

Influence of maintaining apical patency in post-endodontic pain

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Abstract

Background

The purpose of this study was to compare postoperative pain between apical patency and non-patency groups and to evaluate the influence of number of visits, vitality of teeth, group of teeth and preoperative pain on post-operative pain.

Methods

One hundred sixty patients were included in the study. Patients were randomly divided into: Group A (n = 80) contained apical patency maintaining group and Group B (n = 80) contained those treated without maintaining apical patency. Each group was subdivided into equal number of patients treated in single visit (n = 40) and multiple visits (n = 40), including vital (n = 20) and non-vital teeth (n = 20) and single-rooted teeth (n = 10) and multiple-rooted teeth (n = 10). Apical patency was maintained with a size 10 K-file during conventional hand filing step-back shaping procedure. Intensity of pain was recorded before treatment and on days 1, 2, and 7 after treatment using a numerical rating scale. Statistical analysis was done using Mann -Whitney U test and Spearman correlation.

Results

There was statistically significant difference ($p < 0.05$) in postoperative pain scores between the groups on 1st, 2nd and 7th day follow up. Postoperative pain in patency maintaining group was not influenced by number of visit and group of teeth treated. Whereas, vital teeth when patency was maintained in multiple visits root canal treatment post-operative pain was statistically significant ($p = 0.02$) in day 1 follow up. Pre-operative pain also influenced postoperative pain with statistically significant difference and positive correlation between the groups.

Conclusions

Our study concluded that maintenance of apical patency increased postoperative pain. Post-operative pain was not influenced by number of visits, and group of teeth. However, for patency group, vital tooth treated in multiple visits results in more postoperative in 1st day follow up. In addition, pre-operative pain also has influence on post-operative pain.

Background

Root canal treatment is always feared for tiresome procedure and postoperative pain. This has provoked search for the factors increasing the ease of process and decreasing the postoperative pain (1, 2). Either in disinfection method or maintaining the actual length of canal space there are lot of varied opinion

about the protocols to follow. Out of these, maintaining apical patency is also one of the controversies (3).

During the shaping of root canals pulpal and dentinal debris get collected in the apical third area leading to blockage and loss of working length, transportation, ledge and perforation. Hence, to resolve these issues, Buchanan has proposed a concept of apical patency in which small flexible file is repeatedly extended beyond the apical foramen leaving the foramen patent (4, 5). Apical patency according to the Glossary of Endodontic Terms published by the American Association of Endodontists, is defined as a preparation technique in which the apical region of the root canal is maintained as free of debris by recapitulating through the apical constriction with a fine file (6). To maintain apical patency, a fine file is extended 1 mm longer than the working length and after each instrumentation recapitulation is done. A flexible K-file (except Hedstrom file) is overextended intentionally and passively beyond the apical foramen without binding and enlarging it (5, 7). To prevent the apical binding and enlarging the apical foramen, size 10 K-file has been used most frequently (8). Irrigation should be done after the patency file as it will loosen the tissue debris (7). But this sequence is less effective because dentin chips and smear layer will dampen the effect of irrigants (5).

Anaerobic microorganisms are predominant in apical third, including the cementum of root canal system (9, 10). This finding has led to the idea that the endodontic treatment should be extended to the full length of canal involving cemental canal (4, 11). One of the arguments against this procedure is that a file binding to the foramen which acts like an embolus, increasing the possibility of debris extrusion beyond the apex. Another argument is the severe periapical tissue reaction increasing the chance of postoperative pain and flare-up (12). Hence, patency concept is controversial and the procedure is taught only in 50% of U. S. dental schools (8).

There are only few published researches evaluating postoperative pain after maintenance and non-maintenance of apical patency (13, 14, 15). Hence, the purpose of this prospective study was to assess whether maintaining apical patency has an impact on postoperative pain and whether it is affected by number of visits, status of pulp and group of teeth.

Methods

This research was conducted with the approval of the Institutional Review Committee (IRC number 077/19) in the duration from April 2019 to December 2019.

One hundred and sixty patients requiring endodontic treatment for single tooth were included in the study. Endodontic treatment was performed in single or multiple visits of either vital or non-vital tooth and anterior or posterior tooth. Each patient was explained about the aims and design of the study, and written consent were obtained before their inclusion. The exclusion criteria were: complex cases such as pulp canal obliteration, procedural accidents, variable anatomy where maintaining patency is difficult, retreatment cases, teeth with periapical radiolucency, pregnancy patients who are medically compromised and patients under analgesic medication within last 3 days.

