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Original Research

Comparison of Transrectal Ultrasonography-Guided Prostate Biopsies Analgesia's; Rectal Lidocaine Gel Versus Sandwich Anesthesia (Transurethral Plus Transrectal Lidocaine Gel Administration): A Double-Blind, Randomized, Controlled and Prospective Study

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ABSTRACT

Objectives: We aimed to evaluate the effectiveness of the additive transurethral anesthetic agent to transrectal anesthetic agent.

Methods: Transrectal ultrasound-guided 12 core prostate biopsy planned, 237 patients included in our study. The patients randomly divided into two groups. Group 1 (n=113): Only transrectal 2% lidocaine, Group 2 (n=124): Transrectal + Transurethral(Sandwiches) lidocaine gel given to the patients 10 min before the procedure as anesthesia. Immediately after the biopsy, the patient questioned about the level of pain he felt during the needle entry. The evaluation measured by the VAS score. Immediately after biopsy satisfaction rate with the procedure and if rebiopsy was required, acceptance was scored between 1 and 4. The two groups compared statistically.

Results: The mean VAS score of Group 1 and Group 2 was 4.88±1.89 and 3.77±1.83, respectively. The pain level of Group 2 was lower than Group 1' pain level. The difference between the two groups was considered statistically significant (p<0.001). The patient satisfaction rates of Group 1 and Group 2 found to be 2.45±0.71 and 2.78±0.66, and the acceptance rate of rebiopsy was 2.81±0.69 and 3.02±0.51, respectively. The patient satisfaction rate and acceptance rate of the rebiopsy of Group 2 were higher than Group 1. Patient satisfaction level (p<0.001) and rebiopsy acceptance rate (p=0.014) between the two groups found to be statistically significant.

Conclusion: In the TRUS-guided prostate biopsies, sandwich anesthesia is a cheap, convenient, tolerable, and effective method.

Keywords: Anesthesia, pain, prostate biopsy, transrectal ultrasound

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Prostate cancer is one of the most common malignancies in male patients. According to the USA 2016 cancer data, prostate cancer ranks first among the cancers diagnosed in men, and it ranks second among the causes of death from cancer.[1,2]

Changes in PSA value and abnormal digital rectal examination (nodules and stiffness) are the findings that lead the patient to biopsy.[3] Transrectal finger-guided needle prostate biopsy has evolved into the present form with Takahashi et al. using ultrasound in the field of urology and

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1989 by Hodge et al. reporting a TRUS-guided sextant biopsy.[4,5] At present, TRUS-guided 10–12 quadrant prostate biopsy is considered the gold standard.[6]

Despite the advancing technology, the most significant handicap in prostate biopsies is the pain and discomfort felt by the patient. Intense innervation of autonomic fibers in the prostate capsule and stroma is the leading cause of pain during the biopsy. However, Davis et al. [7] reported that 33% of urologists did not perform any analgesia during their biopsy.

Sedation, periprostatic nerve blockage (PPNB), and intrarectal lidocaine are used to reduce these problems and make the procedure more acceptable. Intrarectal lidocaine is administered alone or in combination with other methods. Although PPNB is becoming the most effective local anesthetic technique, this technique requires the correct application and experience.[7,8]

However, this method is not entirely innocent. In the literature, Turgut et al.[9] reported some side effects of PPNB. Those are pain due to needle (27%), need for re-anesthesia during biopsy (4.5%), symptoms related to lidocaine toxicity (1.5%), and injection-related image quality degradation (1%). Besides, each needle entering during PPNB may increase the risk of pain and infection. Administration of lidocaine gel, in addition to PPNB, was reported to be more effective than PPNB alone.[10-12]

The number of prostate biopsies performed due to increased cancer screening and rebiopsy rates is also increasing. Clinicians should know analgesia methods used in TRUS-guided biopsies and should choose the most appropriate method for the patient.[6]

In the routine practice of urology, the transurethral gel application is used for anesthesia before many procedures such as catheter insertion and cystoscopy. This study aims to investigate whether the pain level of the patient will be decreased by combining transrectal lidocaine gel with transurethral lidocaine gel in TRUS-guided prostate biopsies and how patient satisfaction will be affected.

There are many studies in the literature showing that intrarectal lidocaine gel application is a simple, cheap, and easy method for prostate biopsy. However, there are no studies evaluating the application of intrarectal anesthetic gel combined with transurethral lidocaine gel. This study will be the first in the literature.

