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IJMS

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Editorial

Medical Students and Equitable Global Health Research: From Participation to Shared Power

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Introduction

Research conducted in a community does not, by itself, give that community a voice in what is studied or how the findings are used. Controversies over the control of human biospecimens1 and the conduct of clinical trials in low-income settings2 illustrate persistent questions about consent, ownership, and benefit sharing. Resources for health research are also unevenly distributed, with disparities in funding and research capacity between high-income countries (HICs) and low- and middle-income countries (LMICs).[3,4] These inequalities concern authority as well as money: whose questions receive attention, whose contributions are recognized, and whose knowledge shapes interpretation and practice.[5,6]

In this editorial, decolonizing global health research means confronting the colonial histories that shaped the field and examining and redistributing control over funding, research questions, data, and decisions about what counts as legitimate knowledge. Colonial and tropical medicine shaped the development of global health; the history of malaria control provides one example of their lasting influence.7 Indigenous scholarship cautions that decolonization entails commitments to sovereignty and land restitution that cannot be reduced to institutional inclusion.8 Other scholars argue that undoing supremacy in global health requires more than decolonization.9 Our focus here is on research governance. We therefore ask one question of every proposed action: does it redistribute decision-making authority, budget control, or control over data, or does it merely widen participation? Participation without such a transfer sits on the lower rungs of Arnstein's ladder.[10]

Medical students have a place in this effort. Student-led movements have contributed to calls for decolonizing global health, although their capacity to change institutional structures remains limited.[11] Through research projects, electives, student organizations, and scholarly publishing, students encounter decisions about partnership, credit, and accountability during their training. This editorial proposes practical ways for students based in either HICs or LMICs to support locally defined priorities, negotiate transparent research partnerships, and organize collectively for institutional change. Their participation must be accompanied by commitments from faculty, universities, journals, and funders to share authority and provide the resources needed to sustain equitable practice.

Inequity in global health research

The studies summarized in ***Table 1*** describe inequities across several fields and settings. Their findings illustrate recurring problems, although their scope and generalizability differ. Institutional incentives and constraints can help sustain these patterns.

The role of medical students

Students based in HICs and LMICs can advocate for the following changes through their research, education, and collective organizing. Each action depends on a corresponding institutional commitment. ***Table 3*** links these actions to institutional responsibilities and proposed measures of progress.

Advocate for a decolonized curriculum.

Curricula offer a practical starting point for student advocacy. Students can review reading lists, teaching materials, and clinical tools for colonial bias and ask who sets the curriculum, selects speakers, and controls the resources available for teaching. A review should examine both representation and content, including skin tone in medical textbook imagery[32] and the use of race in clinical algorithms.[33] It should also ask whether descriptions of tropical or neglected diseases explain the structural conditions shaping their distribution. Students can invite researchers based in LMICs to speak and advocate for fair compensation. Student-run journal clubs can discuss locally prioritized health problems and scholarship from the regions concerned. Students in LMICs can examine their own curricula, including their reliance on textbooks, guidelines, and cases developed elsewhere, and build seminar series around local and regional scholarship. Because challenging a curriculum can put

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students at odds with the faculty who teach and assess them, such reviews are best presented collectively and supported by faculty commitments to share curricular authority and fund speaker honoraria.

Table 1. Examples of Inequity in Global Health Research and Training

Domain	Examples documented in the cited literature	References
Authorship and credit	Studies in neurosurgery, infectious diseases, and oncology report unequal representation across author roles, including limited representation of researchers based in study countries or LMICs in leadership positions.	12-14
Funding	Limited funding and institutional support can constrain research projects and career development in LMICs. Calls for reform also address how funders allocate resources and authority.	15-18
Publication costs	APCs and other publication charges can restrict publishing options for researchers with limited funds. Country-based waivers and discounts may exclude researchers with financial need in middle-income countries.	16,17/ 19-21
Epistemic injustice	Research can undervalue local knowledge and lived experience. An analysis of WHO drug-resistant tuberculosis guidelines found that experts based in high-burden and lower-income countries were underrepresented in guideline groups and related publications.	6,22-24
Classification and terminology	Income-based labels and broad country groupings can conceal differences within and between countries and reinforce hierarchies in how people and places are described.	25
Education	Studies of international electives describe supervision costs, resource pressures, and unclear clinical responsibilities for hosts. Historical analysis also identifies hierarchical portrayals of doctors migrating from India and Pakistan to the United Kingdom.	26-29
Mobility	Visa requirements, processing delays, and costs can restrict access to international conferences and training. Late invitations and uncertainty about funding can leave applicants insufficient time to secure visas.	30,31

Legend: APCs, article processing charges; LMICs, low- and middle-income countries; WHO, World Health Organization. These examples illustrate findings from specific settings and should not be interpreted as universal patterns or proof of causation.

Practice equitable partnership in student research

Students are increasingly expected to complete research projects, often in partnership with institutions in other countries. Whether these projects model equitable partnership depends largely on decisions made before data collection begins ***(Table 2).*** Student research groups should apply principles of mutual benefit, equity, accountability, humility, sustainability, and engagement with local and global stakeholders.[34] In practice, this means being explicit about who holds decision-making authority, who controls the budget, and who sets the conditions for data reuse. Students should distinguish local academic approval from community participation. A local collaborator's endorsement does not establish that patients or communities helped define a question. Teams should agree on mechanisms through which affected communities can question the project, negotiate benefits, and participate in decisions about whether it proceeds.

Table 2. A Checklist for Student Research Partnerships

• Who proposed the research question, and who will benefit from the answer?
• What mechanisms allow patients and communities, alongside local academic partners, to question the project, negotiate benefits, and participate in decisions about whether it proceeds?
• Has a local partner agreed to lead or co-lead, and is that role reflected in the protocol and budget?
• Have all collaborators agreed in writing on authorship criteria, provisional author order, and a process for reviewing contributions and resolving disagreements, using CRediT to document contributions and ICMJE criteria to determine authorship
• Who owns, stores, and controls the data, and who sets the conditions for access and reuse?
• Have the ethics approvals, exemptions, or reliance arrangements required by the relevant institutions and jurisdictions been identified and documented
• Are fair payment, acknowledgment, and authorship considered separately, with appropriate credit for local staff and collaborators?
• How will results be returned to participants, communities, and local decision-makers?
• Is there a plan for publication or presentation in the host setting as well as internationally?

Authorship expectations should be discussed early among all relevant collaborators and recorded as provisional arrangements to be revisited as contributions evolve. The Contributor Roles Taxonomy (CRediT)[35,36] documents contributions but does not determine eligibility for authorship. It can be paired with the International Committee of Medical Journal Editors (ICMJE) authorship criteria and an agreed process for reviewing contributions and resolving disagreements.[37] Contributors who meet the first ICMJE criterion should have the opportunity to participate in drafting or critical review and final approval; denying them that opportunity must not become a means of excluding them from authorship.[37] Local collaborators should have opportunities to contribute to design, analysis, interpretation, and writing, with appropriate credit, to prevent authorship parasitism and token authorship.[38,39] Fair payment, acknowledgment, and authorship recognize different contributions and should be considered separately.

Students should document the ethics approvals, exemptions, or reliance arrangements required by the relevant institutions and jurisdictions. They should also plan how findings will be returned to participants and communities and consider local journals, policy briefs, and presentations in the host setting alongside international publications. Students based in LMICs can propose projects through their own institutions, journals, research groups, and South-South networks. Because questioning supervisors or institutions can put students at risk, these conversations are best held collectively, with support from faculty allies and student organizations.

Reform electives, exchanges, conferences, and meetings

Electives and exchanges

Learning in global health should flow in both directions. Reverse innovation40 expresses this idea, although empirical work suggests that the term can reinforce the directionality it seeks to challenge.[41] A South-North patient safety partnership described

how hospitals in Liberia, Uganda, and South Sudan offered lessons to Johns Hopkins Medicine through open visiting, bedside rounds, and family involvement in patient care.[42] For electives and exchanges, priorities should be defined by the host, with visiting students' learning objectives compatible with those priorities. Hosts should decide what visiting students may do and should be compensated for supervision and other resource costs.[26,43] Knowledge exchange should be bidirectional and grounded in humility.[43,44] Students can share learning objectives before departure, work within their competence under local supervision,[45,46] and agree with hosts on a useful contribution.45 Student organizations can support reciprocal placements for students based in LMICs. Students in LMICs can also propose South-South exchanges and help set the terms on which their institutions host visitors.

Table 3. A Checklist for Student Research Partnerships

Domain	Student action	Institutional commitment	Proposed measures of progress
Curriculum	Review reading lists, images, and clinical tools. Invite scholars based in LMICs and organize journal clubs around their work.	Give LMIC-based scholars formal roles in curriculum design and review. Fund speaker honoraria and publish the findings of an annual review informed by students.	Share of assigned readings authored by LMIC-based scholars; share of sessions led by them; proportion of honoraria paid within an agreed period; student feedback on teaching and assessment.
Research partnerships	Agree on authority over questions, budgets, and data before collection. Apply ICMJE criteria and CRediT, keep author order provisional, separate payment from credit, and document ethics arrangements.	Require a partnership agreement before a project starts. Give partners and community representatives agreed decision-making roles and fund the return of results.	Share of projects with agreements signed before data collection; budget controlled by local partners; contributions and authorship reviewed; results returned; independent partner feedback on whether their input changed decisions.
Electives, exchanges, and conferences	Share learning objectives, work within competence under local supervision, and agree on a useful contribution. Advocate for visa support, accessible formats, and fee assistance.	Let hosts set priorities and compensate supervision. Offer reciprocal placements, choose accessible venues, issue invitations early, and provide assistance based on need.	Documentation of host-defined priorities; share of hosts compensated; reciprocal placements per year; participation by LMIC-based delegates and speakers; outcomes of visa and fee-assistance requests.
Language, images, and categories	Use accurate disease and virus names. Obtain publication consent in a language the person understands. Explain categories and disaggregate where justified.	Publish guidance on language, images, consent, and classification. Incorporate it into editorial and ethics review and train reviewers.	Share of submissions and protocols assessed against the guidance; justification of categories in outputs; documentation of understandable consent; publication of guidance adoption and review dates.
Institutional and funder accountability	Audit institutional practice collectively and present findings and proposals to academic leaders.	Assign a responsible senior official and fund a written response by an agreed deadline. Provide an independent complaints process and protection from retaliation. Support multiyear funding and agreed exit terms.	Repeat and publish audits at agreed intervals; track proposals adopted or answered; report aggregate complaint outcomes while protecting confidentiality; disclose the share and duration of funding controlled by local partners.
Positionality and diaspora	Reflect on knowledge, relationships, assumptions, privileges, and accountability. Include varied perspectives and use diaspora networks to support local partners.	Recognize and fund diaspora contributions while preserving local partners' authority over priorities, budgets, and data.	Positionality statements explaining effects on the work; partner feedback on diaspora involvement; documentation of local partners' decision-making authority.

Legend: CRediT, Contributor Roles Taxonomy; ICMJE, International Committee of Medical Journal Editors; LMICs, low- and middle-income countries. These are proposed process measures, not validated measures of equity. Partners should agree on targets, reporting responsibilities, and timelines locally and interpret counts alongside qualitative feedback.

Conferences and meetings

Student and professional organizations should consider LMIC venues and other locations where visa requirements, costs, and processing times permit broad participation.[47] For example, the International Health Economics Association moved its 2025 Congress from Calgary, Canada, to Bali, Indonesia, citing delays, costs, and uncertainty in Canadian visa processing.[48] Organizing committees should issue invitations early and provide supporting documentation and institutional assistance where appropriate. Hybrid formats offer another way to participate. The International Journal of Medical Students' World Conference of Medical Student Research provides an example of a fully online international conference run by medical students and early-career researchers.[49,50] Online formats can reduce travel and visa barriers, although language, connectivity, and time zones can still limit participation. Students in LMICs can also establish or join student-run journals, peer-review training programs, and regional meetings through South-South networks,[51] helping set agendas and publication practices closer to where research is conducted.

Costs require separate attention because manuscript submission fees, article processing charges (APCs), abstract fees, and conference registration fees create different barriers. For compliant open access journals and publishing platforms, Plan S requires APC waivers for authors from low-income economies, discounts for authors from lower-middle-income economies, and waivers or discounts for other authors with demonstrable need.[19] Country-based eligibility can nevertheless exclude researchers who lack funds in middle-income countries.[20,21] Assistance should therefore reflect financial need as well as country income classification, consistent with the concerns about broad labels

discussed here.[25] Published descriptions of Wiley's automatic APC waiver program illustrate one form of country-based support,[52] such programs should be complemented by transparent mechanisms for individual needs-based assistance.

Use language, images, and representation with care

Students should describe hosts as partners or collaborators and use language that emphasizes mutual learning. They should distinguish the virus SARS-CoV-2 from the disease COVID-19 and avoid stigmatizing geographic labels.[53] In a Rwandan study, some local learners found visiting students' repeated descriptions of their institution as poorly resourced diminishing.[43] Before publishing identifiable patient images or narratives, students should obtain explicit consent for publication in a language the person understands and follow applicable documentation requirements. Country and resource classifications should identify the specific dimension being measured rather than rely on labels that conceal variation.[25] Ancestry, ethnicity, racialization, nationality, and residence are distinct constructs. The categories used should fit the research question, be explained, and be disaggregated where justified and feasible. Broad groupings such as people of color or Black, Indigenous, and people of color (BIPOC) should not replace more specific categories without justification.[25]

Hold institutions and funders accountable

Students can advocate collectively for institutional policies that support South-South51 and South-North54 partnerships. They can audit their institutions' progress, publish the findings, and submit proposals to academic leaders. Students in LMICs can press their universities and national medical associations to fund local research groups and develop partnership policies. Such proposals should address who holds decision-making authority and budget control, alongside participation. Audits and proposals can expose students to retaliation; they are best undertaken collectively and with institutional protections.

Calls for funders to share authority must also address dependence on external financing. In May 2025, the US National Institutes of Health (NIH) announced restrictions on traditional foreign subawards, through which a prime recipient transfers funds to a partner abroad.[55] A subsequent policy introduced a linked award structure for international components, effective for relevant application due dates on or after January 25, 2026.[56] The change reorganized funding arrangements; it did not end NIH support for international research. Reporting during the 2025 funding disruptions described threats to South African tuberculosis and HIV research capacity.[57] These events underscore the vulnerability of partnerships that depend on decisions made by external funders. Separate awards should be assessed by whether they give international partners meaningful authority over resources and scientific priorities. A fuller approach to shared power would include domestic and South-South financing, multiyear core funding, and contractual protections such as notice periods and agreed exit terms.

Navigating power as an HIC-based student with ties to an LMIC Institutional location can shape access to funding, networks, and recognition. Global health practitioners have described hierarchies that privilege institutions and expertise associated with the Global North.[58] A student based in an HIC may therefore have forms of institutional access unavailable to some colleagues in a country with which that student has family or cultural ties. Shared ancestry does not erase these differences, but institutional privilege should not be assumed to be uniform. Language, migration history, relationships, and sustained involvement can vary substantially, so neither insider nor outsider status should be presumed. Positionality reflection is useful for everyone on a research team: what knowledge, relationships, assumptions, privileges, and accountability obligations does each person bring?[59] Teams should draw on varied perspectives in design, analysis, and interpretation without treating an outsider's interpretation as inherently more rigorous than local knowledge. Diaspora health workers can connect institutions and support opportunities for colleagues in countries of heritage.[60] The Tropical Health and Education Trust's 2021 report, Experts in Our Midst, recommended a network to identify, document, and support diaspora-led relationships and explicitly included student groups among potential participants.[60] Student organizations can adapt this approach while ensuring that diaspora involvement supports local partners' authority rather than substituting for it.

Limitations

Student-led initiatives have limitations. A reading list with a few authors based in LMICs, a pledge without follow-up, or a student-led committee with a restricted budget may benefit an institution's reputation while leaving its practices intact. Expecting students to correct systems sustained by faculty, funders, and institutions places an unfair burden on them. Students remain subject to grading, recommendations, and funding decisions controlled by these actors. Collective organizing through student unions, professional associations, and global networks may help students share risk and negotiate change, but it does not remove their vulnerability. Student action therefore requires institutional support, protection from retaliation, and meaningful authority. It cannot substitute for systemic reform. The measures in Table 3 are proposed process indicators, not validated evidence that equity has been achieved; they should be interpreted alongside feedback from partners and communities.

Conclusion

Decolonizing global health research is ultimately a question of power. Medical students cannot transform its structures alone, but their training can shape how future investigators, funders, editors, and policymakers share authority and resources. The actions proposed here offer practical starting points for research governed with meaningful participation by the people and institutions affected. Their value depends on faculty, universities, journals, and funders providing the resources, protections, and decision-making authority that equitable practice requires.

Accountability must extend to the communities and partners on whom global health research depends.

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Original Article

Association Between Diabetes Mellitus and Intraoperative Awareness During General Anesthesia: A Retrospective Cohort Study

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Abstract

Background: Despite advancements in anesthetic techniques, specific patient populations remain vulnerable to intraoperative awareness. Diabetes mellitus (DM), increasingly prevalent and often accompanied by significant comorbidities, may complicate anesthetic management and mask signs of inadequate anesthetic depth. This study investigates whether DM is independently associated with an increased risk of unintended intraoperative awareness. **Methods:** A retrospective cohort analysis was conducted using the TriNetX research platform, a federated health database. Two cohorts were identified: patients with DM and a control group without DM undergoing surgery under general anesthesia (GA). Propensity-score matching (1:1) was used for demographics, comorbidity categories, procedure categories, and medication classes, with patients having cognitive impairment, chronic obstructive pulmonary disease, substance use disorder, cardiovascular disease or non-GA anesthetic technique excluded. The incidence of intraoperative awareness was compared between groups. **Results:** After matching, 189,787 patients were included in each cohort (total n=379,574). The incidence of intraoperative awareness was significantly higher in the DM group (0.027%, n=52) compared to the non-DM group (0.017%, n=32). DM was associated with a statistically significant increased risk (absolute risk difference: 0.011%, 95% CI: 0.001–0.02%, p=0.0291). This corresponds to a 62.5% higher relative risk of documented intraoperative awareness (RR=1.625, 95% CI: 1.046–2.524; OR=1.625, 95% CI: 1.046–2.524). **Conclusion:** DM was associated with a modestly higher relative risk, but a very small absolute difference, in documented intraoperative awareness. Given the observational design and residual imbalance in diabetes-related comorbidity, causality cannot be inferred. These findings support continued anesthetic vigilance in diabetic patients.

Introduction

Each year, more than 40 million patients in North America undergo anesthesia for surgical procedures.[1] While the safety of anesthetic practice has improved substantially over recent decades, many of the molecular and physiological mechanisms underlying anesthetic action remain incompletely understood. This persistent knowledge gap limits the refinement of existing anesthetic agents and impedes the development of safer, more targeted alternatives. As with all pharmacologic therapies, anesthetics carry inherent limitations, contraindications, and potential adverse effects.

Intraoperative awareness, defined as the unintended recall of events during general anesthesia, is one of the most psychologically distressing and clinically significant complications of anesthetic care.[2] Although rare, its consequences can be profound, often including post-traumatic stress disorder, persistent anxiety, and long-term mistrust of medical systems.[2] The reported incidence of intraoperative awareness varies widely, ranging from 0.006% to 1%, depending on the methodology used. For instance, patient-reported data suggests an incidence of 1–2 per 1,000 anesthetics, while anesthesiologist-reported estimates are as low as 1 in 15,000.3 This discrepancy may reflect under recognition by providers, as many patients report awareness days or weeks after surgery, often only during preoperative assessments for future procedures.[3] These findings underscore the inadequacy of current detection methods and highlight the need for systematic postoperative evaluations.

Numerous risk factors for intraoperative awareness have been identified. Pediatric patients exhibit significantly higher risk, up to 8 to 10 times that of adults, likely due to rapid redistribution of anesthetics and reduced effective plasma concentrations.[4,5] Other recognized patient-related risk factors include high American Society of Anesthesiologists physical status (III or above), chronic alcohol or opioid use, and the need to limit anesthetic depth in settings of cardiovascular instability or severe obesity.[1,6-8] The use of neuromuscular blockers further elevates risk by masking motor responses that typically serve as warning signs of inadequate

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anesthesia.[9] Conversely, benzodiazepines offer a protective effect by promoting amnesia.[10] Notably, obesity has emerged as a relevant concern not only for its pharmacokinetic complexity but also because it is highly prevalent among high-risk populations, over 90% of individuals with type 2 diabetes are overweight or obese, suggesting a potential link between diabetes and anesthesia-related complications.[11]

Diabetes mellitus (DM), which affects approximately 13% of adults in the United States (U.S), is a prevalent and clinically multifaceted comorbidity among surgical patients.[12] Beyond its association with obesity, DM often coexists with cardiovascular disease, hypertension, dyslipidemia, and chronic kidney disease (CKD), each of which complicates anesthetic management.[11] Moreover, DM-related autonomic neuropathy may blunt sympathetic responses to inadequate anesthesia, masking key physiological indicators such as changes in heart rate or blood pressure.[11,13] In parallel, diabetic gastroparesis may delay gastric emptying, affecting the timing and absorption of anesthetic agents, while obstructive sleep apnea and reduced ventilatory reserve further challenge intraoperative monitoring.[11] Together, these factors may obscure conventional markers of anesthetic depth and compromise the anesthesiologist's ability to detect and prevent intraoperative awareness.

Despite the theoretical and mechanistic rationale suggesting a potential link, the relationship between DM and intraoperative awareness remains poorly characterized in the existing literature. To address this gap, we conducted a retrospective cohort study to examine the association between DM and the incidence of intraoperative awareness during general anesthesia. Data were obtained from the TriNetX Research Platform, a federated health research network encompassing 72 healthcare organizations within the U.S. Collaborative Network. TriNetX houses more than 250 million de-identified patient records and provides comprehensive clinical data on demographics, diagnoses, procedures, laboratory results, and medication histories. By leveraging this large, real-world dataset, our study aims to clarify the potential association between diabetes and intraoperative awareness, thereby improving preoperative risk stratification, informing individualized anesthetic management, and guiding targeted strategies to enhance perioperative safety in this high-risk and growing patient population.

Methods

Data Set: This study was conducted using a retrospective cohort design with anonymized patient data extracted from the TriNetX research platform, a federated health research network comprising electronic health record (EHR) data from diverse healthcare organizations across the U.S.

Study Population: Two patient cohorts undergoing procedures requiring general anesthesia (GA) were established for comparative analysis: a diabetic cohort (patients who had at least one documented diagnosis of DM using the 10th version of the International Classification of Diseases codes (ICD-10 codes E08–E13) recorded in the EHR prior to the index surgery date) and a matched non-diabetic control cohort (patients without any documented diagnosis of DM (ICD-10 codes E08–E13) at any point prior to the surgical procedure date). Data were collected from June 2005 to June 2025, and the index event (time zero) was defined as the first recorded anesthetic encounter for each patient during the study period. In addition, diabetes status and all covariates were ascertained from the EHR record strictly prior to this index event. Patients were identified from EHR data based on predetermined inclusion and exclusion criteria within the TriNetX platform. Patients were required to meet all of the following conditions for inclusion:

1. Anesthesia Encounter: Documentation of anesthesia service codes (TriNetX anesthesia code 1002796) indicating anesthesia services.
2. General Anesthetic Medication Administration: Evidence of receiving at least one pharmacological agent strongly indicative of general anesthesia, including:
    i. Volatile anesthetics (sevoflurane, isoflurane, desflurane), OR
    ii. Neuromuscular blocking agents (succinylcholine, rocuronium, vecuronium), OR
    iii. Total intravenous anesthesia (TIVA), specifically a combination of propofol with remifentanil.
3. Surgical or Procedural Context: Underwent at least one invasive procedure frequently associated with GA within one day of documented anesthetic medication administration. Relevant procedures included cardiovascular, neurological, gastrointestinal, endocrine, musculoskeletal, maternity-related surgeries, and interventional radiological therapeutic procedures.

