Oral Health Status of Hospitalized Patients With Type 2 Diabetes

Lisa E. Simon,1,2 Deepti Shroff Karhade,3 and Matthew L. Tobey2,4

1Harvard School of Dental Medicine, Boston, MA; 2Harvard Medical School, Boston, MA; 3University of North Carolina School of Dentistry, Chapel Hill, NC; 4Massachusetts General Hospital, Boston, MA

BACKGROUND | Diabetes is associated with poor oral health, as well as reduced access to dental care. A large percentage of patients hospitalized in the United States carry a diagnosis of diabetes; however, the oral health status of patients with diabetes who are hospitalized is unknown.

METHODS | All patients meeting inclusion criteria on the general medicine service of a tertiary care hospital were invited to participate. Subjects were asked about their access to dental care and perceptions of their oral health. A dental hygienist conducted examinations, including decayed, missing, and filled teeth (DMFT) and periodontal screening and recording (PSR) indices on a subset of subjects.

RESULTS | The 105 subjects had a mean age of 69 ± 12 years and a median A1C of 7.5 ± 2.1%. Rates of comorbidity and polypharmacy were high. The mean number of DMFT was 23.0 ± 7.2, with 10.1 ± 7.2 missing teeth. Forty-four percent of subjects had a removable prosthesis. Sixty-eight percent had a PSR index ≥ 4 in at least one sextant, indicating moderate periodontal disease.

CONCLUSION | Rates of missing teeth, removable prostheses, and periodontal inflammation were high among hospitalized patients with diabetes, but patients did not perceive their oral health to be poor. Health care providers should be aware of the oral health risks of patients with diabetes during hospitalization, and dentists should consider screening patients with diabetes for recent hospitalization.

Type 2 diabetes affects health, oral health, and well-being. It also represents a significant burden on the health care system. Patients with diabetes comprise 20% of all hospitalizations and are more likely to have longer and costlier stays compared to patients without diabetes (1). Furthermore, the number of comorbidities in patients with diabetes is two times that of patients without diabetes, and the rates of hospitalization for these patients are highest in zip codes with the lowest household incomes (1). One well-documented comorbidity common among patients with diabetes is periodontal disease, along with other stigmata of poor oral health (2).

In 2008, 50,000 oral health–related hospitalization charges amounted to $1.218 billion in the United States; >40% of those hospitalized had at least one comorbid condition such as diabetes (3). In the same year, 50,881 emergency department visits for dental problems occurred among patients ≥ 60 years of age, the population in which type 2 diabetes is most prevalent (4). Despite calls for increased collaboration between medical and dental providers to improve diabetes care (5), patients with diabetes are less likely to visit a dentist annually (6) and have a higher risk of tooth loss (7). Studies have previously demonstrated the relationship between periodontal disease and inflammatory markers associated with diabetes severity (8–10). Among patients with diabetes, periodontal intervention has been associated with improved oral health status and substantial reduction in total health care costs and rates of hospitalization (11,12). Inpatient hospital care accounts for 43% of the > $176 billion spent annually to treat complications of diabetes (13). This costly and potentially preventable outcome may nonetheless represent an opportunity to connect patients with diabetes with oral health care services.

Previous studies have found poorer oral hygiene and oral health among hospitalized patients (14–16). Furthermore, oral health has been found to decrease over time during hospitalization (17,18). Although patients with type 2 diabetes

Corresponding author: Lisa E. Simon, Lisa_Simon@hms.harvard.edu
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have worse dental care access in the community, the oral health status of patients with type 2 diabetes who are hospitalized has not been well described, nor is it known how medical illness resulting in hospitalization may affect patients’ access to dental care (19). This observational study was undertaken to determine the baseline oral health status and attitudes toward oral health of patients with a diagnosis of type 2 diabetes who were hospitalized in a major tertiary care medical center. These findings may suggest possible opportunities to improve oral health and access to dental care for this vulnerable population.