Sample size determination

The sample size calculation for each group was 36.8 with level of significance of 0.05, a power of 0.9, an effect size of 0.8 and standard deviation of 1.2 (14). One hundred sixty subjects were included in the study after careful screening of patients reporting to Department of Conservative Dentistry and Endodontics, Universal College of Medical Sciences, Bhairahawa, Nepal.

The preoperative radiographic examination and clinical records were collected from all the patients, like preoperative pain, pulpal status, and group of the teeth (anterior or posterior teeth). The pulpal status was checked with electric pulp tester (Digitest™ Parkell Inc., USA) and Endofrost (Coltene/Whaledent GmbH and Co.KG). This was later reconfirmed upon access opening i.e presence of bleeding and on sensibility tests positive response implied for vital tooth similarly for non-vital tooth absence of bleeding and negative response on sensibility tests. The preoperative pain scores were also recorded and noted for both groups (patency/non-patency group) in Numeric pain rating scale.

The eligible patients were randomly allocated to one of the two groups: patency (Group A) and non-patency (Group B). An equal proportion of randomization allocation ratio for the two groups was done by shuffled deck of cards with number assigned from 1 to 160 (i.e. even number for patency group and odd number for non-patency group). Number of visits were allocated by another set of equal proportion of envelopes containing concealed assignment codes. Single blinding was done where patients were unaware of nature of treatment administered throughout the investigation. Endodontic treatments were performed by one endodontist in single visits and multiple visits.

Group Stratification:

Group A: Patency group (n = 80)

- Sub-group A1: Single Visit(n = 40)

Sub-division A1V: Vital teeth (n = 20)

Division A1Va: Anterior teeth (n = 10)

Division A1Vp: Posterior teeth (n = 10)

Sub-division A1NV: Non-vital teeth (n = 20)

Division A1NVa: Anterior teeth (n = 10)

Division A1NVp: Posterior teeth (n = 10)

- Sub-group A2: Multiple Visits(n = 40)

Sub-division A2V: Vital teeth (n = 20)

Division A2Va: Anterior teeth (n = 10)

Division A2Vp: Posterior teeth (n = 10)

Sub-division A2NV: Non-vital teeth (n = 20)

Division A2NVa: Anterior teeth (n = 10)

Division A2NVp: Posterior teeth (n = 10)

Group B: Non-patency group (n = 80)

- Sub-group B1: Single Visit(n = 40)

Sub-division B1V: Vital teeth (n = 20)

Division B1Va: Anterior teeth (n = 10)

Division B1Vp: Posterior teeth (n = 10)

Sub-division B1NV: Non-vital teeth (n = 20)

Division B1NVa: Anterior teeth (n = 10)

Division B1NVp: Posterior teeth (n = 10)

- Sub-group B2: Multiple Visits(n = 40)

Sub-division B2V: Vital teeth (n = 20)

Division B2Va: Anterior teeth (n = 10)

Division B2Vp: Posterior teeth (n = 10)

Sub-division B2NV: Non-vital teeth (n = 20)

Division B2NVa: Anterior teeth (n = 10)

Division B2NVp: Posterior teeth (n = 10)

Local anesthesia (2% lidocaine hydrochloride and epinephrine 1:200,000; Neon laboratories Ltd., India) using conventional nerve block techniques was given to patients. Root canal procedure was started under rubber dam isolation. The access cavity preparation was done using round bur (SS White, USA) and Endo Z bur (Dentsply Maillefer, Switzerland) with highspeed handpiece. Number 10 Kfile (Dentsply Maillefer, Switzerland) was used to negotiate the canals with the help of Glyde (Dentsply Maillefer, Switzerland). WL was confirmed using Propex II apex locator (Dentsply Maillefer, Switzerland) and then confirmed

radiographically. If there is disagreement between radiographic and electronic working length measurements, the apex locator was selected.

