

# BMJ Open Associations of health literacy with risk factors for diabetic foot disease: a cross-sectional analysis of the Southern Tasmanian Health Literacy and Foot Ulcer Development in Diabetes Mellitus Study

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## ABSTRACT

**Objectives** Poor health literacy (HL) is associated with poorer health outcomes in diabetes but little is known about its effects on foot disease. This study was aimed to determine the associations between HL and diabetic foot disease.

**Design** This is a cross-sectional analysis of baseline data from a prospective study of foot disease.

**Setting** Attendees of the Royal Hobart Hospital's Diabetes outpatient clinics.

**Participants** 222 people with type 1 or type 2 diabetes aged >40 years and without a history of foot disease, psychotic disorders or dementia.

**Measures** Outcomes were peripheral neuropathy, peripheral arterial disease and foot deformity according to published guidelines. The exposure, HL, was measured using the short form Test of Functional Health Literacy in Adults (S-TOFHLA) and the Health Literacy Questionnaire (HLQ). Covariates included demographic characteristics, medical history, psychological measures and foot care behaviour.

**Results** Of 222 participants, 204 had adequate HL. (Mean (SD) S-TOFHLA scores were 31.9 (6.7)), mean(SD) HLQ scores were 134.4 (18.4). In univariable but not multivariable analyses, higher S-TOFHLA scores were associated with lower overall risk for foot disease (OR 0.96, 95% CI 0.93 to 0.99) and loss of protective sensation (OR 0.95, 95% CI 0.91 to 0.995).

**Conclusions** These data provide little support for clinically important impacts of HL on risk factors for diabetic foot disease. However, in the absence of longitudinal data, such effects cannot be ruled out. Longitudinal studies measuring incident foot disease are needed to properly judge the potential for interventions improving HL to reduce the incidence of diabetic foot disease.

## INTRODUCTION

Diabetes mellitus is common and costly with an estimated 425 million adults globally being diagnosed with and a further 629 million at

## Strengths and limitations of this study

- Health literacy may have an important role in diabetic foot disease prevention.
- This study is the first to objectively assess and measure the association between health literacy and risk factors for diabetic foot disease.
- Our study is unique as two measurements of health literacy were used, which provided a broader assessment of an individual's health literacy beyond functional health literacy.
- Limitations of this study potentially include limited generalisability as participants were recruited from only one tertiary hospital clinic, though participant characteristics were similar to another national study of people with diabetes.

risk of developing diabetes in 2025<sup>1</sup>. Conservative projections of financial costs are greater than for the five most costly cancers in the USA.<sup>2</sup>

One of the most expensive and debilitating complications of diabetes is diabetic foot disease, the lifetime risk of which is as high as 25%.<sup>3</sup> In theory, diabetic foot disease is preventable. Fundamental to foot disease development is peripheral neuropathy from prolonged hyperglycaemia.<sup>3</sup> Undetected, repetitive minor trauma to an insensate, deformed foot is often exacerbated by reduced healing capacity from peripheral arterial disease. The consequent chronic wound may be complicated by osteomyelitis, and ultimately can result in limb loss. Diabetic foot disease precedes up to 85% of amputations,<sup>3</sup> and is the leading cause of non-trauma-related amputations worldwide. Early identification of risk factors such as

peripheral neuropathy, peripheral arterial disease and foot deformity is crucial for the early implementation of mitigation strategies including education which can empower people with diabetes to practise good foot care behaviours.<sup>4</sup>

Health literacy is defined as ‘the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health’.<sup>5</sup> It broadly comprises three domains in order of increasing difficulty: basic or functional health literacy relates to basic skills in reading and writing health information, communicative health literacy includes advanced cognitive skills required to extract and apply health information to an individuals’ circumstances and the most advanced critical health literacy pertains to critically analysing information and using it in decision making.<sup>6</sup>

Inadequate health literacy has been identified as a major barrier to self-care in people with diabetes.<sup>7</sup> Health literacy is crucial to the self-management demands of diabetes, which include diet and lifestyle changes, blood glucose management as well as incorporating lifestyle changes to prevent complications of the disease. With respect to foot care, the need for regular foot inspections, knowledge of appropriate footwear selection as well as the importance of timely medical attention when necessary can be demanding, especially for individuals with poor health literacy.<sup>8</sup>

Health literacy influences an individuals’ ability to navigate and use the health system, engage and interact with healthcare providers and their level of knowledge about health conditions.<sup>9</sup> Current literature suggests that people with diabetes have poor health literacy,<sup>8</sup> which could disadvantage them when engaging in diabetes management strategies.<sup>9</sup> Existing research supports this, with established associations between poor health literacy and diabetic complications of retinopathy and cerebrovascular disease.<sup>10</sup> However, little is known about its associations with diabetic foot disease.<sup>10</sup> Therefore, this study was aimed to use baseline data of a longitudinal study, the Southern Tasmanian Health Literacy and Foot Ulcer Development in Diabetes (SHELLED) study to describe the level of functional and multidimensional health literacy among people with diabetes, and determine the associations between health literacy and risk factors for diabetic foot disease.