To more precisely attribute any association between DM and intraoperative awareness, patients were excluded from both cohorts if they had documented ICD-10 diagnoses prior to surgery of the following confounding conditions:

1. Cognitive impairment or dementia preventing postoperative recall
2. Chronic obstructive pulmonary disease
3. Active hepatitis
4. Alcohol dependence or abuse
5. History of myocardial infarction
6. Cerebrovascular accident
7. Transient ischemic attack
8. Coronary artery disease
9. Medication or drug abuse or dependence
10. Procedures performed explicitly under monitored anesthesia care (MAC), sedation-only, or regional anesthesia without general anesthesia documentation

The primary outcome was the documented occurrence of intraoperative awareness, identified by ICD-10-CM codes T88.53 ("Unintended awareness under general anesthesia") or Z92.84

("Personal history of unintended awareness under general anesthesia"), recorded either during the index anesthetic event or within a five-year window following the event. This time frame was selected to minimize underestimation of intraoperative awareness incidence and to capture frequently underreported or delayed documentation of intraoperative awareness that may still be temporally and clinically related to the original surgical procedure.[3] ***(Figure 1).***

Table 1. Baseline Demographic Characteristics of Diabetic and Non-Diabetic Patients Undergoing General Anesthesia Before and After Propensity-Score Matching

Variable	Before Matching Patients (% of Cohort)			After Matching Patients (% of Cohort)		
	No Diabetes (n = 1,156,118)	Diabetes (n = 190,237)	Standardized Difference	No Diabetes (n = 189,787)	Diabetes (n = 189,787)	Standardized Difference
Age at Index	41.7 ± 21.3	57 ± 15.1	0.8308	57.4 ± 15.6	57 ± 15.1	0.0273
Gender						
Female	660,704 (57.585%)	110,675 (58.304%)	0.0146	110,713 (58.335%)	110,675 (58.315[C%)	0.0006
Male	486,232 (42.379%)	79,121 (41.681%)	0.0141	79,043 (41.648%)	79,121 (41.689%)	0.0006
Ethnicity						
Hispanic or Latino	90,110 (7.854%)	15,537 (8.185%)	0.0122	14,240 (7.503%)	15,537 (8.187%)	0.0253
Not Hispanic or Latino	860,088 (74.963%)	142,479 (75.058%)	0.0022	143,429 (75.574%)	142,479 (75.073%)	0.0119
Unknown Ethnicity	197,152 (17.183%)	31,809 (16.757%)	0.0114	32,118 (16.923%)	31,809 (16.760%)	0.0044
Race						
Asian	25,034 (2.182%)	5,005 (2.637%)	0.0297	4,962 (2.615%)	5,005 (2.637%)	0.0014
American Indian or Alaska Native	4,914 (0.428%)	1,161 (0.612%)	0.0255	885 (0.466%)	1,161 (0.612%)	0.0199
Black or African American	143,774 (12.531%)	31,102 (16.385%)	0.1097	29,510 (15.549%)	31,102 (16.388%)	0.0225
Native Hawaiian or Other Pacific Islander	7,128 (0.621%)	1,439 (0.758%)	0.0165	1,264 (0.666%)	1,439 (0.758%)	0.0109
White	853,566 (74.395%)	134,359 (70.78%)	0.0811	137,479 (72.439%)	134,359 (70.795%)	0.0365
Other Race	50,521 (4.403%)	8,089 (4.261%)	0.0070	7,344 (3.87%)	8,089 (4.262%)	0.0197

Legend: Values are reported as mean ± standard deviation for continuous variables and n (%) for categorical variables. Standardized mean differences (SMDs) are shown to evaluate covariate balance; SMD < 0.10 was considered indicative of adequate balance after matching.

Statistical Analysis: Descriptive statistics (frequencies and percentages) were calculated to summarize patient demographics and clinical characteristics within each cohort. Cohorts were balanced using a 1:1 propensity score matching approach to control for potential confounding factors. The TriNetX Analytics Platform performs cohort comparison and propensity-score matching as an integrated, automated procedure: the platform first compares the two cohorts across a comprehensive, predefined variable set that includes (i) demographic characteristics (age at index, sex, race, ethnicity); (ii) all 22 ICD-10 diagnostic chapters; (iii) TriNetX-defined Current Procedural Terminology (CPT) procedure categories (Anesthesia [1002796], Surgery [1003143], Pathology and Laboratory [1011136], Evaluation and Management [1013625], Medicine Services [1012569], Radiology [1010251], etc); and (iv) the full set of VA National Drug File medication classes (Central Nervous System, Cardiovascular, Autonomic, Respiratory, Gastrointestinal, Antimicrobials, Hormones, Blood products, and others). The platform then automatically identifies variables exhibiting significant pre-match differences using its built-in significance indicator, and enters only those flagged variables into the 1:1 greedy nearest neighbor propensity-score matching algorithm (caliper 0.1 standardized logit units, without replacement).[14] The variables that were flagged and entered into matching are reported in full in ***Table 2*** of the main manuscript with their pre- and post-match standardized mean differences. All outcome estimates, risk difference, risk ratio, and odds ratio with their associated 95% confidence intervals and p-values, were calculated directly from event counts in the propensity-score matched cohorts using the TriNetX analytics module. The platform computes the risk difference and its 95% confidence interval using unconditional (asymptotic) standard-error methods for the difference of two independent proportions, and computes risk ratio, odds ratio, and their corresponding 95% confidence intervals from the matched-cohort 2 × 2 contingency table using the standard large-sample estimators implemented in the platform. P-values for the comparison of incidence proportions are derived from the corresponding large-sample test statistic for two independent proportions.[14] The incidence of intraoperative awareness was compared between the diabetic and non-diabetic cohorts. Baseline covariate balance between matched cohorts was assessed using standardized mean differences (SMD), as p-values from chi-square or t-tests can be misleading in very large samples.[15] An SMD <0.1 was considered indicative of adequate balance.[16] For outcome analyses, statistical significance and effect size were evaluated using risk differences, risk ratios, and odds ratios. All statistical analyses were conducted using the TriNetX analytics platform, with statistical significance defined as a p-value <0.05. This study was conducted and reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational cohort studies.

Results

In total, 1,787,558 patients who underwent general anesthesia met the inclusion criteria. After applying the exclusion criteria, 1,346,355 remained eligible for analysis. ***(Figure 1)***. ***Table 1*** summarizes the baseline demographic characteristics of the study population before and after propensity-score matching. The age at index for diabetic cohort was 57.0 ± 15.1 years, whereas it was 57.4 ± 15.6 years in the non-diabetic cohort. Gender distribution was similar between groups, with females comprising 58.305% of the diabetic cohort and 58.335% of the non-diabetic cohort. … "Not Hispanic or Latino" (75.059% in the diabetic cohort vs. 75.574% in the non-diabetic cohort) and "White" (70.794% vs. 72.439%). (All demographic variables were well balanced between cohorts.

Table 2. Comparison of Clinical Comorbidities Between Diabetic and Non-Diabetic Patients Undergoing General Anesthesia Before and After Propensity-Score Matching

ICD-10 Category	Before Matching Patients (% of Cohort)			After Matching Patients (% of Cohort)		
	No Diabetes (n = 1,156,118)	Diabetes (n = 190,237)	Standardized Difference	No Diabetes (n = 189,787)	Diabetes (n = 189,787)	Standardized Difference
E00-E89 Endocrine, nutritional, and metabolic diseases	587,824 (51.233%)	189,825 (100%)	1.3798	131,149 (69.103%)	189,787 (100%)	0.9456
I00-I99 Diseases of the circulatory system	473,016 (41.227%)	159,887 (84.229%)	0.9929	118,001 (62.175%)	159,849 (84.225%)	0.5140
N00-N99 Diseases of the genitourinary system	525,636 (45.813%)	125,883 (66.315%)	0.4222	111,687 (58.849%)	125,846 (66.309%)	0.1546
C00-D49 Neoplasms	365,744 (31.877%)	90,527 (47.69%)	0.3274	90,791 (47.838%)	90,500 (47.685%)	0.0031
L00-L99 Diseases of the skin and subcutaneous tissue	347,592 (30.295%)	86,383 (45.507%)	0.3175	85,425 (45.011%)	86,346 (45.496%)	0.0097
A00-B99 Certain infectious and parasitic diseases	328,208 (28.606%)	80,866 (42.6%)	0.2954	80,002 (42.154%)	80,829 (42.589%)	0.0088
D50-D89 Diseases of the blood	270,919 (23.613%)	79,618 (41.943%)	0.3982	79,034 (41.644%)	79,580 (41.931%)	0.0058
H00-H59 Diseases of the eye and adnexa	224,429 (19.561%)	60,963 (32.115%)	0.2898	59,090 (31.135%)	60,925 (32.102%)	0.0208
U00-U85 Codes for special purposes	45,442 (3.961%)	13,498 (7.111%)	0.1381	13,297 (7.006%)	13,489 (7.107%)	0.0040
P00-P96 Certain conditions originating in the perinatal period	26,202 (2.284%)	1,407 (0.741%)	0.1266	902 (0.475%)	1,407 (0.741%)	0.0342

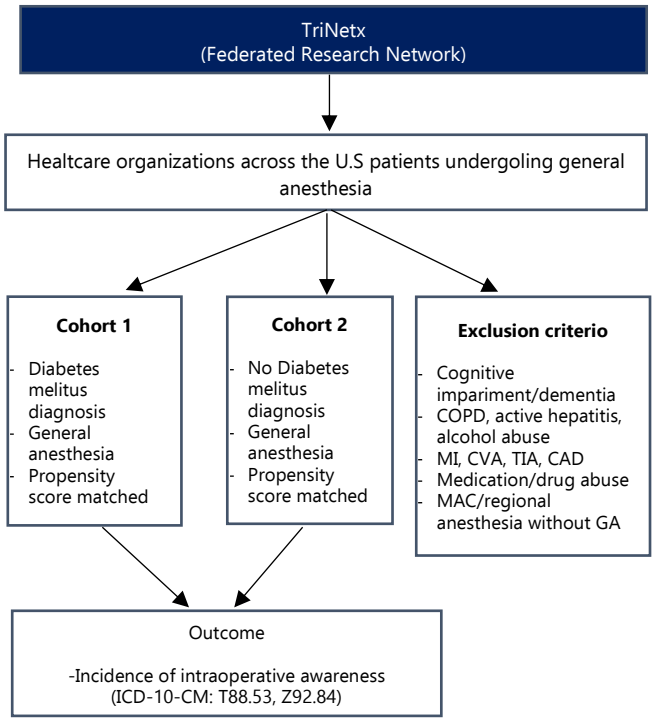
Legend: Values represent the proportion of each cohort with at least one diagnosis in the specified ICD-10 category. Standardized mean differences (SMDs) are reported to assess balance in comorbidity burden; SMD < 0.10 after matching indicates excellent balance between cohorts.

To isolate DM as an independent risk factor for intraoperative awareness, propensity-score matching also accounted for clinical comorbidities between cohorts. Before matching, there were significant imbalances in several diagnostic categories, including neoplasms, infectious diseases, skin and subcutaneous tissue disorders, and blood-related disorders. Following matching, these differences were substantially minimized or eliminated, with post-match distributions in categories such as neoplasms, skin disorders, infectious diseases, diseases of the blood, and eye diseases nearly identical across cohorts. This matching strategy effectively reduced the influence of non-DM-related comorbidities, allowing for a cleaner assessment of DM as an independent variable. ***(Table 2)***

In total, 1,346,355 patients who underwent general anesthesia were identified for inclusion in this analysis. After propensity-score matching, two balanced cohorts were established, each comprising 189,787 patients with and without DM, respectively. As shown in ***Figure 2,*** intraoperative awareness under general anesthesia was identified in 52 patients (0.027%) in the DM cohort and 32 patients (0.017%) in the non-DM cohort, corresponding to an absolute risk difference of 0.011% (95% CI: 0.001%–0.020%, p = 0.0291). The risk ratio (RR) and odds ratio (OR) were both 1.625 (95% CI: 1.046–2.524), indicating increased risk of intraoperative awareness in patients with DM compared to those without. To address hidden confounders, an E-value analysis was carried out, yielding 2.63 as the point estimate based on the RR, and 1.27 as the lower bound of the confidence interval. Baseline characteristics were well balanced after propensity matching, with all standardized mean differences < 0.1 ***(Table 1).*** For comorbidity categories, most non-endocrine diagnostic groups were also well balanced, whereas larger standardized mean differences persisted for the broad endocrine/metabolic, circulatory, and genitourinary categories, reflecting the expected higher burden of diabetes-related conditions in the diabetic cohort ***(Table 2).*** The full pre-matching distribution across all CPT procedure categories and Veterans Affairs (VA) drug classification system that TriNetX compared but did not select for matching are included in Supplementary ***Table S1***.

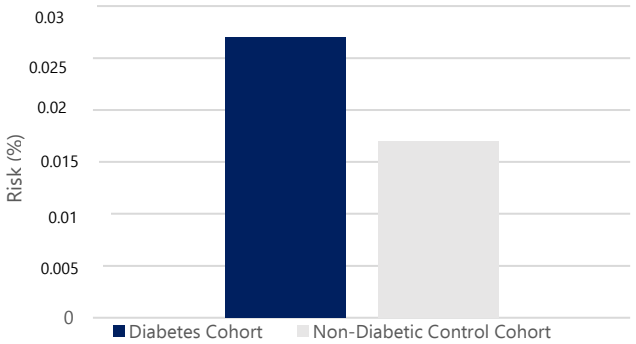
These findings demonstrate a robust and statistically significant association between DM and an increased risk of intraoperative awareness under general anesthesia, even after rigorous control for demographic and clinical confounders ***(Figure 3*** and ***Table 2).***

Figure 1. Selection Criteria for Retrospective Cohort Study



Legend: Flow diagram of cohort selection from the TriNetX U.S. Collaborative Network (2005–2025). Patients receiving general anesthesia were identified, with MAC and regional-only cases excluded. After applying predefined inclusion/exclusion criteria and removing confounders, patients were categorized into diabetic and non-diabetic groups. A 1:1 propensity-score matching procedure produced balanced, equally sized cohorts for outcome analysis.

Figure 2. Overall Outcome of Intraoperative Awareness in Diabetic vs. Non-Diabetic Patients Undergoing General Anesthesia



Legend: Bars represent the number and percentage of patients with documented intraoperative awareness in each cohort after propensity-score matching. Intraoperative awareness occurred in 52 diabetic patients (0.027%) and 32 non-diabetic patients (0.017%), illustrating the higher incidence in the diabetic cohort.

Discussion

This study evaluated the association between DM and the risk of intraoperative awareness during general anesthesia, demonstrating that DM is associated with a significantly increased risk. As shown in ***Figure 3,*** the risk ratio for intraoperative awareness in diabetic patients was 1.625 (95% CI: 1.046–2.524), with a corresponding odds ratio of 1.625 (95% CI: 1.046–2.524; p = 0.0291). While this represents a 62.5% higher relative risk of intraoperative awareness among patients with diabetes, the absolute difference between groups was minimal, 0.027% in the diabetic cohort compared to 0.017% in the non-diabetic cohort, corresponding to an absolute risk difference of 0.011% (95% CI: 0.001%–0.020%, p = 0.0291).

Figure 3. Incidence and Relative Risk of Intraoperative Awareness in Diabetic vs. Non-Diabetic Patients Undergoing General Anesthesia

		Cohort Statistics		
	Cohort	Patients in Cohort	Patients with Outcome	Risk
1	Diabetes Cohort	189,787	52	0.027%
2	Non-Diabetic Control Cohort	189,787	32	0.017%

Risk Difference				Risk Ratio		Odds Ratio	
Risk Difference	95 % CI	z	p	Risk Ratio	95 % CI	Odds Ratio	95 % CI
0.011%	(0.001%,0.02%)	2.182	0.0291	1.625	(1.046,2.524)	1.625	(1.046,2.524)

Legend: This figure summarizes the overall incidence of intraoperative awareness and the corresponding relative risk comparing diabetic and non-diabetic patients after propensity-score matching. Diabetic patients experienced 52 awareness events (0.027%) compared with 32 (0.017%) in the non-diabetic cohort, corresponding to a relative risk of 1.625 (95% CI, 1.046–2.524).

In absolute terms, the unrounded risk difference (52 − 32 = 20 additional events among 189,787 patients per cohort; 0.0105%) corresponds to approximately 10.5 additional documented cases per 100,000 anesthetics. Its reciprocal, often reported as a number needed to harm, is approximately 9,489. This contextualizes the clinical magnitude of the finding: one additional case of intraoperative awareness would be expected for every 9,489 diabetic patients receiving general anesthesia. To provide comparison, this absolute increase remains less frequent as compared to the risk of having perioperative anaphylaxis and failed intubation, which are 1 in 6,531 and 1 in 3,057 respectively.[17,18]

This small absolute difference underscores that intraoperative awareness remains a rare phenomenon in both populations. Nonetheless, the finding carries clinical relevance because awareness, though infrequent, can have severe psychological and medicolegal consequences. Thus, these results should be interpreted as emphasizing the importance of recognizing and mitigating subtle, patient-specific Dashes become commas: "risk

factors, such as those associated with diabetes, rather than suggesting a substantial change in overall anesthetic practice. In everyday anesthetic application, the implications lie in targeted vigilance: ensuring adequate depth of anesthesia, particularly in patients whose metabolic or neurologic alterations may influence anesthetic pharmacodynamics.

Several pathophysiologic mechanisms may underlie the increased susceptibility to intraoperative awareness observed among diabetic patients. Chronic hyperglycemia and metabolic dysregulation can lead to diabetic autonomic neuropathy, which blunts physiological responses, such as tachycardia and hypertension, to inadequate anesthesia, masking clinical indicators of insufficient anesthetic depth.[19] Gastroparesis, a common manifestation of autonomic dysfunction, delays gastric emptying and may reduce the absorption of preoperative oral sedatives and anxiolytics, decreasing their bioavailability and effectiveness.[11] Moreover, DM is associated with widespread microvascular complications that impair capillary blood flow and tissue perfusion.[20] These changes can alter the pharmacokinetics of anesthetic agents by reducing their distribution efficiency and delaying equilibration with central compartments, including the central nervous system. As a result, anesthetic agents may reach subtherapeutic concentrations in target tissues, which could increase the risk of intraoperative awareness.

The clinical implications of intraoperative awareness are substantial, with potential long-term consequences including post-traumatic stress disorder, anxiety, and avoidance of future healthcare encounters, which can negatively impact patient outcomes and quality of life.[2] Given the rising global prevalence of DM, these findings highlight the need for heightened vigilance and personalized anesthetic strategies in this high-risk population.

Since autonomic signs may be unreliable in diabetic patients, anesthesiologists should consider incorporating objective depth-of-anesthesia monitoring tools, such as bispectral index monitoring, which utilizes electroencephalogram data to assess consciousness levels and allows real-time anesthetic adjustment.[21] This approach may help mitigate the risk of awareness in patients with DM. Furthermore, neuromuscular blocking agents (NMBAs), while often necessary for surgical procedures, are associated with an increased risk of awareness due to their suppression of motor responses, which are often used as indirect signs of consciousness.[9] While it may not always be feasible to avoid NMBA use, clinicians should minimize their dosage where appropriate and ensure that depth of anesthesia is adequately maintained when paralysis is required.

Several strengths of this study warrant emphasis. The analysis focused on a single, predefined primary outcome, the incidence of intraoperative awareness, thereby minimizing the risk of Type I error due to multiple analyses. The use of 1:1 propensity-score matching across demographic and clinical variables, combined with a matched sample of nearly 380,000 patients, provided robust statistical power to detect the observed association while controlling for measured confounders. Given that the data from TriNetX were derived from the U.S Collaborative Network, the patient population was sufficiently diverse and nationally representative, supporting the generalizability of these findings across a wide range of healthcare settings.

The exclusion of patients with cardiovascular disease, including coronary artery disease, prior myocardial infarction, and cerebrovascular accident, warrants specific justification. We recognize that these conditions are downstream sequelae of diabetes and, within a strict causal framework, sit on the mediating pathway between diabetes and intraoperative awareness rather than acting as confounders. Our rationale for excluding them was not to control confounding but to limit heterogeneity in anesthetic technique. In patients with significant cardiovascular or cerebrovascular disease, anesthesiologists frequently and intentionally deliver lighter, hemodynamically tailored anesthesia to preserve perfusion pressure.[22] This independently elevates the risk of intraoperative awareness through a mechanism unrelated to diabetes. Similarly, patients with chronic obstructive pulmonary disease (COPD) and active hepatitis were excluded for two reasons rooted in anesthetic pharmacology. COPD alters pulmonary uptake and elimination of inhaled volatile anesthetics through ventilation-perfusion mismatch and air trapping, producing less predictable anesthetic kinetics.[23] These pharmacokinetic complexities, combined with heightened concern for postoperative respiratory complications, may influence anesthetic management in ways that could increase the risk of intraoperative awareness.[24] As for active hepatitis, it impairs hepatic metabolism and clearance of intravenous anesthetic agents, resulting in unpredictable plasma concentration.[25] Additionally, patients with cognitive impairment or dementia were excluded due to the potential for unreliable postoperative recall, which could compromise the accuracy of intraoperative awareness reporting.

We acknowledge that this exclusion strategy limits the generalizability of our findings to the broader surgical population, in which cardiovascular comorbidity is common among diabetic patients. The estimate reported here should therefore be interpreted as the association between diabetes and intraoperative awareness independent of established macrovascular complications, rather than the total effect of diabetes inclusive of its cardiovascular sequelae.

