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ORIGINAL ARTICLE

EFFECTIVENESS OF IMMEDIATE POST-EXTRACTION SOCKET IRRIGATION WITH CHLORHEXIDINE, POVIDONE-IODINE, AND NORMAL SALINE ON PAIN AND WOUND HEALING IN INTRA-ALVEOLAR EXTRACTION

Eficacia de la irrigación inmediata del alvéolo postextracción con clorhexidina, povidona yodada y solución salina normal sobre el dolor y la cicatrización de heridas en la extracción intraalveolar

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ABSTRACT

Introduction: Tooth extraction is a common dental procedure. Immediate post extraction irrigation (IPEI) is done to remove tissue debris, metabolic waste, and tissue exudate to reduce microbial burden. However, due to insufficient clinical trials of high- quality evidence, there are still contradictions around IPEI. **Aims:** This random clinical trial was conducted to 1. Compare pain between groups undergoing IPEI with normal saline (NS), 0.12% chlorhexidine gluconate (CG) and 0.5% povidone iodine (PI). 2. To measure the effect of gender, age, ASA category and clinical status of tooth being extracted on pain, and 3. Compare wound healing between the three groups.

Materials and Methods: Eligible patients (n=69) were randomly assigned to three groups (n=23). IPEI was done with either NS, CG or PI. Two primary outcomes were assessed- Pain (VAS score, 0-10) on post operative day (POD) 3, 5 and 7 and wound healing on POD 7.

Results: Kruskal-Wallis test conducted for age, pain score and pain score difference, which indicated that all three were comparable across the groups at the assessed time points. Multivariate analysis revealed that none of the covariates had a statistically significant effect on the pain score difference between POD 7-3 and POD 5-3. However, the type of irrigating solution used approached significance in both models. Kruskal-Wallis test showed no significant difference between wound healing scores across the three groups.

Conclusion: There was no difference in pain scores or difference in pain scores across the three groups at the assessed time points. The gender, age, ASA category and clinical status of the tooth being extracted had no significant effect on pain. There was no difference in wound healing scores across the 3 groups.

Keywords: Tooth extraction; Povidone-Iodine; Chlorhexidine; Saline solution; Wound healing; Pain.

RESUMEN

Introducción: La extracción dental es un procedimiento odontológico común. La irrigación post-extracción inmediata (IPEI) se realiza para eliminar los restos de tejido, los desechos metabólicos y el exudado tisular para reducir la carga microbiana. Sin embargo, debido a la insuficiencia de ensayos clínicos con evidencia de alta calidad, aún existen contradicciones en torno a la IPEI. **Objetivo:** Este ensayo clínico aleatorio se realizó para 1. Comparar el dolor entre grupos sometidos a IPEI con suero fisiológico (NS), gluconato de clorhexidina al 0,12 % (CG) y povidona yodada al 0,5 % (PI). 2. Medir el efecto del género, la edad, la categoría ASA y el estado clínico del diente extraído sobre el dolor, y 3. Comparar la cicatrización de la herida entre los 3 grupos.

Materiales y métodos: Los pacientes elegibles (n = 69) fueron asignados aleatoriamente a 3 grupos (n = 23). La IPEI se realizó con NS, CG o PI. Se evaluaron dos resultados primarios: dolor (puntuación VAS, 0-10) en los días postoperatorios (POD) 3, 5 y 7 y cicatrización de la herida en el POD 7.

Resultado: Se realizó la prueba de Kruskal-Wallis para la edad, la puntuación del dolor y la diferencia de puntuación del dolor, la cual indicó que las tres características eran comparables entre los grupos en los puntos temporales evaluados. El análisis multivariable reveló que ninguna de las co-variables tuvo un efecto estadísticamente significativo en la diferencia de puntuación del dolor entre el POD 7-3 y el POD 5-3. Sin embargo, el tipo de solución de irrigación utilizada se acercó a la significancia en ambos modelos. La prueba de Kruskal-Wallis no mostró diferencias significativas entre las puntuaciones de cicatrización de la herida en los 3 grupos.