## METHODS

This cross-sectional analysis is of baseline data from the SHELLED study, a 4-year longitudinal study aiming to determine the associations of health literacy with foot ulceration in people with diabetes.

### Subjects

Between January 2015 and July 2016, consecutive patients aged >40 years old and with no history of foot ulceration, who attended the Royal Hobart Hospital (RHH)

Diabetes Centre’s Outpatient Clinics were approached by investigator podiatrist (PC) or a study volunteer to participate in this study. The RHH Diabetes Centre is the only tertiary diabetes service in Southern Tasmania, and patients attending this service had established diabetes, diagnosed according to WHO criteria.<sup>11</sup> Participants were excluded if they had a history of amputation, a diagnosis of peripheral neuropathy attributed to other causes other than diabetes, gestational diabetes, psychotic disorders, dementia or blindness. Those who provided informed consent to participate were then contacted within 2 weeks and requested to complete a questionnaire at home prior to attending an assessment at the Menzies Institute for Medical Research at the University of Tasmania.

### Measures

All participants attended a 90 min individual appointment at the Menzies Institute for Medical Research at the University of Tasmania. During this time, they underwent a foot risk factor assessment for loss of protective sensation, peripheral arterial disease and foot deformity with a registered podiatrist (PC), and a study volunteer or staff member administered cognitive and health literacy assessments. All other measures were from the questionnaire filled by the participant prior to the appointment and checked at the appointment for appropriate completion.

### Outcome measures

Loss of protective sensation was assessed using the 10g Semmes-Weinstein Monofilament and a neurothesiometer.<sup>12</sup> The 10g monofilament was used at 10 sites bilaterally (plantar first, third and fifth toes and metatarsophalangeal joints (MPJ), medial and lateral plantar arch, plantar heel and dorsally in between the first and second toes). Large fibre neuropathy was tested using a calibrated neurothesiometer at the bony prominence of the first MPJ bilaterally. Participants were classified as having peripheral neuropathy if they were unable to detect the 10g monofilament at any one site on either foot or had a vibration perception >25 V.<sup>12</sup>

To measure peripheral arterial disease, systolic blood pressures were measured using handheld Doppler (Hadeco Smartdop 45) and sphygmomanometer for dorsalis pedis, posterior tibial arteries and brachial arteries bilaterally. Ankle brachial index (ABI) was calculated for each side by dividing the highest pressure of either pedal vessel on each foot by the highest pressure in either brachial vessel as the numerator.<sup>13</sup> Individuals were considered to have peripheral arterial disease if their ABI was <0.9 (indicative of arterial stenosis) or >1.3 (indicative of arterial calcification) on either side.<sup>13</sup>

Foot deformity was assessed using the six-point foot deformity score, with each of the following characteristics scored as 0 (absent) or 1 (present): small muscle wasting, Charcot foot, bony prominences, prominent metatarsal heads, hammer/claw toes and limited joint mobility. Significant foot deformity was deemed present if the total

score was  $>3$  (out of 6) on either foot.<sup>12</sup> The foot deformity score is predictive of diabetic foot ulceration.<sup>14</sup>

Participants' overall level of risk for foot disease was classified according to Australian guidelines<sup>12</sup> by the number of diabetic foot disease risk factors present (loss of protective sensation, peripheral arterial disease and foot deformity). Individuals with no risk factors were classified as low risk, with one risk factor as intermediate risk and with two or more risk factors as high risk.

### Exposure measures

Health literacy was measured with two questionnaires. The short form Test of Functional Health Literacy in Adults (S-TOFHLA) was used as an established measure of functional health literacy. The Health Literacy Questionnaire (HLQ) was used as it assesses nine dimensions of health literacy and captures a broader representation of the constructs of health literacy.

