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Short Communication

The utility of point-of-care haemoglobin A1c tests in a very remote Aboriginal and Torres Strait Islander community: an agreement analysis with routine laboratory testing

AUTHORS


Hasthi Udyangani Wanamali Dissanayake[1] PhD, Research Fellow *

Sabine Braat[1,2] Associate Professor [https://orcid.org/0000-0003-1997-3999]

George Gurruwiwi[1,3]

Ruth Gulamanda[1] Indigenous Research Leader

Josh C Tynan[1] Senior Project Officer

Lindy Marlow[1]

Benjamin Harrap[4] Research Fellow [https://orcid.org/0000-0002-0889-6214]

Kenny Gongnini[1]

John M Wentworth[2,5,6] [https://orcid.org/0000-0002-5197-3529]

Lou Sanderson[7]


Beverley-Ann Biggs[1,8] MBBS, FRCP, FRACP, PhD, Head, Global and Indigenous Health Group [https://orcid.org/0000-0002-2961-9793]

CLAN Study Group

CORRESPONDENCE

* Hasthi Udyangani Wanamali Dissanayake hasthi.dissanayake@unimelb.edu.au

AFFILIATIONS

[1] Department of Infectious Diseases, Peter Doherty Institute for Infection and Immunity, The University of Melbourne, Melbourne, Vic. 3000, Australia

[2] Division of Population Health and Immunity, The Walter and Eliza Hall Institute, Parkville, Vic. 3052, Australia

[3] Northern Institute, Charles Darwin University, Darwin, NT 0800, Australia

[4] Yardhura Walani, National Centre for Epidemiology and Population Health, Australian National University, Canberra, ACT 2601, Australia

[5] Department of Medical Biology, The University of Melbourne, Parkville, Vic. 3052, Australia

[6] Department of Diabetes and Endocrinology, Royal Melbourne Hospital, Parkville, Vic. 3052, Australia

[7] Miwatj Health Aboriginal Corporation, Galiwin'ku, NT 0822, Australia

[8] The Victorian Infectious Diseases Service, Royal Melbourne Hospital, Parkville, Vic. 3050, Australia

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Abstract

Introduction: Optimal blood glucose control is critical to the prevention of diabetes complications. Point-of-care testing (POCT) provides a flexible alternative to conventional approaches that rely on laboratory processing of venous blood samples, with variable time to receiving results. We determined the level of agreement between the A1CNow+ glycated haemoglobin POCT system and routine laboratory haemoglobin A1C (HbA1c) testing in a remote Aboriginal Australian community.

Methods: HbA1c was measured in Aboriginal and Torres Strait Islander adults using capillary blood and the point-of-care device and venous blood using standard laboratory procedures. Agreement between the point-of-care and laboratory results was examined using a modified Bland–Altman analysis and diagnostic agreement for type 2 diabetes using Cohen's kappa coefficient. Capillary and venous blood collection were conducted in a clinical setting.

Results: Participants (n=49) were on average age of 43±10 years, 65% were female, and with mean BMI of 30±5 kg/m^2. Median HbA1c was 5.7% (39 mmol/mol) for both methods of measurement. The mean difference between the A1CNow+ point-of-care test and laboratory HbA1c measurement was 0.03% (0.34 mmol/mol), with limits of agreement of –0.75 to 0.81% (–8.15–8.83 mmol/mol). Diagnostic agreement for type 2 diabetes (HbA1c ≥6.5% (48 mmol/mol)) was moderate (Cohen's kappa statistic 0.70), with minor discrepancies observed at higher HbA1c levels.

Discussion: These findings support the clinical usefulness of portable HbA1c point-of-care testing beyond traditional clinic settings. While clinic-based models have improved diabetes care, they do not reach all remote communities effectively. Home-based outreach health care utilising A1CNow+ point-of-care testing may improve access to care, strengthen family engagement, and reduce cultural and logistical barriers. Despite sparse data at HbA1c levels greater than 55 mmol/mol, overall benefits appear meaningful.