Methods

The Sisli Hamidiye Etfal Training and Research Hospital ethics committee approved our study (dated 20.11.2018, no: 2174). Our study was conducted in accordance with the declaration of Helsinki. All patients included in the study were informed about the study and written consent obtained.

G-Power 3.1 program was used to determine the sample size of the study.

According to the group averages in the reference studies, when the effect size is 0.37, the α-error rate is 5%, and the power of the study is 80%, and a total of 235 patients were planned to be included in the study. (Considering that there might be a few patients who might be excluded from the study, extra patients were included in the study.)

Between September 2018 and April 2019, 241 patients between the ages of 40 and 81 who were decided to undergo TRUS-guided prostate biopsy were included in our study. Patients with anal region diseases such as anal fissure, hemorrhoids, and prostatodynia were excluded from the study because of additional pain and the possibility of wrong pain measurement. Our study is designed to be prospective, double-blind, and randomized.

Four of 241 patients were excluded from the study. Two of them were tearing before the biopsy; those patients felt pain after the rectal anesthetic gel application. The other two were not well suited for communication.

The patients randomly divided into two groups. Group 1: Only transrectal lidocaine given to the patients as anesthesia. Group 2: Transrectal + transurethral lidocaine gel given to the patients as anesthesia. The consort flow chart is summarized in Fig. 1.

Patients included in the study did not know the group's difference, and they did not know which group they were included in the study.

To ensure randomization, random group names were written in the envelopes containing the patient evaluations. The patients were given one of the mixed envelopes. Thus, a randomized, blinded group was identified.

Patients' age, body mass index, PSA values, prostate volume, and the reasons leading to biopsy were collected before the procedure.

Urine culture, bleeding time, and prothrombin time tests were performed in all patients who underwent prostate biopsy. Patients with normal values were taken for biopsy. All patients underwent antibiotic prophylaxis and done cleansing enema before the biopsy, as recommended by the guidelines. Lidocaine gel was applied 10 min before the biopsy for all patients. The doctor who performed the gel and the biopsy was different. All biopsies were performed by the same urologist. Transrectal ultrasound-guided 12 core biopsy was performed in lateral decubitus position with 18 gauge biopsy needle. None of the patients developed a complication requiring hospitalization.