Our findings should be interpreted in light of several methodological limitations inherent to the data source and study design. Propensity score matching effectively reduced measurable differences between cohorts, with the exception of three system categories endocrine/metabolic (post-matching SMD 0.9456), circulatory (SMD 0.5140), and genitourinary (SMD 0.1546) diseases. The endocrine/metabolic imbalance is largely structural as diabetes itself is coded within ICD-10 chapter E00–E89, so every patient in the diabetic cohort carries a code in this

category and it cannot be balanced against a non-diabetic control cohort. These conditions frequently co-occur with diabetes, therefore, full adjustment for these conditions is not feasible because doing so would remove core clinical features of the diabetic population and lead to overmatching, where controlling for downstream consequences of diabetes masks the very pathways through which DM may influence anesthetic risk. Consequently, residual confounding remains possible, particularly from comorbidities closely linked to DM that were not comprehensively controlled for, such as chronic kidney disease (CKD) and obesity. CKD can significantly alter anesthetic pharmacokinetics and pharmacodynamics by impairing drug metabolism and clearance, thereby prolonging anesthetic effects. Similarly, obesity— which is common among patients with DM, affects drug distribution, cardiac output, and monitoring reliability, all of which may influence anesthetic depth. While these comorbidities may partially contribute to the observed association between DM and intraoperative awareness, eliminating them from analysis would distort the real world diabetic phenotype and undermine external validity. To assess the effect of unmeasured confounding factors, an E-value analysis was conducted. An E-value of 2.63 was calculated from the risk ratio of 1.625, which indicates that a relatively strong unmeasured confounder would be required to fully explain away the association. For the lower bound of the 95% CI of 1.046, an E-value of 1.27 was calculated, which suggests that it may be more sensitive to residual confounding. Accordingly, the estimate should be interpreted as the association between diagnosed DM, together with its frequently co-occurring circulatory and genitourinary (including renal) comorbidity, and documented intraoperative awareness, rather than as an isolated effect of DM Future studies using detailed perioperative data may help clarify the extent to which these intertwined comorbidities modify this relationship.

Another important limitation arises from reliance on ICD-10-CM coding within the TriNetX database to detect intraoperative awareness events. This approach likely underestimates the true incidence, as awareness episodes are often recognized only through structured postoperative interviews or narrative clinical documentation rather than formal billing codes.

Two limitations relate to the operational definitions used to construct the cohort. First, the non-diabetic cohort was defined by the absence of an ICD-10 E08–E13 diagnosis prior to surgery and may therefore include patients with undiagnosed diabetes or prediabetes. We considered tightening this definition by excluding patients with abnormal Hemoglobin A1c values or exposure to antidiabetic medications, but neither criterion could be applied reliably within TriNetX. HbA1c results are not consistently captured or harmonized across the federated network, and antidiabetic agents, particularly metformin, glucagon-like peptide-1 agonists, and sodium-glucose co-transporter 2 inhibitors, are increasingly prescribed for non-diabetic indications including polycystic ovary syndrome, obesity, and heart failure, which would have introduced a new layer of misclassification rather than resolving the existing one. We therefore retained the conservative ICD-based definition. Any undiagnosed diabetes or prediabetes contamination of the control cohort would be expected to bias the observed association toward the null. Second, the operational definition of general anesthesia exposure required three concurrent criteria: an anesthesia service code, administration of a qualifying anesthetic agent, and a temporally proximate invasive procedure. However, the algorithm could not be validated against the structured anesthetic record, as TriNetX does not provide depth-of-anesthesia documentation, end-tidal volatile concentrations, or processed-electroencephalogram (EEG) values. Residual exposure misclassification therefore cannot be excluded, particularly at the boundary between general anesthesia and deep sedation, and heterogeneity in anesthetic depth within the cohort remains unmeasured. Future work using institutional datasets with linked anesthesia records will allow direct validation of this exposure algorithm and the application of more restrictive definitions to assess the robustness of the present findings.

The capture of intraoperative awareness events is also constrained by the database. Detection in this study relied on ICD-10-CM coding, which likely underestimates the true incidence. This is because awareness episodes are typically recognized through structured postoperative interviews or narrative clinical documentation rather than formal billing codes, and TriNetX does not provide access to anesthesia records, postoperative interviews, or intraoperative monitoring data. Moreover, patients may not immediately recognize or report their experiences, and even when reported, these events are not uniformly coded across providers or institutions, leading to variability. Coding practices also differ across health systems, even when awareness is documented in chart notes, causing additional under detection of cases. Variability in ICD-10-CM coding practices across institutions may produce non-differential misclassification of both exposure (DM) and outcome (intraoperative awareness). Temporal misclassification is also possible, as awareness episodes may be recorded outside of the 5 year window after the index anesthetic, and these delayed entries may not be consistently included in the study. Consequently, these lead to a fraction of true awareness events undetected. The possibility of differential outcome ascertainment must also be discussed: patients with fewer post-index encounters had fewer opportunities for an awareness diagnosis to be recorded, which would bias the observed incidence downward. Diabetic patients, however, typically require more frequent healthcare contact than non-diabetic controls, which could disproportionately increase awareness capture in the exposed cohort and bias the effect estimate upward. The net direction of these competing biases is uncertain, although the bidirectional pull suggests the observed association is unlikely to be explained by ascertainment differences alone. For our study, no minimum post-index follow-up duration was required for

cohort eligibility, as the TriNetX platform does not provide patient-level data that would permit the restriction.

Several structural features of the TriNetX platform also restricted our analysis. The network aggregates data from 72 healthcare organizations with variable documentation practices, differences in perioperative management and site-level heterogeneity may vary. Robust or cluster-robust standard errors accounting for institutional correlation are not available because TriNetX does not expose the contributing institution as a patient-level identifier. As an EHR-derived dataset, TriNetX also does not capture several variables that are clinically relevant to intraoperative awareness risk, including American Society of Anesthesiologists (ASA) physical status, emergency vs elective surgical designation, exact procedure duration, intraoperative anesthetic dose, processed-EEG/bispectral index monitoring, intraoperative anesthetic depth, anesthesia provider experience and training, and institution-level practice patterns. Therefore, these variables could not be matched on or adjusted for. The platform's automated significance threshold may leave some compared-but-unflagged variables imbalanced at baseline ***(Supplementary Table S1),*** these variables are included for transparency. Finally, conditional logistic regression appropriate for matched-pair data is not implemented within the platform's standard analytics module and could not be applied through the access model used in this study. However, unconditional logistic regression has been argued to be appropriate for matched designs in which the matching is non-unique, that is, when one case could be matched to other controls without substantially changing the association. 1:1 nearest-neighbor propensity-score matching from a large control pool shares this non-unique structure, and the qualitative interpretation of the association is therefore unlikely to be substantively affected.[26]

The statistical inference rests on a matched-cohort 2 × 2 contingency table in which all four cells contain non-sparse observed counts (minimum cell count = 32) and the smallest expected count under the null hypothesis is 42 — well above the conventional threshold of 5 that motivates the use of small-sample methods. The asymptotic standard-error methods implemented in the TriNetX analytics module are therefore appropriate, and the small-sample concerns that motivate Firth-type penalization and exact methods, sparse cells, separation, or zero counts, do not arise here. These approaches would nonetheless be the appropriate inferential strategy in sparser data, such as analyses stratified by diabetes subtype (type 1 vs type 2), by anesthetic class, or within smaller surgical subpopulations. Neither Firth-corrected logistic regression nor exact (mid-P) methods is directly implemented within the TriNetX analytics module, and both require patient-level computation, which the federated platform does not permit. Future analyses with smaller event counts should employ these methods in datasets that allow patient-level statistical access.

Future research should further investigate whether the observed association differs between type 1 and type 2 diabetes mellitus (DM), given their distinct pathophysiologic mechanisms, age of onset, and comorbidity profiles, all of which may variably influence anesthetic pharmacodynamics, metabolism, and susceptibility to intraoperative awareness. In addition, future studies should incorporate richer phenotyping of diabetes, including repeat diagnostic codes, validated medication exposure, longitudinal A1c trajectories, and disease duration, to characterize a potential dose–response relationship between diabetes severity and intraoperative awareness. Such details would also permit meaningful subgroup analysis by glycemic control and insulin dependence, which our administrative dataset could not support. Although we attempted to perform subgroup analyses, the number of patients with type 1 DM experiencing intraoperative awareness in our dataset was insufficient for meaningful statistical comparison. Stratification by DM subtype and insulin-dependence in larger datasets may help clarify potential differences in anesthetic risk profiles.

Furthermore, while neuromuscular blocking agents (NMBAs) are well recognized to increase the risk of awareness by masking motor responses indicative of inadequate anesthesia, our ability to stratify awareness events based on NMBA exposure was constrained by the structure of the TriNetX database. Although the platform records medication exposures, it does not consistently include temporal data regarding dose, duration, or intraoperative context. Consequently, precise classification of NMBA administration was not feasible. Future studies that leverage more comprehensive perioperative datasets are needed to elucidate the relationship between NMBA use and intraoperative awareness, particularly among high-risk populations such as patients with diabetes.

Finally, further investigation in specific surgical subgroups, such as obstetric patients with gestational DM undergoing cesarean delivery, may inform tailored anesthetic and monitoring strategies, thereby enhancing perioperative safety for both mothers and infants.

Taken together, this large-scale study identified an association between DM and a modestly higher relative risk of documented intraoperative awareness These findings underscore the importance of individualized anesthetic planning, proactive intraoperative monitoring, and structured postoperative assessments in this high-risk population. Routine follow-up beyond the post-anesthesia care unit, including post-discharge contact or outpatient follow-up, may help identify delayed recall and enable timely intervention. Finally, although the data showed a statistically significant difference in incidence of anesthesia awareness between DM and non-DM patients, the absolute risk difference remained small at 0.011%. While this increase may appear modest in clinical practice given the rarity of the event, the findings nonetheless highlight the need for continued vigilance in anesthetic monitoring for patients with diabetes.

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Author Contributions

Conceptualization: Z.W, N.B.N, E.E. Data Curation: Z.W, N.B.N. Formal Analysis: Z.W, N.B.N. Investigation: Z.W, N.B.N. Methodology: Z.W, N.B.N. Project Administration: Z.W, N.B.N. Supervision: E.E. Validation: E.E. Writing - Original Draft: Z.W, N.B.N. Writing - Review & Editing: Z.W, N.B.N.

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Supplementary Material

Supplementary Table S1: Pre-Matching Cohort Comparison Across Procedure and Medication Variables by the TriNetX

Variable	TriNetX code	Diabetes cohort n (% of 141,645)	Non-diabetic cohort n (% of 264,154)	Δ (pp)*
A. CPT Procedure Categories (TriNetX-defined procedure groupings)				
Anesthesia procedures	1002796	141,644 (100.0%)	264,154 (100.0%)	-0.0
Surgery	1003143	141,514 (99.9%)	261,613 (99.0%)	+0.9
Pathology and Laboratory Procedures	1011136	136,159 (96.1%)	226,919 (85.9%)	+10.2
Evaluation and Management	1013625	133,503 (94.3%)	238,803 (90.4%)	+3.8
Medicine Services and Procedures	1012569	130,072 (91.8%)	210,403 (79.7%)	+12.2
Radiology Procedures	1010251	129,315 (91.3%)	217,950 (82.5%)	+8.8
B. VA Medication Classes (VA National Drug File classification)				
Central nervous system medications	CN000	141,283 (99.7%)	262,332 (99.3%)	+0.4
Ophthalmic agents	OP000	140,581 (99.2%)	259,574 (98.3%)	+1.0
Dermatological agents	DE000	140,258 (99.0%)	256,238 (97.0%)	+2.0
Nasal and throat agents, topical	NT000	139,488 (98.5%)	252,870 (95.7%)	+2.7
Gastrointestinal medications	GA000	139,156 (98.2%)	252,175 (95.5%)	+2.8
Respiratory tract medications	RE000	139,059 (98.2%)	251,835 (95.3%)	+2.8
Cardiovascular medications	CV000	138,858 (98.0%)	234,182 (88.7%)	+9.4
Therapeutic nutrients/minerals/electrolytes	TN000	138,300 (97.6%)	247,454 (93.7%)	+4.0
Hormones/synthetics/modifiers	HS000	137,619 (97.2%)	234,757 (88.9%)	+8.3
Pharmaceutical aids/reagents	PH000	136,391 (96.3%)	242,595 (91.8%)	+4.5
Irrigation/dialysis solutions	IR000	135,895 (95.9%)	241,794 (91.5%)	+4.4
Musculoskeletal medications	MS000	134,537 (95.0%)	248,297 (94.0%)	+1.0
Genitourinary medications	GU000	133,327 (94.1%)	227,420 (86.1%)	+8.0
Antimicrobials	AM000	132,433 (93.5%)	232,626 (88.1%)	+5.4
Autonomic medications	AU000	120,631 (85.2%)	204,115 (77.3%)	+7.9
Rectal, local	RS000	110,039 (77.7%)	162,734 (61.6%)	+16.1
Other medications (VA)	Other	105,187 (74.3%)	145,118 (54.9%)	+19.3
Blood products/modifiers/volume expanders	BL000	97,792 (69.0%)	122,536 (46.4%)	+22.7
Antihistamines	AH000	92,146 (65.1%)	143,492 (54.3%)	+10.7
Antidotes, deterrents, and poison control	AD000	71,246 (50.3%)	123,004 (46.6%)	+3.7
Dental and oral agents, topical	OR000	63,485 (44.8%)	78,540 (29.7%)	+15.1
Immunological agents	IM000	61,532 (43.4%)	83,911 (31.8%)	+11.7

Legend: : Procedure and medication variables compared at baseline but not selected for propensity-score matching by the TriNetX Signal indicator. Not being selected does not indicate statistical similarity. *Δ (pp) denotes the difference in cohort proportions (Diabetes minus Non-Diabetic), in percentage points.

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Original Article

County-Level Food Environment Indices and Diabetes Burden in the United States: An Ecological Cross-Sectional Study

Jeevan Nammi,[1] Roshini Pasala.[2]

Abstract

Background: Background: Diabetes remains a major public health challenge in the United States, and structural food environments may contribute to geographic differences in diabetes burden. However, national county-level evidence comparing alternative Retail Food Environment Indices (RFEI) in relation to diabetes prevalence and incidence remains limited. We examined associations between county-level retail food environment indices and diabetes prevalence and incidence in the United States. **Methods:** This ecological cross-sectional study used county-level data from the 2021 CDC Diabetes Surveillance System and the USDA Food Environment Atlas. A total of 2,951 U.S. counties with complete data were included. Primary exposures were the RFEI and expanded variants (RFEI1 and RFEI2), which quantify the relative balance of less healthy and healthier food outlet categories. Primary outcomes were age-adjusted diabetes prevalence and incidence. Pearson correlation coefficients and multivariable linear regression models assessed associations after adjustment for demographic, socioeconomic, behavioral, and food-access covariates. Model diagnostics and sensitivity analyses were performed. **Results:** Higher RFEI values were weakly correlated with diabetes prevalence (r = 0.18) and incidence (r = 0.17). Similar positive correlations were observed for RFEI1 and RFEI2. In adjusted models, RFEI remained significantly associated with diabetes prevalence (β = 0.01, 95% CI 0.00-0.02, p = .004) and incidence (β = 0.07, 95% CI 0.04-0.09, p < .001). Associations were modest. **Conclusion:** Poorer county-level retail food environments were statistically associated with higher diabetes prevalence and incidence. However, effect sizes were small, and findings should be interpreted as hypothesis-generating county-level associations rather than evidence of individual-level risk or causality.

Introduction

Diabetes mellitus, particularly type 2 diabetes (T2DM), continues to pose a major public health challenge in the United States. As of 2021, an estimated 38.4 million people of all ages, or 11.6% of the U.S. population, had diabetes.[1,2] Among adults aged 18 and older, the prevalence was even higher at 14.7%, with a disproportionate burden observed in older adults; nearly 3 in 10 adults aged 65 or above were living with the disease.[1–3] Additionally, 8.7 million adults met laboratory criteria for diabetes but were unaware or undiagnosed, reflecting a gap in disease recognition and management. That same year, approximately 1.2 million new cases of diabetes were diagnosed among adults, reinforcing the continuing and widespread nature of the epidemic.[1,3,4]

Multiple risk factors contribute to the development of T2DM. Some are non-modifiable, such as family history, age, race or ethnicity, and a history of gestational diabetes, factors that can increase susceptibility regardless of lifestyle. Others are modifiable and offer opportunities for prevention.[5,6] These include excess body weight, physical inactivity, high blood pressure, smoking, and dietary patterns.[5-7] While individual lifestyle factors remain important, there is increasing recognition of the role of structural and environmental determinants of health, including the availability and accessibility of healthy foods.[8-10]

Many communities, particularly in low-income and underserved areas, experience an imbalance in their food environments, with limited access to supermarkets or farmers markets and greater exposure to fast-food outlets and convenience stores.[11-14] These environments, often described as "food deserts" or "food swamps," are thought to influence dietary behaviors and long-term cardiometabolic outcomes.[12–14] However, these constructs remain simplifications of complex food systems and may not fully capture food quality, affordability, or purchasing behavior.

To quantify local food environments, the Retail Food Environment Index (RFEI) has been widely used as an outlet-based structural measure comparing the relative density of less healthy and healthier food retailers.[15,16] Higher RFEI values indicate a greater concentration of fast-food restaurants and convenience stores relative to grocery stores. Despite its widespread use, the conventional RFEI may oversimplify local food access, particularly because the classification of certain outlet types, such as supercenters, remains context dependent.

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To address this limitation, we examined two expanded variants, RFEI1 and RFEI2, which apply different assumptions regarding the classification of supercenters and include additional food retail categories. Supercenters may function as sources of affordable groceries in some communities while also increasing access to energy-dense processed foods in others. Therefore, evaluating alternative RFEI specifications may provide a more nuanced assessment of the association between retail food environments and health outcomes.

Although ecological and neighborhood-level studies have linked food environments to dietary behavior, obesity, and cardiometabolic outcomes, fewer national county-level analyses have systematically compared alternative RFEI specifications in relation to both diabetes prevalence and incidence.[15,16] This distinction is important because different index constructions may yield different inferences regarding the role of the food environment as a structural correlate of disease burden.

Therefore, this study aimed to examine the association between county-level retail food environment indices and diabetes prevalence and incidence across U.S. counties. We also assessed whether these associations were consistent across alternative RFEI specifications that differ in the classification of supercenters and healthier food retail outlets. Given the ecological and cross-sectional design, this study was intended to generate population-level hypotheses rather than establish individual-level risk or causal effects.

Methods

Study Design and Data Sources

This ecological cross-sectional study used publicly available county-level data from the United States. The primary outcomes were age-adjusted diabetes prevalence (%) and diabetes incidence (new cases per 1,000 adults), obtained from the CDC Diabetes Surveillance System (2021).[3] Food environment measures, including the Retail Food Environment Index (RFEI) and its expanded variants (RFEI1 and RFEI2), as well as county-level demographic, socioeconomic, behavioral, and food-access covariates, were obtained from the USDA Food Environment Atlas using the most recent available measures for each indicator in the dataset release.[17]

All datasets were merged using the standardized five-digit Federal Information Processing Standard (FIPS) county codes.[18] This study was reported in accordance with the STROBE guideline for observational studies.[19]

Because the unit of analysis was the county, all exposures, outcomes, and covariates were analyzed as aggregate county-level measures. No individual-level data were included, and all findings were interpreted as ecological associations rather than individual-level relationships.

Study Counties

The initial dataset included all 3,141 U.S. counties and county equivalents available in the merged source files. Counties were included in the final analysis if complete data were available for all exposure, outcome, and covariate variables used in the regression models. Counties were excluded if one or more required variables were missing. A total of 190 counties were excluded, resulting in a final complete-case analytic sample of 2,951 counties.

A complete-case analytic approach was used, and no imputation was performed. Potential bias from missing data was evaluated by comparing included and excluded counties descriptively, where data were available.

Exposure Variables

The primary exposure of interest was the Retail Food Environment Index (RFEI), an outlet-based measure comparing the relative availability of food outlet categories typically classified as less healthy with those classified as healthier retail food sources. The standard RFEI was calculated as the ratio of fast-food restaurants and convenience stores to grocery stores. RFEI1 was calculated using fast-food restaurants, convenience stores, and supercenters in numerator and grocery stores, farmers markets, and specialized food stores in the

denominator. RFEI2 was calculated using fast-food restaurants and convenience stores in the numerator andgrocery stores, farmers markets, specialized food stores, and supercenters in the denominator. Thus, RFEI1 treats supercenters as part of the less favorable food outlet environment, whereas RFEI2 treats supercenters as part of healthier food access.

RFEI = (fast food restaurants + convenience stores) ÷ grocery stores
RFEI1 = (fast food restaurants + convenience stores + supercenters) ÷ (grocery stores + farmers markets + specialized stores)
RFEI2 = (fast food restaurants + convenience stores) ÷ (grocery stores + farmers markets + specialized stores + supercenters)

The distinction between RFEI1 and RFEI2 reflects uncertainty in the classification of supercenters. In some settings, supercenters may improve access to affordable groceries, while in others, they may increase access to highly processed foods. Therefore, RFEI1 classifies supercenters as less favorable outlets, whereas RFEI2 classifies them as part of the healthier food access denominator. For all indices, higher values indicate a less favorable retail food environment.

Counties with undefined index values due to zero denominators were coded as missing and excluded from index-specific analyses.

Outcome Variables and Covariates

The primary outcomes were county-level age-adjusted diabetes prevalence, defined as the percentage of adults with diagnosed diabetes, and age-adjusted diabetes incidence, defined as the number of newly diagnosed cases per 1,000 adults.

Covariates included county-level demographic, socioeconomic, behavioral, and food-access characteristics. Demographic variables included percentages of racial and ethnic groups (White, Black, Hispanic, Asian, American Indian or Alaska Native, and Native Hawaiian or Pacific Islander). Socioeconomic variables included median household income, poverty rate, SNAP participation, and food insecurity. Behavioral variables included obesity prevalence and physical inactivity prevalence. Food-access context was represented by the percentage of Food-access context was represented by the percentage of grocery access to the residents

All covariates were analyzed as continuous variables. Percentage variables were interpreted per one-percentage-point increase unless otherwise specified. Median household income was analyzed in its original scale, and units for all variables were defined in the regression table footnotes.

Statistical Analysis

All analyses were performed using R software (version 4.5.0) with relevant statistical packages for regression modelling, diagnostics and visualization.

Descriptive statistics were calculated for all variables. Continuous variables were summarized using means and standard deviations. Pearson correlation coefficients were used to assess unadjusted associations between food environment indices and diabetes outcomes.

County-level diabetes prevalence and incidence were analyzed as continuous outcomes using linear regression models. Linear regression was selected because the outcomes represent aggregated county-level rates rather than individual-level binary outcomes. Although diabetes prevalence is bounded between 0 and 100, observed values were not near boundary extremes, supporting the use of linear models for ecological interpretation. Univariate linear regression models were first used to examine the association of RFEI, RFEI1, RFEI2 with diabetes outcomes. Multivariable linear regression models were then constructed using RFEI as the primary exposure, adjusting for demographic, socioeconomic, behavioral, and food-access covariates.

To avoid multicollinearity among race variables, the percentage of White population was treated as the implicit reference and excluded from the multivariable model.

A complete-case analytic approach was used and no imputation was performed.

Model Diagnostics

Model assumptions were evaluated using multiple diagnostic approaches. Residual-versus-fitted plots were used to assess linearity and variance patterns, and Q–Q plots were used to assess residual normality. Heteroscedasticity was formally tested using the Breusch–Pagan test. Influential observations were identified using Cook's distance, with a threshold of 4/n. Multicollinearity was assessed using variance inflation factors (VIF).

Sensitivity Analyses

Several sensitivity analyses were conducted to evaluate robustness. First, regression models were repeated using heteroscedasticity-robust standard errors (HC3). Second, models were repeated using log-transformed RFEI [log(RFEI + 1)] to address skewness. Third, analyses were repeated after excluding influential observations identified by Cook's distance. Finally, alternative exposure specifications using RFEI1 and RFEI2 were evaluated in adjusted models.