Methods

The study occurred at a 999-bed tertiary care hospital serving as a major referral center in Boston, Mass. Patients were included if they were hospitalized on any of three general medicine wards within the hospital, were >18 years of age, and carried a diagnosis of type 2 diabetes within the hospital’s electronic health record (EHR) system (Epic Systems, Verona, Wisc.). Exclusion criteria included meeting indications for antibiotic prophylaxis for the prevention of infectious endocarditis per American Dental Association/American Heart Association guidelines (20), anticoagulation to an internal normalized ratio >2.5 (21,22), a platelet count of <100,000, a history of prosthetic joint replacement in the past 2 years (23), or altered mental status. Patients’ medical team or nurse could also decline to enroll a patient in the study. Patients who were fully edentulous were asked if they had their dentures with them in the hospital but were otherwise excluded from subsequent data collection. Informed consent was obtained from all subjects. Human subjects research approval was obtained by the Partners Human Subjects Research Board (2016P001460/BWH).

All subjects were asked a series of questions intended to evaluate oral health–related quality of life (OHRQoL). The three questions were selected to include a question on global oral health status, as well as the psychological dysfunction, psychological disability, and functional limitation domains of previously validated OHRQoL surveys (24). Responses were collected on a Likert scale. Participants were also asked about their most recent dental visit and the services provided at that time. Subjects were also asked about their perceived barriers to dental care and oral health care provided while in the hospital. As part of a randomized trial (ClinicalTrials.gov identifier NCT02914743), target enrollment of 72 subjects was obtained through preliminary power calculations, assuming a 20% increase in attitudes about oral health over time with an SD of 2 on a 10-point scale. Patients on one of the three wards were also selected for an oral evaluation. Periodontal probing depths were recorded using the periodontal screening and recording (PSR) system, in which each tooth is probed at six sites, and the deepest pocket in each sextant is recorded using a custom probe with codes 0–4, representing pocket depths of <1.5 mm without gingival bleeding or swelling, >0 to 3.5 mm with gingival bleeding but no swelling, >0 to 3.5 mm with swelling and visible calculus adherent to the tooth surface, 3.5–5.5 mm, and >5.5 mm, respectively (25). The status of oral hard tissues was recorded using the decayed, missing, and filled teeth (DMFT) index, which counts the number of teeth that have untreated decay, are missing, or have restorations within each subject’s mouth at the time of exam. Data were collected as part of the previously mentioned randomized clinical trial with ongoing follow-up (NCT02914743).

A registered dental hygienist administered all questionnaires and performed the oral evaluation of all subjects. Patients who spoke a language other than English were administered the questionnaire through an in-person interpreter. The same dental hygienist evaluated all subjects.

Subject demographics, including age, sex, and ethnicity, were extracted from the EHR, along with medical comorbidities; most recent blood pressure, blood glucose, and A1C values; and total number of prescribed medications.

Descriptive statistics and statistical analyses were performed using SPSS statistics software version 25 (IBM Corp., Armonk, N.Y.). Multiple linear regression and Student’s t tests were used for statistical comparison of secondary analyses with $P <0.05$ considered significant.

Results

Subjects were recruited from three general medicine wards with 136 beds and an average length of stay of 6.21 days. Eligible subjects were identified by preliminary chart review on a weekly basis from October 2016 to September 2017. Subjects’ medical and nursing teams were then approached for approval. The dental hygienist then approached patients for consent. A total of 105 subjects participated in the study, and 120 potential subjects with type 2 diabetes were excluded. Twenty-one patients were completely edentulous. The remaining 84 patients were asked to complete the surveys about their oral health. As part of our enrollment approach, subjects on one of the three general medicine services received an oral evaluation, whereas subjects on the other floors only completed surveys. Through this randomization procedure, a total of 19 subjects received an oral evaluation. Subject demographics are displayed in Table 1. Participants in the cohort as a whole had a mean age of 69 ± 12 years and were predominantly male (57%) and white (61%). No significant differences in age, sex distribution, or race/ethnicity...
were observed between subjects who received an oral evaluation and those who did not.