Filing was done cautiously to prevent surpassing of patency file beyond the working length for non-apical patency group (i.e. Group B) at all times during treatment for both single visit and multiple visits, vital and non-vital, anterior and posterior teeth. Likewise, for patency group (i.e. Group A), a size 10 K-file was passed 1 mm beyond the working length between each instrument change. Irrigation was performed with saline, 5 ml of 5% sodium hypochlorite (NaOCl) solution (Dentpro, India), and 2% chlorhexidine (Dentochlore, Ammdent, India) after each instrumentation. Cleaning and shaping was done with hand K-files (Dentsply Maillefer, Switzerland) using step-back technique. For multiple visit (Group A2 and B2), canal was medicated with calcium hydroxide (RC CAL Prime Dental products Ltd, India), temporarily sealed with cavit (3M ESPE) and recalled after a week for follow-up. In single visit (Group A1 and B1) and asymptomatic multiple visit (Group A2 and B2) the obturation was done in following steps: The master cone radiograph was taken to re-confirm the length. Canals were dried using paper points. AH Plus sealer (Dentsply Maillefer, Ballaigues, Switzerland) was applied on the walls of the canal. After that, obturation was done with lateral condensation technique and access cavity was restored using direct composite resin. Postoperative pain scores were recorded on Numeric pain rating scale forms by the patients on 1st, 2nd and 7th day.

Normality of the data was tested using Kolmogorov Smirnov test. The data were not distributed normally hence, non-parametric test i.e Mann-Whitney U test was used. The relation between pre-operative pain and post-operative pain was evaluated by Spearman correlation test.

Results

Statistically significant difference of pain scores was present in Group A (patency group) and Group B (non-patency group) with higher mean rank of pain scores in group A than group B in all three visits of 1st, 2nd and 7th day as shown in Table 1.

Table 1
Comparison of Mean \pm SD and Mean Rank of pain score between Patency (Group A) and non-patency group (Group B).

Follow-up	Group A (n = 80)		Group B (n = 80)		p-value*
	Mean \pm SD	Mean Rank	Mean \pm SD	Mean Rank	
Day 1	4.11 \pm 2.760	88.23	3.24 \pm 2.630	72.77	0.033
Day 2	2.60 \pm 2.411	87.98	1.91 \pm 2.414	73.03	0.036
Day 7	0.49 \pm 0.779	86.68	0.34 \pm 0.810	74.32	0.031
Notes: *Mann Whitney U test, Significant at the 0.05 level					

No statistical significant difference ($p > 0.05$) in mean rank of pain scores was observed between subgroups of single visit (A1 and B1) and multiple visits (A2 and B2) during follow up on 1st ,2nd and 7th day as depicted in Table 2.

Table 2

Comparison of Mean \pm SD and Mean Rank of pain score between Patency (Group A) and non-patency group (Group B) for single visit and multi visit.

Visits	Variables	Mean Rank		Mean \pm SD	Mann-Whitney U	p-value*
		Group A	Group B (n = 40) (n = 40)			
Single (1) (n = 80)	Day 1	43.96	37.04	3.41 \pm 2.539	661.500	0.179
	Day 2	45.39	35.61	2.04 \pm 2.384	604.500	0.050
	Day 7	43.45	37.55	0.36 \pm 0.716	682.000	0.140
Multiple (2) (n = 80)	Day 1	44.89	36.11	3.94 \pm 2.888	624.500	0.089
	Day 2	43.29	37.71	2.48 \pm 2.470	688.500	0.274
	Day 7	43.75	37.25	0.46 \pm 0.871	670.000	0.116

Notes: *Mann Whitney U test, Significant at the 0.05 level.

No statistically significant difference of mean rank of pain scores was observed between sub-divisions of single visit vital teeth (A1V versus B1V), single visit non-vital teeth (A1NV versus B1NV) and multiple visit non-vital teeth (A2NV versus B2NV) whereas multiple visit vital teeth (A2V versus B2V) showed statistically significant difference ($p < 0.05$) in 1 day follow up with mean rank of pain scores of 24.78 in Group A and 16.23 in Group B as illustrated in Table 3.

Table 3

Comparison of Mean \pm SD and Mean Rank of pain score between Patency (Group A) and non-patency group (Group B) for single visit and multi visit vital and non-vital tooth respectively.

