Assignment 2 Case Analysis: Stage 2 - Team 4

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

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Word Count: 426

Assignment 2: Stage 1

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Introduction:

Word count: 1167

Two studies by Auyueng et al. and Promsudthi et al. encompassing the effect of non-surgical debridement (NSD) on patients with diabetes mellitus (DM) type II and periodontal disease (PDD) were compared.^{1,2}

		Categorical, Nominal	Continuous, numerical, ratio data
Promsudthi et al.IV• Periodon Treatment (PT+syste antibiotics • Control g • Diabetic s systemic status, sr status, pr oral infec of antibio gender, r		 Periodontal Treatment (PT) group (PT+systemic antibiotics) Control group Diabetic status, systemic disease status, smoking status, presence of oral infections, history of antibiotic intake, gender, race 	 Age Duration of DM
	DV	• N/A	 Probing depth (PD), clinical attachment level (CAL), plaque score, bleeding on probing (BOP), fasting plasma glucose (FPG), glycated hemoglobin (HbA1c)
Auyueng et al.	IV	 Smoking, alcohol, education, medical history of diabetes 	• N/A
	DV	• N/A	 Plaque index (PI), gingival index (GI), PD, CAL HbA1c, low density lipoprotein (LDL) IL-beta, C-reactive protein (CRP) Age, height, weight, BMI

1. Dependent variables (DV) and independent variables (IV):

Auyueng et al. - perio: (mild vs moderate to severe) is an IV- discrete binomial categorical

2. Methodology & Study type:

	Promsudthi et al.	Auyueng et al.
Exclusion Factors	Participants with oral infection, smokers, allergy to tetracycline, systemic disease, history of antibiotic use, and previous PT within 3 month.	Participants with abnormal hepatic and renal function, hemoglobinopathy, bleeding disorders, pregnancy, and antibiotic prophylaxis indication.
Sample Population	60 patients from Thailand (55-80 years old) with uncontrolled type II DM and severe PDD.	100 individuals (50-65 years old) with type II DM with mild or moderate-severe PDD.
Treatment	Control group: No treatment Treatment group: PT with oral hygiene instruction (OHI), removal of supra + sub-g calculus: 4 sessions within 2 weeks. Systemic doxycycline 100mg/day for 2 weeks.	All received NSD, OHI at initial therapy, 3, 6, 9 and 12 months after initial therapy.
Study Type	Randomized controlled trial (RCT) No blinding	Clinical trial (CT)

Auyueng et al.: CTs have no control group, are prospective, experimental or observational, dependent of sample size, and are used to answer known interventions that require further comparison and validity.^{3,4}

3. Strengths and limitations:

	Promsudthi et al.	Auyueng et al.
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Strengths	 RCT trial design = causality, comparison between initial and 3 months. Elimination of confounding factors. Equal treatment to each participant. 	 Sample size: >30, assume normality Good reliability: Inter-examiner was the same, biochemical measures were duplicated. Periodontal examination was performed by calibrated examiners Statistical test: Fischer test: n>30 for mild PDD Chi squared: n<30 for moderate-severe PDD
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Limitations	Sample size	Sample Size:
	 n<30, normality not assumed, 	 Decrease in power and
	loss of power of SS.	generalizability: Mild perio
	Convenience Sampling	n = 28, n < 30, central limit
	 Pool of PDD and DM patients, 	theorem is breached. ^{5,6}
	not generalizable to whole	Convenience sampling:
	population.	 Same as study
	Selection bias	Selection bias:
	 Volunteer bias: those not 	 Only localized to Taiwan
	interested in NSD were placed	individuals with DM, and
	in control group, therapy group	age 50-65
	may have participants less	No control group: Unable to
	inclined to perform PSC =	compare effectiveness of NSD
	severe PDD.	and OHI. Unequal baseline data
	Examiner bias: lack of blinding	Calibration of Inter-examiners:
	Participant bias: Hawthorne Effect. ⁷	subjectivity in periodontal readings
	Study duration: short duration	and OHI to subjects. Unsure if
	Statistical tests:	blinded. ⁷
	 Independent and paired t-test 	Lack of reproducibility
	not appropriate due to small	Unable to control client: Unable
	sample size.	to control client habits = influence
	 Should use Mann-Whitney test 	results. ⁸
	and Wilcoxon signed rank test.	Statistical tests:
		Multiple paired t-tests for
		periodontal, inflammatory,
		and metabolic parameters.
		ANOVA one-way should
		be used.