Conclusión: No hubo diferencias en las puntuaciones de dolor ni diferencias en las puntuaciones de dolor en los 3 grupos en los puntos temporales evaluados. El género, la edad, la categoría ASA y el estado clínico del diente extraído no tuvieron un efecto significativo en el dolor. No hubo diferencias en las puntuaciones de cicatrización de la herida en los 3 grupos.

Palabras Clave: Extracción dental; Povidona yodada; Clorhexidina; Solución salina; Cicatrización de heridas; Dolor.

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INTRODUCTION

Tooth extraction is one of the most common minor oral surgical procedures performed in dental clinics.[1] The indications of tooth extraction include dental caries, pulpal/periapical pathology, severe periodontal disease, fractured teeth, retained dental roots, impacted teeth, orthodontic extraction, pre-prosthetic extraction, tooth with associated pathology, or prior to radiotherapy.[2] Simple tooth extraction which involves extraction of fully erupted tooth only by simple luxation techniques, bone expansion, and forceps delivery.[3]

Even simple exodontia may have complications such as alveolitis (0.13% - 11.7%), trismus (18%), pain (3.9% - 5.5%), dehiscence (3.48%), postoperative infections (0.03 0.4%), retained roots (0.25%) and hemorrhage (0.22% - 1.3%).[4] These symptoms negatively impact patients' quality of life for at least 2-3 days.[5] Even though several factors may be attributed to these symptoms,[4] most are due to inflammation arising from trauma to hard and soft tissues.[6] Several methods are used to reduce inflammation following a tooth extraction, including anti-inflammatory medications, antibiotics, mouthwashes, and irrigation, among others.[7] In addition to reducing inflammation, various methods have been tested to promote the healing of hard and soft tissues. These include the use of grafts, growth factors, and resorbable membranes.[8]

Surgical irrigation may be defined as a process of washing a surgical site or wound with a solution.[9] The purpose of irrigation is to remove tissue debris, metabolic waste and tissue exudate to reduce microbial burden.[10]

There are several conflicting views regarding the irrigation of extraction sockets. Some debates focus on whether irrigation should be performed at all, while others center around which irrigating solutions are most effective. Some experts argue against irrigation, suggesting it may increase the risk of dislodging the blood clot and lead to dry socket. On the other hand, some studies report improved post-surgical outcomes with the use of specific irrigating solutions. The contradictions surrounding socket irrigation stem from a lack of high-quality clinical trials providing clear evidence.[11] In relation to the standardization of irrigation parameters, Barnes *et al.*,[12] have mentioned 3 "critical variables" in the surgical irrigation process: delivery method (pressure), volume, and additives.

However, there is an absence of any guidelines on either irrigation pressure or volume. Bailey et al. in their Cochrane review have reported only one study each from the 1970s that compare manual and mechanical irrigation and two irrigation volumes (high and low) respectively, leading to insufficient evidence for any recommendations.[13] In case of immediate post extraction irrigation, pressure of irrigation is specifically important, so that the blood clot is not dislodged. Despite this, no clinical trials have reported or standardized irrigation pressure across the study subjects. Lee et al. have specified that the gauge of the needle, the flow rate, and the distance of the needle from the surgical wound determine the pressure of irrigation.[14]

Third molar extractions most often constitute "complex exodontia", due to the need for more instrumentation, longer operating time and more invasive procedures. There are many clinical trials which assess different irrigating solutions in the 3rd molar extraction. However, we did not find any clinical trial where different irrigating solutions were used immediately after simple/non-surgical extractions.[3,4]

Thus, in this clinical trial we aim to firstly compare pain between groups undergoing IPEI with

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normal saline (NS), 0.12% chlorhexidine gluconate (CG) and 0.5% povidone iodine (PI). Secondly, to measure the effect of gender, age, ASA category and clinical status of teeth being extracted on pain, and, thirdly, to compare wound healing between the above 3 groups.