The most common comorbidities in these patients with type 2 diabetes were hypertension (74%), joint or abdominal pain (25%), congestive heart failure (23%), gastroesophageal reflux disease (16%), and depression (16%). The mean blood pressure was 131 ± 6 mmHg systolic and 68 ± 11 mmHg diastolic, the mean blood glucose was 189 ± 79 mg/dL, and the mean A1C was 7.5 ± 2.1%. Subjects were taking an average of 16.3 ± 6.7 medications, and 36% of subjects were administering insulin as part of their diabetes treatment. Subjects had a mean of 12 ± 7 comorbidities ranging from 2 to 40 concurrent medical conditions.

Subjects were asked three OHRQoL questions on a Likert scale ranging from 1 to 10, with 1 indicating “strongly agree” and 10 “strongly disagree.” A total of 84 subjects responded to these questions, as shown in Table 2. Subjects were slightly more likely to agree that their mouth and teeth were healthy (median response 4.0, interquartile range [IQR] 6.0). Subjects disagreed that problems with their mouth and teeth made it difficult to eat, talk, or live their life (median response 10.0, IQR 5.0), as well as that they were embarrassed by how their teeth looked (median response 9.5, IQR 5.0). Patients with a removable prosthesis were not significantly more likely to report that their mouth was unhealthy, that they had problems with their mouth, or that they were embarrassed by their teeth. In a multiple linear regression analysis adjusting for age and sex, there was no significant association between A1C and agreement that mouth and teeth were healthy, problems with mouth and teeth, or embarrassment about how teeth looked (P = 0.70, P = 0.25, and P = 0.98, respectively, for the first, second, and third questions in Table 2).

Most patients (59%) reported having a dentist of record. On average, it had been 19 ± 6 months since the subjects’ most recent dental visit. Subjects were asked why they were unable to visit a dentist (Table 3). The most common reason given was the cost of treatment (30%), followed by dental anxiety (25%), inability to travel to a dentist

### Table 1: Demographic Characteristics and General Health Status of Subjects

<table>
<thead>
<tr>
<th></th>
<th>All Participants (n = 84)</th>
<th>Participants With Oral Examination (n = 19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years (SD)</td>
<td>69 ± 12</td>
<td>69 ± 19</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>48</td>
<td>13</td>
</tr>
<tr>
<td>Female</td>
<td>36</td>
<td>6</td>
</tr>
<tr>
<td>Race/ethnicity, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>51</td>
<td>11</td>
</tr>
<tr>
<td>Caucasian</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Black</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Mean time since last dental visit, months (SD)</td>
<td>19 ± 6</td>
<td>22.1 ± 11.2</td>
</tr>
<tr>
<td>Comorbidities, n*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>62</td>
<td>12</td>
</tr>
<tr>
<td>Joint pain or abdominal pain</td>
<td>21</td>
<td>7</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>19</td>
<td>3</td>
</tr>
<tr>
<td>Gastroesophageal reflux</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>disease</td>
<td>13</td>
<td>1</td>
</tr>
<tr>
<td>Depression</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Obesity</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Chronic obstructive...</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Chronic renal impairment</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Cancer</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Hypothyroid</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Anxiety</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Chronic renal impairment</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Dementia</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

*Total number of comorbidities exceeds sample size because many subjects had more than one comorbidity.
Participants’ oral health status is presented in Table 4. Subjects had an average DMFT of 23.0 ± 7.2, with an average of 1.6 ± 1.9 decayed teeth, 10.1 ± 7.2 missing teeth, and 9.5 ± 5.8 filled teeth. The average PSR score across all sextants was 3.4 ± 0.45. Average scores in sextant 4 and sextant 6 (bilateral mandibular molars) were highest, at 3.4 ± 0.5 and 3.5 ± 0.5, respectively, indicating attachment loss of >4 mm. Sixty-eight percent of subjects had a PSR score ≥4 in at least one sextant, indicating moderate periodontal disease. In a multiple linear regression correcting for age and sex, higher mean PSR scores were not associated with higher A1C values (95% CI for coefficient -6.42 to 5.52, P = 0.87).