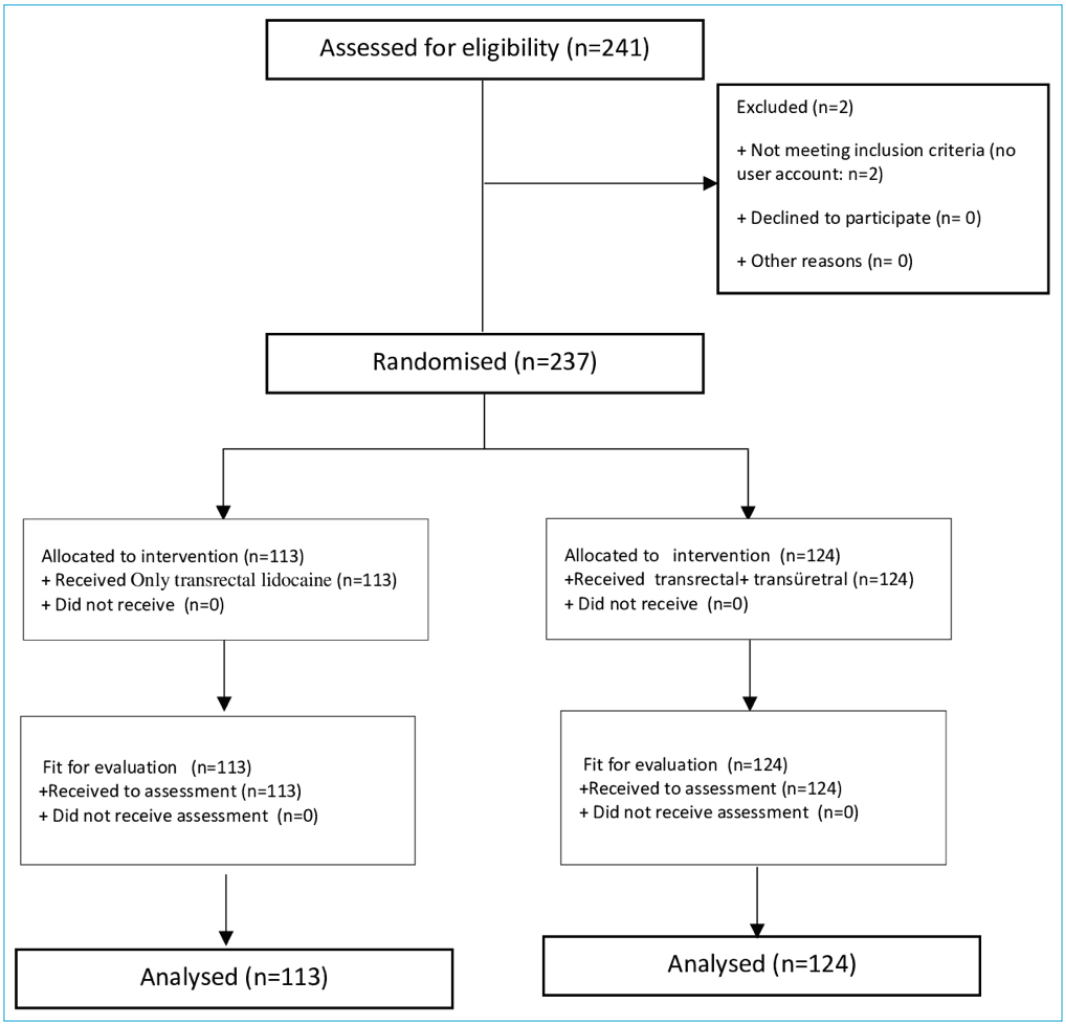

Figure 1. Consort flow chart.

The visual pain scoring questionnaire was scored immediately after the biopsy. Patients asked severity of pain, with 0 indicating no pain, and 10 unbearable pain.

Immediately after the biopsy, the patient satisfaction scale and the rate of acceptance of the rebiopsy, if required, were evaluated over 4 points. Patients asked how satisfied they were with the biopsy. As an answer, they were asked to choose one of these options. 1 – Not satisfied (1 point), 2 – I Somewhat satisfied (2 points), 3 – Satisfied (3 points), and 4 –Very satisfied (4 points).

After the procedure, patients asked, "If rebiopsy is needed, do they approve?" As an answer, they were asked to choose one of these options. 1 – I will Never (1 point), 2 – I will try my best not to do it (2 points), 3 – If I have to I will do it (3 points), and 4 – I will do it again without any hesitation (4 Points).

These questionnaires were filled in by different medical personnel following the procedure.

Statistical Method

Statistical analysis was performed using SPSS 23.0 for Windows (IBM, Armonk, NY) software.

Descriptive statistics of evaluation results; for categorical variables number and percentage, for numerical variables mean, standard deviation, minimum, maximum, and median values were given. The Mann–Whitney U test was used for continuous variables. The ratio of the categorical variables between the groups was tested by Chi-square analysis. All $p<0.05$ were considered statistically significant.

Results

The mean age of the patients included in the study was 66 year (48–86), mean BMI was 26.9 (14.9–41.9) kg/m^2, mean PSA was 33.7 (1.32–2724) ng/ml, and mean prostate volume was 54 (15–380) cc. There was no statistically significant difference between the two groups (Table 1).

Table 1. General Characteristics of Patients

Parameters→ ↓Groups		AGE (Year)	*BMI (Kg/m²)	*PSA (ng/ml)	Prostat Volume (cc)
Total	Mean±SD	66.0±7.0	26.9±4.0	33.7±197.5	54.8±39.3
(n=237)	Min	48	14.9	1.32	15
	Max	86	41.9	2724	380
Group 1	Mean±SD	66.5±8.3	26.5±4.0	48.9±271.2	57.6±48.1
(n=113)	Min	48	16.9	1.32	15
	Max	86	41.9	2724	380
	Median	66	26.5	7.43	45
Group 2	Mean±SD	65.6±7.3	27.2±4.1	20.0±86.3	52.1±28.7
(n=124)	Min	48	14.9	1.34	15
	Max	82	41.5	703	180
	Median	67	26.8	6.9	45
p		0.520	0.157	0.137	0.794

*BMI: Body mass index (kg/m²); *PSA: Prostat spesific antigen.

