetes and its complications and the increasing range of new medications and technology represents increasing opportunities for implementing risk reduction strategies, prevention and early treatment. Screening, preventing and communicating risks to relevant individuals are essential elements of risk reduction (Kuriyama *et al.*, 1997). Research into diabetes risk communication is limited: what research there is suggests many people are not aware of their individual risks or how to reduce them, and this may be particularly relevant to the risk of anaemia.

However, while screening for anaemia is desirable, management once anaemia is detected is less clear. Various clinical measures are used to prevent or slow the progression of diabetic CKD and may also slow or prevent the development of renal anaemia. Until recently erythrocyte stimulating agents (EPO) were advocated to treat CKD-related anaemia; however, recent research suggests higher Hb targets and the erythropoietic (ESA) regimens used to achieve the targets may be harmful (Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT) Pfeffer *et al.*, 2009). TREAT demonstrated small improvements in energy and quality of life but there was an increased risk of stroke in DM with CKD and Hb target 12.5 gm/L.

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Publication of the TREAT findings sparked a debate about the risks and benefits of current CKD-related anaemia management guideline recommendations. Subsequently, the US Food and Drug Administration (FDA) convened a public advisory committee in 2010 to examine the use of EPO in managing anaemia associated with CKD. Likewise, various experts recommended undertaking randomised controlled trials to determine optimal Hb targets and management regimens for managing anaemia in CKD (Goldsmith & Covic, 2010; Unger *et al.*, 2010). Once completed, current guideline developers such as the National Kidney Foundation Disease Outcomes Quality Initiative (KDOQI) and Kidney Disease: Improving Global Outcomes (KDIGO) and diabetes organisations might need to review their recommendations. Our study, combined with other research, suggests diabetes guideline developers might need to consider including Hb testing in existing diabetes complication screening guidelines when they are reviewed.

Managing anaemia associated with diabetes-related CKD is complicated. Determining the cause of mild asymptomatic anaemia and proceeding to identify reversible factors may be cost-effective and improve outcomes, if instituted early. Nutritional review and regular Hb monitoring may be useful to differentiate lethargy from other causes such as hyperglycaemia and detect and treat anaemia early. Contributing or confounding factors such as excess alcohol intake, which reduces folate and vitamin B12 levels and exacerbates existing anaemia, chronic blood loss and gastrointestinal disease, which can affect the absorption of essential nutrients, and medication review to determine whether medicines such as aspirin and non-steroidal anti-inflammatory agents and metformin could be underlying contributory factors, need to be considered. We did not assess these factors in our study but they could easily be incorporated into a risk screening tool that could be completed when the POCT Hb test is performed. However, such a tool would need to be validated.

### Implications of the findings

- Routine anaemia screening in diabetes outpatient clinics is feasible and nurses can be educated to accurately perform POCT Hb and microalbumin tests, but testing is time-consuming and adds to the workload, especially if patients are not proficient in English.
- Training staff to ensure they are competent to use the analysers, is important.
- People with diabetes attending routine diabetic outpatient clinics have high rates of anaemia. Rates are likely to be similar in general practice settings, thus, POCT Hb testing could be considered in general practice settings.
- Research to determine the cost benefit of including POCT Hb testing in current diabetes management guidelines would be useful, but was not part of our study.

### Strengths and limitations of the study

The strength of the study lies in the large sample size and the fact it was undertaken in a “real life” clinical setting with a heterogeneous group of participants. The limitations include the lack of a control group; however, the study was designed

to test the feasibility and usability of POCT in routine clinical practice. It is not clear whether the 136 PWD who were not screened were different from the 544 who were screened but the demographic data obtained in the study is similar to random samples undertaken in the same OPC in other studies, thus they are unlikely to be significantly different. There could be other explanations for the anaemia besides CKD. The possible reporting bias and lack of a validation of the nurses' POCT tests with laboratory values are also limitations of the study.

The microalbumin mean and SD data we presented suggests there was a wide range of values and the median and IQ range should have been used.

### Conclusions

Clinic nurses can be trained to competently undertake POCT anaemia and microalbumin screening but such screening is time-consuming and adds to the nurses' workload. There was a significant prevalence of anaemia in our clinic population and a significant percentage of people with anaemia had microalbuminuria. The high prevalence of anaemia is consistent with several previous studies and suggests there could be a need for routine Hb testing in people with diabetes, especially those CKD.

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### Conflict of interest

No conflicts to declare.

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