Conclusion: Capillary measurement of HbA1c using a portable point-of-care device demonstrated promising agreement with routine laboratory-tested venous blood HbA1c. This supports the development of novel outreach models of diabetes care that meet remote Aboriginal and Torres Strait Islander community needs.

Keywords

Aboriginal and Torres Strait Islander, Australia, blood glucose, point-of-care testing, type 2 diabetes.

Introduction

The Yolŋu People of North East Arnhem Land are one of Australia's oldest continuing cultures and maintain strong cultural traditions and knowledge systems. North East Arnhem Land is a geographically vast region of approximately 40,000 km² comprising numerous remote communities, homelands and island settlements accessible primarily by air or seasonal road transport. Yolŋu communities experience substantial health inequities, which have contributed to some of the highest rates of avoidable mortality in Australia, predominantly due to cardiovascular disease[1]. This is a consequence of Australia's history of colonisation, which has led to culturally inappropriate and unsafe healthcare settings[2]. This disparity is particularly acute in remote areas of Australia[2], where healthcare services delivered through remote primary healthcare clinics often face ongoing workforce and infrastructure challenges, making timely access to pathology testing and specialist services difficult.

Type 2 diabetes is a key modifiable risk factor for cardiovascular disease, and the best outcomes are achieved with early diagnosis and management to prevent health complications. However, managing diabetes in remote areas is challenging. The Yolŋu region of East Arnhem consists of six main communities and their health centres, which are on average 627 km from the nearest laboratory, making access to pathology results and follow-up of patients logistically challenging. We have observed that many clinics in the region are chronically understaffed, and patients may have limited opportunities to discuss results, ask questions and engage in shared decision-making regarding type 2 diabetes and cardiovascular disease prevention and management[3]. Therefore, a need for approaches such as portable point-of-care testing (POCT) for haemoglobin A1c (HbA1c) that can be applied in supportive outreach settings (eg home-based) are required.

Accordingly, we examined the agreement between the portable A1CNow+ glycated haemoglobin POCT system (PTS Diagnostics; https://www.ptsdiagnostics.com/a1cnow-training) and routine laboratory HbA1c testing in a very remote North East Arnhem Land community.

Methods

In 2022, we undertook a single-arm pre–post intervention trial in overweight and obese Aboriginal and Torres Strait Islander adults living in a remote Yolŋu community in North East Arnhem Land, Northern Territory (trial registration ACTRN12622000174785)[4]. The intervention was a novel, co-designed 4-month nutrition and lifestyle program centred around traditional knowledge and practices. The team included Yolŋu and non-Indigenous researchers who had worked together previously. Study design, implementation and interpretation were informed by Yolŋu leadership, local knowledge and community priorities. Full methodology and inclusion and exclusion criteria have been reported elsewhere[4]. In this analysis we examine the agreement between point-of-care capillary HbA1c and routine laboratory HbA1c testing in this remote setting. Data collection for this occurred from 7 November to 14 December 2022. Participant eligibility included those with a post-intervention point-of-care capillary HbA1c and a venous blood sample.

Post-intervention capillary and venous blood samples for HbA1c testing were collected in the non-fasting state by a registered nurse during the same clinic visit. A 5 µL sample of capillary blood was obtained and HbA1c measured using the A1CNow+ POCT system, according to manufacturer guidelines[5]. This device measures HbA1c immunochemically, producing a result within 5 minutes, and results can be given to participants during the same clinic visit. The A1CNow+ system performs more than 50 internal electronic and chemical quality control checks during each analysis. Device quality assurance was undertaken in accordance with the manufacturer's recommendations and site-specific standard operating procedures to ensure appropriate performance throughout the study period[5-7]. Venous blood samples were drawn into EDTA anticoagulant-containing tubes and stored at 4°C before being sent to Western Diagnostic Pathology, Perth, Australia, for testing using routine procedures. Agreement was examined using a modified Bland–Altman analysis, presenting the systematic bias and observed limits of agreement, and diagnostic agreement for HbA1c≥6.5% using Cohen's kappa coefficient[8,9].