Exploratory interaction analyses between RFEI and poverty rate were also performed to assess potential effect modification, with results interpreted cautiously. Statistical significance was assessed using two-sided p-values, with $p < 0.05$ considered statistically significant. Given the large sample size, statistical significance was interpreted alongside effect size and confidence intervals rather than as evidence of substantive importance.

Potential Sources of Bias

Several sources of bias were considered in the design and interpretation of this study. First, because the analysis was ecological and county-level, observed county-level associations may not reflect individual-level relationships. Second, outlet-based food environment indices may misclassify the nutritional context of communities because they do not capture food quality, affordability, in-store product availability, or consumer purchasing behavior. Third, the complete-case approach may introduce selection bias if excluded counties differed systematically from included counties. Finally, residual confounding is possible because not all relevant structural or individual-level determinants of diabetes could be measured. Residual confounding, ecological fallacy, and exposure misclassification related to outlet-based indices were considered in interpretation:

Results

Data Completeness

Of the 3,141 U.S. counties and county equivalents in the initial dataset, 2,951 counties had complete data for all exposure, outcome, and covariate variables required for analysis. Counties with incomplete data were excluded, resulting in the removal of 190 counties from the final analytic sample.

Missingness was primarily observed in food environment indices and selected covariates. A complete-case analytic approach was retained because the proportion of excluded counties was relatively small; however, the possibility of selection bias cannot be excluded. Because excluded counties were missing one or more required exposure, outcome, or covariate variables, a complete side-by-side comparison was limited by data availability. However, the complete-case sample retained 2,951 of 3,141 counties and county equivalents, representing most counties in the national dataset. Therefore, while selection bias cannot be fully excluded, the analytic sample preserved broad national county-level coverage.

Table 1. Descriptive Characteristics of U.S. Counties Included in the Analysis (N = 2,951)

Variable	Mean ± SD
Retail Food Environment Index (RFEI)	6.76 ± 4.37
Expanded Retail Food Environment Index (RFEI1)	4.50 ± 2.73
Expanded Retail Food Environment Index (RFEI2)	4.04 ± 2.26
Diabetes prevalence (%)	8.59 ± 1.56
Male diabetes prevalence (%)	9.22 ± 1.56
Female diabetes prevalence (%)	8.01 ± 1.58
Diabetes incidence (per 1,000 adults)	9.36 ± 3.48
Percent White population	78.67 ± 19.70
Percent Black population	8.68 ± 14.53
Percent Hispanic population	8.15 ± 13.12
Percent Asian population	1.11 ± 2.45
Percent American Indian/Alaska Native population	1.74 ± 6.87
Percent Native Hawaiian/Pacific Islander population	0.07 ± 0.38
Median household income (USD)	48506.69 ± 12143.35
Poverty rate (%)	16.24 ± 6.36
Grocery access (%)	22.30 ± 18.43
SNAP participation (%)	12.90 ± 3.18
Food insecurity (%)	12.89 ± 2.21
Obesity prevalence (%)	28.36 ± 6.47
Physical inactivity prevalence (%)	19.42 ± 4.01

Legend: RFEI = Retail Food Environment Index. "RFEI1 and RFEI2 represent expanded food environment specifications differing in supercenters classification." with "RFEI1 includes supercenters in the numerator as less favorable food outlets, whereas RFEI2 includes them in the denominator as healthier retail food sources. These classifications reflect alternative analytical assumptions rather than definitive assessments of supercenter food quality."

Descriptive Analysis

A total of 2,951 U.S. counties with complete data were included in the descriptive analysis. The mean Retail Food Environment Index (RFEI) was 6.76 ± 4.37, indicating that counties had, on average, substantially greater availability of fast-food restaurants and convenience stores relative to grocery stores. The expanded variants showed lower mean values, with RFEI1 = 4.50 ± 2.73 and RFEI2 = 4.03 ± 2.26, reflecting differences in index construction related to supercenters and additional food retail categories.

The mean age-adjusted diabetes prevalence across counties was 8.59%, while the mean diabetes incidence rate was 9.36 cases per 1,000 adults. Diabetes prevalence was higher among males than among females. Descriptive statistics for food environment indices, diabetes outcomes, and covariates are presented in ***Table 1.***

Correlation Analysis

Pearson correlation coefficients were calculated to assess unadjusted bivariate relationships between food environment indices and diabetes outcomes. The standard Retail Food Environment Index (RFEI) demonstrated weak but positive correlations with both diabetes prevalence (r = 0.18) and diabetes incidence (r = 0.17). The expanded indices showed slightly stronger but still modest positive correlations. RFEI1 was correlated with diabetes prevalence (r = 0.23) and diabetes incidence (r = 0.24), whereas RFEI2 was correlated with diabetes prevalence (r = 0.22) and diabetes incidence (r = 0.25). Although statistically significant, these correlations demonstrated low explanatory strength, suggesting that food environment indices alone accounted for only a small proportion of variation in county-level diabetes burden. Sex-specific prevalence correlations were removed from the primary analysis because no formal effect-modification testing by sex was performed. Correlation results are presented in ***Figure 1.***

Table 2. Univariate Linear Regression Analyses of Food Environment Indices and Diabetes Outcomes

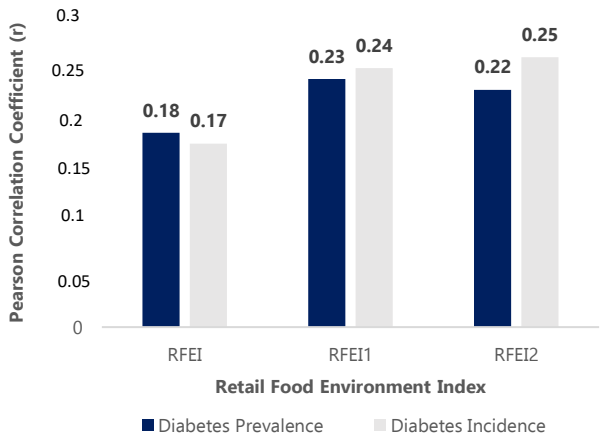
Outcome	Exposure	β coefficient	95% CI	p-value	R^2
Diabetes prevalence	RFEI	0.06	0.05 to 0.08	< .001	0.03
Diabetes prevalence	RFEI1	0.13	0.11 to 0.15	< .001	0.05
Diabetes prevalence	RFEI2	0.15	0.13 to 0.18	< .001	0.05
Diabetes incidence	RFEI	0.13	0.11 to 0.16	< .001	0.03
Diabetes incidence	RFEI1	0.31	0.27 to 0.36	< .001	0.06
Diabetes incidence	RFEI2	0.38	0.33 to 0.43	< .001	0.06

Legend: β coefficients represent unadjusted linear regression estimates. Diabetes prevalence is expressed in percentage points. Diabetes incidence is expressed as cases per 1,000 adults.

Univariate Regression Analysis

Univariate linear regression analyses demonstrated statistically significant positive associations between all food environment indices and both diabetes prevalence and diabetes incidence. For diabetes prevalence, RFEI was associated with a 0.06 percentage-point increase in prevalence per one-unit increase in index value (β = 0.06, p < .001). Similarly, RFEI1 and RFEI2 demonstrated positive associations with diabetes prevalence. For diabetes incidence, RFEI was associated with a 0.13 case-per-1,000-adults increase in incidence (β = 0.13, p < .001). Similar positive associations were observed for RFEI1 and RFEI2. However, unadjusted R^2 values were low across models, indicating weak explanatory power despite statistical significance. Detailed univariate regression results are presented in ***Table 2.***

Figure 1. Pearson Correlations between Food Environment Indices and Diabetes Outcomes



Legend: RFEI = Retail Food Environment Index. RFEI1 and RFEI2 represent alternative food environment specifications differing in the classification of supercenters and healthier food retail outlets.

Table 3. Multivariable Linear Regression Models for Diabetes Prevalence and Incidence

Variable	Diabetes prevalence β (95% CI)	p-value	Diabetes incidence β (95% CI)	p-value
RFEI	0.01 (0.00 to 0.02)	.004	0.07 (0.04 to 0.09)	< .001
Percent Black population	0.03 (0.03 to 0.03)	<.001	0.07 (0.06 to 0.08)	<.001
Percent Hispanic population	0.01 (0.00 to 0.01)	<.001	-0.01 [(-0.02) to 0.00]	0.09
Percent Asian population	0.03 (0.01 to 0.05)	<.001	-0.03 [(-0.09) to 0.03]	0.33
Percent American Indian/Alaska Native population	0.03 (0.03 to 0.04)	<.001	0.06 (0.04 to 0.08)	<.001
Percent Native Hawaiian/Pacific Islander population	-0.05 [(-0.15) to (0.06)]	0.38	0.16 [(-0.16) to 0.48]	0.33
Median household income (per10.0000u USD)	-0.080 [(-0.135) to (-0.025)]	<.0.0045	-0.286 [(-0.455) to (-0.117)]	<.001
Poverty rate	0.01 (0.00 to 0.03)	0.02	0.09 (0.06 to 0.13)	<.001
Grocery access	0.00 (0.00 to 0.00)	0.93	-0.01 [(-0.01) to 0.00]	0.01
SNAP participation	0.05 (0.04 to 0.07)	<.001	0.08 (0.04 to 0.12)	<.001
Food insecurity	-0.04 [(-0.05) to (-0.02)]	<.001	-0.03 [(-0.08) to 0.02]	0.26
Obesity prevalence	0.08 (0.08 to 0.09)	<.001	-0.01 [(-0.03) to 0.02]	0.62
Physical inactivity prevalence	0.13 (0.11 to 0.14)	<.001	0.13 (0.09 to 0.17)	<.001

Legend: β coefficients represent adjusted linear regression estimates. Diabetes prevalence is expressed as a percentage-point change. Diabetes incidence is expressed as cases per 1,000 adults. The percentage of the White population was excluded from multivariable models as the implicit reference category to reduce multicollinearity among race variables. Median household income 10000 USD; therefore, regression coefficients appear numerically small because they represent per-dollar increases.

Multivariable Regression Analysis

Multivariable linear regression analyses were conducted to evaluate the associations between the Retail Food Environment Index (RFEI) and diabetes outcomes after adjustment for county-level demographic, socioeconomic, behavioral, and food-access covariates. In the adjusted diabetes prevalence model, each one-unit increase in RFEI was associated with a 0.01 percentage-point increase in diabetes prevalence (β = 0.01, 95% CI 0.00–0.02, p = .004). In the adjusted diabetes incidence model, each one-unit increase in RFEI was associated with a 0.07 case-per-1,000-adults increase in diabetes incidence (β = 0.07, 95% CI 0.04–0.09, p < .001).

Among covariates, physical inactivity, SNAP participation, and the percentage of Black population were significantly associated with both diabetes outcomes. Obesity prevalence was significantly associated with diabetes prevalence (p < .001), but not incidence (p = .62). The adjusted prevalence model explained approximately 66% of the variance in diabetes prevalence, whereas the adjusted incidence model explained approximately 37% of the variance in diabetes incidence. These adjusted R^2 values reflect the combined contribution of demographic, socioeconomic, behavioral, and food-access covariates and should not be interpreted as the proportion of variance explained by RFEI alone. Although RFEI remained statistically significant after adjustment, the magnitude of association was modest in absolute terms. Adjusted multivariable regression results are summarized in ***Table 3.***

Table 4. Regression Diagnostic Assessment

Diagnostic measure	Diabetes prevalence model	Diabetes incidence model
R^2	0.67	0.37
Adjusted R^2	0.66	0.37
Breusch–Pagan test p-value	< .001	< .001
Maximum VIF	4.9	4.9
Influential counties identified	143	174

Legend: VIF = Variance inflation factor.
Influential counties were identified using Cook's distance threshold of 4/n

Table 5. Sensitivity Analyses of the Association Between Food Environment Indices and Diabetes Outcomes

Sensitivity analysis	Diabetes prevalence β (95% CI)	Diabetes incidence β (95% CI)
Robust standard errors	0.01 (0.00 to 0.02)	0.07 (0.06 to 0.08)
Log-transformed RFEI	0.14 (0.07 to 0.21)	0.60 (0.40 to 0.81)
Excluding influential counties	0.01 (0.01 to 0.02)	0.06 (0.04 to 0.08)
RFEI1 adjusted model	0.03 (0.01 to 0.04)	0.13 (0.09 to 0.17)
RFEI2 adjusted model	0.04 (0.02 to 0.05)	0.15 (0.10 to 0.20)

Legend: These findings indicate that the direction of association was not dependent on a single analytic specification. Robust standard errors were estimated using HC3 heteroscedasticity-consistent estimators.

Model Diagnostics

Model diagnostic analyses were performed to assess the assumptions and stability of the linear regression models. Residual-versus-fitted plots demonstrated mild heteroscedasticity, particularly at lower fitted values. Q-Q plots showed approximate normality of residuals with mild tail deviation. The Breusch-Pagan test demonstrated evidence of heteroscedasticity in both the diabetes prevalence model (p <

.001) and diabetes incidence model ($p < .001$). Multicollinearity assessment demonstrated acceptable VIF values, with a maximum VIF below commonly accepted thresholds for severe collinearity. Cook's distance analysis identified potentially influential counties in both models. However, exclusion of influential observations did not meaningfully alter the direction or statistical significance of the primary findings. Diagnostic findings are summarized in ***Table 4.***

Sensitivity Analyses

Several sensitivity analyses were performed to evaluate the robustness of the primary findings. In models using heteroscedasticity-robust standard errors, the association between RFEI and diabetes prevalence remained directionally consistent (β = 0.01, 95% CI 0.00 to 0.02), and the association with diabetes incidence remained positive (β = 0.07, 95% CI 0.06 to 0.08). Models using log-transformed RFEI [log(RFEI + 1)] also demonstrated positive associations with diabetes prevalence (β = 0.14, 95% CI 0.07 to 0.21) and diabetes incidence (β = 0.60, 95% CI 0.40 to 0.81). After excluding influential counties identified using Cook's distance, RFEI remained positively associated with diabetes prevalence (β = 0.01, 95% CI 0.01 to 0.02) and diabetes incidence (β = 0.06, 95% CI 0.04 to 0.08). Adjusted models using RFEI1 and RFEI2 also showed directionally consistent positive associations with both outcomes. Overall, these sensitivity analyses suggest that the observed county-level associations were modest but generally robust across alternative model specifications. Sensitivity analysis results are presented in ***Table 5.*** These findings indicate that the direction of association was not dependent on a single analytic specification.

Discussion

This national county-level ecological study found that less favourable retail food environments were associated with higher diabetes prevalence and incidence across U.S. counties. Although these associations were statistically significant, their magnitude was modest, and the unadjusted correlations demonstrated limited explanatory strength. Therefore, the findings should be interpreted as hypothesis-generating ecological associations rather than evidence that food retail environments independently or causally determine diabetes risk.

The positive correlations observed between food environment indices and diabetes outcomes were weak but directionally consistent across RFEI, RFEI1, and RFEI2. This consistency across alternative specifications suggests that the observed associations were not solely dependent on a single operational definition of the retail food environment. However, the relatively small effect sizes indicate that food environment indices likely represent only one component of a broader structural and socioeconomic context associated with diabetes burden.

In adjusted analyses, RFEI remained significantly associated with both diabetes prevalence and diabetes incidence after accounting for demographic, socioeconomic, behavioural, and food-access covariates. Although RFEI remained significantly associated with both diabetes outcomes, its estimated associations were modest. Other county-level factors, including physical inactivity, SNAP participation, and the percentage of Black population, were also significantly associated with both outcomes, whereas obesity prevalence was associated with diabetes prevalence but not incidence. Because these predictors were measured on different scales, their unstandardized coefficients should not be directly compared to determine relative association strength. An important consideration in interpreting these findings is the distinction between statistical significance and substantive significance. Given the large number of U.S. counties included in the analysis, the study had substantial statistical power to detect relatively small associations. Therefore, statistical significance should not be interpreted as evidence of strong predictive or causal importance. Instead, the findings indicate that less favorable food environments may coexist with broader patterns of structural disadvantage associated with diabetes burden. From a practical public health perspective, these findings should be viewed as a signal for identifying structurally disadvantaged places and prioritizing further longitudinal evaluation, rather than as an estimate of the effect of any single food-environment intervention.

These findings are generally consistent with prior studies linking local food environments to obesity, dietary behaviour, and cardiometabolic outcomes.20-24 Previous research has suggested that communities with greater relative access to fast-food outlets and convenience stores may experience less favourable dietary patterns and increased chronic disease burden.20-22 At the same time, the current findings extend prior literature by demonstrating that these associations remain directionally consistent across multiple RFEI specifications at the national county level.

Our analysis of RFEI1 and RFEI2 demonstrated slightly stronger unadjusted correlations with diabetes outcomes than the standard RFEI. These findings may reflect differences in how supercenters and expanded food outlet categories are classified within the indices. However, stronger correlations should not be interpreted as evidence that one specification is definitively superior. Rather, the comparison of RFEI variants should be viewed as an exploratory robustness assessment.

Importantly, RFEI and its expanded variants remain simplified outlet-based structural proxies rather than direct measures of nutritional exposure. These indices do not capture food affordability, food quality, in-store product availability, transportation access, cultural dietary practices, purchasing behaviour, or individual dietary intake. Consequently, exposure misclassification is possible, and the observed associations should be interpreted within the limitations of ecological food environment measures. County-level socioeconomic context also appeared strongly associated with diabetes outcomes in adjusted analyses. Median household income demonstrated an inverse

relationship with diabetes burden, whereas poverty-related indicators and SNAP participation demonstrated positive associations. These findings are consistent with broader literature suggesting that structural disadvantage, socioeconomic inequality, and chronic disease burden are closely interconnected.[14, 25-27]

The relatively high adjusted R^2 values observed in multivariable models should also be interpreted cautiously. These values likely reflect the combined explanatory contribution of multiple correlated demographic, socioeconomic, behavioural, and food-access variables rather than the independent contribution of RFEI itself. Ecological covariates frequently cluster geographically and socially, and therefore, the adjusted models are best interpreted as conditional association models rather than causal explanatory models.

The distinction between diabetes prevalence and incidence is also relevant when interpreting these findings. Prevalence reflects not only disease occurrence but also survival, diagnosis patterns, and population composition, whereas incidence more directly reflects new case occurrence. The fact that less favourable food environments were associated with both outcomes in the same direction strengthens the overall consistency of the observed pattern, although these outcomes should not be interpreted as reflecting identical mechanisms.

The presence of heteroscedasticity and influential observations further underscores the importance of cautious interpretation in ecological regression analyses. However, the direction and statistical significance of the primary findings remained generally consistent across robust standard error models, log-transformed exposure models, exclusion of influential counties, and alternative RFEI specifications, supporting the overall robustness of the observed associations despite their modest magnitude.

Taken together, these findings support the relevance of the county-level food retail environment as one component of the broader structural context associated with diabetes burden. However, these findings should not be interpreted as direct evidence that modifying retail food environments alone would reduce diabetes prevalence or incidence. Future longitudinal, multilevel, and quasi-experimental studies are needed to determine whether changes in food environments are followed by meaningful changes in diabetes-related outcomes after accounting for broader social and structural determinants of health.

Limitations

This study has several limitations. First, the ecological cross-sectional design precludes causal inference and does not establish temporality between the food environment and diabetes burden. Second, because analyses were conducted at the county level, the findings are subject to ecological fallacy and should not be interpreted as evidence that individuals living in counties with higher RFEI values necessarily experienced poorer diets or developed diabetes because of the local food environment.

Third, county-level averages may obscure substantial within-county heterogeneity, particularly in geographically large counties containing diverse urban and rural populations. In addition, counties are large and heterogeneous geographic units, and residents may obtain food, healthcare, and other services across county boundaries. Therefore, county-level RFEI values may not accurately represent the food environment experienced by all individuals within a county. Fourth, RFEI and its expanded variants are outlet-based structural proxies and do not capture food quality, affordability, transportation access, in-store product availability, purchasing behaviour, or individual dietary intake. Therefore, exposure misclassification is possible.

Fifth, although models adjusted for multiple demographic, socioeconomic, behavioural, and food-access variables, residual confounding remains likely. Important unmeasured factors such as healthcare access, insurance coverage, educational attainment, diabetes screening intensity, diagnostic practices, medication access, family history, and individual-level socioeconomic characteristics were unavailable. These factors may influence county-level diabetes prevalence and incidence independently of the retail food environment.

Sixth, several ecological covariates were moderately correlated with one another. Although multicollinearity diagnostics were acceptable, the adjusted models should be interpreted as conditional association models rather than causal models estimating total effects.

Seventh, the complete-case analytic approach may have introduced selection bias if excluded counties differed systematically from included counties. Finally, evidence of heteroscedasticity and influential observations was identified in regression diagnostics. Although sensitivity analyses demonstrated generally consistent findings, these issues remain important limitations of ecological modelling approaches.

Conclusion

In this national county-level ecological study, less favorable retail food environments were statistically associated with higher diabetes prevalence and incidence. However, the observed associations were modest in magnitude and should be interpreted as hypothesis-generating ecological findings rather than evidence of individual-level risk or causality.

RFEI may function as a structural contextual marker associated with broader patterns of disadvantage rather than as an independent determinant of diabetes burden. Future longitudinal, multilevel, spatially refined, and quasi-experimental studies are needed to determine whether changes in retail food

environments are followed by meaningful changes in individual level diabetes risk and population level diabetes burden.

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Original Article

Feasibility Study of Self-Directed Mock Oral Examinations in the Assessment of General Surgery Resident Clinical Decision-Making

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Abstract

Background: This feasibility study describes the implementation of a self-directed mock oral examination (SD-MOE), which is administered in the absence of faculty examiners, and explores its potential as a supplemental tool in preparation for the American Board of Surgery Certifying Examination. **Methods:** During a multi-institutional MOE, all examinees completed the conventional MOE (C-MOE) and were presented the option to additionally participate in the SD-MOE. Rates of technical issues were compared between formats. Exploratory analyses evaluated participant satisfaction, resource intensity, exam performance metrics, and interrater reliability. **Results:** The C-MOE included 62 faculty examiners and 55 examinees, while the SD-MOE included 25 faculty examiners and 41 examinees. The frequency of technical issues did not differ between formats. Faculty examiner satisfaction was lower with the SD-MOE compared with the C-MOE (65% vs. 93%, P<0.01). Post-graduate year (PGY)-level correlated with mean case score (PGY-3: 2.45; PGY-4: 2.58; PGY-5: 2.70; P=0.01) and proportion of questions passed (PGY-3: 81.7%; PGY-4: 87.3%; PGY-5: 90.1%; P<0.01) in the C-MOE, but not the SD-MOE. PGY-level did not correlate with overall exam pass rates in either exam format. Interrater reliability estimates for the SD-MOE (weighted κ=0.32, 95% CI [0.19, 0.46]) and C-MOE (weighted κ=0.25, 95% CI [0.16, 0.35]) had overlapping confidence intervals. **Conclusion:** The SD-MOE was successfully administered with minimal logistical challenges. While limited by optional SD-MOE participation and differences in case counts between formats, this feasibility study suggests the SD-MOE can be considered as a supplemental tool for resource-limited institutions.