4. Statistical and clinical significance of the study results

	Statistical Significance (SS)	Clinical Significance (CS)
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Promsudt hi et al.	Baseline: mean plaque score and BOP in treatment higher than control, FPG is lower in treatment than control. SS: Periodontal status improved in participants after treatment. No SS reduction in FPG and HbA1c levels.	PT with systemic antimicrobial treatment improved periodontal condition of poorly controlled DM. Decreased PI, BOP, PD, and CAL, suggesting PT effective with or without DM. CAL progression in control similar to those who never received NSD = diabetics have greater PDD risk. No CS on beneficial effects of PT on GC.
Auyueng et al.	More severe periodontal parameters amongst moderate-severe PDD. Reduction in PI, GI, and PD after 12 months post therapy for moderate-severe PDD. HbA1c in moderate-severe PDD patients were significantly higher than mild PDD at baseline, but no SS in mean HbA1c for cohort. No SS to sociodemographic and lifestyle factors.	 SS was present, however periodontal parameters would be impossible to clinically compare GI and PI: cannot be detected with a probe or radiographs. Difficult for a clinician to observe inflammatory and metabolic parameters. Average improvement of PD of 0.41 mm is difficult to determine with a manual probe.

5. Findings and their significance and/or implications including extent to which causality is evidenced

From Hill's Postulates,⁹ causality is evident in both studies. Temporal causality, the most important factor, is met in both.

Promsudthi et al.	Auyueng et al.
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Proper temporal sequence	RCT design: exposure prior to outcome. PD and DM we present before exposure of NS and OHI.		
Consistency of association	The results agreed with previous studies' results. ¹⁰⁻¹² No SS findings on FPG and HbA1c reduction, inconsistent with other studies.	In agreement with studies; NSD improves periodontal parameters. ¹³⁻¹⁸ Compared to studies 8,26-30 stated different results, due to different methodologies.	
Strength of Association	Relative risk nor correlation was not indicated. Strength of association cannot be included.		
Biological Plausibility	Mechanical PT disrupts biofilm improving periodontal conditions. Systemic antibiotic use (doxycycline) may reduce bacterial mass subgingivally. ¹⁹⁻²⁰ A possible bidirectional relationship exists between periodontitis vs diabetes. ²¹ However, effects of PT on reducing HbA1c levels have produced varying results. ²²⁻²⁴	Cytokine induced low grade inflammation, plays a role in insulin resistance at type 2 DM and PDD. Gram neg. perio infections perpetuate systemic inflammatory, increasing insulin resistance and poor glycemic control (GC). ^{10, 25-27}	
Dose-respo nse	Hypothesis: more frequent NSD results in improved inflammatory, and metabolic parameters.	d periodontal,	

	Control group present to test effect of PT and no PT.	There was no control group to test effect of frequency of maintenance interval.
Experiment	RCT has high experimental evidence to support the association between exposure and outcome and may indicate causal association. However, improper randomization, no blinding, and subject dexterity, dietary habits, PSC were not controlled.	Lack of academic literature and scientific theories grounding the association between DM and NSD, and OHI.

6, 7, 8. Which study provides y	ou with the most valid and reliable evidence to support
your dental hygiene practice?	

	Validity Factors	Promsudthi et al.	Auyueng et al.
Validity Factors	Selection Bias	(-)Volunteer bias, convenience sampling	(-)No control group, convenience sampling, loss to follow-up
	Measurement Bias	(-)Examiner bias-unintentio nal	(+)Debridement and measurement by different examiners
	Confounding Bias	(-)Diet, exercise, PSC	(-)Medication, exercise, gender, diet, severity of diabetes, PSC
Other Factors	Inter-Examiner Bias	(+)Debridement measured by same examiner	(+)Same examiners throughout in each PDD group for periodontal, inflammatory, metabolic parameters
	Single or Double Blinding	(-)Absent	
	Causality (Hill's Postulates)	Equal	

Sample Size/Generalizabil	ity (-)n<30 in both groups, poor reliability of SS	 (-)n<30 for mild PDD, poor reliability of SS (+)n>30 for moderate-severe PDD, greater reliability of SS (-) n=25 drop out
		(-) 11–25 drop out

Conclusion: Due to the presence of systematic errors, the validity of both studies were significantly decreased. Neither study randomized, blinded, or had sufficient sample groups. The strength of association and SS was not great enough, causing neither study to be applicable in clinical practice. Double blinded, large scale, RCTs are required to support evidence-based decision making amongst dental hygienists regarding NSD and DM type 2 patients with PDD.

9. Recommendations to dental hygienists based on your analysis

The strength of association between status of PDD and NSD still remains unclear due to short duration of study. As a result, frequent care is crucial in order to maintain and prevent the effects of PD on DM and vice versa. It is critical for dental hygienists and clients with DM and PDD to understand the importance of lifelong maintenance of periodontal health, as well as inflammatory parameters.