Most subjects (n = 43; 52%) had cleaned their teeth since they were hospitalized; two of these subjects reported that a nurse had cleaned their teeth, two reported that a family member had cleaned their teeth, and the rest had cleaned their teeth themselves. Thirty-seven subjects (44%), including the 21 edentulous subjects, had a removable prosthesis; of these subjects, 29 had their dentures or partial dentures with them in the hospital, and 17 reported wearing their prosthesis during sleep.

Discussion

Both diabetes and hospitalization are known risk factors for poor oral hygiene, and this was confirmed by this study of hospitalized patients with diabetes (7,18). Subjects exhibited both acute manifestations of dental disease in the form of untreated caries and active periodontal disease, as well as signs of chronic dental problems such as missing an average of 10 teeth. Previous studies of oral health status in the hospitalized population have shown similarly high levels of active dental disease independent of diabetes status (17,26,27); this has also been replicated in the community setting (28). However, to our knowledge, this is the first observational study focusing specifically on hospitalized patients with diabetes.

Rather than hospitalizations representing a period of decline in oral health, hospitals are positioned in a unique point of engagement with the community in that they are able to reach patients with high oral health need and difficulty accessing dental care. Despite this, only 1% of dentists work in a hospital setting (29), and nursing staff may have limited exposure to oral health concepts (30). Physicians receive minimal training in oral health during medical school and residency training (31). These knowledge deficits may result in improper management of oral problems by medical professionals. Additionally, lack of access to dental professionals in the hospital setting may result in unresolved oral health needs that may cause patients to return to the emergency department or primary care setting when they are ultimately unable to access a dentist (29,32). Given the high rate of medical system utilization for untreated dental problems, this situation represents a significant needless expenditure for the health care system, as well as a health risk for patients. In 2008, 20 patients died after being hospitalized due to dental disease (4,33,34).

Improved access to oral health services, and thus improved oral health, may be accomplished through increased

### TABLE 2 Respondent Agreement with OHRQoL Statements (n = 84)

<table>
<thead>
<tr>
<th>OHRQoL Statements</th>
<th>Median Response on 10-Point Likert Scale*</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>I agree that my mouth is healthy.</td>
<td>4.0</td>
<td>6.0</td>
</tr>
<tr>
<td>I disagree that the problems with my mouth and teeth make it difficult to eat, talk, or live my life.</td>
<td>10.0</td>
<td>5.0</td>
</tr>
<tr>
<td>I am embarrassed by the way my teeth look.</td>
<td>9.5</td>
<td>5.0</td>
</tr>
</tbody>
</table>

*Questions 1 and 3 asked for agreement, with 10 indicating the greatest agreement. Question 2 asked for disagreement, with 10 indicating the greatest disagreement.

### TABLE 3 Subjects’ Perceived Barriers to Visiting a Dentist (n = 84)

<table>
<thead>
<tr>
<th>Respondents, n (%)</th>
<th>Cost of treatment</th>
<th>23 (30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental anxiety</td>
<td>19 (25)</td>
<td></td>
</tr>
<tr>
<td>Cannot find a ride to visit the dentist</td>
<td>11 (14)</td>
<td></td>
</tr>
<tr>
<td>Insurance not accepted</td>
<td>9 (12)</td>
<td></td>
</tr>
<tr>
<td>Have a healthy mouth and do not feel the need to visit a dentist</td>
<td>7 (9)</td>
<td></td>
</tr>
<tr>
<td>No reported barriers to visiting to a dentist</td>
<td>7 (9)</td>
<td></td>
</tr>
<tr>
<td>Too sick to travel</td>
<td>5 (6)</td>
<td></td>
</tr>
<tr>
<td>Have dentures and do not feel the need to visit a dentist</td>
<td>3 (4)</td>
<td></td>
</tr>
</tbody>
</table>
integration of oral health into the medical system (35,36). From 2014 to 2017, the U.S. Department of Health and Human Services implemented an Oral Health Strategic Framework to accomplish this goal (37). Integration efforts have included changes to dental insurance structures, increased interoperability of electronic dental and medical records, and, importantly, the provision of oral health services in the medical setting (38-40).