The S-TOFHLA is a 36-item timed test of comprehension which uses a modified cloze procedure. Participants complete two passages, one from an upper gastrointestinal tract series about having an X-ray, and another from the 'patient rights and responsibilities' section of an American Medicaid application form.<sup>15</sup> We advised participants verbally of Australian equivalents for two American terms, namely Medicaid (Medicare in Australia) and Temporary Assistance for Needy Family (Centrelink for Australia). The S-TOFHLA has excellent reliability (Cronbach's  $\alpha=0.98$ ) and good convergent validity with the Rapid Estimate of Adult Literacy in Medicine (0.80).<sup>15 16</sup> It is scored out of 36, with participants scoring  $<17$  considered to have inadequate health literacy, those scoring between 17 and 22, marginal health literacy and those scoring  $>22$  considered to have adequate health literacy.

The HLQ was developed in 2013 using a validity-driven approach. The HLQ consists of nine scales covering different dimensions of health literacy.<sup>17</sup> The scales are (1) feeling understood and supported by healthcare professionals (four items), (2) having sufficient information to manage my health (four items), (3) actively managing my health (five items), (4) social support for health (five items), (5) appraisal of health information (five items), (6) ability to actively engage with healthcare providers (five items), (7) navigating the health system (five items), (8) ability to find good health information (five items) and (9) understanding health information well enough to know what to do (five items). Scales 1 to 5 are scored out of 4 (strongly disagree, disagree, agree, strongly agree), and scales 6 to 9, which measure difficulty of health-related tasks to the individual, are scored out of 5 (cannot do or always difficult, usually difficult, sometimes difficult, usually easy and always easy). Individual scales of the HLQ have excellent reliability (composite reliability ranging between 0.77 and 0.89).<sup>17</sup> The content of items of scales 8 and 9 were deemed by the authors of this paper to be most similar to functional health literacy as measured by the S-TOFHLA.

### Other covariates

Demographic characteristics and medical history were assessed by questionnaire (age, sex, years of formal education and highest educational qualifications, employment status, source of income, annual household income bracket, smoking status, medical history including of diabetes (including type, age of diagnosis, monitoring of diabetes and insulin therapy)).

A battery of psychological measures were also used. Descriptions on scoring, reliability and validity of these are available in [table 1](#). Diabetes self-efficacy was assessed using the Australian version of the Diabetes Management Self-Efficacy Scale which measures the extent to which participants are confident they can perform a range of diabetes-related tasks such as managing blood glucose and foot care.<sup>18</sup> Foot care self-efficacy was assessed using the Foot Care Confidence Scale,<sup>19</sup> which measures the extent to which participants are confident of performing a range of foot care behaviours such as checking their feet or trimming their toenails. Diabetes knowledge was assessed using the diabetes knowledge questionnaire.<sup>20</sup> Depression was assessed by the Patient Health Questionnaire-9 (PHQ-9), a depression screening tool with a sensitivity and specificity of 92% and 82%, respectively, for the diagnosis of major depression according to DSM-IV criteria<sup>21</sup> and can be used to assess severity of depression symptoms. The Montreal Cognitive Assessment (MOCA) was administered during the appointment.<sup>22</sup> This is a validated screening tool with scores  $<26/30$  considered positive for mild cognitive impairment in people with diabetes.<sup>22</sup>

Foot care behaviours were also assessed. There is no gold standard approach for this.<sup>23</sup> We used the foot care behaviour scale (see [table 1](#)) as this 17-item questionnaire is a standardised questionnaire based on diabetic foot care guidelines<sup>19 24</sup> that has been used previously<sup>24</sup> including in an Australian setting<sup>25</sup> to assess frequency of diabetic foot care behaviours.

### Statistics

The sample size of 220 was estimated based on the number needed to detect associations of S-TOFHLA categories (adequate vs inadequate health literacy) with foot ulcer incidence over 4 years in the longitudinal study. Based on estimates by the Australian Bureau of Statistics,<sup>26</sup> we projected that 60% of our study sample will have inadequate health literacy. Furthermore, based on worldwide reports of incidence of foot ulceration of between 2% and 5% in developed countries,<sup>14 27</sup> a sample of 220 would give power at 80% to be able to detect a 3.8% difference in incidence of foot ulceration between people with inadequate and adequate health literacy.