Ethics approval

This study followed the National Health and Medical Research Council ethical guidelines for research with Aboriginal and Torres Strait Islander Peoples. The Northern Territory Health and Menzies School of Health Research Human Research Ethics Committee approved the study protocol (HREC:2021-4166).

Results

Point-of-care capillary HbA1c was measured in 52 participants and laboratory venous HbA1c in 50 participants. A total of 49 participants with both measurements were included in the agreement analysis. Mean age was 43.3±9.8 years and 32 (65%) participants identified as female (Table 1). One or more comorbidities were present in 45 (92%) participants at enrolment, most commonly liver impairment (27, 55%), renal impairment (16, 33%) and type 2 diabetes (16, 33%).

Mean and median HbA1c concentrations for point-of-care HbA1c (range 4.5–9.8%, 26–84 mmol/mol) and laboratory HbA1c (range 4.7–10.3%, 28–89 mmol/mol) were similar (6.0% and 5.7%, 43 and 39 mmol/mol respectively, Table 1). Correlation between the two HbA1c measurements was high (Pearson's coefficient 0.95, 95% confidence interval (CI) 0.91–0.97) (Fig1A). The mean difference was not clinically meaningful (mean bias 0.03%, (0.34 mmol/mol) 95%CI –0.08–0.15% (–8.15–8.83 mmol/mol)) and constant over the range of HbA1c values (Spearman's correlation 0.03) when comparing point-of-care HbA1c to laboratory HbA1c (Fig1B,C). The observed limits of agreement ranged from –0.75% to 0.81%. There were seven (14%) participants with an absolute difference greater than 0.5%. Overall, 10 participants had HbA1c ≥6.5% (≥48 mmol/mol); six had elevated HbA1c using both tests, two using point-of-care HbA1c and two using laboratory HbA1c (92% agreement). Diagnostic agreement for type 2 diabetes (HbA1c≥6.5%) was moderate (Cohen's kappa statistic 0.70, 95%CI 0.40–1.00).

Table 1: Characteristics of study participants, laboratory and point-of-care haemoglobin A1c results

Characteristic	Variables	With type 2 diabetes	Without type 2 diabetes	Total
(Total, *n* (%))		8 (16)	41 (84)	49 (100)
Age (years), mean±SD		47.4±9.3	42.4±9.8	43.3±9.8
Gender, *n* (%)	Male	3 (38)	14 (34)	17 (35)
	Female	5 (62)	27 (66)	32 (65)
Indigenous status, *n* (%)	Aboriginal	6 (75)	38 (93)	44 (90)
	Both Aboriginal and Torres Strait Islander	2 (25)	3 (7)	5 (10)
BMI (kg/m^2), mean±SD		32.3±5.9	29.5±4.8	30.0±5.1
Smoker during past month, *n* (%)		5 (62)	25 (61)	30 (61)
Laboratory venous HbA1c (*n*=50)				
HbA1c (%), mean±SD		8.2±1.6	5.6±0.4	6.0±1.2
HbA1c (%), median (IQR)		8.0 (6.7–9.8)	5.6 (5.3–5.9)	5.7 (5.3–6.2)
HbA1c (mmol/mol), mean±SD		66.4±17.7	37.5±4.7	42.2±13.4
HbA1c (mmol/mol), median (IQR)		64.0 (50.0–83.0)	38.0 (34.0–41.0)	39.0 (34.0–44.0)
HbA1c (%), *n* (%)	≤5.5% (normal)	0 (0)	20 (49)	20 (41)
	>5.5% to <6.5% (pre-diabetes)	0 (0)	21 (51)	21 (43)
	≥6.5% (diabetes)	8 (100)	0 (0)	8 (16)
Point-of-care capillary HbA1c (*n*=52)				
HbA1c (%), mean±SD		8.1±1.8	5.6±0.5	6.0±1.2
HbA1c (%), median (IQR)		8.5 (6.4–9.8)	5.6 (5.4–5.9)	5.7 (5.4–6.2)
HbA1c (mmol/mol), mean±SD		65.0±19.5	38.1±4.9	42.5±13.3
HbA1c (mmol/mol), median (IQR)		70.0 (46.5–83.1)	37.7 (35.5–41.0)	38.8 (35.5–43.9)
HbA1c (%), *n* (%)	≤5.5% (normal)	0 (0)	19 (46)	19 (39)
	>5.5% to <6.5% (pre-diabetes)	2 (25)	20 (49)	22 (45)
	≥6.5% (diabetes)	6 (75)	2 (5)	8 (16)