MATERIALS AND METHODS

A single-blinded randomized controlled clinical trial was carried out at the Oral and Maxillofacial Surgery Department of Dental Clinic, Manipal University College Malaysia.

Participants

Patients who needed simple/ non-surgical extraction under local anesthesia were recruited into the study after obtaining informed consent. Ethical clearance was obtained from the Institutional Research Ethics Committee at Manipal University College Malaysia [MUCM/FOD/AR/ B10/ EC-2022].[15]

Inclusion Criteria

Adult patients (18-59 years) who were under ASA I (Healthy with no systemic diseases) and ASA II categories (Mild systemic diseases such as controlled hypertension, diabetes, hypercholesterolemia) who did not take any antibiotics or anti-inflammatory medication in 7 days prior to extraction were included in the study.

Exclusion Criteria

Patients who required general anesthesia for the extraction, patients allergic to LA, who required trans-alveolar extraction or multiple extraction in a single visit, patients who were on bisphosphonates or steroids. Smokers were excluded from the study as smoking may affect healing.[15] Pregnancy and lactation were also excluded. The study excluded patients with a history of radiation therapy and those aged 60 or older.

Sample size

The sample size was calculated with a 20% drop out rate, and accordingly the minimum required sample size in each arm was n=23.

Randomization, Sequence Generation and Concealment

Non-probability purposive sampling was done. The patients who fulfilled the inclusion and exclusion criteria were randomly allocated to one of the three groups Normal saline, chlorhexidine gluconate and povidone iodine. Random numbers were generated with *https://www.random.org/* using simple randomization. Allocation concealment was done using sequentially numbered (simple randomization), opaque and sealed envelopes denoting the irrigation solution to be used. Figure 1 shows the process flow.

Local Anesthesia

All patients received mepivacaine hydrochloride 2% with adrenaline 1:100,000, 1-2 cartridges (2.2 ml/ cartridges).

Intervention procedure

After the non-surgical extraction was performed under local anesthesia, the extraction sockets were irrigated with normal saline (Group 1), chlorhexidine gluconate (Group 2) or povidone iodine (Group 3). The other critical variables in the surgical irrigation process —irrigation pressure and irrigation volume— were kept constant across the study population. The irrigation pressure was kept constant by controlling 3 parameters across the study groups:

1. Using the same gauge irrigation needle -18 gauge.
2. Keeping the distance of irrigation needle and wound constant: Needle placed at the margin of extraction socket.
3. Keeping the rate of deposition of irrigating solution constant: 20 ml in 10-15 seconds.

All the patients received the same post extraction instructions, and analgesics prescription (Paracetamol 500mg, TID, for 3 days). Since this was not a single

operator study, the intervention providers were conditioned and trained to follow the standardized protocol across the three groups.

Outcomes and outcome measures

Two outcomes were assessed wound (soft tissue) healing and post operative pain. Wound healing was measured using Soft Tissue Healing Index by Landry *et al.,*[16] only on 7th post operative day (POD). The index classifies the healing pattern based on color of soft tissue, margin characteristics, presence or absence of granulation tissue, and the exposure of connective tissue into 5 categories ranging from very poor to excellent. Table 1 gives the details of the Healing Index by Landry.[16] The assessment for all the participants was done by a single trained assessor who was not involved in intervention and was blinded. The patient and intervention provider were not blinded.

Pain experience was self-evaluated by patients using Visual Analogue Scale (VAS, 0-10) and recorded on POD 3, 5, and 7.

Statistical methods

Data for pain was collected on POD 3, 5, and 7. Data for wound healing was collected only on POD 7. The participants who did not report to the clinic on POD 7, were called to collect data for pain, however for wound healing they were considered dropouts. Gender, age, ASA category (I and II) and clinical status of tooth being extracted (irreversible pulpitis/apical periodontitis, mobile tooth with poor prognosis, healthy tooth) of the tooth were recorded as covariates. The test was conducted for normality of data. Most of the variables were not normally distributed, thus nonparametric tests were performed.