Visits/Status	Variables	Mean Rank		Mean \pm SD	Mann-Whitney U	p-value*
		Group A (n = 20)	Group B (n = 20)			
Single/Vital (1V) (n = 40)	Day 1	21.00	20.00	3.90 \pm 2.619	190.000	0.799
	Day 2	21.83	19.18	2.58 \pm 2.735	173.500	0.478
	Day 7	21.65	19.35	0.45 \pm 0.714	177.000	0.547
Multiple/Vital (2V) (n = 40)	Day 1	24.78	16.23	4.40 \pm 3.217	114.500	0.020
	Day 2	23.70	17.30	3.03 \pm 2.896	136.000	0.086
	Day 7	23.25	17.75	0.73 \pm 1.086	145.000	0.142
Single/Non-vital (1NV) (n = 40)	Day 1	23.40	17.60	2.93 \pm 2.390	142.000	0.121
	Day 2	24.05	16.95	1.50 \pm 1.854	129.000	0.056
	Day 7	22.35	18.65	0.28 \pm 0.716	163.000	0.327
Multiple/Non-vital (2NV) (n = 40)	Day 1	20.05	20.95	3.48 \pm 2.470	191.000	0.820
	Day 2	19.78	21.23	1.93 \pm 1.831	185.500	0.698
	Day 7	20.90	20.10	0.20 \pm 0.464	192.000	0.841

Notes: *Mann Whitney U test, Significant at the 0.05 level

When patency was maintained the post-operative pain scores of anterior teeth (A1Va,A1NVa,A2Va,A2NVa) versus posterior teeth (A1Vp,A1NVp,A2Vp,A2Vp) was statistically non-significant as shown in Table 4. The result were similar for non-patency group of teeth as shown in Table 5.

Table 4

Comparison of Mean \pm SD and Mean Rank of pain score between anterior and posterior tooth for single visit and multi visit vital and non-vital tooth respectively when apical patency was maintained.

Visits/Status	Variables	Mean Rank		Mean \pm SD	Mann-Whitney U	p-value*
		Anterior (a) (p) (n = 10)	Posterior (n = 10)			
Single/Vital (A1V) (n = 20)	Day 1	10.40	10.60	4.00 \pm 2.428	49.000	0.971
	Day 2	9.85	11.15	2.80 \pm 2.441	43.500	0.631
	Day 7	10.50	10.50	0.50 \pm 0.688	50.000	1.000
Single/Non-vital (A1NV) (n = 20)	Day 1	11.50	9.50	3.45 \pm 2.417	40.000	0.481
	Day 2	9.75	11.25	1.90 \pm 1.619	42.500	0.579
	Day 7	9.50	11.50	0.30 \pm 0.470	40.000	0.481
Multiple/Vital (A2V) (n = 20)	Day 1	9.55	11.45	5.65 \pm 3.265	40.500	0.467
	Day 2	8.95	12.05	3.85 \pm 3.031	34.500	0.234
	Day 7	9.20	11.80	0.95 \pm 1.146	37.000	0.295
Multiple/Non-vital (A2NV) (n = 20)	Day 1	9.50	11.50	3.35 \pm 2.390	40.000	0.481
	Day 2	8.80	12.20	1.85 \pm 1.899	33.000	0.218
	Day 7	9.50	11.50	0.20 \pm 0.410	40.000	0.481

Notes: *Mann Whitney U test, Significant at the 0.05 level

Table 5

Comparison of Mean \pm SD and Mean Rank of pain score between anterior and posterior tooth for single visit and multi visit vital and non-vital tooth respectively when apical patency was not maintained.

Visits/Status	Variables	Mean Rank		Mean \pm SD	Mann-Whitney U	p-value*
		Anterior (a) (p) (n = 10)	Posterior (p) (n = 10)			
Single-Vital (B1V) (n = 20)	Day 1	9.70	11.30	3.80 \pm 2.858	42.000	0.579
	Day 2	9.75	11.25	2.35 \pm 3.048	42.500	0.579
	Day 7	9.95	11.05	0.40 \pm 0.754	44.500	0.684
Single/non-vital (B1NV) (n = 20)	Day 1	8.00	13.00	2.40 \pm 2.303	25.000	0.063
	Day 2	10.40	10.60	1.10 \pm 2.024	49.000	0.971
	Day 7	9.50	11.50	0.25 \pm 0.910	40.000	0.481
Multiple/Vital (B2V) (n = 20)	Day 1	9.70	11.30	3.15 \pm 2.700	42.000	0.579
	Day 2	10.15	10.85	2.20 \pm 2.567	46.500	0.796
	Day 7	9.70	11.30	0.50 \pm 1.000	42.000	0.579
Multiple/nonvital (B2NV) (n = 20)	Day 1	11.40	9.60	3.60 \pm 2.604	41.000	0.491
	Day 2	10.00	11.00	2.00 \pm 1.806	45.000	0.698
	Day 7	11.05	9.95	0.20 \pm 0.523	44.500	0.503
Notes: *Mann Whitney U test, Significant at the 0.05 level						