HbA1c, haemoglobin A1C. IQR, interquartile range. SD, standard deviation.

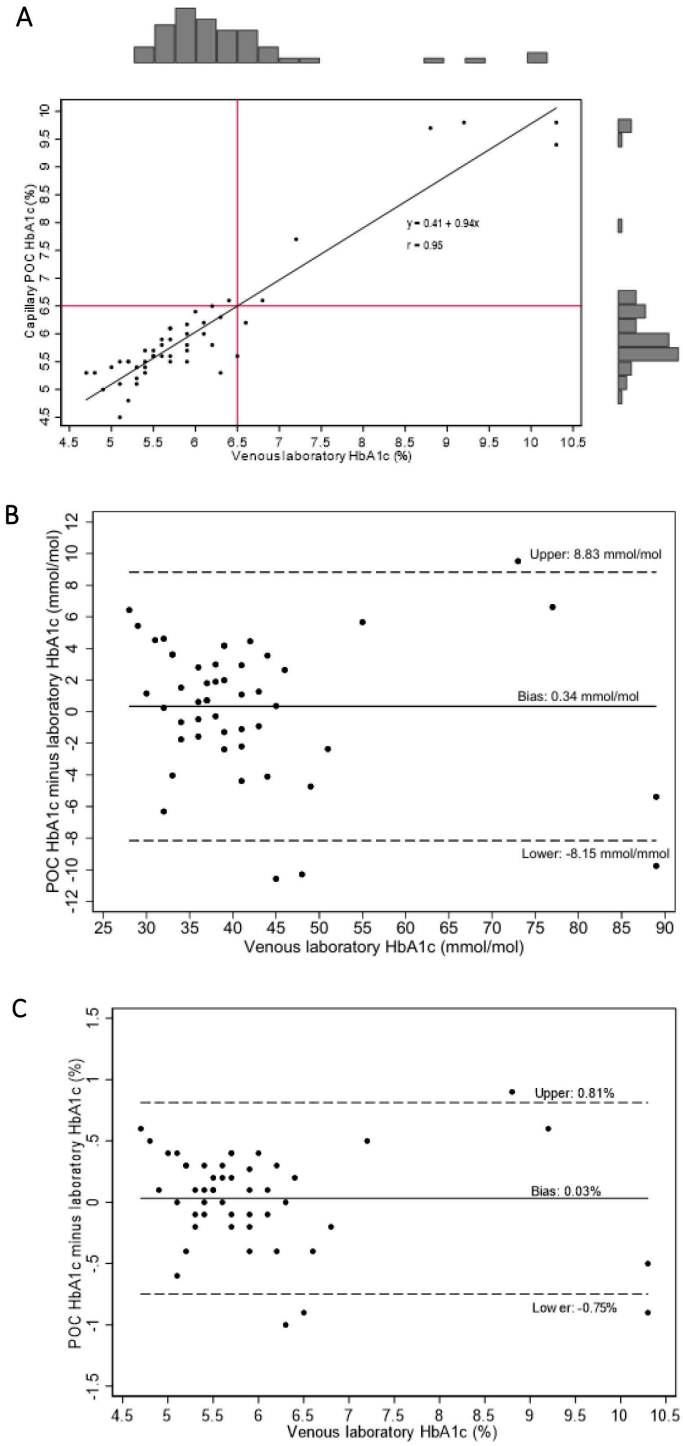


Figure 1: A. HbA1c scatter plot. B. Modified Bland–Altman plot (HbA1c units in mmol/mol). C. Modified Bland–Altman plot (HbA1c units in %). HbA1c, haemoglobin A1c. POC, point of care.