For this cross-sectional analysis, we estimated the prevalence of foot disease risk factors from published community findings of risk factor incidence.<sup>28 29</sup> With the sample size of 220 required for the longitudinal study, this cross-sectional analysis can detect a 2-point difference (mean effect size of 0.4) in S-TOFHLA scores

**Table 1** Description of psychological and behavioural questionnaires administered in the SHELLED study

Questionnaire	Number of items	Scoring	Validity or reliability	Example questions
Diabetes Management Self-Efficacy Scale	20	0–10 per item, possible score range 0–200. Low scores indicate low confidence in self-management of diabetes	Cronbach's alpha=0.91 <sup>18</sup>	I am able to take my medication as prescribed
Foot Care Confidence Scale	12	1–5 per item, possible score range 12–60. Low scores indicate poor confidence in caring for feet	Cronbach's alpha=0.92 <sup>19</sup>	I can protect my feet
Diabetes Knowledge Questionnaire	12–15*	1 for each correct answer	Cronbach's alpha=0.73 <sup>20</sup>	What is the ideal range for blood glucose (sugar) levels a person with diabetes should aim for? Select ONE answer only <ul style="list-style-type: none"> <li>▶ 2–6 mmol/L</li> <li>▶ 7–13 mmol/L</li> <li>▶ 4–8 mmol/L</li> <li>▶ 4.5–15 mmol/L</li> <li>▶ Unsure</li> </ul>
Patient Health Questionnaire-9 (Depression)	9	0–3 for each question, possible score range 0–27. High scores indicate frequently experiencing depressive symptoms	Sensitivity: 92% Specificity: 82% <sup>21</sup>	Feeling down, depressed or hopeless
Diabetes Distress scale	17	1–6 for each item, high scores indicate aspects of distressed behaviours are a serious problem	Cronbach's alpha =0.93 <sup>50</sup>	Feeling that diabetes is taking up too much of my mental and physical energy every day
Montreal Cognitive Assessment	30	0–30. Scores <26/30 indicate mild cognitive impairment <sup>22</sup>	Internal consistency 0.83 <sup>22</sup>	Clock face drawing, delayed recall etc.
Foot Care Behaviour scale	17	1–6 for some items, 1–4 for others; items were re-scaled from 0 to 1 and summed.	Comment in text	During the past week, how often did you examine your feet? <ul style="list-style-type: none"> <li>▶ Twice daily</li> <li>▶ Daily</li> <li>▶ Every other day</li> <li>▶ Twice a week</li> <li>▶ Once a week</li> <li>▶ Never</li> </ul>

\*Twelve items if diabetes managed without medication, 14 items if diabetes managed with medication and 15 items for people living with type 1 diabetes.

SHELLED, Southern Tasmanian Health Literacy and Foot Ulcer Development in Diabetes.

between overall foot risk groups. The minimum clinically important difference in S-TOFHLA scores is not known; however, this detectable difference is small relative to the difference in 10 points across the three categories of health literacy (inadequate, marginal, adequate). Furthermore, a 5-point increase in S-TOFHLA score is associated with a 0.1% greater HbA1c; thus, the ability to detect a 2-point change is conservative and minimises risk of type II error.<sup>30</sup>

There were four outcome measures—each individual risk factor and the overall risk for foot disease (low, intermediate and high). There were also three exposure measures—the continuous S-TOFHLA score, continuous HLQ score and category of HLQ from cluster analysis.

The continuous HLQ score was calculated by rescaling participants' scores on scales out of 4 to 5 to enable equal weighting of all items then summing the scores across all scales. Clusters of HLQ were determined using agglomerative cluster analysis with Ward's linkage method (minimal increase in sum of squares).<sup>31</sup> The number of clusters was chosen based on the distribution of mean scores of all covariates and approximated groups of participants with lowest, intermediate and highest levels of health literacy scored on the HLQ.

Logistic regression was used to estimate the association of health literacy with the presence of individual risk factors. Adjacent categories ordinal logistic regression models were used to estimate the association of health