These integration efforts may have the most impact for vulnerable populations who have the most difficulty entering the parallel dental care system. Our study and others have found that patients with diabetes are less likely to meet Healthy People 2020 goals of increased preventive dental care utilization, reduced rates of tooth extraction, and reduced rates of untreated decay (41). Given that a substantial proportion of respondents also noted they were unable to travel to a dentist because of their illness, oral health improvement from integration of dental care into the health system already used by these patients may present substantial benefits.

Nursing has embraced oral health care for patients who are being mechanically ventilated, with oral care leading to substantially reduced rates of pneumonia in these vulnerable patients (45). More intensive oral care, including dental prophylaxis, periodontal disease treatment, and even tooth extraction in critically ill, mechanically ventilated patients may further reduce pneumonia rates (46). However, given that only four subjects reported assistance with cleaning their mouths during hospitalization, this advance has not yet progressed to include patients who are not being mechanically ventilated.

Although the bidirectional relationship between diabetes and periodontal disease is well documented, the use of periodontal therapy to improve glycemic control in patients with diabetes and periodontitis has yielded mixed results (47-49). These results have included decreased risk of increased insulin dosing to maintain glycemic control, even over a 4-month study period, and overall improvement in A1C levels after consistent periodontal treatment, with the greatest gains made in patients with the highest initial A1C levels (50). Of note, one multicenter, randomized controlled trial found no significant benefit of periodontal treatment for people with diabetes; that study included individuals with a mean A1C (7.48%) that is consistent with the average A1C we found among hospitalized patients with diabetes (7.5%) (48).

Severity of periodontitis does appear to increase risks of complications of diabetes (51). More recent interventions have noted improvement in both periodontal health and A1C levels from nonsurgical periodontal therapy such as scaling and root planning, as well as from oral hygiene instruction alone in patients with diabetes (8). In light of these recent findings, the role of periodontal health in the reduction of systemic inflammation and improved outcomes in patients with diabetes continues to evolve.

In the present study, most patients hospitalized because of diabetes did report having a dental home, but the average time since their last visit was >1 year. Patients with systemic illnesses are more likely to regularly visit a physician than a dentist, a finding confirmed in this study (52).

Although both medical and dental providers have expressed enthusiasm for increased interdisciplinary practice, barriers to integration, including insurance coverage, provider knowledge, and referral processes, still restrict the ability of medical and dental providers to collaborate in caring for patients (53-55). Our own experience introducing a dental hygienist into the hospital setting has been described elsewhere (56). In addition to more integrated forms of oral health care delivery in the medical setting, patients with

<table>
<thead>
<tr>
<th>TABLE 4 Oral Health Status of Subjects</th>
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<tbody>
<tr>
<td>DMFT index, n</td>
</tr>
<tr>
<td>Decayed teeth</td>
</tr>
<tr>
<td>Missing teeth</td>
</tr>
<tr>
<td>Filled teeth</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>PSR scores</td>
</tr>
<tr>
<td>Sextant 1</td>
</tr>
<tr>
<td>Sextant 2</td>
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<tr>
<td>Sextant 3</td>
</tr>
<tr>
<td>Sextant 4</td>
</tr>
<tr>
<td>Sextant 5</td>
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<tr>
<td>Sextant 6</td>
</tr>
<tr>
<td>Total of all sextants</td>
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<table>
<thead>
<tr>
<th>Patients with prosthesis</th>
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<tbody>
<tr>
<td>Worn while hospitalized</td>
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<tr>
<td>Worn while hospitalized</td>
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<tr>
<td>Worn while sleeping</td>
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diabetes may benefit from merely being screened by medical providers about dental care access to address this gap.