The Kruskal Willis test was done to compare the median difference in pain between three groups. Multivariate analysis was done to measure the effect of recorded covariates on the pain score difference between POD 7-3 and POD 5-3.

Figure 1.
Study Process Flowchart.

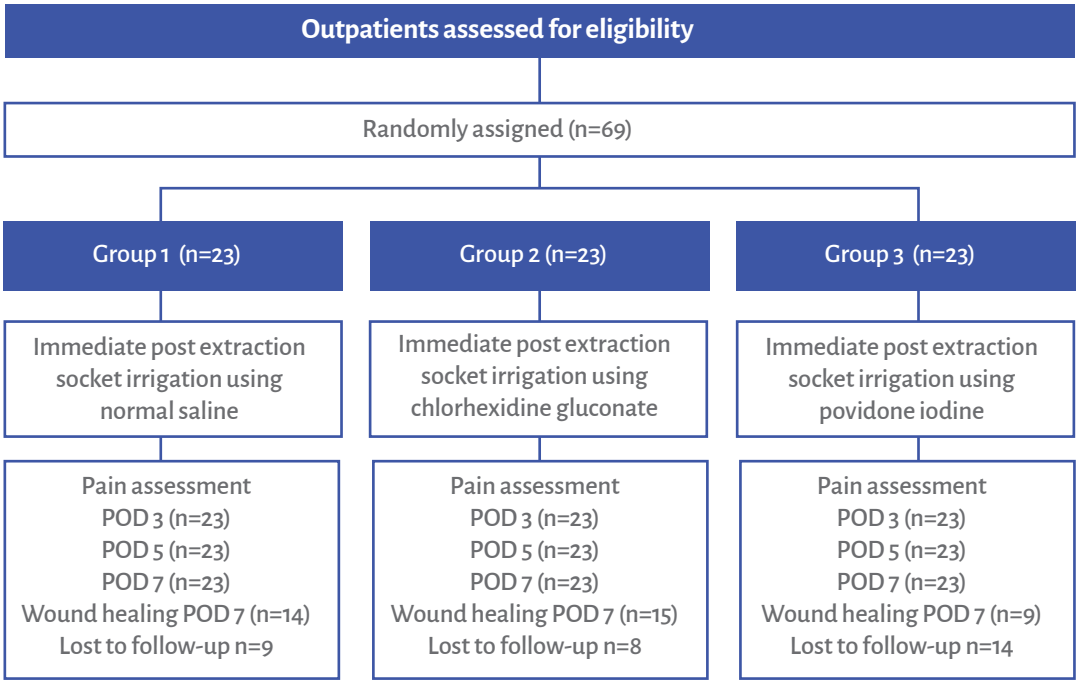

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Table 1.

Healing Index of Landry[16] utilized to assess wound healing.

Healing index	Tissue colour	BoP	GT	Incision margin	Sup
1. Very Poor: 2 or more signs present	≥ 50% of red gingiva with loss of epithelium beyond incision margin	Yes	Yes	not epithelialized,	Yes
2. Poor	≥ 50% of red gingiva with exposed connective tissue	Yes	Yes	not epithelialized,	No
3. Good	25% - 50% of red gingiva	No	No	no exposed connective tissue	No
4. Very Good	< 25% of red gingiva	No	No	no exposed connective tissue	No
5. Excellent	all pink tissues	No	No	no exposed connective tissue	No

Table 2.

Distribution of categorical covariates across the three groups.

Variables	Categories	Intervention		
		Group 1 (n=23 %)	Group 2 (n=23 %)	Group 3 (n=23 %)
Gender	Female	12 (32.43)	12 (32.43)	13 (35.14)
	Male	11 (34.38)	11 (34.38)	10 (31.25)
ASA Status	ASA I	13 (28.07)	18 (37.50)	17 (35.42)
	ASA II	10 (47.62)	5 (23.81)	6 (28.56)
Clinical status of tooth	Healthy tooth	7 (43.75)	5 (31.25)	4 (25.00)
	Apical periodontitis	5 (29.41)	5 (29.41)	7 (41.18)
	Irreversible pulpitis	11 (30.56)	13 (36.11)	12 (33.33)

Table 3.