**Table 2** Characteristics of SHELLED participants

Variable	n	Overall sample	Low risk (n=127)	Medium risk (n=81)	High risk (n=14)
Age (years)	222	60.5 (10.7)	59.2 (9.8)	63.4 (11.1)	68.1 (11.6)
Female, n (%)	222	92 (41.4)	67 (52.8)	24 (29.6)	1 (7.1)
BMI (kg/m <sup>2</sup> )	221	33.6 (8.1)	33.03 (8.6)	34.4 (7.0)	33.1 (9.3)
Years of formal education	220	11.3 (3.3)	11.4 (3.3)	11.0 (3.5)	11.6 (2.8)
Household income, n(%)					
<\$49 999	222	148 (66.7)	82 (64.6)	55 (67.9)	11 (78.6)
\$50 000–\$99 999		27 (12.2)	16 (12.6)	11 (13.6)	0 (0)
>\$100 000		18 (8.1)	12 (9.4)	5 (6.2)	1 (7.1)
Rather not say		29 (13.1)	17 (13.4)	10 (12.3)	2 (14.3)
Diabetes history					
Duration in years	222	18.0 (13.4)	16.2 (13.2)	20.7 (13.9)	18.8 (9.6)
Insulin therapy, n(%)	222	173 (77.9)	93 (73.2)	66 (81.4)	14 (100)
Current smoker, n(%)	222	33 (14.9)	23 (18.1)	10 (12.3)	0 (0)
Current or ex-smoker, n(%)	222	129 (58.1)	73 (57.5)	49 (60.5)	7 (50)
S-TOFHLLA score	222	31.9 (6.7)	33.0 (5.3)	30.8 (5.1)	29.0 (8.3)
S-TOFHLLA score*	222	34 (32–36)	35 (33–36)	20 (17–21)	9 (5.5–11.25)
HLQ score	222	134.4 (18.4)	135.2 (18.2)	135.7 (18.2)	127.1 (21.1)
Foot Care Confidence Scale	222	49.4 (9.7)	50.4 (9.6)	48.9 (9.5)	43.3 (10.4)
PHQ-9	221	7.2 (6.3)	7.5 (6.5)	7.1 (6.1)	5.1 (5.2)
Diabetes distress	221	1.7 (0.8)	1.8 (0.8)	1.7 (0.7)	1.9 (1.1)
MOCA	222	25.7 (3.5)	26.2 (3.1)	25.2 (3.8)	24.2 (3.8)
DMSSES	222	9.5 (1.7)	9.5 (1.7)	9.7 (1.6)	8.5 (2.2)
Foot care behaviour	222	0.7 (0.2)	0.7 (0.2)	0.7 (0.2)	0.8 (0.2)
Diabetes knowledge	222	73.2 (19.0)	75.0 (19.3)	70.8 (19.0)	71.5 (14.5)

\*Additional data for S-TOFHLLA are presented as Median (IQR).

Data presented as mean(SD) unless otherwise stated;

Diabetes Distress scored out of 6.

Diabetes Knowledge Questionnaire scored out of 100.

Foot care behaviour scored out of 2.

BMI, body mass index; DMSSES, Diabetes Management Self-Efficacy Scale (scored out of 30); HLQ, Health Literacy Questionnaire (scored out of 176); MOCA, Montreal Cognitive Assessment (maximum score 30); PHQ-9, Patient Health Questionnaire (nine items, maximum score 27); SHELLED, Southern Tasmanian Health Literacy and Foot Ulcer Development in Diabetes; S-TOFHLLA, short form Test of Functional Health Literacy in Adults (scored out of 36).

literacy with overall risk of foot disease. The odds ratios estimated for a unit increase in health literacy represent the odds of moving from any outcome category to an adjacent (higher) risk category. We ensured all assumptions for regressions were met, with only diabetes and foot care self-efficacy having a statistically significant correlation. We selected potential confounders based on clinical and biological plausibility of an association of a factor with both the outcome and exposure of interest. These were included in the model if their inclusion caused a change of >10% in the estimated coefficient for the effect of the exposure.<sup>32</sup>

As the number of individuals with missing data for relevant variables was very small (one to two people, see table 2), those with missing data required for a given regression analysis were excluded.

All analyses were done in R V.1.0.44 (R Core Team, 2018) using the packages VGAM<sup>33</sup> and cluster<sup>34</sup>.

### Patient and public involvement

No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for recruitment, design or implementation of the study. No patients were asked to advise on interpretation or writing up of results.

## RESULTS

### Participant characteristics

Four hundred and eleven people who were approached indicated an initial interest in participating in the study, of whom 222 ultimately consented to participate. The most

common reason for declining was lack of time, or of difficulty with transport to attend an assessment. Of the 222 participants, one individual was wheelchair-bound and unable to provide height and weight measures; another declined to complete the PHQ and diabetes distress measures, citing diagnosis and treatment for depression.

Characteristics of the whole study sample and of the participants by their overall risk of diabetic foot disease are given in table 2. Data on characteristics of those who chose not to participate are not available. Participants were predominantly (58.6%) male, with a mean age of 60.5 (SD 10.7) years. The average BMI was 33.6 (SD 8.1) kg/m<sup>2</sup>. The duration of diabetes was an average of 18.0 years and 77.9% of participants were insulin-treated. Thirty-three (14.9%) participants were current smokers, and an additional 96 (43.2%) were regular smokers in the past. Mean (SD) MOCA score was 25.7 (3.5) (range 0–30), with 88 participants considered to have mild cognitive impairment.<sup>22</sup> Mean (SD) diabetes knowledge score was 73.2 (19.0) (/100).