Study participants were most likely to report high cost as the reason they were unable to visit a dentist, consistent with adults in the general population (57). The second most common reason for avoiding dental visits in this study was dental anxiety, reported by one-fourth of respondents. This rate is higher than that detected among adults seeking dental care (58), which is unsurprising given patients with higher levels of dental anxiety are less likely to seek dental care until their dental disease is more advanced (59). Patients with visibly poor oral health status or decreased functional oral status are more likely to report rates of dental anxiety, in part due to fear of judgment as well as physical discomfort (60,61). Patients with dental anxiety may be more likely to present to medical providers with dental concerns (62). Providers caring for patients with recent hospitalization or with diabetes should be proactive in inquiring about dental anxiety in these patients because such anxiety may represent a substantial barrier to care.

In spite of subjects’ overall poor oral health status, most indicated that they did not believe their oral health was particularly poor or that it represented a limitation for them. This is consistent with previous studies that have found a lack of association between oral health status and OHRQoL in patients with serious systemic illnesses (28,63–65). Subjects in our study may have been substantially burdened by medical illness that prevented them from focusing on their oral health concerns, even if their oral health was poor. Additionally, subjects may not have felt embarrassed by the appearance of their mouth and teeth while in the hospital because they were too ill.

There are several possible avenues to improve oral health for patients during hospitalization. First, nursing staff can be encouraged to provide oral hygiene for patients and to assist patients with removal of dental prostheses before sleep. Nursing leadership on oral hygiene has already become the standard of care in intensive care units, which represents a possible model for expansion to less acute settings (66). Employment of dentists as consultants in the hospital is another potential model for improved oral health care (29). Finally, the discharge process, during which patients often have specialty appointments booked, could be an opportunity to connect patients with dental care in the community alongside other necessary medical care.

Limitations

This is the first study to examine the oral health status, oral health care access, and attitudes toward oral health of patients with type 2 diabetes who were hospitalized in a major tertiary care medical center. However, our study faced numerous limitations, and additional multi-institution studies should be done to validate the reported findings.

Our data are only representative of patients presenting to a single tertiary care medical center, and our study had a very small sample size; thus, the results may not be generalizable to other populations, especially because oral health access may be dramatically affected by state- and local-level health policy trends (67). Our small sample size and lack of control group without diabetes (or outside the hospital) did not allow us to determine associations between oral health and hospitalization or diabetes status. Although the DMFT and PSR indices have been used in resource-limited settings for decades, they provide less information than complete evaluations, and we were unable to conclude which tooth surfaces were most likely to be decayed, which teeth were more likely to be missing, or other critical clinical indicators reported in larger studies (68). Finally, all evaluations were completed by a licensed dental hygienist rather than a dentist; however, our high rate of agreement between the dental hygienist and a dentist, as well as previous validation of dental hygienists’ assessment in the public health setting, suggest that this evaluation method may not have strongly affected the conclusions of our study (69).

Conclusion

In this study of patients with diabetes hospitalized at a large tertiary care medical center, subjects had high rates of missing teeth, removable prosthesis use, and periodontal inflammation. Lack of access to dental hygiene while in the hospital may compound these conditions in this medically complex population at high risk for poor oral health outcomes and facing substantial barriers to dental care. Patients with diabetes, who have a disease entity with known impact on both oral and systemic health, represent a population who may benefit from medical and dental integration. Health care workers, including medical and nursing staff, should consider patients’ oral health while they are hospitalized, and dental providers should screen patients for recent hospitalization as part of their medical assessment.

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DUALITY OF INTEREST

No potential conflicts of interest relevant to this article were reported.
FEATURE ARTICLE  
Oral Health Of Hospitalized Patients With Diabetes

AUTHOR CONTRIBUTIONS
L.E.S. and M.L.T. devised the study design. L.E.S. analyzed the data and wrote the manuscript. D.S.K. analyzed the data and contributed to the introduction and discussion. M.L.T. reviewed/edited the manuscript. L.E.S. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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