Introduction

Mock oral examinations (MOEs) are administered by expert clinicians to prepare residents for the American Board of Surgery Certifying Examination (ABSCE), a summative assessment of safe clinical decision-making.[1] Resident participation in MOEs predicts first-time passage rates on the ABSCE[2-5] and informs program efforts to refine educational curricula.[6-8] In response to the COVID-19 pandemic, several programs successfully adapted MOEs to virtual platforms and demonstrated resident satisfaction and feasibility.[9-11] Nevertheless, MOE administration remains logistically challenging, limiting utility for resident education and assessment.

During conventional MOEs (C-MOE), two faculty examiners present case prompts to the examinee and score responses in real-time. Consequently, C-MOE administration requires numerous faculty examiners to be available simultaneously, which can be especially challenging if recruited from multiple institutions in an effort to better simulate ABSCE testing conditions. Thus, C-MOE implementation can be profoundly hindered by limited availability and time constraints among faculty and residents.[7,10,12,13] This study explores the implementation of a novel self-directed MOE (SD-MOE) format, in which examinees deliver video-recorded verbal responses to written prompts in the absence of a faculty examiner, as a potential supplemental tool given these obstacles. The SD-MOE offers several potential logistical advantages. Most notably, the use of video-recorded submissions would obviate the need for faculty examiners to personally administer the SD-MOE, instead allowing them to later view and score recordings at a time of their convenience. Although prior investigations of live versus video-based assessment have demonstrated agreement in scoring between methods, such studies have focused on assessment of technical skills rather than clinical decision-making.[14-16]

The primary objective of this study was to evaluate the feasibility of the SD-MOE format as a supplemental tool during a multi-institutional MOE. As an exploratory aim, this study compared

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performance metrics between formats, acknowledging that removal of the live probing that occurs naturally during examiner-examinee interactions could meaningfully alter the construct being assessed. The hypothesis of this study is that the SD-MOE can be administered with minimal logistical challenges while demonstrating favorable participant satisfaction ratings.

Methods

A multi-institutional virtual MOE was administered for surgical trainees from five regional general surgery residency programs. Eligible examinees included all general surgery residents of post-graduate year (PGY) levels 3, 4, and 5 from these institutions. All examinees participated in the C-MOE and were presented the option to additionally complete the SD-MOE. Surveys were completed by faculty examiners and resident examinees at the conclusion of the entire MOE program. All case topics for the C-MOE and SD-MOE were derived from the Surgical Council on Resident Education (SCORE) curriculum and selected through consensus by the MOE organizational committee faculty. Case scenarios, prompts, and grading criteria for the C-MOE and SD-MOE were developed by expert surgeons on the organizational committee and reviewed for content accuracy and flow by authors FC, JXW, and JPW. Approval was obtained from the University of California Los Angeles Institutional Review Board (IRB #21-000707). The procedures used in this study adhere to the tenets of the Declaration of Helsinki. This study is reported in accordance with the Guideline for Reporting Evidence-based Practice Educational interventions and Teaching (GREET) 2016 checklist.

Conventional Mock Oral Examination (C-MOE)

Modeled after the ABSCE, the C-MOE has garnered high satisfaction and ease-of-use ratings among participants.9 Each examinee in the study completed 12 standardized C-MOE cases divided evenly across three categories: Trauma Surgery and Critical Care, Gastrointestinal and Acute Care Surgery, and Subspecialty Surgery and Surgical Oncology. One week prior to the examination, faculty were distributed a personalized link to a Qualtrics survey containing case information, prompts, and grading criteria (Qualtrics, Provo, UT).

The C-MOE was administered in Zoom breakout rooms corresponding to the three aforementioned clinical categories; in each breakout room, two faculty examiners read aloud case prompts to a single examinee who provided verbal responses (Zoom Communications, San Jose, CA). At the conclusion of each case, faculty examiners used a Qualtrics survey to independently grade responses according to the supplied rubric, assigning a case-specific score of 1 (failure), 2 (borderline performance), or 3 (pass). Examinees were allotted a maximum of 30 minutes to complete four total cases in each breakout room. At the conclusion of each 30-minute testing period, examinees proceeded to the next MOE session as dictated by their individual randomized schedule until completing all three assigned rooms.

Self-Directed Mock Oral Examination (SD-MOE)

Examinees were notified regarding the opportunity to participate in the optional SD-MOE first via email several weeks in advance and again verbally during orientation on the day of the MOE. During the SD-MOE, examinees were instructed to read case information shared on the screen of the testing computer and provide verbal responses to each prompt. Case development for the SD-MOE and C-MOE occurred via identical processes. No faculty examiners were present in the SD-MOE sessions, and examinees were not provided with any verbal cues or other interaction to guide case progression. Examinees were responsible for deciding when to advance to the next prompt after completing each verbal response. Participating examinees were allotted a maximum of 30 minutes to complete three cases in the SD-MOE, and the entirety of each SD-MOE was video-recorded. A trained, non-faculty proctor was present for the SD-MOE only to facilitate video-recording and provide technical support as needed. The non-faculty proctor was not present during scoring, which was performed later by faculty examiners as they independently viewed the video recordings. The scheduling sequence of the SD-MOE session relative to the C-MOE breakout rooms was randomized for each participant.

Faculty examiners for the SD-MOE were recruited initially from the pool of C-MOE examiners, with additional examiners being recruited as needed among faculty who had not participated in the C-MOE. Similar to the C-MOE, two faculty examiners were assigned to each SD-MOE session to review the associated video recording and score the examinee using a standardized rubric. SD-MOE faculty examiners were instructed to score each case while viewing the recording and to do so at their earliest convenience.

Scoring

Proportion of questions passed among questions answered and mean case scores were calculated for both MOE formats. Questions and cases that were not completed or recorded were excluded from the denominator when calculating these metrics; incomplete cases were not scored as failures, and this approach was applied consistently across both formats. The threshold for overall passing in both MOE formats was established as a mean case score ≥2.2. Pass/fail was considered a binary variable.

Resident and Faculty MOE Experience Surveys

Immediately following the MOE, anonymous non-piloted surveys (Online Resource 1) developed by the authors were emailed to examinees. Examinees who completed the SD-MOE reported their satisfaction with the exam format, ability to concentrate on the prompts, and perceived impact of video-recorded responses on exam efficiency and fairness. Technical issues were assessed via a survey item with three predefined response options: "Major issues, significant impact on examination performance"; "Minor issues, no significant impact on examination performance"; and "No issues." Examinees who participated only in the C-MOE completed a similar survey but were not presented with questions

pertaining to the SD-MOE. The examinee post-examination survey included 15 total items, with five Likert-scale items, six multiple choice items, and four open-ended response items. A separate anonymous non-piloted survey (Online Resource 2) developed by the authors was emailed to SD-MOE faculty examiners after scoring their assigned video-recorded submissions. SD-MOE faculty examiners were asked to report the average time required to score video-recorded submissions and rated their perception of the validity of scores obtained from the SD-MOE. The faculty post-scoring survey included eight items, with two Likert-scale items, five multiple choice items, and one open-ended response item. Missing survey data for examinees and examiners were managed by excluding non-respondents from item-specific denominator calculations.

Study Outcomes

The primary outcome of feasibility was defined as successful completion of the SD-MOE without major technical issues. Secondary exploratory outcomes included participant perceptions of the SD-MOE format, resource intensity (operationalized as the average time required by faculty examiners to score SD-MOE video recordings), interrater reliability, and performance metrics across formats. Examinee perceptions assessed in this study included satisfaction, ability to concentrate on prompts, perceived appropriateness of case content, and perceived impact of recording responses on examination efficiency and fairness. Faculty perceptions assessed in this study included overall satisfaction, perceived appropriateness of case content, perceived validity of SD-MOE scores, and ease of format.

Statistical Analysis

All analyses comparing participant perceptions, resource intensity, interrater reliability, and performance metrics across formats were exploratory in nature. Fisher's exact tests were used to compare resident survey responses across examination formats and report descriptive statistics for remaining responses. Pearson's Chi-square test, one-way analysis of variance (ANOVA), Welch's independent-samples t-test, and Fisher's exact test were used to compare examinees who participated in both the SD-MOE and C-MOE with those who participated only in the C-MOE. The calculated Pearson's correlation coefficient (r) was used to report the correlation of continuous performance metrics across examination formats. Weighted Cohen's kappa coefficients (·) with 95% confidence intervals (95% CI) were calculated to report pooled estimates of interrater reliability for each examination format. Pearson's Chi-square tests and one-way ANOVA were used to evaluate the association between PGY-level and performance metrics. Sensitivity analyses were performed to repeat pass/fail outcome analyses at mean case score thresholds of ≥2.0 (at or above borderline) and ≥2.5 (at or above the midpoint between borderline and full pass). P values <0.05 were considered statistically significant. All statistical analyses were conducted using R (R Core Team, Vienna, Austria) in RStudio (Posit Software, PBC, Boston, MA)

Results

A total of 55 examinees participated in the C-MOE, of which 41 (75%) also completed the SD-MOE. There was no significant difference in PGY-level between examinees who participated in the SD-MOE and those who participated only in the C-MOE (Table 1). A total of 62 faculty examiners participated in the C-MOE and 25 faculty examiners participated in the SD-MOE. Of the 25 faculty members participating in the SD-MOE, 19 (76%) also served as examiners in the C-MOE.

Of the 41 examinees who completed the post-examination survey (75% response rate), 32 (78%) participated in both the C-MOE and SD-MOE while nine (22%) participated only in the C-MOE (Table 2). There was no difference in the overall frequency of technical issues between the SD-MOE and C-MOE; six examinees reported minor technical issues with no significant impact in the SD-MOE, compared with one examinee who reported minor technical issues with no significant impact in the C-MOE. No examinees reported major technical issues in either examination format. There was no difference between formats in resident satisfaction, ability to concentrate on prompts, or perceived appropriateness of case content. Of the 32 examinees who completed the SD-MOE, 18 believed scores being derived from video-recorded responses contributed to a more efficient (56%) and fair (56%) examination. Open-text feedback from examinees communicated a desire for real-time, post-case feedback and noted that SD-MOE case flow ambiguities were difficult to navigate without the ability to ask for clarification.

Table 1. Comparison of SD-MOE Participating Residents with Non-Participating Residents.

	C-MOE and SD-MOE (N=41)	C-MOE Only (N=14)	*P* value
Post-Graduate Year, (No., %)			0.07
PGY-3	8 (19.5%)	4 (28.6%)	
PGY-4	10 (24.4%)	7 (50.0%)	
PGY-5	23 (56.1%)	3 (21.4%)	
Mean Case Score on C-MOE[a]	2.60 ± 0.22	2.60 ± 0.29	0.93
Questions Passed on C-MOE (%)	87.7% ± 6.9%	85.0% ± 5.3%	0.14
Pass Rate on C-MOE (No., %)	39/41 (95.1%)	13/14 (92.9%)	>0.99

Legend: Abbreviations: C-MOE: conventional mock oral examination; SD-MOE: self-directed mock oral examination; PGY: post-graduate year. aMaximum case score was 3 points[C

Among faculty examiners, 56 of 62 (90%) C-MOE participants completed the post-examination survey and 20 of 25 (80%) SD-MOE participants completed the post-scoring survey. On average, faculty examiners required 18.5 minutes to fully score each SD-MOE video recording (Table 3). A significantly lower proportion of faculty examiners reported overall satisfaction with the SD-MOE compared with the C-MOE (65% vs. 93%, P<0.01).

There was no significant difference between formats in satisfaction with case content or ease of format among faculty examiners. The SD-MOE and C-MOE were perceived as equally valid by 50% of SD-MOE faculty examiners. Open-text feedback from examiners reflected an appreciation for logistical flexibility but noted technological difficulties and the inability to probe examinees as limitations.

There was no significant difference in proportion of questions passed, mean case score, or pass rates on the C-MOE between examinees who participated in both the C-MOE and SD-MOE compared with those who participated only in the C-MOE (Table 1). PGY-level was significantly associated with mean case score (PGY-3: 2.45; PGY-4: 2.58; PGY-5: 2.70; P=0.01) and proportion of questions passed (PGY-3: 81.7%; PGY-4: 87.3%; PGY-5: 90.1%; P<0.01) in the C-MOE, but not the SD-MOE (Table 4). PGY-level was not associated with overall exam pass rate in either format. Sensitivity analyses demonstrated that there remained no significant association between PGY-level and overall exam pass rate for either format at alternative mean case score thresholds of ≥2.0 and ≥2.5. There was no significant correlation between proportion of questions passed in each format (r=0.19, P=0.24) ***(Figure 1).*** A moderate positive correlation of mean case scores was identified between formats (r=0.34, P=0.03) ***(Figure 2).*** Interrater reliability was low in both formats, as reflected by fair agreement in the SD-MOE (weighted ·=0.32, 95% CI [0.19, 0.46]) and modest-to-fair agreement in the C-MOE (weighted ·=0.25, 95% CI [0.16, 0.35]). The confidence intervals were noted to overlap, but no formal statistical comparison of kappa values between formats was performed.

Table 2. Resident Agreement with Survey Statements Regarding the C-MOE and SD-MOE

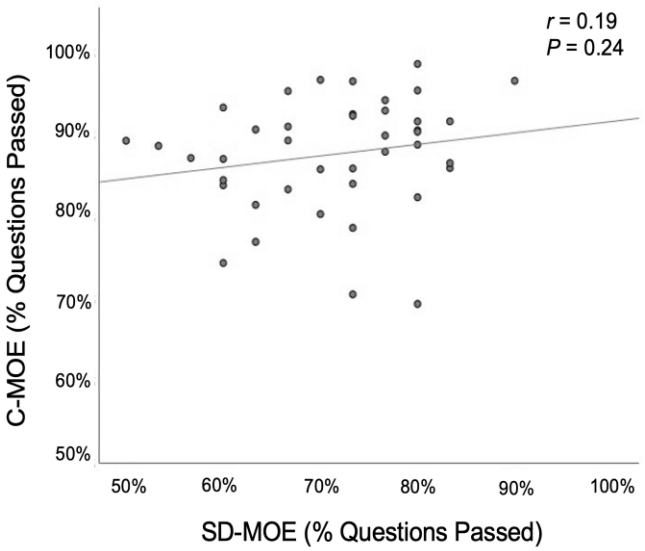
	C-MOE (N=9)[a]	SD-MOE (N=32)[b]	*P* value
Satisfied with the examination (No., %)	8/9 (89%)	22/31 (71%)	0.40
Able to concentrate on the prompts	8/9 (89%)	27/32 (84%)	>0.99
Appropriate case content	8/9 (89%)	27/32 (84%)	>0.99
Technical Issues Experienced			>0.99
Major, had an impact on the examination	0/9 (0%)	0/32 (0%)	
Minor, had no impact on the examination	1/9 (11%)	6/32 (19%)	
No technical issues	8/9 (89%)	26/32 (81%)	
Recording responses makes the examination more efficient	--	18/32 (56%)	--
Recording responses makes the examination more fair	--	18/32 (56%)	--

Legend: Abbreviations: C-MOE: conventional mock oral examination; SD-MOE: self-directed mock oral examination aA total of 14 residents completed only the C-MOE, and 9 of those completed the post-examination survey. bA total of 41 residents completed the C-MOE and SD-MOE, and 32 of those completed the post-examination survey. One resident in this group did not respond to the satisfaction item (n=31).

Discussion

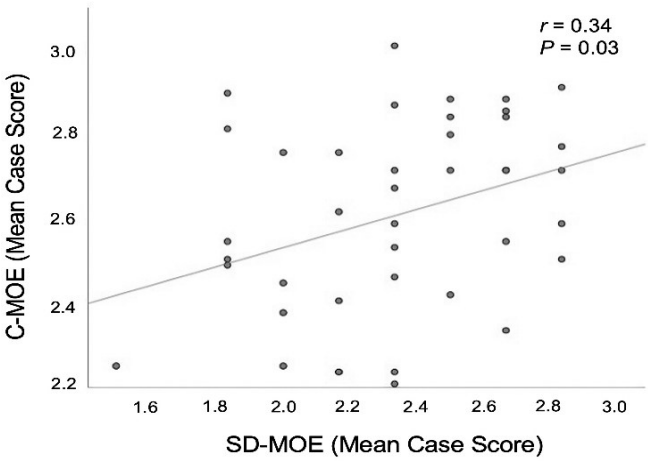
In this feasibility study of a novel self-directed MOE format for use as a supplemental tool in preparation for the ABSCE, the SD-MOE was successfully implemented during a multi-institutional MOE program without the need for faculty examiners to be present for its administration ***(Figure 3).*** There were no significant differences in self-reported technical issues between the SD-MOE and C-MOE. Among faculty examiners, satisfaction ratings were lower for the SD-MOE compared with the C-MOE. PGY-level was a significant correlate of performance in the C-MOE, but not in the SD-MOE.

Figure 1. Correlation of Proportion of Questions Passed Across Examination Formats.



Legend: This figure depicts the correlation between the proportion of questions passed on the C-MOE and SD-MOE. Each data point represents one examinee's performance on each examination. Abbreviations: C-MOE: conventional mock oral examination; SD-MOE: self-directed mock oral examination

Figure 2. Correlation of Mean Case Score Achieved Across Examination Formats.



Legend: This figure depicts the correlation between the mean case score on the C-MOE and SD-MOE. Each data point represents one examinee's performance on each examination. Abbreviations: C-MOE: conventional mock oral examination; SD-MOE: self-directed mock oral examination.

Among examinees, there was no significant difference between the SD-MOE and C-MOE with respect to overall satisfaction, ability to concentrate on prompts, and perceptions of case content appropriateness. In contrast, faculty examiner satisfaction ratings were significantly lower for the SD-MOE relative to the C-MOE. Open-text faculty survey responses indicated that some examiners were dissatisfied by the lack of bidirectional interaction, precluding their ability to probe for reasoning to better assess clinical judgment. Other examiners described difficulty navigating the video recording and scoring interface simultaneously, although some respondents appreciated the ability to replay responses. Additional sources of examiner dissatisfaction with the SD-MOE format were not clearly elucidated in this study, and potential explanations are consequently speculative. While there was no significant difference in reported ease of format between modalities, it is possible faculty examiners were dissatisfied by the asynchronous structure of the SD-MOE, which required setting aside a separate time to view and grade videos. Addressing potential sources of dissatisfaction would first require more detailed investigation into examiner perspectives, but strategies might entail both logistical and technical streamlining of the SD-MOE scoring process; for example, ensuring protected academic time to complete asynchronous grading and integrating SD-MOE video recordings and score input into a single webpage may help to improve the examiner experience.

Table 3. Faculty Agreement with Survey Statements Regarding the C-MOE and SD-MOE

	C-MOE (N=56)[a]	SD-MOE (N=20)[b]	*P* value
Satisfied with the examination (No., %)	52/56 (93%)	13/20 (65%)	<0.01
Appropriate case content	52/56 (93%)	16/20 (80%)	0.20
Ease of format	47/56 (84%)	16/20 (80%)	0.73
Validity of scores derived from scoring recordings compared with scoring in real-time			
Less valid	--	4/20 (20%)	
Equally valid	--	10/20 (50%)	
More valid	--	3/20 (15%)	
No response	--	3/20 (15%)	
Average time to grade a recording (minutes)	--	18.5	

Legend: Abbreviations: C-MOE: conventional mock oral examination; SD-MOE: self-directed mock oral examination a56 of 62 faculty examiners for the C-MOE completed the post-examination survey. b20 of 25 faculty examiners for the SD-MOE completed the post-scoring survey

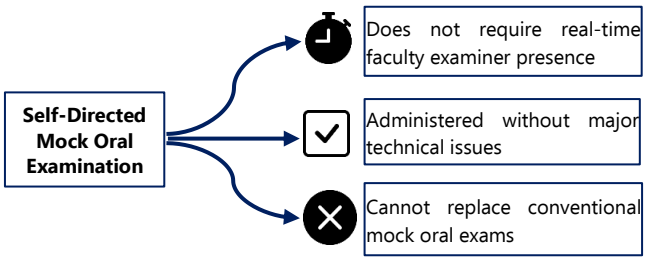
In the C-MOE, PGY-level was correlated with both mean case score and percentage of questions passed but not with overall exam pass rates. In contrast, PGY-level was not significantly associated with any of these performance metrics in the SD-MOE. These divergent patterns are likely driven in part by the SD-MOE featuring fewer cases, thus contributing to lower statistical power. Additionally, they may also reflect that the SD-MOE and C-MOE potentially constitute different assessment constructs, not simply different delivery modalities. Navigating the unfamiliar assessment structure of the SD-MOE moreover may have introduced variability in performance and scoring among examinees and examiners, respectively. Additionally, examinees may have perceived the SD-MOE as having lower stakes and educational value in its profound departure from the standard oral examination structure, given that similarity to the ABSCE is a well-recognized benefit of C-MOEs.[17,18] It is possible that such perceptions may have attenuated examinees' level of engagement and effort on the SD-MOE.

Table 4. Correlation of Examination Outcomes with PGY for the C-MOE and SD-MOE

	C-MOE (N=55)	*P* value	SD-MOE (N=41)	*P* value
Mean Case Score		<0.01		0.93
PGY-3	2.45 ± 0.16		2.35 ± 0.35	
PGY-4	2.58 ± 0.26		2.30 ± 0.42	
PGY-5	2.70 ± 0.20		2.35 ± 0.32	
Questions Passed (%)		<0.01		0.07
PGY-3	81.7% ± 5.7%		65.0% ± 9.3%	
PGY-4	87.3% ± 5.4%		71.0% ± 10.1%	
PGY-5	90.1% ± 5.3%		73.8% ± 8.2%	
Pass Rate (No., %)		0.08		0.48
PGY-3	10/12 (83.3%)		5/8 (62.5%)	
PGY-4	16/17 (94.1%)		7/10 (70.0%)	
PGY-5	26/26 (100.0%)		19/23 (82.6%)	

Legend: Abbreviations: C-MOE: conventional mock oral examination; SD-MOE: self-directed mock oral examination; PGY: post-graduate year.

Figure 3. Utility and Feasibility of the Self-Directed Mock Oral Examination



The SD-MOE presents a theoretical opportunity to decrease bias by minimizing unintentional coaching from examiners through standardized prompt presentation; however, eliminating two-way communication also removes the ability to probe for understanding of key concepts and prompt examinees to demonstrate complex judgment, two factors that are key to oral assessments.[19,20] Given that interrater reliability has been described as poor even when experienced examiners grade in isolation, the lack of interaction between faculty examiners may have also negatively impacted interrater reliability in the SD-MOE.[21] Although beyond the scope of the present study, the inherent contrast between written SD-MOE prompts compared with verbal C-MOE prompts may have had varying impacts on performance across certain subgroups of examinees. For example, learners with dyslexia or attention deficit hyperactivity

disorder and those who are non-native English speakers may favor and perform better when case information is presented verbally, rather than in written form.[22-24]

There are multiple limitations to this feasibility study and the SD-MOE format. While participation in the SD-MOE was high at a rate of 75%, the opt-in nature of this study raises concern for potential selection bias. However, no significant differences were observed between examinees who participated in the SD-MOE compared with those who opted out with respect to PGY-level or C-MOE performance, as defined by mean case score, questions passed, and overall pass rate. Although the majority of SD-MOE faculty examiners participated in the C-MOE, non-identical groups of faculty examiners participating in the two MOE formats may have led to biases in scoring. In addition, a central limitation of this study is that there were fewer cases in the single SD-MOE session than each C-MOE breakout room, which likely led to compressed score ranges, attenuated correlations, and obscured PGY-level gradients. The small number of observations per SD-MOE examiner dyad also contributed to unstable estimates, which precluded reliable comparison of dyad-level kappa values between formats. Potential order effects on performance could not be investigated because the sequence in which individual examinees completed the SD-MOE relative to C-MOE cases was not recorded. While presenting identical cases in the SD-MOE and C-MOE format may have created opportunities for more robust direct comparison, this was not pursued as part of this feasibility study after considering the logistical limitations with respect to ensuring a standardized C-MOE experience for all examinees irrespective of their participation in the SD-MOE. Uneven survey response denominators between SD-MOE examinees and C-MOE-only examinees as well as between SD-MOE examiners and C-MOE examiners raise concern for potential non-response bias, limiting the reliability of between-format survey comparisons. Furthermore, survey items were not formally piloted before administration. These limitations thus create fragile survey comparisons and must be considered when interpreting results.