A majority (n=127, 57.2%) of participants had no risk factors for foot disease, 81 (36.5%) were at intermediate risk with one risk factor and 14 (6.3%) were at high risk of foot disease with >1 risk factor present. Of the total sample, 12 (5.4%) had inadequate, 6 (2.7%) marginal and 204 (91.9%) adequate functional health literacy according to S-TOFHLA cut-offs.

Participants at high risk of foot disease were older, had a higher proportion of people in the lowest income group, had lower S-TOFHLA and HLQ scores and poorer diabetes and foot care self-efficacy. Scores for cognition, diabetes knowledge, BMI, as well as years of formal education were similar across all three categories. Participants at medium and high risk for foot disease reported a longer duration of diabetes compared with those at low risk of foot disease. Furthermore, all participants at high risk of foot disease were undergoing insulin therapy, compared with only 73.2% of those at low risk and 81.4% of those at medium risk of foot disease.

### Associations of health literacy with risk factors for and overall risk of diabetic foot disease

Table 3 shows odds ratios (ORs), estimated for a unit increase in health literacy, for having risk factors for foot disease. Each unit increase in S-TOFHLA scores was associated with 4% lower odds of being in a higher risk category for foot disease (OR 0.96, 95% CI 0.93 to 0.99) in univariable analyses. However, this association did not persist after adjusting for age, sex and other covariates. Although the direction of effect was similar for total HLQ score and for HLQ clusters, there were no statistically significant associations with these HLQ measures.

For the individual risk factors (table 3, online supplementary tables S1, S2 and S3), in univariable analyses S-TOFHLA and HLQ score but not HLQ clusters were significantly associated with loss of protective sensation, but again these associations did not persist after adjustment for age and sex, or other covariates. There were no

associations between any measure of health literacy and peripheral arterial disease or foot deformity.

Of individual HLQ scales, scales 8 (ability to find good health information) and 9 (understanding health information well enough to know what to do) were associated with being in a higher overall risk category for foot disease and loss of protective sensation in univariable analyses only (online supplementary tables S4). For overall risk for foot disease, the odds ratios were 0.93 (95% CI 0.88 to 0.99) and 0.93 (95% CI 0.87 to 0.99) for scales 8 and 9, respectively, and for loss of protective sensation, these were 0.90 (95% CI 0.82 to 1.01) and 0.84 (95% CI 0.79 to 0.99). There were no other statistically significant associations between any HLQ subscale and any outcome.

### DISCUSSION

This novel study is the first to examine the relationship between health literacy and the number of risk factors for diabetic foot disease, the first to examine relationships with peripheral neuropathy using objective clinical measures of this risk factor and the first to assess associations with peripheral vascular disease in a broad diabetic population. There was a small reduction in the odds of being in a higher risk category (ie, having a greater number of risk factors) for diabetic foot disease per unit increase in S-TOFHLA score and per unit increase in HLQ subscale 8 and 9 scores in univariable analysis. Similarly, there was a small reduction in the odds of having loss of protective sensation with higher S-TOFHLA and HLQ total scores, and a more substantial decrease in odds (approaching 70%) in participants in the high versus low HLQ cluster in univariable analysis. However, as these effects did not persist after adjusting for potential confounders, overall, there is little evidence to support there being clinically important impacts of health literacy on the presence of risk factors for diabetic foot disease. This lack of effect may reflect the complex, multifactorial nature of diabetic foot disease development and the different aetiologies of different foot disease risk factors. However, the results are insufficient to as yet judge the potential for interventions that improve or overcome low health literacy to reduce the incidence of diabetic foot disease.

Few studies have examined the links between health literacy and individual foot disease risk factors. Overall foot disease risk level and the individual risk factors of peripheral neuropathy were significantly associated with S-TOFHLA scores and scores of the subscales 8 and 9 of the HLQ but this appears to have been due to confounding by age and gender. This similarity of pattern between these HLQ subscales and S-TOFHLA is unsurprising as these most closely approximate measures of functional health literacy. Current evidence pertaining to the influence of each domain of health literacy with self-management or clinical outcomes is conflicting<sup>35 36</sup>; however, for risk factors for diabetic foot disease, our findings suggest that functional health literacy may be a more important domain. Further research is required to