Kruskal Wallis test to compare the median difference in pain scores between three groups.

Mean Rank		Group 1 (n=23 %)	Group 2 (n=23 %)	Group 3 (n=23 %)	Chi- square	*p*-value*
Age, Mdn (IQR)		46 (29)	46 (22)	44 (12)	1.156	0.561
Pain	POD 3	42.43	33.61	28.96	5.629	0.06
	POD 5	39.91	32.93	32.15	2.657	0.265
	POD7	39.98	34.04	30.98	3.906	0.142
PD	POD 5-3	41.24	34.33	29.43	4.349	0.114
	POD 7-3	42.46	32.78	29.76	5.309	0.07
	POD 7-5	38.83	32.04	34.13	1.923	0.382

Table 4.

The regression model summary for the pain score difference between POD 7-3 and POD 5-3.

Model	R- square	Adjusted	R- square
POD 7-3	0.076	0.003	
POD 5-3	0.066		-0.008

Table 5.

Multivariate analysis for group, gender, age, ASA status and clinical status of tooth in POD 7-3 and POD 5-3 regression models.

	Variables	t-stats	*p*-value
POD 7-3	Group	-1.821	0.073
	Gender	0.029	0.977
	Age	-0.229	0.820
	ASA status	0.844	0.402
	Clinical status of tooth	0.358	0.722
POD 5-3	Group	-1.597	0.115
	Gender	0.132	0.895
	Age	-0.395	0.694
	ASA status	0.873	0.386
	Clinical status of tooth	0.296	0.768

Table 6.

Comparison in the wound healing across 3 groups on POD 7.

	Wound healing score	
Intervention	**Mdn (IQR)**	***p*-value***
Group 1 (n=15)	4 (2)	0.123
Group 2 (n=14)	5 (1)	
Group 3 (n=9)	5 (0)	

Kruskal Wallis test was used to compare the wound healing scores between the three groups on POD 7. The level of significance was taken as $p<0.05$ for all the statistical tests.

RESULTS

The distribution of categorical covariates is given in Table 2. The Kruskal Willis test (Table 3) for age showed no statistically significant difference between the three groups (Chi-square = 1.156, $p = 0.561$).

For pain on POD 3, POD 5 and POD 7, the Kruskal Willis test indicated no significant difference between the groups ($p = 0.06$, 0265, 0.142 respectively). For the difference in pain between POD 5-3, POD 7-3 and POD 7-5, no significant difference was found between the groups ($p = 0.114$, 0.07, 0.382 respectively). The Chi-square value, *p*-value and mean rank are presented in Table 3.

In summary, the Kruskal-Willis tests conducted for various pain measurements and age did not show any statistically significant differences between the three groups, indicating that the median pain levels and age were comparable across the groups at the assessed time points.

Multivariate analysis to measure the effect of clinical status of tooth, ASA status, gender, group (irrigating solution used) and age on the pain score difference between POD 7-3 and POD 5-3 was done.

The model summary for the pain score difference between POD 7-3 and POD 5-3 is given in Table 4. The R-squared values indicate that approximately 7.6% of the variance for pain score difference between POD

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7-3 and 6.6 % of the variance for pain score difference between POD 5-3, can be explained by the clinical status of tooth, ASA status, gender, group, and age. The Adjusted R- squared values of both models had very low explanatory power.

Table 5 gives the *p*-values for clinical status of tooth, ASA status, gender, group, and age in both regression models. None of the covariates were statistically significant in either of the two models. Although Group *i.e.* the type of irrigating solution used approached significance in models for both pain score difference between POD 7-3 and POD 5-3 ($p = 0.073$ and $p = 0.115$).