While the SD-MOE did not require faculty examiners for its administration, the examination process was not entirely autonomous, as non-faculty proctors were utilized in each SD-MOE session to facilitate video recording and provide logistical support as needed. Further optimizing SD-MOE administration such that support staff are not required would help to make this tool more accessible for prospective users at resource-limited institutions. The SD-MOE may also be further improved by including more dynamic functionality with standardized follow-ups to mimic examiner probing and adaptive branching logic based on examinee responses. With such improvements, residency programs could consider deploying the SD-MOE as a supplemental self-study resource in oral exam curricula and as a means of identifying residents who may benefit most from additional coaching while preparing for the C-MOE and ABSCE. Meaningful future research directions include a study with matched SD-MOE and C-MOE case counts and sets, integrating artificial intelligence-enhanced dynamic functionality, and evaluating the correlation of SD-MOE performance with ABSCE first-time pass rates.

This feasibility study demonstrates the successful implementation of the SD-MOE with minimal logistical challenges during a multi-institutional MOE. Administered in the absence of faculty examiners, the SD-MOE may offer valuable opportunities particularly in resource-limited environments for independent study, self-critique, and use of video recordings to educate other trainees.[3,25,26] Without criterion validity testing against performance on the ABSCE, however, the SD-MOE cannot be proposed as a substitute for the multi-institutional C-MOE and should be considered exclusively as a supplemental educational tool. Thus, the C-MOE should remain the preferred format for ABSCE preparation when possible.

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Author Contributions

Conceptualization: TP, IAH, FC. Data Curation: TP, IAH. Formal Analysis: MN. Investigation: TP, IAH, MF, JXW, JPW, AT, FC. Methodology: TP, IAH, MN. Project Administration: TP. Supervision: FC. Writing - Original Draft: TP, IAH, MF. Writing - Review Editing: TP, MN, MF, JXW, JPW, AT, FC.

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Supplementary Material

Online Resource 1. Resident Post-Examination Survey on the Mock Oral Examination

This resource was the resident survey on the mock oral examination, which was completed online via Qualtrics (Qualtrics, Provo, UT). Residents who responded on Question 5 that they participated in the SD-MOE were presented with Questions 6 and 8. In the display logic note before Question 6, the term "asynchronous room" refers to the self-directed MOE room in Question 5; these terms were used interchangeably

MOE Resident Survey

Start of Block: MOE Resident Survey

Q0.
Mock Oral Examination Resident Survey
Thank you for your participation in the mock oral examination. Please answer the survey questions below. This survey will take approximately 5 minutes.

Q1. What is your PGY (in clinical years)?

- ○ PGY-3
- ○ PGY-4
- ○ PGY-5

Q2. If not yet committed, please indicate your top choice specialty.

_____

Q3. How many standardized mock orals examinations have you participated in, ***prior to this current examination***?

- ○ None, today was my first
- ○ 1
- ○ 2
- ○ 3+

Display This Question:

If How many standardized mock orals examinations have you participated in, prior to this current examination? != None, today was my first

Q4. Did you participate in our virtual mock orals examination last year?

- ○ Yes
- ○ No

Q5. Did you participate in the self-directed mock oral examination room this year?

- ○ Yes
- ○ No

Display This Question:

If Did you participate in the asynchronous room this year? = Yes

Q6. Regarding the **self-directed MOE only...**

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
I was satisfied with the self-directed examination	○	○	○	○	○
The content of cases was appropriate	○	○	○	○	○
I was able to concentrate on the clinical prompts	○	○	○	○	○
I felt comfortable in the examination room	○	○	○	○	○
Recording responses makes the examination more efficient	○	○	○	○	○
Recording responses makes the examination more fair	○	○	○	○	○
I am confident I will pass the ABSCE on my first attempt	○	○	○	○	○
This examination helped me identify areas of my knowledge that need improvement	○	○	○	○	○

Display This Question:

If Did you participate in the self-directed room this year? = No

Q7. Regarding the **mock oral examination...**

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
I was satisfied with the examination overall	○	○	○	○	○
The content of cases was appropriate	○	○	○	○	○
I was able to concentrate on the clinical prompts	○	○	○	○	○
I felt comfortable in the examination rooms	○	○	○	○	○
I am confident I will pass the ABSCE on my first attempt	○	○	○	○	○
This examination helped me identify areas of my knowledge that need improvement	○	○	○	○	○

Display This Question:

If Did you participate in the self-directed room this year? = Yes

Q8. Did you experience any technical issues with the audio or video connection in the **self-directed MOE room**? If so, please describe the issues you experienced.

○ Major issues, significant impact on examination performance_____

○ Minor issues, no significant impact on examination performance_____

○ No issues

Display This Question:

If Did you participate in the self-directed room this year? = No

Q9. Did you experience any technical issues with the audio or video connection during the examination? If so, please describe the issues you experienced.

○ Major issues, significant impact on examination performance_____

○ Minor issues, no significant impact on examination performance_____

○ No issues

Q10. In your opinion, how was your performance in each case category?

	Poor	Somewhat poor	Neither good nor poor	Somewhat good	Very good
Trauma Critical Care	○	○	○	○	○
Acute Care and GI Surgery	○	○	○	○	○
Subspecialty and Oncologic Surgery	○	○	○	○	○

Q11. In your opinion, how likely are you to have passed the **mock oral examination** today?

- ○ Very unlikely
- ○ Somewhat unlikely
- ○ Neither likely nor unlikely
- ○ Somewhat likely
- ○ Very likely

Q12. In your opinion, how likely are you to pass the **ABS Certifying Examination** if you took it today?

- ○ Very unlikely
- ○ Somewhat unlikely
- ○ Neither likely nor unlikely
- ○ Somewhat likely
- ○ Very likely

Q13. Which topics would you like to have covered in future exams?

_____

_____

_____

_____

Q14. Please enter in any feedback for your examiners (anything they did that was very helpful or not helpful for the examination)

_____

Q15.
Please provide any additional comments (e.g. case flow, case content, etc.).

_____

_____

_____

_____

_____

Online Resource 2. Faculty Post-Examination Survey on the SD-MOE

This resource was the faculty survey on the SD-MOE, which was completed online via Qualtrics (Qualtrics, Provo, UT). Only faculty examiners who participated in the SD-MOE were asked to complete this survey. In Question 1 and Question 2, the response options labeled ">5" and ">3" were intended to signify "5 or more" and "3 or more," respectively.

MOE Faculty Survey (SD-MOE)

Q0. Please complete the following survey only **ONE TIME** after scoring all recordings assigned to you.

Q1. Prior to this year, how many times had you been an examiner for **in-person** standardized mock oral examinations?

- ○ 0, I have never been an examiner for in-person MOE
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ >5 (fill in approximate # times if >5) _____

Q2. Prior to this year, how many times had you been an examiner for **virtual/online** standardized mock oral examinations?

- ○ 0, this is my first year as an examiner for virtual/online MOE
- ○ 1
- ○ 2
- ○ >3 (fill in approximate # times if >3) _____

Display This Question:

If Prior to this year, how many times had you been an examiner for in-person standardized mock oral. != 0, I have never been an examiner for in-person MOE

Q3. How *valid* are scores derived from scoring recorded responses of clinical decision-making, when compared to scoring in real-time?

- ○ Not valid
- ○ Less valid
- ○ Equally valid
- ○ More valid
- ○ Much more valid

Q4. On average, how much time (minutes) did it take to score a resident's recording?

	0 6 12 18 24 30 36 42 48 54 60
Time (minutes) ()	

Q5. Did you listen to recordings at normal playback speed or increase the video playback speed (e.g. 1.5x speed)?

- ○ Normal playback speed
- ○ Increased playback speed to: _____

Q6. Please rate the following

	Extremely dissatisfied	Somewhat dissatisfied	Neither satisfied nor dissatisfied	Somewhat satisfied	Extremely satisfied
Overall Satisfaction With Self-Directed Room	○	○	○	○	○
Variety and content of cases	○	○	○	○	○
Ease of format	○	○	○	○	○

Q7. Would you rate yourself as a hawk (strict grader) or a dove (lenient grader) when assessing resident performance in general?

- ☐ **Hawk** (strict grader)
- ☐ **Dove** (lenient grader)

Q8. Please provide any additional comments you wish to share.

_____

IJMS INTERNATIONAL JOURNAL of MEDICAL STUDENTS

Review

Obesity Education and Prevention in Rural Pediatric and Adult Populations in the U.S.

Jordyn Yokoyama,[1] Sandhya J Kadam,[2] Priscilla Mariscal.[3]

Abstract

Background: With the ever-increasing incidence of obesity in pediatric and adult populations nationwide, the need to find impactful and long-term solutions to the epidemic is paramount. Urban and rural populations both show climbing rates of obesity, with significantly more children and adults being affected in rural areas. Many of the most prominent factors leading to obesity are related to socioeconomic status, behavior, lack of access to quality food resources, and lack of knowledge of healthy food groups. Obesity increases the risk of disease in nearly every organ system in the body. **Methods:** The authors conducted a narrative review by searching for relevant articles written in English in electronic databases such as PubMed/MEDLINE, Web of Science, Semantic Scholar, and Google Scholar. A total of 88 articles were studied, and finally, 47 articles were included. **Results:** Environmental factors such as low access to fresh produce and living in rural areas increase the risk of adults and children developing obesity. Early intervention in pediatric obesity cases have shown promising effectiveness on obesity prevention and it is suggested that stepwise, realistic goal-setting can lead to greater success in weight loss and management. **Conclusion:** With the rates of obesity amongst children and adults continuing to climb in rural areas, addressing the causes is paramount. Biological, behavioral and social factors all contribute to obesity rates in rural areas, often due to the challenges of accessing healthy food and fewer spaces for physical activity.

Introduction

The climbing obesity rates in the United States and the resultant obesity epidemic were first identified among the adult population in the 1970s. Since then, the incidence of obesity has steadily risen, with over 72 million adults in the United States affected by the disease, according to recent studies.[1] However, the rise in pediatric obesity in the last 30 years is newer and equally concerning.[2] It is a risk factor for diseases such as early-onset diabetes mellitus type 2 (DM2) and children with obesity are also more prone to significant problems with mental health and self-esteem. It is also a risk factor for Non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH), hypertension, and obstructive sleep apnea. More children in the U.S. are suffering from being overweight and obese,[3] with these same children have a higher chance of becoming obese adults.[4] It has become clear that preventing pediatric obesity will also be an important part of improving the quality of life of the U.S. population.[4]

Obesity is connected to several leading causes of preventable deaths in the U.S., making the need for understanding and finding solutions to the multifactorial causes of obesity significant to ensure it does not soon outpace smoking as the leading cause of preventable premature death. One of the challenges of obesity prevention stems from its complex causes, ranging from biological and psychological causes to socioeconomic and geographical factors and beyond.[5]

The distribution of these afflicted communities is neither linear nor static. However, people living in rural areas were found to have higher occurrences of obesity.[6] These individuals, especially those living in a rural area of low socioeconomic status, are especially vulnerable. Various social determinants of health often afflict these areas, some of the most prominent being a lack of access and transportation to healthcare, a lack of affordable healthy food options, and low health literacy. These challenges make obesity prevention even more challenging because they often lead to the main causes of both pediatric and adult obesity.[6]

Calorie intake exceeding caloric expenditure is one of the leading causes of obesity.[3] High-calorie, sugar-sweetened drinks are especially related to both pediatric and adult obesity. In addition, the sedentary lifestyle promoted by the dawn of the new technological age is another large contributor to the increasing rates of obesity.[7] However, while it is easy to assign blame to these behaviors, one cannot ignore the environmental and psychological factors that also play a role. Fresh produce, which is incredibly important for a healthy diet, is often too expensive for low-income families to afford. This can lead to cheaper food options such as frozen meals and fast food as affordable alternatives. In addition, personal conflicts such as mental health problems and stigmatization have been seen to correlate with

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obesity rates, especially in adult populations.[8] Such complexities have made finding effective prevention and education measures difficult despite past and current efforts. Weight loss programs, drugs for weight loss, and bariatric surgery are among a few of the methods by which public health and healthcare workers are attempting to mitigate the obesity epidemic.[9] However, with the varying or even low success of some of these programs and the financial and safety burdens implicated in using pharmacological or surgical options, the goal of finding and implementing programs or medical options to enhance long-term weight loss success is still an ongoing challenge.[9]

Epidemiology

As per WHO, since 1990, obesity in adults has doubled, and obesity in adolescents has increased by four times. In 2022, one in eight people in the world was living with obesity. . 2.5 billion adults are overweight (43% of adults), including 890 million with obesity (16% of adults). 37 million children under the age of five, over 400 million children and adolescents aged five-nineteen years were overweight, and 170 million were living with obesity.[10]

According to the CDC, during August 2021–August 2023, the prevalence of obesity in the US was 40.3%, in adults, approximately the same in males and females. For age-specific data, prevalence was higher in the age group of 40–59 than in ages 20–39 and 60 and older. The prevalence of obesity was lower in adults with higher education levels. The prevalence of severe obesity in adults was 9.4% and was higher in females than males for each age group. From 2013–2014 through August 2021–August 2023, the age-adjusted prevalence of obesity did not change significantly, while severe obesity prevalence increased from 7.7% to 9.7%.[11] Approximately 1 in 5 U.S. children and adolescents have obesity. Obesity affects some groups more than others, including adolescents, Hispanic and non-Hispanic Black children, and children in families with lower incomes. Health care for obesity is expensive for patients and the health care system. Between 2017-2020, 19.7% children and adolescents in the US were found to have obesity. Predictions estimate that by 2030, nearly half of the U.S. adult population will become obese, significantly, including severe obesity.[12]

Obesity is a serious and common chronic disease affecting some groups more than others, including, non-Hispanic Black adults and adults with less education.[13] To determine whether an individual is obese, body mass index (BMI) is a quick and reliable measure. For adults, the following formula and ranges have been established.[13] [BMI = weight(kg) / Height (m)2].[13]

For adults, BMI categories are underweight, healthy weight, overweight, and obesity which is further classified into three categories. The following values are referenced for adults age 20 and older.[14] For children and teens who are growing, BMI is compared to other children and teens of the same sex and age. This is accomplished using BMI for age percentiles or growth charts. Percentiles are used to rank an individual by indicating what percent of the reference population the individual equals or exceeds and are the best indicator to evaluate growth patterns in children.[13] Please refer to ***table 1*** for BMI classifications of adults and Children.[13]

Etiology of Pediatric and Adult Obesity

Obesity is a multifactorial condition that is greatly affected by environmental and social factors, as well as some genetic predispositions. Specific genes, such as leptin, pro-opiomelanocortin, and melanocortin 4 receptor genes, have all been linked to obesity.[15] Although their occurrence is rare, the resulting association with obesity of the mutations within these genes has been key to better understanding obesity's pathogenesis.[16]

Studies have shown that a very prominent etiology for pediatric and adult obesity is related to environmental components.[16] Sedentary lifestyles and dietary intake both profoundly impact the risks of obesity. Children who have one or both parents who are overweight in the house have a much higher chance of developing obesity. And consequently, overweight children are far more likely to become overweight adults.[17]

There are also risks associated with developing obesity depending on the nutritional and lifestyle environments pregnant women and children experience at specific times. Epigenetic changes play the role of intergenerational transmission of obesity along with genetic factors. Exposure to factors in the environment makes children susceptible to obesity even without inheriting genetic factors.[17] Please refer to ***Figure 1*** for causes of obesity in the pediatric and adult population.[15-17]

Pathophysiology

The pathophysiology of obesity is related to energy expenditure in calories being less than the amount of energy intake.[18] Fat, also called adipose tissue, is our main energy storage source. White fat, the main component of adipose tissue, plays a major role in storage of energy and physiology. The triglycerides stored in this white fat store the body's available energy and are broken down and circulated throughout the body as free fatty acids during fasting or starvation.[18]

As an endocrine organ, adipose tissue also plays essential roles in energy balance and reproduction within organisms.[19] It is stored most prominently in the cephalad regions of the trunk for men and caudal regions of the trunk and subcutaneously for women. Increased weight eventually leads to the hypertrophy of the adipose tissue.20 This change in their structure leads to changes and effects in their supporting tissue and blood supply, resulting in further complications as weight gain continues.[20]

Specific to energy storage is a hormone called leptin, secreted by adipose tissue. Leptin is secreted in specific amounts to help maintain ideal energy balance within organisms.[20] Increased body weight increases plasma leptin concentrations, often leading to a

negative energy imbalance and can perpetuate weight gain. The rate at which leptin is produced is proportional to the amount of adipose tissue in the body, and its role in increasing hunger signaling in the brain can lead to increased appetite. Past studies have shown that disruption in the central and peripheral hunger pathways, of which leptin plays a key role, leads to leptin resistance.[21] This result aligns with the findings that a majority of those with obesity are leptin resistant, making endogenous and exogenous forms of the hormone no longer effective.[22] This resistance to leptin and its concentration in plasma play a role in adipocyte production and, causatively, weight gain.[21,22] Leptin plays an important role in monogenic obesity, especially in congenital leptin deficiency.[21]

The central and peripheral pathways that control hunger and, consequently, play a role in energy intake, expenditure, and weight loss play significant roles in obesity. Within the arcuate nucleus of the hypothalamus, pathways and signals regulating hunger and energy homeostasis are integrated and regulated. Two pathways, the agouti-related peptide (AgRP)/neuropeptide Y (NPY)-expressing neurons and the pro-opiomelanocortin (POMC)/cocaine-and amphetamine-regulated transcript (CART)-expressing neurons play essential and opposite roles in regulating energy intake.[22] The AgRP/NPY pathway is orexigenic, which promotes hunger and food consumption while down-regulating energy expenditure during periods of low energy intake. The hormones insulin and leptin, which facilitate glucose uptake into cells and send "hunger signals" to the brain, respectively, play a large part in regulating this pathway.[22]

The POMC/CART pathway performs the opposite function. As an anorexigenic signaling pathway, it promotes energy expenditure and encourages decreased food consumption.[23] These neurons are stimulated by leptin to release a neuropeptide called alpha-melanocyte-stimulating hormone (α-MSH), which leads to decreased food consumption. Opposite to the AgRP/NPY pathway, the POMC/CART pathway is inhibited during low energy, so its appetite-suppressing actions are inhibited, and greater energy uptake is promoted. The AgRP/NPY pathway is also inhibited by activating 1B receptors for the neurotransmitter serotonin 5-hydroxytryptamine (5-HT).[22] A decrease in the signaling for 5-HT is highly correlated with increased appetite and weight gain, while increased signaling for 5-HT has the opposite effect. Norepinephrine (NE) is another neurotransmitter that could potentially affect hunger and weight gain. It increases food uptake via the stimulation of the dorsal pathway and inhibits food uptake by activating the ventral pathway in the hypothalamus.[24] Please refer to ***Figure 2*** below for a diagram of the effects of the POMC/CART and AgRP/NPY pathways on food intake.[22-24]

However, integration and signaling in the hypothalamus are not the only locations where obesity-related hormones are made. Hormones secreted in the gastrointestinal system play a role in the peripheral pathway of hunger and energy regulation.[22] Intestinal hormones glucagon-like peptide-1 (GLP-1), cholecystokinin (CCK), and peptide YY (PYY) are secreted when there is food intake and play an anorexigenic role by promoting satiety. Ghrelin, a hormone secreted by the stomach, is the single known orexigenic hormone, also called the hunger hormone, and it promotes increased appetite and energy consumption. Low levels of this hormone during fasting have an inverse correlation with BMI, and it has been seen that altered suppression of this hormone has been correlated to obesity. These central and peripheral pathways play a role in energy homeostasis and, as a result, play a key role in obesity.[22]

Complications

People who are overweight or obese have an increased risk for many severe diseases, including early death, hypertension, elevated low-density lipoprotein (LDL) cholesterol, reduced high-density lipoprotein (HDL) cholesterol, and elevated triglyceride levels, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and breathing problems, many types of cancers, lower quality of life, mental illness, and body pain.[25]

According to the WHO, being overweight in childhood and adolescence affects immediate health and increases risk and earlier onset of non-communicable diseases in them. Childhood and adolescent obesity also have adverse psychosocial consequences. It affects school performance and quality of life, compounded by stigma, discrimination and bullying.[26]

There are additional findings in pediatric patients who are obese. Obese adolescents have advanced puberty with advanced menarche, although this advance is not so constant in males. Boys with obesity frequently present with gynecomastia and it also increases risk of pediatric obstructive sleep apnea (OSA).[27] Psychosocial problems develop as a result of weight-based stigma. One aspect of stigma is poor integration of the network of friends in a social environment, which initially leads to passive marginalization due to diminished attractiveness as a friend.[27] Similar to weight-based stigma, bullying occurs in boys or girls who are obese, specifically in places where no preventative measures are in place.[26] Another common finding is low self-esteem consisting of an emotional self-evaluation of one's worth - it contributes to a certain state of happiness or unhappiness.[26] Please refer to ***Table 2*** for summary of complications of obesity.[10,25,26]

Methods

Search strategy and selection criteria

The authors conducted a narrative review by searching for relevant articles written in English in electronic databases such as PubMed/MEDLINE, Web of Science, Semantic Scholar, and Google Scholar pertaining to the topics of obesity in pediatric patients and in adults in rural as well as urban areas. We selected keywords identified through the literature, and for each keyword, we undertook a search of the existing literature. Keywords used are Obesity, physical activity, Obesity complications, Obstructive

sleep apnea (OSA), Rural and urban population, Leptin, and Pro-opiomelanocortin (POMC). All three authors performed the search separately and included it in the manuscript after agreeing on the existing literature. Authors JY and PM did the initial search, and SK addressed the differences of opinion based on scientific data and evidence-based medicine. The purpose of this review is not to perform a systematic review but to identify available evidence that can be useful for informing providers about obesity. The included articles met all the following inclusion criteria: literature published in English from 2001 onwards, evidence for specific causes, pathophysiology for children with obesity, and evidence targeting children under the age of 18 and adults. Additionally, thirteen articles are included from the past five years, especially for World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) guidelines inclusion. One author specifically examined and evaluated the titles as well as the abstracts of each of the retrieved records to determine which ones were appropriate and should be selected per the eligibility criteria. Articles not written in English and articles which are not related to obesity topics were excluded. A total of 88 articles were studied, and finally, 47 articles were included to write this piece of narrative review.