**Table 3** Associations of health literacy with risk factors for diabetic foot disease

	Overall risk for foot disease*			Loss of protective sensation			Peripheral arterial disease			Foot deformity		
	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI		
Univariable												
S-TOFHLA	0.960†	0.932 to 0.989	0.951†	0.910 to 0.995	0.963	0.924 to 1.003	0.999	0.929 to 1.126				
HLQ total	0.994	0.982 to 1.006	0.975†	0.955 to 0.995	1.007	0.991 to 1.023	0.995	0.963 to 1.029				
HLQ cluster‡												
HLQ low												
Reference												
HLQ intermediate	0.759	0.432 to 1.334	0.678	0.286 to 1.669	0.844	0.383 to 1.930	0.804	0.201 to 3.958				
HLQ high	0.683	0.373 to 1.427	0.325†	0.113 to 0.930	1.250	0.548 to 2.849	0.351	0.056 to 2.192				
Model 1§												
S-TOFHLA												
0.981	0.949 to 1.015	0.995	0.947 to 1.051	0.972	0.930 to 1.015	1.024	0.942 to 1.163					
HLQ total	1.000	0.986 to 1.012	0.980	0.958 to 1.002	1.010	0.994 to 1.027	1.0003	0.967 to 1.036				
HLQ cluster‡												
HLQ low												
Reference												
HLQ intermediate	0.713	0.385 to 1.320	0.641	0.246 to 1.729	0.828	0.370 to 1.916	0.787	0.193 to 3.940				
HLQ high	0.773	0.400 to 1.494	0.347	0.105 to 1.094	1.422	0.619 to 3.394	0.426	0.053 to 2.739				
Model 2¶												
S-TOFHLA												
0.977	0.939 to 1.016	0.986	0.917 to 1.064	0.985	0.928 to 1.044	1.036	0.945 to 1.188					
HLQ total	1.003	0.986 to 1.020	0.990	0.960 to 1.021	1.005	0.985 to 1.027	1.004	0.968 to 1.041				
HLQ cluster‡												
HLQ low												
Reference												
HLQ intermediate	0.781	0.388 to 1.574	0.965	0.311 to 3.133	0.757	0.305 to 1.919	0.717	0.168 to 3.685				
HLQ high	0.844	0.372 to 1.916	0.532	0.110 to 2.465	1.079	0.393 to 3.046	0.462	0.057 to 3.077				

\*Ordinal logistic regression (adjacent category) modelling; overall risk for foot disease model indicates transition from a lower category to an adjacent higher category. Risk factor models have binary outcomes (yes/no).

†Denotes p<0.05.

‡HLQ clusters determined using Ward's method and references lowest levels of health literacy.

§Model 1 for all outcome measures adjusted for age and sex.

¶Model 2 for overall risk for foot disease adjusted for age, sex, insulin therapy, PHQ-9 (depression) and distress scores, diabetes knowledge, foot care and diabetes self-efficacy, BMI, number of years of formal education, current smoking status and household income. Model 2 for loss of protective sensation adjusted for age, sex, BMI, years of formal education, duration of diabetes, foot care self-efficacy, diabetes distress, cognition, diabetes self-efficacy and diabetes knowledge. Model 2 for peripheral arterial disease adjusted for age, sex, BMI, years of formal education, duration of diabetes, insulin therapy, current smoking status, foot care confidence, diabetes distress, cognition and diabetes knowledge. Model 2 for foot deformity adjusted for age, sex, BMI, years of formal education, duration of diabetes and insulin therapy.

BMI, body mass index; HLQ, Health Literacy Questionnaire; PHQ-9, Patient Health Questionnaire-9; S-TOFHLA, short form Test of Functional Health Literacy in Adults.

ascertain definitively if this is the most important aspect of health literacy in regard to foot disease prevention and management.

The lack of even univariable associations between health literacy and foot deformity and peripheral arterial disease may reflect the different mechanisms and aetiologies of these two risk factors. We postulate that the relationship between health literacy and presence of risk factors for diabetic foot disease may be mediated by glycaemic control. Low levels of health literacy are associated with poorer glycaemic control,<sup>10,37</sup> which is a predominant aetiology of peripheral neuropathy in people with diabetes. By contrast, peripheral arterial disease (being macrovascular in nature) has a multifactorial aetiology of which diabetes is a component. Similarly, foot deformity has several aetiologies, most of which are biomechanical and unrelated to systemic conditions such as diabetes and so may be least attributable to diabetes management and thus health literacy.