Discussion

In this study of adults living in a remote Northern Territory community, the A1CNow+ point-of-care device demonstrated good agreement with laboratory HbA1c measurement, with minimal mean bias (0.03%; 0.34 mmol/mol), acceptable limits of agreement, and moderate diagnostic agreement for type 2 diabetes (Cohen's kappa statistic 0.70)[10].

The national Quality Assurance in Aboriginal and Torres Strait Islander Medical Services Program has previously demonstrated the reliability of HbA1c POCT in Aboriginal Medical Services[11]. A 2014 audit of the program showed that when performed onsite in the remote health clinics, glycaemic control and timeliness of results delivery improved[12]. While clinic-based POCT is an important component of chronic disease care, it may not achieve population-wide reach within remote communities or adequately serve people living in surrounding homelands. Outreach models that deliver POCT in homes, community settings and homelands can complement clinic-based services by increasing access to diabetes and cardiovascular disease screening, monitoring and health education[3]. Portable POCT in home-based settings through outreach health services may better serve some communities, empowering family-based engagement around health and reaching younger populations. The need for family-based health care is becoming more apparent as the rate of type 2 diabetes among people aged 15–24 years increased by 97% between 2014 and 2021 in the Northern Territory[13].

The implementation of portable HbA1c POCT in outreach, family-based services has exciting potential in remote Aboriginal communities. By bringing health care directly to the people in their homes or community settings, POCT can reduce barriers related to transportation, waiting times and administrative procedures[14]. It may also help address, linguistic, cultural or psychological barriers by providing care in familiar, culturally safe environments, with immediate access to health test results, enabling the involvement of family members. This facilitates communication in local languages, and reduces the anxiety, shame and discomfort that some individuals experience when attending a clinic[15]. The outreach concept is supported by previous studies, including a randomised control trial in 12 remote communities in Far North Queensland showing that a model of diabetes care for high-risk patients, led by community health workers, was effective in improving blood glucose control[16]. The Tulku wan Wininn mobile ('Health to You') clinic was developed to improve access to health care for Aboriginal people in rural Victoria, Australia. The service was highly acceptable to the community and successfully addressed key barriers to care, including transport difficulties and cultural safety concerns[17]. Currently there are no such mobile services across North East Arnhem[18].

This study has several strengths. To our knowledge, it is one of the first studies to evaluate the agreement of the portable A1CNow+ HbA1c POCT system against laboratory testing in a remote Australian setting. The study was conducted under real-world conditions, with capillary and venous samples collected during the same clinic visit, providing a pragmatic assessment of device performance in a setting where timely access to laboratory testing is challenging. The A1CNow+ POCT system offers key advantages but has some limitations, including unknown accuracy compared to laboratory methods when HbA1c levels are greater than 55 mmol/mol. Furthermore, precision of serial point-of-care HbA1c measurements was not assessed, limiting conclusions regarding use for monitoring individual changes in HbA1c over time. Nevertheless, in resource-limited settings, the benefits may outweigh the drawbacks, especially when POCT is used as a platform for clinic referrals as well as health education in the home environment. Future studies should evaluate implementation of portable HbA1c testing within outreach services across multiple remote communities, including assessments of user acceptability, monitoring responses to treatment for type 2 diabetes, health service impact and long-term diabetes outcomes. In summary, our agreement analysis between the portable A1CNow+ POCT and routine laboratory blood HbA1c testing in a very remote North East Arnhem Land community showed very good concordance with routine testing and is a platform for developing novel models of outreach care and engagement to improve diabetes prevention and management in very remote Aboriginal Australian communities.

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Conflicts of interest

The authors declare no conflicts of interest.

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ChatGPT was used only to help with sentence structure editing. The authors have reviewed all AI changes and take full responsibility for the final published work.

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