Assignment 2 Case Analysis: Stage 1- Team 4

Entry to Practice Dental Hygiene Degree Program, Class of 2019
University of British Columbia

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Introduction:

This report highlights two studies examining effects of non-surgical periodontal treatment (NSPT) on periodontal health of Type 2 Diabetes Mellitus (DM2) patients, as previous literature suggests a positive correlation between the conditions. Components include variables, strengths, limitations, results, methodology, and study type.

	The effect of periodontal therapy on uncontrolled type 2 diabetes mellitus in older subjects [1]	**Evaluation of Periodontal Status and Effectiveness of Non-Surgical Treatment in Patients With Type 2 Diabetes Mellitus in Taiwan for a 1-Year Period** [2]
Independent and dependent variables	**Independent:** - Age - Gender - Presence of treatment (four NSPT, PSC instruction, systemic doxycycline) **Dependent:** - Periodontal disease (PeD) - HbA1c levels - Fasting plasma glucose (FPG) levels - Plaque index (PI) - Bleeding-on-probing (BOP) - Probing depths (PD) - Recession - Clinical attachment loss (CAL)	**Independent:** - Sex - Age - Education level (EL) - DM2 duration - Body mass index (BMI) - Height - Weight - Smoking - Alcohol use - Betel nut chewing - NSPT in mild and moderate-to-severe (MS) PeD. **Dependent:** Parameters: - Metabolic: HbA1c, LDL - Inflammatory: IL-1β, CRP - Periodontal: PI, gingival index (GI), PD, CAL
Variable type(s)	**Categorical/Nominal** - Gender - NSPT - BOP **Numerical, Continuous** - Age - PI - PD - Recession	**Categorical/Nominal:** - Sex - Smoking - Alcohol Use - Betel nut chewing - NSPT in mild and MS PeD **Numerical, Continuous:** - Age

	- CAL - HbA1c - FPG	- BMI - Height - Weight - Hemoglobin levels - LDL - IL-1β - CRP - PI - GI - PD - CAL **<u>Categorical, Ordinal:</u>** - EL - DM2 Duration

Methodology and study type	**<u>Semi-Randomized Control Trial (RCT)</u>**
	- **Complete case analysis**
	- **Quasi-experimental design**
	- 60 patients, aged 55-80, with uncontrolled DM2 and PeD recruited
	- PI, BOP, PD, CAL, FPG, and HbA1c taken at baseline and three months later
	- Independent t-Test → analyzed differences between baseline and three months
	- Paired t-Test → analyzed differences within groups
	- Chi-squared → examined changes within HbA1c subgroups
		<u>Prospective cohort clinical trial:</u>
		- Measurements taken at baseline, three, six, nine, twelve months.
		- Inclusion factors included to remove confounding factors:
		  - Glucose levels
		  - Age (50-65 years)
		- Independent t-Test → analyzed continuous data between mild and MS PeD
		- Spearman correlation → analyzed remaining continuous data
		- Chi-square → analyzed categorical data or Fisher exact test
		- Mixed-effects ANOVA → compared periodontal, metabolic, and inflammatory parameters at different times
		
		<u>Analytical ecological study</u>:
		- NSPT applied to examine periodontal, metabolic, and inflammatory parameters between mild and MS PeD in DM2 patients

Recommended Tests:	**Levene's Test:** Equality of variances is a parametric test assumption. It is unclear whether this test was conducted with the independent t-Test. **Wilcoxon-Mann Whitney Test:** Normality cannot be assumed since neither group had sufficient sample sizes (n) (<30); parametric tests may not be appropriate. This is the non-parametric equivalent of independent t-Test. **Wilcoxon-signed ranks Test:** Since normality cannot be assumed, parametric tests are not appropriate. This test can be conducted instead of paired t-Test.	**Levene's Test:** See first column. **Shapiro-Wilk Test:** Test for normality is used for small n. The test also suggests normality, $p<0.05$. **ANOVA:** Categorical variables analyzed by comparing mild versus MS group for variances. Paired t-Test compares the means of two n.