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Checklist 1:

	Quality Assessment Questions				
Study #1	Is this question answered? (Y/N)*	If yes, is the answer correct/convincing? (Y/No/Somehow)	If yes or somehow, how do you rate the answer? **	If no or somehow, what do you recommend? (Please be concise and brief ;<20 words for each item)	
(Promsudthi et al.)					
What are the study's dependent and independent variables?	Y	Somehow	3	Include PSC instructions and make formatting for variables (dependent/independent) more clear for readers to understand.	
What type of data is being collected	Y	Somehow	3.75	Format is hard to follow.	
What is the study methodology and design	Y	Y	2	Insufficient evidence to suggest RCT. Higher level of evidence- refer to levels of evidence table. Randomization should eliminate non-random errors. Therefore, selection bias should not be applicable if the study was truly randomized.	
What are the study's strength and limitations: What is the study population? Is sample size adequate? Was the sampling method appropriate?	Υ	Somehow	2.75	Expand on sample size being adequate and sample method appropriate. What criteria/evidence was used? Are other sampling methods appropriate? Inconsistency in explanation: (RCT may not = causality?) Perhaps mention large SD.	
Is their measurement tool/s used accurate?	Ν	Somehow	2.5	Explanation for accuracy not included. Also, this category should be explicitly stated.	

Was the statistical method/s used accurate and complete?	Y	Somehow	3	Requires explanation. Recommended studies under limitations is not explained.
Was study statistically/clinically significant?	Y	Y	4	
Are the Hill's Postulates applicable to the findings?	Y	Somehow	3	Recommend to expand on Hill's Postulates and identify unfulfilled criteria. "Relative risk nor correlation was not indicated." → sentence is confusing. Strength of association was concluded based on the present research articles.
To what extend causality is evident?	Y	Somehow	2.5	Causality was not directly discussed and would have to be interpreted by the reader. Recommend including a sentence with explanation on causality based on the two studies.
Total score = 26.5/36				

(Word count: 165)

Checklist 2:

	Quality Assessment Questions			
	Is this question answered? (Y/N)*	If yes, is the answer correct/convincing? (Y/No/Somehow)	If yes or somehow, how do you rate the answer? **	If no or somehow, what do you recommend? (Please be concise and brief;<20 words for each item)
Study #2 (Auyueng et al.)				

What are the study's dependent and independent variables?	Y	Somehow	3	We recommend including all variables (sex and betel nut use) and changing formatting (see Checklist 1 notes from same category).
What type of data is being collected	Υ	Yes	3.5	As represented in the study, Diabetes Mellitus type 2 duration was represented as a categorical/ordinal variable, and periodontal status as a categorical/nominal variable.
What is the study methodology and design	Y	Somehow	2	The team chose a clinical trial, however did not explain why they came to this conclusion and was not integrated in the answers beyond this point.
What are the study's strength and limitations: What is the study population? Is sample size adequate? Was the sampling method appropriate?	Y	Yes	3	Clarify which group they are referring to in this section. Calibration is noted as a strength and weakness. Reproducibility was not explained. Explanation of recommended studies is needed under limitations.
Is their measurement tool/s used accurate?	Y	Yes	3	Formatting is poor because there is no category for measurement tools, should be explicitly stated. Did not provide further explanation for recommendations
Was the statistical method/s used accurate and complete?	Y	Somehow	3	Explanation of accuracy for tests not included.
Was study statistically/clinically significant?	Y	Yes	4	
Are the Hill's Postulates applicable to the findings?	Y	Yes	3	See Checklist 1 comments.

To what extent causality is evident?	Y	Somehow	2.5	A brief sentence about the association not being significant was included. We would recommend including more information and details.
Total score = 27/36				

(Word Count: 153)

Checklist 3:

	Quality Assessment Questions				
	Is this question answered? (Y/N)*	If yes, is the answer correct/convincing? (Y/No/Somehow)	If yes or somehow, how do you rate the answer? **	If no or somehow, what do you recommend? (Please be concise and brief, <20 words for each item)	
Comparison of two studies					
a. Are studies ranked?	Ν	No	0	Direct comparison between studies needed, rather than generalizing both studies. Did not state which study has a higher ranking.	
b. Is the logic behind ranking provided?	Y	Somehow	1	Valid points are made regarding limitations of the studies but not the strengths. Did not rank studies.	
c. Is conclusion made?	Y	Somehow	2	Conclusion does not mention which study has a higher ranking and why (choose one).	
d. Are recommendations made?	Y	Somehow	3	No suggestions for further research.	
Total score = 6/16					

(Word Count: 55)

Checklist 4:

	Yes/No*	If yes, how do you rate the answer?	Considerations (please write briefly and concisely)
a. Is the word limit considered?	Y	3	
b. Is the quantity and quality of the references adequate?(>5 could be considered as adequate).	Υ	2.75	Duplicate references (1 and 14).
c. Are the references picked from reliable and current sources?	Y	3	
d. Is Vancouver Style used?	Y	3	
Total score = 11.75/12			

(Word Count: 5)

Overall Score: 71.25/100 = 71.25% (Acceptable)

Conclusion: (word count: 48 words)

In the future, the team should rank studies using the rubric criteria. Further explanation should be provided for further direction of research and recommendations. The format was confusing and could have been clearer. However, information was conveyed professionally and significance was explained in great detail with credible sources.