Table 2. Findings Leading to Biopsy

Reason for biopsy	DRE	PSA elevation	Both
Total (n=237)	6 (2.5%)	150 (63.3%)	81 (34.2%)
Group 1 (n=113)	3 (2.7%)	69 (61.1%)	41 (36.3%)
Group 2 (n=124)	3 (2.4%)	81 (65.3%)	40 (32.3%)
p	1.000	0.497	0.514

*DRE: Digital rectal examination.

Table 3. Pain-patient Satisfaction and Rebiopsy Acceptance Level

Measurement type→		VAS** (1–10 P*)	PSLR*** (1–4 P*)	RBAR**** (1–4 P*)
Total	Mean±SD	4.30±1.94	2.62±0.70	2.92±0.61
(n=237)	Min	0		
	Max	10		
Group 1	Mean±SD	4.88±1.89	2.45±0.71	2.81±0.69
(n=113)	Min	2	2	3
	Max	10		
	Median	4		
Group 2	Mean.±SD	3.77±1.83	2.78±0.66	3.02±0.51
(n=124)	Min	0	3	3
	Max	9		
	Median	4		
p		<0.001	<0.001	0.014

p*: Point; VAS**: Visual analog score; PSLR***: Patient satisfaction level ratio; RBAR****: Rebiopsy acceptance rate.

The most common finding leading to biopsy was PSA elevation (63.3%). There was no statistically significant difference between the causes of biopsy in both groups (Table 2).

The mean VAS score of the patients in Group 1 was 4.88±1.89 and 3.77±1.83 in Group 2. The VAS score of Group 2 was significantly lower than Group 1 (p<0001) (Table 3).

The satisfaction level of the patients was 2.45±0.71 for Group 1 and 2.78±0.66 for Group 2. Patient satisfaction rate of Group 2 was found to be statistically higher than Group 1 (p<0.001).

When the patients needed rebiopsy, the acceptance rate was 2.81±0.69 for Group 1 and 3.02±0.51 for Group 2. The

rebiopsy acceptance rate of Group 2 found to be statistically significantly higher than Group 1 (p=0.014) (Table 3).

Discussion

PPNB is a frequently preferred method for TRUS-guided biopsies. It is accepted that PPNB provides more effective analgesia compared to a placebo group or intrarectal lidocaine gel alone.[6-8]

Rodriguez et al.[10] compared 10cc 2% intrarectal lidocaine gel analgesia versus bilateral %1 lidocaine injection analgesia. They found that VAS was 2.76±1.69 in the lidocaine gel group and 1.73±1.26 in the bilateral apical injection group. According to these results, they concluded that the periprostatic nerve block is superior to intrarectal lidocaine gel application in pain control. In our study, the mean pain score, according to VAS measurement, was 3.77±1.83 in Group 1 and 1.86±0.90 in the sandwiches anesthesia group (Group 2). According to this study, our VAS score was high.

Song et al.[11] in a study of 90 patients compared 10 quadrant TRUS-guided biopsy analgesics. Patients were divided into three groups as intrarectal 20cc 2% Lidocaine Gel, Peri Prostatic nerve block (2% Lidocaine 5 cc 2.5cc per lobe), and for the control group, Peri Prostatic 5 cc 0.9% NaCl (2.5cc in each lobe) injected. They measured pain based on VAS. The pain scores of PPN were significantly lower than those of the other two groups. According to these results, it was emphasized that periprostatic nerve block was effective in reducing pain due to prostate biopsy, and intrarectal gel had no effect on pain control.

The VAS value of patients who received 20 cc 2% Lidocaine Gel only intrarectally was higher than ours (4.88±1.89). The VAS value of patients who underwent PPNB was similar to our sandwich anesthesia group (3.77±1.83) and provided the same degree of anesthesia.

Alavi AS et al.[12] also compared PPNB and intrarectal lidocaine gel in 8–14 quadrant prostate biopsy. They applied 10cc %1 lidocaine for PPNB and 10cc %2 lidocaine gel for analgesia. Pain score < 5, according to the 10-point VAS measurement, was reported to be 85.3% in the PPNB and 61.3% in the lidocaine gel group. According to this study, periprostatic 1% of lidocaine injection is more effective in pain control than 2% of intrarectal lidocaine gel.