Strengths and limitations of each study	**Strengths:** - Specific subject assignment criteria - Quantifiable data - Control for confounding factors (excluded subjects with previous NSPT) **Limitations:** - Skewed assignment: subjects refusing treatment → automatically in control group - Insufficient n and selection bias: subjects from same facility - Longer term study for accurate evaluation of conditions: follow-up data collected once - No examiner calibration/blinding - Insufficient data to estimate intention to treat analysis → complete case analysis performed rather than RCT (bias) - Standard deviation (SD) of 1.24 is larger than previous studies of 0.6, suggesting inconsistency.[7] The study assumed SD=0.6 to produce a 90% chance of detecting difference at 5% significance level → results are not precise and confidence interval is unclear	**Strengths:** - Examiner calibration - Specific subject assignment criteria **Limitations:** - No control group - No randomization - Required n to ensure 95% confidence level was not determined → n may not be adequate → 25 subjects withdrew skewing results - Selection bias: selected from one location. - Measurement bias: PD and CAL rounded down, underestimating PeD - Normality cannot be assumed as the mild group had less than 30 subjects (28 → 21).
Statistical and clinical significance of the study results	**Clinically:** - NSPT significantly improved periodontal status of treatment group - Control group: significant attachment loss increase **Statistically:**	**Periodontal parameters:** - Significant reduction (SigR) for all at 12 months post-therapy for MS group; same noted for PD of mild group. PI differed between groups

	- NSPT: SigR of PI, BOP, PD, and CAL - Control: CAL increase - Difference between groups for PD and CAL were not significant	**Metabolic parameters:** - Significantly higher HbA1c in MS group **Inflammation parameters:** - SigD observed for CRP in MS group - Nine months post-treatment, IL-1β was positively correlated with CAL - Twelve months post-treatment, HbA1c negatively correlated with PI and LDL, but positively correlated with PD
Findings and their significance and/or implications including extent to which causality is evidenced	**Treatment:** Periodontal health: - Significantly improved three months post-NSPT with adjunctive systemic antimicrobial treatment - Rapidly deteriorated without NSPT **Hill's Postulates:** Causality cannot be assumed **Strength**: SigR in PI, BOP, PD, and attachment loss (p-value<0.05) in treatment group. Reduction in FPG and HbA1c did not reach significance. **Consistency**: PD reduction and CAL gain in treatment group aligned with results from other studies. Without treatment, rate of attachment loss is ~0.96 millimetres year.[3-8] Reduction in PI and BOP was less than expected of treated periodontal patients.[9] They found that HbA1c decreased post-NSPT, but did not	**Treatment:** - Periodontal health improved in MS group at each interval - No decrease in metabolic parameters **Hills Postulates:** Causality partially assumed **Strength**: SigD in periodontal groups with PI, p-value=0.016. Twelve months post-therapy, GI and PD showed significant improvements: p-value=0.001 and 0.0001, respectively. **Consistency:** Findings reproduced in other studies and consistent; observing healthy individuals with clinical improvements after six months. NSPT results in periodontal improvements without changes in glycemic controls.[12] Another study found no association between HbA1C and NSPT. However, a negative effect was reported

	significantly improve glycemic control. This aligns with the general direction of previous studies, although this association did not reach significance in this study. SigR of HbA1c seen at one and three months post-antimicrobial NSPT.[7,10,11] **Temporality:** Improvement in PeD is seen only post-NSPT. **Dose-response**: Not applicable - equal exposure. **Plausibility**: TNF*α* is a key molecule in insulin resistance. NSPT reduces TNF*α* levels which should improve insulin sensitivity and metabolic control in DM2 patients.[12] **Experiment:** Study design does not include proper randomization. Conclusions drawn remain insignificant and invalid due to statistical inconsistencies.	twelve months post-therapy.[13] This is inconsistent with studies observing improvement three and six months post-NSPT.[14,15] **Temporality**: Improvement in PeD seen post-NSPT. **Dose-Response:** Continued NSPT improves PeD, while severity increases as DM2 is uncontrolled or no NSPT is applied. **Experiment**: Ecological studies are considered observational studies, therefore this category is not fulfilled.[16]
Which study provides you with the most valid and reliable evidence to support your dental hygiene practice?	Auyeung et. al presented more valid and reliable evidence. Despite lack of randomization, selection bias, and control group; examiners calibrated with prospective cohort tendencies in this ecological study, confirming reliability. The study fulfilled the purpose for an ecological study, and is internally valid. Further, most of Hill's Postulates were fulfilled, implying causal association. The RCT design by Promsudthi et al. contains deficiencies including lack of randomization, examiner non-calibration, insufficient n, and questionable statistical data, weakening internal validity. Due to study limitations, the results contained uncertainty, compromising internal validity. Several of Hill's Postulates were not fulfilled, suggesting little causation.	

Conclusion:

Type II Diabetes Mellitus (DM2) and periodontitis are positively correlated. Two research articles were examined based on the effect of NSPT on periodontal health and DM2, but neither article provided valid and reliable evidence to suggest a causal association. The evidence in both articles acknowledge the bidirectional relationship, further guiding dental hygiene clinical practice and shaping future hypotheses.

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