Results

Factors Most Affecting Pediatric and Adult Obesity in Rural vs. Urban Areas

Several factors affect the likelihood of pediatric obesity, regardless of whether the child grows up in a rural or urban area. Maternal obesity and diabetes are correlated to a higher birth weight in newborns.[27] While the mechanism behind this is unclear, it cannot be stated definitively whether the infant's early exposure to glucose or changes in mechanisms of energy balance is the cause of this higher birth weight. However, this correlation is strong enough to warrant further investigation. Another impact that affects the likelihood of childhood and adult obesity is environmental factors. If the child and their guardian(s) live in areas with ethnically-targeted food marketing, low access to fresh produce, and high access to fast food, these aspects can also lead to a greater risk of pediatric obesity in these populations.[28] However, despite some similarities, there is a clear disparity between the risk of obesity in pediatric and adult populations in rural vs. urban areas.

Children living in rural areas have a 26% higher odds of obesity compared with children living in urban areas (OR = 1.26; 95% CI, 1.21–1.32).[28] One of the factors that has affected this statistic is access to areas where children can play safely. Recreational areas such as parks close to the city to increase relative safety and give more opportunities for children to play and exercise are more available in city areas but not in rural communities.[29] Children in rural areas have also been found to watch more television and play more video games that promote a sedentary lifestyle.[29] Because children are also more likely to consume high-fat or high-calorie foods while watching television may also lead to an increased obesity rate in rural pediatric populations. A lack of resources for weight management in smaller schools is another barrier faced by children in rural areas.[29]

Adults in rural populations also face specific barriers that increase their risks for obesity more than their urban counterparts and can also affect their children as a result. One of the significant barriers is a lack of nutritional education and access to resources such as nutritionists.[29] Many are unaware of nutritional recommendations and portion sizes, and are further challenged by the high costs of healthier food options and time limitations. This lack of nutritional literacy and socioeconomic challenges are further exemplified by adults in rural areas consuming, on average, fewer portions of fruits and vegetables and consuming more high-sugar soft drinks.[31] The lack of access to nutritionists trained explicitly in advising and coaching on nutrition is also a benefit that more urban residents have that is very limited to rural communities. To make matters more complicated, it has also been found that nutritionists are more unlikely to work in underserved areas than other health professionals.[32] The prevalence of obesity was higher among adults residing in rural areas (39.6%) than among those in urban areas (33.4%), representing an absolute difference of 6.2 percentage points (p= .006).[33]

Table 1. BMI Classifications for Weight in Adults and Children

BMI category	BMI Range (kg/m^2) in adults (ages 20 and older)	BMI Range in children (ages 2 to 19)
Underweight	Less than 18.5	Less than 5th percentile
Healthy Weight	18.5 to less than 25	5th percentile to less than 85th percentile
Overweight	25 to less than 30	85th percentile to less than 95th percentile
Obesity	30 or greater	95th percentile or greater
Class 1 Obesity	30 to less than 35	
Class 2 Obesity	35 to less than 40	
Severe Obesity (or Class 3 Obesity in Adult)	40 or greater	120% of the 95th percentile or greater, or 35 kg/m2 or greater
Class 2 Obesity (Pediatric)		120% to less than 140% of the 95th percentile, or BMI 35 kg/m^2 to less than 40 kg/m^2
Class 3 Obesity (Pediatric)		140% of the 95th percentile or greater, or BMI 40 kg/m^2 or greater

Legend: Body Mass Index (BMI) has slightly different classifications based on whether the individual is an adult or a child.

Management

Management includes the prevention of occurrence and treatment of obesity and its complications. WHO recommends starting both preventive and treatment of complication measures to be implied as soon as possible. Several programs and existing initiatives are already in place to promote healthier living habits and decrease the occurrence of obesity. Schaap et al in 2018 studied the fidelity of obesity prevention programs in the school. The study recommended better reporting of methods used as

preventive measures against obesity.[34] Lombard et al.[35] reviewed papers from five different databases written for the prevention of weight gain, discussing nine methods applied for the prevention of weight gain in adult patients over a period of one to three years of duration. Some studies showed a difference in weight of 1-3.5 kg between the study and control groups. The study concluded that they could not find a successful formula for the prevention of weight gain, and high-intensity ways are not more successful, but a mixture of mail and in-person intervention was useful.[35]

Management starts with the very basic and most important step in history. The history of onset, progress, and associated complications of obesity is equally important as medication-induced obesity. Providers should ask about all over-the-counter and prescription medications, and weight-gain-causing medications should be used in the minimum dose and for the shortest duration possible. Lab tests should be ordered based on specific history as well as routine labs. Asking in detail about the strategies that have helped in weight loss can be a starting point for restarting the weight loss journey. The Obesity Medicine Association suggests bariatric surgery and medications for eligible patients along with healthy eating habits, physical activity, and behavioral counseling.[36]

Table 2. Summary of Complications of Obesity [10,25,26]

Complications of obesity
Greater height and growth rate
Advanced puberty, menarche, gynecomastia
Polycystic Ovarian Syndrome begins at puberty
Musculoskeletal Disorders
Sleep Disorders, Obstructive Sleep Apnea
Respiratory complications, asthma, breathing issues
Increased risk of diabetes, hypertension, heart issues
Psychosocial Problems: Stigma, bullying, low self esteem
Non alcoholic fatty liver, gallstones

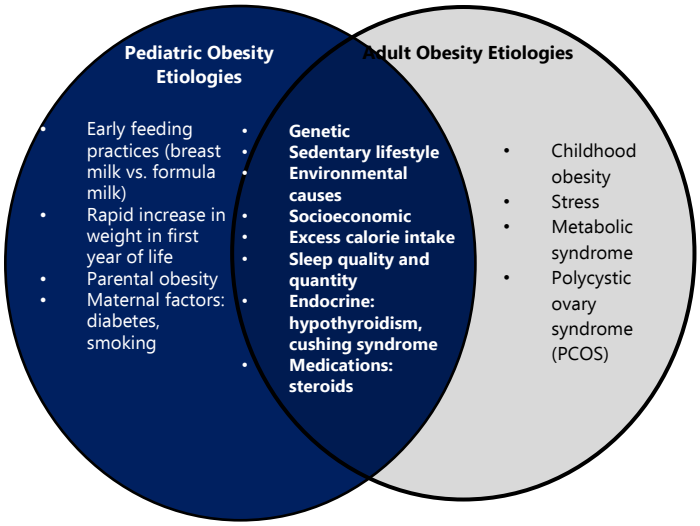
Table 3. Statistics of Rural vs. Urban Obesity Prevalence[28,30,31,33]

Rural vs. Urban Obesity Prevalence				
Study	State (if applicable)	Rural Obesity (children or adults)	Urban Obesity (children or adults)	Statistical Significance
Johnson & Johnson, 2015[28]	N/A	26% higher odds of obesity than urban children	20.6% lower odds of obesity than rural children	odds ratio=1.26 95% confidence interval (1.21–1.32)
Tai-Seale & Chandler, 2010[30]	Michigan	3-9% greater prevalence than urban children	3-9% less prevalence than rural children	Tai-Seale & Chandler, 2010[30]
Tai-Seale & Chandler, 201034	North Carolina	50% greater risk of obesity than urban children	50% decreased risk of obesity than rural children	p=0.0001
Trivedi et al., 2015[31]	N/A	35.6% prevalence	30.4% prevalence	p<0.01
Befort et al., 2012[33]	N/A	39.6% prevalence	33.4% prevalence	p=.006

The position statement of Italian society also emphasizes lifestyle intervention, medication use, and surgery for weight loss as the first, second, and third steps. As per the position statement, the availability of new safe and efficacious medications and medications under trials is increasing hopes for weight management in pediatric patients, especially adolescents.[37]

According to the American Academy of Pediatrics, clinical practice guidelines (CPG), obesity in pediatric patients is a treatable condition, and despite gaps and complexities, available evidence provides hope that increasing obesity can be managed by pediatricians. Instead of watchful waiting or a stage-wise approach, CPG recommends obesity management at a higher intensity level as per availability by collaboration of pediatricians, other primary care physicians, dietitians, nutritionists, exercise specialists, policy makers, and community partners.[38]

Figure 1. Pediatric vs. Adult Obesity Etiology [15-17]



Discussion

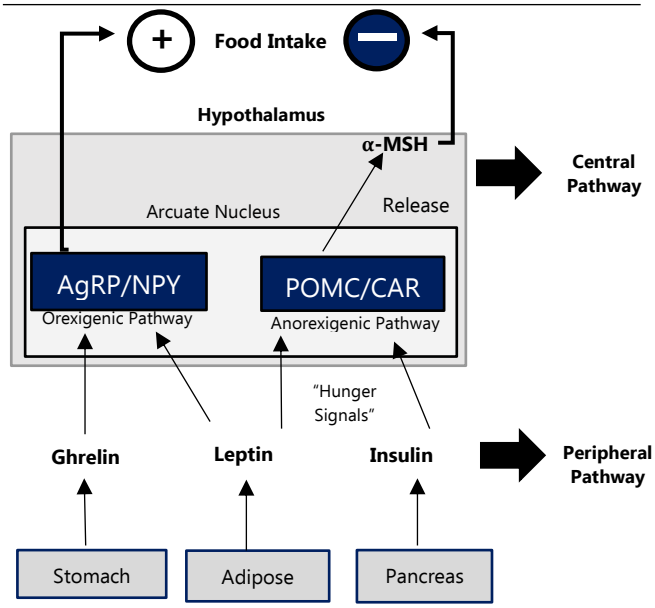
Prevention

Despite a lack of standardized or structured obesity prevention, some promise has been seen with targeted prevention.[39] A two-year study done in Finland found that their intervention program on 13-15 year old patients resulted in promising improvement in known comorbidities of obesity, such as improved food consumption habits and decreased cholesterol. However, there was no significant decrease in obesity itself. Even without this decrease, the results of this study indicate that this intervention strategy could be potentially effective.

Based on these results and experience from individual patient cases, it is recommended that obesity prevention initiatives should be focused on the following: (1) early prevention strategies in the pediatric population, (2) increased education of patients and guardians about the comorbidity risks that come with pediatric and adult obesity, and a (3) stepwise, tailored prevention and management of obesity plans for patients.[40] To implement all preventive and management strategies effectively,

it is recommended to use the methods of motivational interviewing (MI). Providers can start the conversation by using the 5As technique, which consists of "Asking" about a specific health-related behavior," Advising" the patient about the behavior, "Assessing" readiness to change, "Assisting" with goal setting, and "Arranging" follow-up.[39] Four communication skills such as "OARS", asking open-ended questions, providing affirmations, emphasizing points which the patient had said by reflective listening and putting everything to summarize can help to build the motivation for the change in the patients with obesity. Patients can be encouraged to come up with a SMART goal, which stands for specific, measurable, attainable, result-focused, and timed.[41]

Figure 2. T The POMC/CART and AgRP/NPY signaling pathways' Effect on Food Intake [22-24]



Legend: The agouti-related peptide(AgRP)/neuropeptide Y (NPY)-expressing neurons and the pro-opiomelanocortin (POMC)/cocaine-and amphetamine-regulated transcript (CART)-expressing neurons have opposite roles in regulating energy intake.

More specifically, according to the CDC, there are various ways families can help prevent obesity.[42] Healthy eating style adopted by the entire family helps children maintain a healthy weight, beginning with modeling a healthy eating pattern - parents can offer a variety of fruits and vegetables throughout the day, such as frozen and canned fruits and vegetables, as they are often less expensive than fresh and are still a great nutritional source.[42]

Families can maintain physical activity levels together. Activities such as walking the family pet before and after school, walking to the school and back home from the school, riding a bike, washing vehicles, or raking leaves count as physical activity.[4] Lack of sleep is another contributing factor that is usually neglected. Setting a consistent sleep routine to good quality and quantity sleep also helps to prevent type 2 diabetes, injuries, and problems with attention and behavior, along with obesity.[42] CDC recommends 14-17 hours of sleep for newborns, 12-16 hours for infants, 11-14 hours for toddlers, 10-13 hours for preschoolers, 9-12 hours for school-going children, 8-10 hours for adolescents, and more than 7 hours for adults.[43]

Wills-Ibarra et al. 2024 studied Family Systems Theory (FST), which included various factors related to family intervention in obesity management, including interaction, support, and skills of parents and their effects on body mass index, changes in lifestyle, and effects on mental health. The study found improvement in BMI. The review discussed the role of existing FST and provided recommendations for future practice and research.[44]

In adults, recommendations to prevent obesity include tracking food intake. Eating five to nine servings of fruits and vegetables daily (One vegetable serving includes 1 cup of raw vegetables or ½ cup of cooked vegetables or vegetable juice while one fruit serving includes one small to medium fresh fruit, ½ cup of canned or fresh fruit or fruit juice, or ¼ cup of dried fruit).[44] Adults are also recommended to select whole-grain foods (brown rice, whole wheat bread) while avoiding highly processed foods. Additionally, adults are recommended to engage in at least five days of moderate physical activity combined with resistance and strengthening exercises.[44] Not only calculating the calories, but also education for reading the nutrition labels and calculating the portion size should be made a part of the prevention plan.[45]

Future directions:

A multi-faceted approach by an individual, family, and community is needed to combat obesity. Prioritizing healthy and appropriate portion size eating, following a daily routine of physical activity, getting age-recommended sleep hours, managing stress, tension, and seeking professional health care on time should be considered for every patient for the effective management of obesity.[46]

Conclusion:

Obesity is a chronic disease that afflicts children, teens, and adults alike. Childhood obesity can lead to obesity in adulthood and will increase the risk of developing chronic conditions such as diabetes, hypertension, and heart disease. With the rates of obesity amongst children and adults continuing to climb in rural areas, addressing the causes is paramount. Biological, behavioral, and social factors all contribute to obesity rates in rural areas, often due to the challenges of accessing healthy food and fewer spaces for physical activity. By targeting treatments and interventions at these social determinants of health, we can improve individual health and foster healthier communities. By providing more comprehensive weight-loss plans, we hope to help reverse the current obesity trends in pediatric and adult populations in rural America.

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Author Contributions

Writing, visualization, data analysis, conceptualization, and supervision. All authors have read and agreed to the published version of the manuscript. All authors agree to be accountable for the article's content and conclusions.

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Case Report

Purple Urinary Bag Syndrome in a Patient with Acidic Urine: A Case Report

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Abstract

Background: Purple urine bag syndrome (PUBS) is a rare condition classically affecting chronically catheterized elderly women with alkaline urine and constipation. Presentations without these traditional risk factors are exceedingly rare. **The Case:** A 76-year-old chronically catheterized Salvadoran man with benign prostatic hyperplasia presented with a 15-month history of recurrent purple urine bag discoloration, dysuria and suprapubic pain. Notably, he lacked fever, flank pain, or constipation. Examination confirmed a purple drainage system and suprapubic tenderness. Urinalysis revealed acidic urine (pH 6). Urine culture identified extended-spectrum β-lactamase (ESBL)-producing Proteus mirabilis susceptible to trimethoprim/sulfamethoxazole but resistant to ciprofloxacin. At the initial encounter, empiric ciprofloxacin was started alongside routine catheter exchange. At a seven-day follow-up, despite the isolate's resistance, he showed clinical improvement and was transitioned to a targeted regimen. Ultimately, the patient achieved complete resolution after catheter replacement and culture-directed antibiotic therapy, with negative repeat urinalysis and culture at the final follow-up. **Conclusions:** This case report expands the recognized clinical spectrum of PUBS by documenting its occurrence in a chronically catheterized male patient with measured acidic urine and no history of constipation. This presentation highlights the importance of clinical awareness to avoid delayed diagnosis of potentially resistant pathogens. To the best of our knowledge, this represents the first published case of PUBS in El Salvador.

Introduction

Purple urine bag syndrome (PUBS) is a clinical condition where the urine bag and/or drainage system turns purple. It was first described in 1978 by Barlow et al in The Lancet.1 The striking coloration is due to the accumulation of metabolites of tryptophan. Normally tryptophan from the diet is metabolized to indole by the bacteria present in the gastrointestinal tract. Indole is then converted to indoxylsulfate in the liver for excretion in the urine. In the urinary system, certain bacteria (Proteus mirabilis, Klebsiella pneumoniae and Providencia spp.) possess enzymes such as indoxyl sulfatase and indoxyl phosphatase that metabolize indoxyl sulfate to indoxyl, which is oxidized into indirubin (red) and indigo (blue). These substances concentrate in the drainage system and react with the synthetic materials of the catheter and urinary bag.[2,3]

PUBS is seen in patients with a history of long-term indwelling urinary catheters. The main risk factors that have been described for PUBS are female gender, dementia, alkaline urine, high bacterial loads in the urine, constipation and chronic kidney disease.[4] Underscoring the rarity of presentations lacking these classic factors, a systematic review of 246 patients found that males accounted for only 29.3% of cases, and acidic urine was documented in just eight individuals. However, PUBS remains poorly characterized because most published data come from case reports and small retrospective studies.[5] PUBS is rarely reported in acidic urine because the oxidative conversion of indoxyl to indigo and indirubin is inhibited at low pH. Increased proton concentration shifts the redox environment against indoxyl oxidation. The objective of this case report is to describe a rare instance of PUBS in a male patient from El Salvador with acidic urine and without a history of constipation. This atypical presentation highlights the necessity of clinical vigilance regardless of risk factors. Purple urine discoloration is a visual manifestation of bacterial metabolic activity within the urinary tract. While this phenomenon is frequently associated with asymptomatic colonization, its presence in symptomatic individuals should prompt immediate investigation. In this case, the initial misattribution of the discoloration to beet consumption led to a diagnostic delay. To the best of our knowledge, this represents the first published case report of PUBS from El Salvador.

The Case

Patient background

A 76-year-old man, living in a poor rural setting, presented to the outpatient clinic for a scheduled urinary catheter change. His past medical history included hypertension treated with valsartan 320 mg and amlodipine 10 mg once daily, atrial fibrillation managed with bisoprolol 5 mg once daily and benign prostatic hyperplasia. He had been lost to urology follow-up due to fear of surgical intervention and had therefore been maintained on long-term

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indwelling urinary catheterization for approximately two years. The catheter was routinely changed every 15 days. He reported no allergies or relevant family history.

Over the preceding 15 months, his urine appeared normal at the time of catheter exchange, with discoloration developing several days later. During the same period, he experienced mild, constant, non-radiating suprapubic pain described as a burning sensation predominantly associated with the urge to void. Symptoms were temporally related to catheter exchanges. He denied fever, flank pain, constipation, nausea, vomiting, or other associated symptoms. No further evaluation had been pursued previously, as the discoloration had been attributed to dietary beet consumption.

Clinical examination

On physical examination, the patient was afebrile with normal vital signs: blood pressure: 120/80 mmHg, temperature: 37.0°C, oxygen saturation: 98% on room air, respiratory rate: 17 breaths/min, and heart rate: 70 beats/min. The abdomen was flat with normal bowel sounds, but tender to palpation in the suprapubic region. There was no costovertebral angle tenderness. The urine collection bag and catheter showed purple discoloration (Figure 1).

Timeline

Symptom onset: Following routine catheter exchanges, purple discoloration of the urine collection system repeatedly appeared over ~15 months, accompanied by mild suprapubic burning pain .

Presentation: The patient presented for a scheduled catheter change with concurrent urinary symptoms and visible purple discoloration of the catheter and drainage bag.

Initial treatment: Empiric outpatient antibiotic therapy and symptomatic treatment were initiated while diagnostic testing was pending.

Follow-up 1: Seven days after the initial visit, before the first dose of trimethoprim/sulfamethoxazole, the patient returned review of urine culture and susceptibility results. Purple discoloration was already absent. Having undergone initial catheter exchange and received empiric ciprofloxacin, he was subsequently transitioned to culture-directed trimethoprim/sulfamethoxazole based on the antibiogram.

Follow-up 2: Fourteen days after the initial visit, repeat urinalysis and a post-treatment urine culture were done and were negative, confirming resolution of infection.

Laboratory findings

Laboratory findings were as follows: leukocytes: 7,740/mm^3, hemoglobin: 14 g/dL, platelets: 293,000/mm^3, creatinine: 0.77 mg/dL, eGFR: 88.15 mL/min/1.73 m^2, blood urea nitrogen: 13.7 mg/dL, sodium: 140.9 mEq/L, potassium: 3.9 mEq/L, and glucose: 99.9 mg/dL.

Urinalysis revealed turbid urine with positive leukocyte esterase (500 cells/µL), microscopic hematuria (37.9 RBCs/HPF), marked pyuria (78.7 WBCs/HPF), leukocyte clumps (10/HPF), and moderate bacteriuria. Nitrites were negative. Mild proteinuria was detected (30 mg/dL), with an elevated albumin-to-creatinine ratio (≥300 mg/g). No casts, crystals, yeast, or renal tubular epithelial cells were observed. Urine pH was 6.0 and specific gravity was 1.011.

Urine culture: extended-spectrum β-lactamase (ESBL)-producing Proteus mirabilis resistant to amoxicillin/clavulanic acid, cefotaxime, ceftazidime, ceftriaxone, ciprofloxacin. Susceptible to trimethoprim/sulfamethoxazole.

Diagnosis:

Clinical presentation, positive urinalysis, and urine culture confirmed a chronic symptomatic catheter-associated urinary tract infection (CA-UTI) caused by ESBL-producing Proteus mirabilis. The associated purplish discoloration of the urine collection system in the setting of chronic catheterization supported the diagnosis of Purple Urine Bag Syndrome.

Diagnostic challenges included delayed evaluation of recurrent episodes due to prior attribution to dietary beet consumption. Additionally, access to care was limited by financial constraints and lack of personal transportation.

When the discoloration was first noted, our differential diagnosis included hematuria, bladder pathology, and pigmenturia related to foods or medications. However, careful examination showed that the urine itself was relatively clear; the purple discoloration was confined to the synthetic plastic of the catheter bag and tubing. This distinction made hematuria and most dietary causes less likely, as these typically alter the color of the urine itself, and instead strongly suggested purple urine bag syndrome (PUBS).

Treatment:

Immediate management consisted of routine urinary catheter exchange to achieve source control. Because the patient had symptomatic CA-UTI and a history of recurrent discoloration, empiric ciprofloxacin (500 mg twice daily) was started at presentation alongside oral phenazopyridine (200 mg three times daily for 2 days) for symptom relief. After culture identified ESBL-producing Proteus mirabilis susceptible to trimethoprim/sulfamethoxazole and resistant to ciprofloxacin, therapy was adjusted accordingly. At the seven-day follow-up visit, the patient was immediately transitioned to trimethoprim/sulfamethoxazole 160/800 mg twice daily for an additional seven days.

Outcome

At the initial seven-day follow-up visit, the patient reported significant improvement in urinary symptoms, and the purple discoloration was absent. This early clinical improvement, despite

discordant empiric antibiotic therapy, was attributed to adequate source control achieved via the initial catheter exchange. Following the transition to targetedtrimethoprim/sulfamethoxazole therapy, the patient reported no medication side effects and, to the best of our knowledge, was adherent to treatment. At the second follow-up fourteen days after initial presentation, repeat urinalysis and a post-treatment urine culture were negative, with sustained absence of discoloration ***(Figure 1).*** No adverse or unanticipated events were reported.