For the second outcome - wound healing scores, the drop-out rates were very high for all 3 groups (39% for group 1, 34% for group 2 and 60% for group 3), as many patients did not report back to the clinic on POD 7 for clinical examination. Kruskal Wallis test showed that wound healing was similar in all 3 groups (p=0.123). The results of Kruskal Wallis test for wound healing are presented in Table 6. No adverse effects were reported.

DISCUSSION

This clinical trial was conducted to compare the effect of immediate post extraction irrigation using the 3 most used irrigating solutions on pain and soft tissue healing, during simple extractions. In this trial we have also attempted standardization of irrigation pressure across the study subjects and proposed that this standardization and its reporting is crucial.

Normal saline is a crystalloid with no antimicrobial properties. Approved for irrigation by the Food and Drug Administration (FDA), it is the most used irrigation fluid. The rationale behind the use is that it is isotonic and can enable the removal of debris when used judicially.[12,17,18]

As additives, two antimicrobial agents are most frequently used in dentistry. chlorhexidine gluconate and povidone iodine. Chlorhexidine gluconate is a gluconate salt, whose broad-spectrum antimicrobial effect is attributed to the di-cationic structure.[19,20] 0.12 % chlorhexidine is prescribed as mouthwash. At a concentration lower than 0.1% it is bacteriostatic only. 0.12% of chlorhexidine is thus the minimum effective strength.

Povidone Iodine is a broad-spectrum anti-microbial agent which can act against bacteria, fungi as well as viruses. 0.5% povidone iodine has been particularly advocated for tissue, with higher concentrations tipping towards tissue damage.[21] Hence this concentration was used in the present study.
Two primary outcomes were assessed in the present trial pain and soft tissue healing of the extraction wound. One primary outcome being patient reported outcome *i.e.,* pain and one being physician reported outcome *i.e.,* soft tissue healing. Even though the patient reported outcome poorly correlates with physician reported outcome, they are still important for obtaining patient's perspective.[22]

Pain is the most common symptom experienced by patient post extraction. Self-report measures are the 'gold standard' for pain assessment of pain outcome.[23] VAS scale is one of the most commonly used tools to measure pain intensity.[24] In the present clinical trial pain was assessed using VAS- scale at 3 time points. For physician reported outcomes, soft tissue healing was assessed at a single time point. Adverse effects attributed to extraction procedures were recorded as secondary outcomes.

There was no statistical difference between the 3 groups, for both primary outcomes. Clinically none of the 3 irrigating solutions stood out in its potential to reduce or increase pain and/or influence the pattern of soft tissue healing. The multivariate analysis showed that even though none of the covariates had a statistically significant effect on pain score

difference between POD 7-3 and POD 5-3, the type of irrigating solution used approached significance in both models.

The sample size in this trial was small and with a bigger sample size multivariate analysis can give more reliable results. The drop-out rate for the wound healing outcome was more than 20%, considerably reducing the sample size and making it unequal across the groups.

However, since the sample size in each group was more than 5, Kruskal- Wallis test could be conducted. For future the authors recommend a study design that will ensure low drop- out rate for wound healing outcome. Even though no significant effect was observed on either clinical outcome, there may be differences at the molecular level, however, they are beyond the scope of the present clinical trial.

CONCLUSION

There was no difference in pain scores or difference in pain scores across the 3 groups at the assessed time points. The gender, age, ASA category and clinical status of the tooth being extracted had no significant effect on pain. There was no difference in wound healing scores across the 3 groups.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest.

ETHICS APPROVAL

Study obtained approval from the Institutional Research Ethics Committee at Manipal University College Malaysia [MUCM/FOD/AR/ B10/ EC-2022].

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AUTHORS' CONTRIBUTIONS

Rethish Elangovan: conceptualization, methodology, project administration, resources, supervision, writing – review and editing.

Arunima Chauhan: Methodology, Writing – Original Draft, Writing – Review and Editing.

Htoo Htoo Kyaw Soe: Methodology, Formal Analysis.

Sameer Kumar Vandrangi: Project Administration; Resources.

Anand Francis Farias: Project Administration; Resources.

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