Foot disease risk factors are only intermediate outcomes and proxy measures for the more important clinical outcome of diabetic foot disease. To our knowledge, only three studies have reported on health literacy and diabetic foot disease outcomes of ulceration,<sup>38</sup> amputation<sup>7</sup> and foot ulcer size and duration.<sup>39</sup> In 408 patients with diabetes mellitus from primary care clinics, the odds of sustaining lower extremity amputation were nearly 2.5 times higher in patients with inadequate versus adequate health literacy, though this was not a statistically significant effect (OR 2.48, 95% CI 0.78 to 8.34).<sup>7</sup> In another primary care study of 1002 people with diabetes who were asked to report neuropathic symptoms and healthcare provider diagnosis of diabetes-related ulcers or sores on the leg or foot, there were no statistically significant associations between health literacy level and foot/leg problems (OR 0.52, 95% CI 0.24 to 1.16 for inadequate health literacy and OR 1.39, 95% CI 0.47 to 4.12 for marginal health literacy).<sup>38</sup> We performed a meta-analysis pooling all available data and found a non-statistically significant, but potentially important clinically doubling of the odds of foot disease among people with inadequate compared with adequate health literacy (OR 1.99, 95% CI 0.83 to 4.78).<sup>40</sup> With only three studies available, the effect of health literacy on diabetic foot disease cannot be ruled out, and longitudinal studies will provide further important evidence on this topic.

Our findings alone are insufficient to judge whether it is justified to proceed to further research such as randomised control trials on health literacy interventions to improve diabetic foot disease. At face value, our results would suggest not, but a recent systematic review suggested that significant HbA1c reductions were achieved with educational strategies which accommodated patients with low health literacy.<sup>41</sup> It is also well established that tight glycaemic control with target HbA1c levels of 7% (53 mmol/mol) greatly reduces risk of microvascular complications among people with diabetes.<sup>42,43</sup> This makes obtaining longitudinal data on

foot ulcer outcomes even more critical to guide future research directions.

Strengths of our study include its sample size being sufficient to detect small differences in health literacy across risk groups; utilisation of different measures to assess functional and multidimensional aspects of health literacy and our use of a range of validated patient-reported outcome measures to measure potential confounders. Nonetheless, our study has several limitations. Being cross-sectional in nature, our data prohibit attributing causation between health literacy and diabetic foot disease risk factors. Also, we were able to assess only associations with the overall risk for diabetic foot disease and its risk factors—longitudinal data with foot ulcer outcomes are essential to properly assess the potential for health literacy levels to impact on diabetic foot disease. The fact it was conducted at one tertiary hospital outpatient clinic in Hobart and the response rate of 54% could have limited generalisability to the wider population of people with diabetes. However, this does not seem to be the case. Our participants' characteristics were not dissimilar to those from centre of excellence/tertiary diabetes treatment centres in a national audit of diabetes centres, particularly given that the Australian National Diabetes Audit (ANDA) included people with gestational diabetes and people with a history of ulceration, which our sample did not. For example, body mass index and percentage treated with insulin were 33.6 vs 31.3 kg/m<sup>2</sup> and 77.9% vs 72.2% in our sample and ANDA, respectively.<sup>44</sup> The mean S-TOFHLA scores from our population was high (31.9), possibly attributable to the high levels of formal education reported (>11 years). Although this is similar to other Australian-based health literacy studies,<sup>45,46</sup> we had initially projected having up to 60% of our population being assessed as having inadequate health literacy, which was based on the national survey.<sup>26</sup> It may be that there is a threshold below which low health literacy has more substantial impacts on health outcomes, and we had insufficient participants below such a threshold to detect effects. There are no validated tools for foot deformity, but we used the recommended tool, being the 'six point foot deformity score' in our study.<sup>12</sup> However, it could be criticised for requiring a score of 3 or more to be considered positive, when a single deformity could be clinically significant in contributing to foot ulcer development—individual aspects of foot deformity such as rigid or retracted lesser toes, hallux rigidus/limitus or abductovalgus deformities have been previously associated with foot ulceration.<sup>47</sup> Finally, while we did not have public involvement in our study, the importance of health literacy for diabetes care is highlighted in the Australian National Diabetes Strategy 2016–2020<sup>48</sup>, which was formulated after extensive public consultation, supporting the relevance of our study to people with diabetes.

In conclusion, foot disease remains one of the most costly and debilitating outcomes of diabetes, with a 40% greater 10-year mortality compared with those with diabetes alone.<sup>49</sup> Our study, which is the first to examine



the relationships between health literacy and foot disease and its risk factors using objective measurements, only showed associations of health literacy with risk factors for diabetic foot disease in univariable analyses. This suggests that focusing on health literacy alone may not be effective for reducing foot ulcer risk factors, but as cross-sectional evidence is weak, longitudinal or interventional studies are crucial to be able to attribute causation and to improve targeted diabetic foot care education, to ultimately improve diabetic foot disease prevention.

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