The result of Spearman correlation test showed that the preoperative pain was significantly correlated with post-operative pain in both patency group and non-patency group as shown in Table 6. There was statistically significant low degree positive correlation between pre-operative pain and post-operative pain in day 1 in both patency group ($\rho = 0.285$, $p = 0.01$) as well as non-patency group ($\rho = 0.576$, $p < 0.001$). Whereas, there was statistically significant high degree positive correlation between pre-operative pain

and post-operative pain in day 2 in both patency group ($\rho = 0.871$, $p < 0.001$) as well as non-patency group ($\rho = 0.798$, $p < 0.001$).

Table 6
Correlation of Preoperative pain and Postoperative pain when patency is maintained (Group A) and not maintained (Group B).

Variables	Group A		Group B	
	Correlation (ρ)	p-Value*	Correlation (ρ)	p-Value*
P ₀ -P ₁	0.285	0.011	0.576	0.0001
P ₁ -P ₂	0.871	0.0001	0.798	0.0001
P ₂ -P ₇	0.574	0.0001	0.622	0.0001

Notes: P₀ = Preoperative pain P₁ = Day 1 pain score P₂ = Day 2 pain score and P₇ = Day 7 pain score,
*Spearman correlation.

Discussion

The present study aimed to assess postoperative pain while maintaining apical patency. Pain is a subjective sign, so it is difficult to assess accurately and quantify in any statistical analysis (16). Hence, it is crucial to select proper pain assessment tool such as NRS which has high reliability and validity (17). A systematic review in 2011, authors found that even though the studies were inconclusive regarding preference for a particular tool, the NRS was considered superior in 11 studies and the VAS (Visual Analogue Scale) was recommended in only four studies (18). Determination of working length accurately was also essential for this report. It was determined with Propex II electronic apex locator as well as with a radiograph. Propex II apex locator was used as it is accurate and its accuracy is comparable to Root ZX apex locator (19, 20).

Studies on apical patency has shown variable results such as Arias et al (13), Sharaan et al (21), Garg et al (15) reported maintaining apical patency did not increase post-operative pain whereas Yaylali et.al (22), Arora et. al (14) found decrease in post-operative pain than non-patency group. Even a systematic review (22) also indicated that maintaining apical patency did not increase postoperative pain however quality of evidence in this review is low. While other group of researches states apical patency might enlarge apical constriction leading to increase extrusion of debris of the canal into periapical tissue inducing post-operative pain and persistence of periradicular lesion (23, 24). Hence, in current study efforts were made to check whether maintaining apical patency causes post-operative pain or not. Whether postoperative pain is influenced by number of visits for treatment of root canal, type of tooth, status of pulp and preoperative pain or not. As literature has shown these factors intensify inflammatory reaction leading to pain (23, 25, 26).

We used a #10 K file to maintain apical patency in this study to ensure least apical enlargement and transportation, decreased extrusion of debris and less injury of periapical tissues as all of these effects increase the incidence of post-endodontic pain and risk the outcome of treatment (24, 27).

Overall data revealed decrease in mean pain intensity over time after endodontic treatment in both patency and non-patency groups. These findings were in accordance with other studies which showed a significant decline in pain after endodontic treatment (28, 29, 30). This decrease in postoperative pain may be due to healing after endodontic treatment (31).

In this investigation, mean rank of postoperative pain scores was higher in apical patency group than non-patency group in 1st, 2nd and 7th day follow up with statistically significant difference. The increase in post-operative pain might be due to greater periapical extrusion of debris with manual filing technique as supported by Deonizio et al. (32). Torabinejad et al. (29) also stated intentional over-instrumentation of files may disrupt the apical stop leading to extrusion of filling materials and might increase the postoperative pain. The result is in contrast to the study done by Arias et al. (13), Arora et al. (14) and Garg et al. (15) which states no statistically significant difference in postoperative pain incidence between patency and non-patency group. This variation of results might be due to difference in filing technique, difference in file system and difference in pain perception by different population. In our study, shaping and cleaning was done by manual K files with step back technique which requires more number of filing and recapitulations than for rotary instrumentation which might increase the possibility of more extrusion and peri-apical injury thereby increasing the chance for more post-operative pain in an attempt to maintain apical patency.