According to these results, the intrarectal gel group and our Group 1, PPNB group, and our Sandwiches anesthetized group gave similar results.

Otunctemur et al.[13] compared lidocaine gel and lidocaine gel + PPNB (2.5cc 2% Lidocaine on each side) in a study with 473 patients. According to the 10-point Linear VAS measurement, the average pain score was found 4.54±1.02 in the lidocaine gel group and 2.06±0.79 in the gel + PPN block group. They sited that Peri Prostatic nerve block + Intrarectal Lidocaine gel was more effective in the control of pain felt during the entry of the biopsy needle.

Compared to our study, the rectal lidocaine gel + PPNB group's VAS was lower and significant. However, our sandwich analgesia group is superior to their rectal lidocaine gel group. This gives an indirect idea about the effectiveness of sandwich anesthesia.

Obek et al.[14] evaluated anesthesia techniques during prostate biopsy in 300 patients. They divided patients into four groups. They identified the first group as the control group and did not administer any anesthesia to the patients. In the second group, PPNB was applied to each side with 2.5cc of 2% lidocaine. In the third group, PPNB plus intrarectal 100% 2% lidocaine gel was administered. Group 4 received 1.5 mg/kg Tradamol in 100 cc saline for analgesia. Then they evaluated the patients' pain scores according to the 10-point Linear VAS measurement. The pain score (Group 1) was 4.63±2.19, (Group 2) was 2.57±1.78, (Group 3) was 2.03±1.82, and (Group 4) was 3.11±1.83. According to these results, PPNB administration with intrarectal lidocaine gel was superior to PPNB and Tradomol infusion alone in pain control. Group 1 in our study and Group 1 in this study had similar results. However, the VAS score of Group 2 in our study was higher than Group 2 and Group 3 in this study, but was similar to Group 4, but was significantly lower than Group 1.

Although PPNB is a preferred method in TRUS-guided biopsies, there are also studies in the literature comparing PPNB with intraprostatic + PPNB combination. Bingqian et al.,[15] in their study with 300 patients, they compared combined PPNB + Intraprostatic local anesthesia. They divided patients into three groups. Group 1: 5 cc 2% Lidocaine with PPNB (2.5cc in each lobe) + 5cc 2% Lidocaine solution injected into the prostate gland (2.5cc in each lobe). Group 2: PPNB + Intraprostatic 5 cc 0.9% NaCl injection (2.5 cc per lobe). Group 3: No, anesthesia. They measure the pain levels with 10-point Linear VAS. VAS values of the groups reported as Group 1: 2.89±1.09, Group 2: 3.56±1.09, and Group 3: 4.81±1.77. According to these results, combined analgesia, PPNB + intraprostatic injection, provides superior analgesia compared to PPNB alone.

Compared to our study, PPNB groups' VAS score was close to our sandwiches anesthesia group (3.77±1.83).

In the literature, there are studies comparing intrarectal applications with PPNB. One of these is Basar et al.[16] study. In their 80-patient study, they divided patients into four groups. Group 1 received placebo intrarectal cream, Group 2 received intrarectal surface analgesia with 1 g of 2.5%

Lidocaine + 2.5% prilocaine, Group 3 received PPNB with 1% Prilocaine, and Group 4 received PPNB with 1% Lidocaine. Pain levels were evaluated after the biopsy with VAS assessment. The mean VAS scores were as follows: Group 1: 5.5, Group 2: 2.9, Group 3: 2.4, and Group 4: 2.2. According to these results, intrarectal surface analgesia with 2.5% Lidocaine + 2.5% prilocaine cream provides equal analgesia with PPNB groups.

In this study, the VAS score of the groups was lower than that of our groups, except for the placebo group.

Furthermore, there are some studies comparing local anesthesia with placebo. One of these is Desgrandchamps et al.'s [17] study. For local anesthesia, they administered intrarectal 15 mL 2% lidocaine gel 15 min before the procedure (Group 1). In the control group, they applied intrarectal 15 mL hydrophilic ultrasound gel (Group 2). Then, they compared the percentages of patients' pain levels during biopsy into four categories. In this study, who underwent sextant biopsy, the majority of the patients were those who expressed no pain or mild pain. The rate of patients who reported moderate and severe pain was found to be 11% for Group 1 and 12.5% for Group 2, and no significant difference was reported between the two groups.