Figure 1. Urine Bag Discoloration at Presentation and Day 7 Follow-up



Legend: (Left) Characteristic purple discoloration predominantly affecting the synthetic plastic components of the urinary drainage system (catheter tubing and collection bag) rather than the freshly voided urine. (Right) Absence of discoloration following targeted antibiotic therapy and catheter replacement.

Ethical Approval and Informed Consent

Written informed consent for publication of this case report and accompanying anonymized images was obtained from the patient. The case was conducted in accordance with the ethical standards of the institutional and national research committees and with the 1964 Helsinki Declaration and its later amendments.

Discussion

Although PUBS is often considered a benign manifestation of asymptomatic bacterial colonization, in this patient it served as a prominent clinical feature of a chronic, recurrent, and symptomatic CA-UTI. Specifically, the patient met the clinical criteria for symptomatic infection through chronic catheterization, suprapubic pain, pyuria, bacteriuria, and culture growth of ESBL producing Proteus mirabilis. Furthermore, this case demonstrates that PUBS can manifest despite a measured acidic urine pH. Urinary pH measured in bulk urine may not reflect the physicochemical conditions at the catheter–biofilm interface, where pigment formation primarily occurs. Catheter-associated biofilms exhibit metabolic plasticity and can generate localized microenvironments, including pH variation driven by urease activity.[6] Consequently, the enzymatic hydrolysis of indoxyl sulfate and subsequent oxidation of indoxyl likely occurred at the catheter surface or within the collection bag where bacterial density is maximal.[7]

Consistent with this mechanistic explanation, a systematic review found that approximately 6.9% of PUBS cases occur with urinary pH below 7.0.8 Our case is comparable to one reported by Chung et al. describing an 85 year old male with a chronic indwelling catheter and acidic urine (pH 5.5).[9] Both patients were elderly men requiring long term catheterization, with benign prostatic hyperplasia in our patient and neurogenic bladder in the comparison case. While both patients shared the primary risk factor of chronic indwelling catheterization, their secondary profiles differed; the patient reported by Chung et al. was paraplegic with chronic constipation, whereas our patient remained mobile with regular bowel movements.

This case has two main limitations. First, molecular or enzymatic testing was not available to confirm phosphatase and sulfatase production by the isolated Proteus mirabilis. Second, empiric ciprofloxacin represents a therapeutic limitation. Despite the patient's long-term catheterization and high risk for resistant organisms (subsequently confirmed as ESBL-producing), optimal empiric therapy with intravenous carbapenems was constrained by outpatient management protocols. Because the patient's stable condition did not meet criteria for emergency hospital referral, we were unable to access broad-spectrum intravenous antibiotics.

Conclusion

This case emphasizes three clinical lessons. First, purple urine bag syndrome should prompt evaluation for urinary tract infection, as misinterpretation of urine discoloration may delay diagnosis. Second, the potential association with multidrug-resistant organisms reinforces the importance of culture-guided antimicrobial therapy in catheter-associated infections. Third, and most significantly, this case expands the recognized clinical spectrum of PUBS by documenting its occurrence in a chronically catheterized male patient with measured acidic urine and no history of constipation.

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Case Report

Early Multifocal Recurrence of Incidentally Discovered Pulmonary Epithelioid Hemangioendothelioma Following Complete Surgical Resection

Lilia Crew,[1] Jeanine Chiaffarano,[2] Brian Mott.[3]

Abstract

Background: Pulmonary epithelioid hemangioendothelioma is a rare, highly vascularized tumor with variable clinical presentation including recurrence and metastases. The treatment is complicated by the lack of standardized guidelines along with differing responses to trialed treatments, leaving patient prognosis unpredictable. Although often indolent, recurrence patterns remain poorly characterized in literature, specifically in patients with initially localized disease. **Thes Case:** We report a case of a 77-year-old man in whom a left, 21 mm lower-lobe pulmonary nodule was incidentally discovered during pre-coronary artery bypass graft evaluation. A concurrent wedge resection was performed with histopathology confirming epithelioid hemangioendothelioma, with negative margins. The patient opted for surveillance due to asymptomatic presentation. A year later, a recurrence with a right lower-lobe lesion, 10 × 7 mm, and numerous scattered lesions were identified and resected, both consistent with metastatic/recurrent epithelioid hemangioendothelioma. Histology from the initial and recurrent resections showed epithelioid nests and necrosis with immunopositivity for CD31, CD34, ERG, CAMTA1, and vimentin. **Conclusion:** This case emphasizes the importance of long-term surveillance in pulmonary epithelioid hemangioendothelioma due to the potential for early or unexpected recurrence as well as the need for more research to investigate a standardized, yet customizable, approach for better patient outcomes.

Introduction

Epithelioid hemangioendothelioma (EHE) is a rare vascular neoplasm that can arise in multiple organs, such as the lung, liver, and bone, with variable metastatic behavior.[1,2] Epidemiologically, EHE has an estimated incidence of less than one case per million population.[3,4] It typically occurs in adults between their third and fifth decades, with a slight predominance in females.

Pulmonary EHE accounts for less than 1% of vascular tumors and is often an incidental finding on imaging, as 50-76% of patients with EHE are asymptomatic.[5] In older individuals, pulmonary nodules typically raise suspicion for primary lung carcinomas or metastatic disease, making the diagnosis of EHE particularly challenging. Additionally, the unpredictable course of EHE can further add to its misdiagnosis or late diagnosis, delaying treatment.

Histologically, EHE is characterized by epithelioid endothelial cells within a myxohyaline stroma with varying mitotic activity.6 Immunohistochemical staining for typical endothelial/vascular markers such as CD31, CD34, and FLI-1 is essential in confirming the diagnosis and distinguishing the lesion from epithelial and mesenchymal malignancies.

EHE ranges from indolent to aggressive with metastatic potential.[7,8] The mainstay of treatment is surgical resection; however, multifocal lesions make this unfeasible in advanced cases, resulting in the need for chemotherapy. Previous studies have shown that the 5-year disease-specific survival for EHE is 81%, sharply contrasting the 50% mortality rate at 1 year for soft-tissue angiosarcomas.[8]

Prognosis varies widely and is influenced by factors such as pleural effusion, presence of symptoms at diagnosis, and extrapulmonary metastasis–all of which are associated with poorer survival outcomes.[3,9]

Multifocal recurrence within one year of resection is rarely reported in pulmonary EHE. To contextualize this case within existing literature, a targeted search of PubMed and Google Scholar using the terms 'pulmonary epithelioid hemangioendothelioma", "pulmonary EHE recurrence,' and 'pulmonary EHE resection' identified only a small number of case-level reports describing recurrence within this timeframe following negative-margin resection. The case discussed herein adds to the limited body of evidence and highlights the need for long-term surveillance post-resection.

The Case

Patient Presentation

The patient was a 77-year-old Caucasian male, a former smoker with fewer than 10 pack-years, having quit 16 years prior. He had

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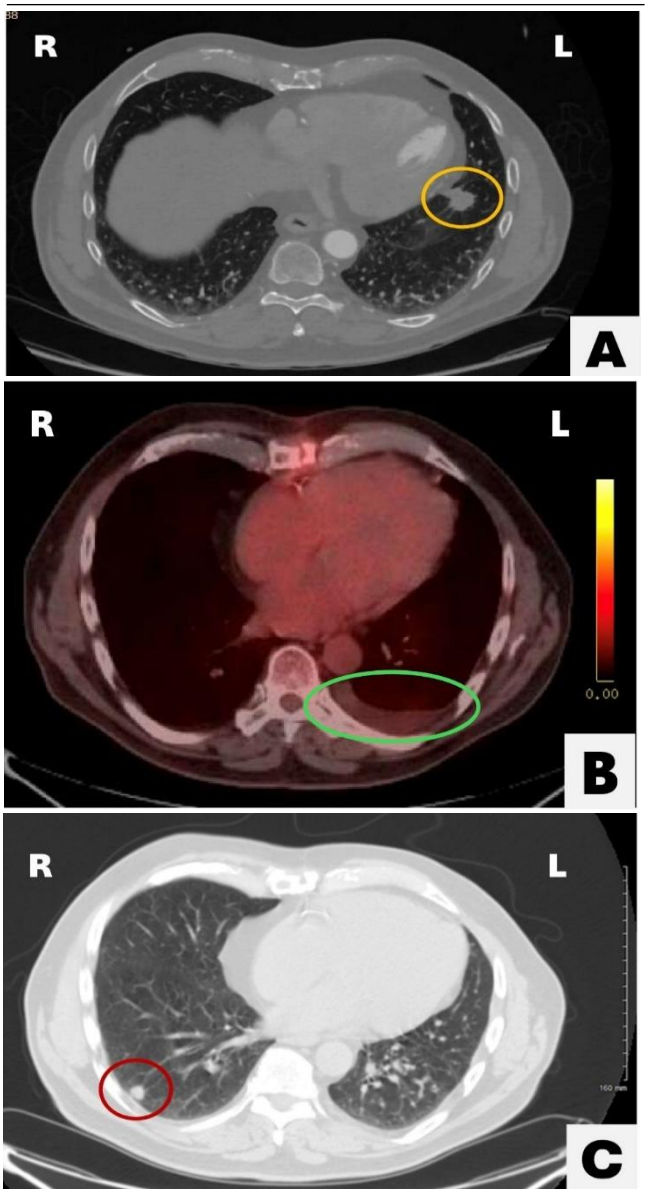
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no known occupational exposures or family history of malignancy. His past medical history included hypertension, hyperlipidemia, type 2 diabetes mellitus, osteoarthritis, spine radiculopathies, coronary atherosclerosis, and a cavernous hemangioma of the spine. He reported minor alcohol usage and used a marijuana tincture for pain related to the spinal hemangioma. He was not on cytotoxic agents or steroids despite his multiple comorbidities. The patient denied chest pain, cough, hemoptysis, fever, and chills.

Figure 1. Epithelioid Hemangioendothelioma — Serial Axial Chest CT and PET/CT Imaging

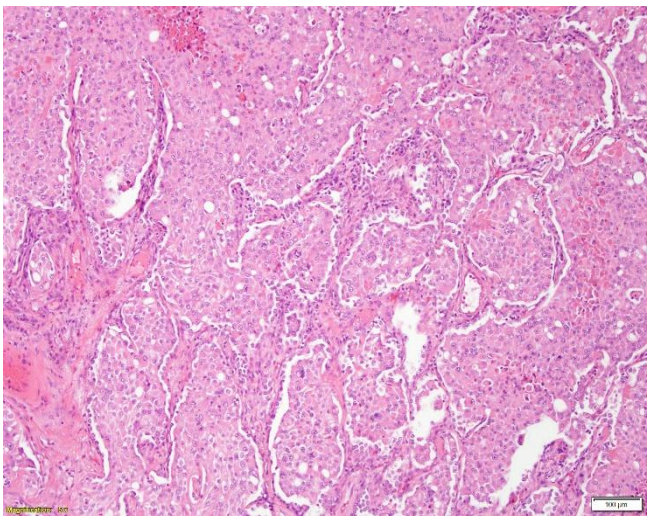


Legend: (A) Pre-operative axial CT demonstrating a left lower lobe pulmonary nodule (orange circle), representing the primary resected lesion. (B) Axial PET/CT performed 3 months post-operatively demonstrating a residual left pleural effusion (green circle) without evidence of metabolically active recurrence or residual nodule(s). (C) CT component of axial PET-CT at 12 months post-operatively demonstrating bilateral pulmonary nodules, including a right lower lobe subpleural nodule (red circle, largest approximately 10 × 7 mm). The CT portion is displayed as non-avid lesions are better characterized by CT.

During cardiac evaluation for coronary artery disease, pre-operative CT chest imaging identified a 21 mm spiculated left lower lobe pulmonary mass. Subsequent PET-CT demonstrated moderate radiotracer uptake at this site (Standard Uptake Value-SUV 2.3, ***Figure 1A***), raising suspicion for primary lung malignancy. Routine preoperative laboratory workup, including complete blood count (CBC) and comprehensive metabolic panel (CMP), was unremarkable. Further targeted workup, including inflammatory markers (CRP, ESR) and sputum AFB, was not obtained, as the imaging characteristics and clinical presentation were not suggestive of an infectious etiology.

One month after pre-surgical screening, the decision was made to perform a three-vessel coronary artery bypass grafting (CABG) with a concurrent generous wedge resection due to peripheral location and localization of the tumor, while minimizing the need for multiple operations ***(Table 1).*** Pathology from the resected lesion revealed epithelioid hemangioendothelioma with negative surgical margins, representing localized, single-lesion pulmonary disease. The patient expressed a preference for surveillance over systemic therapy, citing his stable condition and desire to avoid treatment-related morbidity. One-month postoperatively, a small left pleural effusion was identified on imaging but was not drained due to its minimal size.

Figure 2. Histology Hematoxylin and Eosin Stain, 10x



Legend: (Wedge resection of lung showing solid nests of tumor cells expanding airspaces. Rhabdoid features and foci of necrosis are noted. This morphology, along with subsequent immunostaining, is consistent with epithelioid hemangioendothelioma.

At 3 months post-operatively, surveillance PET-CT demonstrated a decreased left pleural effusion, consistent with post-operative changes, with no nodules or suspicious metabolic uptake identified ***(Figure 1B).*** Following this, the patient opted for yearly surveillance imaging; he was counseled that earlier imaging would be warranted should his clinical status change. One year after his initial surgery, PET-CT surveillance imaging performed by oncology identified a 10 × 7 mm right lower lobe (RLL) nodule with low metabolic activity (SUV 0.9), along with multiple non-

avid bilateral pulmonary nodules ***(Figure 1C).*** The patient again elected for surveillance over intervention given low-avidity nodules and continued asymptomatic status. A follow-up scan four months later showed the RLL nodule increased to 14 mm with moderate metabolic activity (SUV 2.6); additional non-avid bilateral pulmonary nodules were also noted. No metabolically active mediastinal lymphadenopathy was observed. The patient continually denied B symptoms, cough, and hemoptysis. On exam, no cervical lymphadenopathy was present. Pulmonary function tests were obtained preoperatively and values deemed adequate for surgical resection, at which point the patient decided to proceed with surgery. Due to the peripheral occurrence of the RLL lesion, a repeat robotic surgical wedge resection was performed, and pathology confirmed recurrent EHE. During this procedure, multiple pleural-based whitish nodules, each measuring approximately 1–2 mm, were observed scattered across the lung surface. A biopsied nodule confirmed EHE, supporting the presence of multifocal bilateral pulmonary disease. The postoperative course was uncomplicated.

Table 1. Clinical Timeline: Summary of key diagnostic, surgical, and surveillance events throughout the patient's disease course.

Timepoint	Event
Pre-operative evaluation	Pre-operative CT chest followed by PET-CT identified 21 mm spiculated left lower lobe mass (SUV 2.3)
Month 0	Three-vessel CABG with concurrent left lower lobe wedge resection; pathology confirmed localized EHE, negative margins
Month 1 post-op	Small left pleural effusion identified on imaging; managed conservatively
Month 3 post-op	Surveillance PET-CT clear, pleural effusion resolving
Month 12 post-op	Surveillance PET-CT chest: 10 × 7 mm RLL nodule (SUV 0.9) and multiple bilateral pulmonary nodules identified
Month 16 post-op	Follow-up CT: RLL nodule increased to 14 mm (SUV 2.6); robotic wedge resection performed; pathology confirmed multifocal recurrent EHE
Ongoing	Patient clinically stable; no systemic therapy; active oncologic surveillance

Outcome

At two months following the second resection, the patient remained clinically stable with no new symptoms and postoperative laboratory studies were unremarkable. No systemic therapies had been administered. The patient continued under active oncologic surveillance with serial imaging.

Histology

The hematoxylin and eosin-stained sections, from the initial and most recent sampling, show an epithelioid neoplasm with solid nests expanding airspaces ***(Figure 2).*** Foci of tumor necrosis and rhabdoid features are noted. The tumor cells are positive for CD34, CD31, ERG, CAMTA1, and vimentin. They are negative for pancytokeratins, TTF-1, p40, S100, SOX10, HMB45, NKX3.1, PAX8, CD45 and calretinin. Overall, morphology and immunophenotype are consistent with epithelioid hemangioendothelioma with rhabdoid features. Molecular testing was not performed in this patient.

This case report was prepared in compliance with the CARE (Case Report) guidelines, informed written patient consent was obtained, and the case was deemed IRB exempt due to deidentification.

Discussion

Pulmonary nodules, particularly in older individuals with comorbidities, warrant a more extensive and thorough workup with a broad differential diagnosis. The initial considerations should include primary lung carcinoma, metastatic disease, and granulomatous infections such as tuberculosis or fungal causes. For this patient, the initial lesion with spiculated morphology and an SUV of 2.3 raised suspicion of malignancy, prompting biopsy. Histology showed an epithelioid neoplasm forming solid nests with focal necrosis and rhabdoid features, findings associated with more aggressive behavior and higher mortality in vascular neoplasms.[9] In the case of EHE, immunohistochemistry is critical in confirming the diagnosis, demonstrated by the presence of endothelial/vascular marker CD34 positivity in this patient's lesion.[9] The negative pancytokeratin, TTF-1, and p40 excluded epithelial malignancies such as adenocarcinoma or squamous cell carcinoma.[10]

Diagnosis of EHE requires histopathologic evaluation with positive endothelial markers such as CD31, CD34, or FLI-1.9 It often occurs incidentally, as in this case, detected during pre-operative imaging for the CABG. Despite complete resection and negative margins of the 21 mm lesion, the patient developed a new right lower lobe lesion and scattered nodules within one year. In the registry analysis by Lau et al., progression from localized to uncontained or multifocal disease typically occurred over several years, with a median time to progression of 2.0 years.[4] The Surveillance, Epidemiology, and End Result (SEER) database studied by Liu et al., further highlights the rarity of respiratory EHE and its association with worse overall survival in comparison to other anatomic locations, underscoring the clinical significance of early multifocal recurrence in this setting.[3] This pattern raises the question of whether these lesions represent a single multifocal disease or independent occurrences. This case contributes to the evolving understanding of pulmonary EHE behavior.[7,11]

Of note, a study in 2011 identified recurrent WWTR1-CAMTA1 and YAP1-TFE gene fusions as characteristic molecular alterations in EHE. These fusions can be detected by FISH or RNA sequencing. CAMTA1 immunohistochemical positivity serves as a reliable surrogate marker for the WWTR1-CAMTA1 fusion, though it does not constitute molecular confirmation. In this case, molecular testing was not performed, which represents a limitation in the characterization of the disease, given the increasing clinical relevance of molecular classification in EHE.[12]

In the absence of standardized guidelines, management varies from surgical resection to systemic therapy for multifocal lesions or symptomatic cases. Agents such as interferon-alpha,

bevacizumab, and mTOR inhibitors (e.g. sirolimus) have been used with variable success in advanced disease.[13-15] In this case, the patient remained asymptomatic through both the initial diagnosis and recurrence, making an informed decision to opt for continued surveillance in both instances. Systemic therapy was deferred due to his stable condition and desire to avoid treatment-related morbidities, reflecting a shared decision-making approach that prioritized quality of life.

This case contributes to the growing understanding of EHE, specifically pulmonary EHE, by documenting early multifocal recurrence following complete resection in an elderly individual. The rapid recurrence observed in this case underscores the importance of long-term surveillance, even in patients with initially localized disease. In the absence of EHE-specific surveillance guidelines, structured imaging intervals like those used in post-treatment lung cancer follow-up may provide a potential framework for discussion, though this suggestion is hypothesis-generating rather than practice-informing and requires prospective validation. As more cases are reported, registries and longitudinal studies will be essential in defining prognostic factors and facilitating evidence-based management of this neoplasm. Documenting such early recurrence helps refine patients' and providers' expectations for surveillance intervals.
This report is limited by its single-patient nature, the rarity of pulmonary EHE, the patient's decisions regarding systemic treatment and routine surveillance restricting generalizability, the absence of molecular fusion testing, the unavailability of immunohistochemical staining images for inclusion, and the absence of targeted infectious workup including inflammatory markers (CRP, ESR, etc.) and sputum AFB studies, as these were not clinically pursued given the presentation.

Learning Points

Solitary lung nodules typically point clinicians towards primary lung cancers, metastasis or benign conditions like hamartomas or infections. A high suspicion for rare tumors, such as EHE, should be maintained when the clinical picture does not align with common etiologies. The use of immunohistochemistry is integral in establishing this diagnosis. Early tissue acquisition is important to enable timely multidisciplinary discussion, recognizing that evidence-based therapeutic standards for pulmonary EHE remain limited.

Conclusion

This case highlights the importance of long-term surveillance in patients with pulmonary EHE, even with localized initial lesions. The absence of standardized treatment guidelines shows that more research is required to allow patients and providers to approach this disease with greater direction and confidence.

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Author Contributions

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Letter

Commentary on "Evaluating Hypoglossal Nerve Stimulation Outcomes in Obstructive Sleep Apnea: Impact of Predisposing Conditions in a Retrospective Cohort"

Faraz Ahmed Shah,[1] Areeba Eeman Ahmad.[1]

To the Editor,

We read with great interest the article by Adwer et al.[1] evaluating hypoglossal nerve stimulation (HNS) outcomes in obstructive sleep apnea (OSA). While the study provides valuable insights into the impact of comorbidities on treatment response, we would like to highlight several methodological considerations that could enhance future research.

First, the assessment of comorbidities such as depression and insomnia relied on clinician documentation without standardized tools like the PHQ-9 or Insomnia Severity Index.[2,3] This approach may introduce diagnostic variability, especially given the symptom overlap between OSA and these psychiatric conditions. Second, the pathway classification incorporated self-reported device usage data. Although patient-reported outcomes are valuable, previous research has shown discrepancies between subjective and objective adherence in sleep therapies.[4] Incorporating device-recorded usage metrics could enhance future analyses by reducing reliance on subjective reporting. In addition, the study did not use validated patient-reported outcome measures (PROMs) such as the Epworth Sleepiness Scale (ESS) or the Functional Outcomes of Sleep Questionnaire (FOSQ), which are widely used to quantify sleepiness and quality of life in OSA populations. Utilizing such tools would improve the consistency, sensitivity, and comparability of subjective benefit assessments. The 75.7% attrition rate warrants particular attention. While acknowledged by the authors,[1] a comparison of baseline characteristics between included and excluded patients could reveal selection bias affecting generalizability. Such attrition analysis is particularly important given the study's retrospective design.

Several potentially significant confounders were not addressed, including:

- Medication use (e.g., sedatives affecting sleep architecture)
- Socioeconomic factors influencing treatment access
- Variability in titration protocols across patients

Moreover, all chart data were extracted by a single investigator. Although this was done using a standardized abstraction template, single-reviewer extraction may introduce reviewer bias or inconsistency. Best practices in retrospective chart reviews recommend dual, independent abstraction to enhance data reliability. Additionally, the two-month follow-up period[1] provides limited insight into long-term treatment efficacy. Given that OSA management typically requires sustained therapy, longer observation would help establish treatment durability, especially in patients with comorbidities.[5]

By highlighting these methodological considerations, we aim to support future research in developing more robust and generalizable findings regarding HNS outcomes. These considerations notwithstanding, the study contributes meaningfully to understanding predictors of HNS response. The findings emphasize the importance of comprehensive pre-implantation assessment and suggest valuable directions for optimizing treatment approaches in comorbid populations.

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