The studies (13) (15) in which apical patency was maintained in single visit RCT, showed no significant difference in post-operative pain scores with non-patency group. Whereas, Yaylali et al. (22) reported higher mean pain scores for non-patency group compared to patency group. In addition, the studies in which apical patency was maintained in multiple visit RCT, result showed variable results such as increase in post-operative pain in 6 hour and 12 hours follow up in patency group compared to non-patency group (21) whereas, study done by Arora et al. (14) showed less pain in apical patency group in 1st, 2nd, 3rd and 4th day follow up. These studies have evaluated postoperative pain in either single or multiple visits RCT, whereas literature search has revealed paucity of research comparing postoperative pain after maintaining apical patency in both single visit and multiple visit. Our study compared post-operative pain in single visit RCT and multiple visit RCT after patency maintenance and non-maintenance, the result showed no significant difference in mean rank of pain scores in follow up of day 1, 2 and 7.

When vitality of pulp status was concerned, non-vital teeth did not increase the post-operative pain when apical patency was maintained either in single visit or multiple visit but mean rank of postoperative pain scores in vital tooth of multiple visit RCT was higher for patency group than non-patency group with statistically significant difference ($p < 0.05$) which might be due to highest inflammatory response within 24 hours of periapical injury. Our result was similar to the study done by Arias et al. (13) which showed

lower incidence of pain in non-vital tooth when apical patency was maintained. Whereas, the study done by Siqueira et al. (23) showed non-vital teeth more prone for post-operative pain than vital teeth when apical patency was maintained might be due to extrusion of infected debris in addition to the direct mechanical trauma caused by instruments leading to more severe periapical inflammatory response (33).

The result of present report showed that postoperative pain is not influenced by the type of tooth (i.e. Anterior or posterior) treated by apical patency maintenance or non-maintenance which can be explained by the fact that postoperative pain is dependent upon the amount of periapical injury followed by inflammatory response and not just with the number of roots. The result is coherent to the study conducted by Garg et.al (15) and Arias et.al (13). However, Studies has found that tooth type did affect the post-operative pain due to complexity of canal morphology and number of canals (25, 29). Another influencing factor on postoperative pain was pre-operative pain. The result showed statistically significant postoperative pain scores in patency group and non-patency groups which is similar to study done by Garg et. al (15) and Elmubarak et.al (34). This might be due to severe inflammatory response in already inflamed tooth or due to perception of pain in previously sensitized tooth. Whereas, the results were conflicting to studies done by Ng et al. (25) and Albashaireh el al. (35) showed no effect of pre-operative pain in post-operative pain.

Hence, it can be implied that apical patency does have an effect on postoperative pain. It cannot be imposed upon for apical cleaning as there are several other methods like ultrasonic agitation, negative pressure irrigation, lasers etc. So, rather doing benefit to the patient we are unnecessarily increasing the discomfort to the patient. But there are certain limitations of the study such as small sample size, different file system would have been compared, outcome cannot be evaluated due to shorter follow up period.

Conclusions

The present study has shown the maintenance of apical patency has significantly increases the post-operative pain. The categorization of the teeth into anterior and posterior has not shown effect on the postoperative pain in patency versus non-patency group. However, in the first day of multiple visit of vital tooth, it has been observed statistical significant difference between patency and non-patency group. Moreover, pre-operative pain influences the post-operative pain as shown by correlation analysis in patency and non-patency groups.

Abbreviations

RCT - root canal treatment

NaOCl - sodium hypochlorite

PO – preoperative

Declarations

Ethics approval and consent to participate

This study was conducted after approval of the Institutional Review Committee of Universal College of Medical Sciences (UCMS/IRC/077/19). The study followed the Declaration of Helsinki protocol and ethics. Informed consent of the participant for participation in the study and publication was according to the Institutional Review Committee which comes under National regulation of Nepal. Written consent was obtained from each patient enrolled in the study.

Consent for publication

Consent for publication was obtained from study participants according to the Institutional Review Committee, Universal College of Medical Sciences, Bhairahawa, Nepal.

Availability of data and materials

The datasets used and analyzed during the study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' Contributions

SS has developed the conceptual framework and carried out patient's procedure. SS and NM analyzed the data and evaluated the result. SS and NM wrote the manuscript. MR and DK reviewed the manuscript and proof reading. All the authors read and approved the manuscript.

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