Same as Desgrandchamps et al.'s [17] study, Leung et al. [18] also compared intrarectal local anesthesia with a placebo. In their study with 338 patients, 6-quadrant prostate biopsy-applied patients were evaluated. They divided patients into two groups as given intrarectal 2% lidocaine Gel (Group 1) and flat gel (Group 2). Then, evaluated pain levels during biopsy with 10-point linear VAS. They found that the mean pain score of Group 1 was 1.75±1.55, and Group 2 was 1.79±1.51. According to these results, it is reported that intrarectal lidocaine gel application is not effective in reducing pain levels during the biopsy, and normal gel usage may decrease the cost. The VAS scores of the groups in this study were lower than the two groups in our study. On the other hand; even in the control group during the biopsy, 1.79 out of 10 felt pain in the TRUS-guided biopsy procedure suggests that there is no need to apply any anesthesia. In some of the studies above, even in patients who underwent PPNB, only this level of pain is felt.

In their study with 360 patients, Saad et al. [19] also compared intrarectal 2% Lidocaine Gel (Group 1) and flat gel (Group 2). In this study, the average pain score was 2 for Group 1 and 3 for Group 2, according to the 10-point Linear VAS measurement. In contrast to Desgrandchamps and Leung et al. studies, intrarectal lidocaine gel application in pain control has been reported to be effective, safe, and straightforward in reducing pain levels during the biopsy. In this study, the VAS score of both groups was reported to be lower than in our study. Same as Saad et al., Issa et al. compared intrarectal 2% lidocaine gel (Group 1) and flat gel (Group 2). In their study, they also performed the pain rating according to the 10-point Linear VAS. The pain scores of the groups were found as 2 and 5, respectively. It was concluded that intrarectal lidocaine gel is an effective, reliable, and simple method to reduce pain during the biopsy. They recommended local anesthesia should be done that all patients are undergoing to TRUS prostate biopsy.[20] Furthermore, VAS scores in this study were lower than ours.

Because adequate anesthesia increases patient satisfaction, it is crucial to help the patient to accept the necessity of repeated biopsy due to various reasons. In our study, the satisfaction of patients undergoing sandwich anesthesia was significantly higher, and they accepted rebiopsy significantly easier.

When we look at literature, many studies contradict each other and support each other in TRUS biopsy analgesia. Such as PPNB block is superior to intrarectal lidocaine gel[10-12] combining PPNB with intrarectal lidocaine gel is superior to PPNB alone,[13,14] PPNB + Intraprostatic lidocaine injection alone is superior to PPNB,[15] Intrarectal lidocaine gel has no effect.,[17,18] intrarectal lidocaine gel is an effective method to achieve analgesia,[19,20] intrarectal lidocaine gel provides the same level of analgesia as PPNB.[16]

We think that the conflict in the literature arises because of that the physician performing the biopsy is not the only physician, the evaluating staff is not the only one, and the studies are not randomized controlled prospective well-designed.

Studies reporting the efficacy of intrarectal lidocaine gel alone or in combination[13,14,16,19,20] indirectly support the efficacy of our study. According to our results, sandwich anesthesia provides more effective anesthesia than intrarectal lidocaine gel alone.

There is no study comparing sandwich anesthesia with PPNB and its combinations. Studies comparing these two methods are needed.

Conclusion

In TRUS-guided prostate biopsies, sandwich anesthesia is cheap, easy to apply, tolerable, and effective method. It increases patient satisfaction and affects accepting the rebiopsy decision.

Disclosures

Ethics Committee Approval: The study was approved by the Ethics Committee of University of Health Sciences Türkiye, Sisli Hamidiye Etfal Training and Research Hospital (No: 2174, dated 20.11.2018).

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – N.T., C.K., S.L.K., A.H.Y., S.T., S.G.; Design – N.T., C.K.; Supervision – N.T., C.K., S.L.K., S.G.; Fundings: N.T., C.K., A.H.Y.; Materials – N.T., C.K., S.T.; Data collection and/or processing – N.T., C.K., A.H.Y., S.T.; Analysis and/or interpretation – N.T., C.K., A.H.Y.; Literature review – N.T., C.K., S.T., S.L.K.; Writing – S.K.; Critical review – N.T., C.K., S.L.K., A.H.Y., S.G.

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