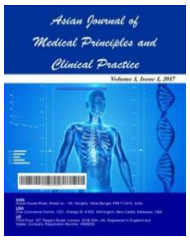

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Comparison of Efficacy of Intravenous Morphine and Sublingual Buprenorphine for Analgesia after Lower Limb (below the Knee) Orthopedic Surgery

G. Akhavan Akbari[1*], A. Ghazi[2], A. Mohammadian Erdi[3] and T. Mirza Rahimy[4]

[1]Ardabil University of Medical Sciences, Pain Fellowship, Fatemi Hospital Ardabil University of Medical Sciences, Ardabil, Iran.
[2]Department of Anesthesiology, Alavi Hospital, Ardabil University of Medical Sciences, Ardabil, Iran.
[3]Department of Anesthesiology, Ardabil University of Medical Sciences, Pain Fellowship, Fatemi Hospital Ardabil University of Medical Sciences, Ardabil, Iran.
[4]Department of Obstetrics and Gynaecology, Alavi Hospital Ardabil University of Medical Sciences, Ardabil, Iran.

Authors' contributions

This work was carried out in collaboration between all authors. Authors GAA and AG designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Author AG managed the analyses of the study. Authors AME and TMR managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Background and Objective: Postoperative pain is a common post operative side effect that can postpone patient's discharge from hospital. Pain control in orthopedic patients can significantly reduce limitation range of motion and patients can quickly return to normal life. In this study we aimed to compare the efficacy of Iv Morphine with sublingual Buprenorphine in postoperative pain control following orthopedic surgery of the lower extremities.

**Corresponding author: E-mail: Dr.GhaziAhmad@gmail.com;*

Methods: This double blind clinical trial was performed on 60 patients ASA class I&II (American Society of Anesthesiologists) referring to orthopedic surgery of the lower extremities and under spinal anesthesia. The patients were divided into two groups of sublingually Buprenorphine (0.4 mg, every 8h hours) and PCA Morphine Pump (20 mg in 100 cc). This trial was practiced after surgery and in the recovery room. The amount of Meperidine usage, pain score and side effects including nausea and vomiting, level of sedation and itching were recorded at 1, 8, 16 and 24 hours after surgery.

Results: 60 Patients in Morphine and Buprenorphine groups were studied. There were no significant difference between the two groups in terms of gender distribution (p=0.766), average age (p=0.350), weight (p=0.195), ASA score (p=0.519) and operation time (p=0.510). The average pain score in the Buprenorphine group was significantly lower than the Morphine group in 8 (p=0.025), 16 (p<0.044) and 24 (p<0.003) hours after surgery. The need to meperidine usage during the first 24 hours after surgery in Buprenorphine group (38±16 mg) were significantly lower than that in the Morphine group (49±19 mg) (p=0.019). There were no significant difference between the two groups in terms of side effects (nausea and vomiting, level of sedation and itching).

Conclusion: This study showed that Sublingual Buprenorphine administration after orthopedic surgery of the lower extremities can lead to better postoperative pain control in comparison to Morphine PCA pump. Also it has minimal side effects and is compatible with Morphine in this field.

Keywords: Iv Morphine; sublingual buprenorphine; postoperative pain; orthopedic surgery.

1. BACKGROUND

Pain is one of the most common causes resulting in delay at post-operative discharge. The pain experience is complex and multi-factorial, and it presents itself as an unpleasant feeling. In other words, pain is a personal and internal experience that follows tissue damage and is affected by sensory, psychological and behavioral factors [1,2]. Individual differences can be effective in responding to surgical injuries, which include personality, gender, age, cultural background, genetics, type of surgery, and physiological factors such as fear, anxiety, depression and anger [3,4,5]. More than 70% of patients, experience moderate to severe pain after surgery, and more than 25% of patients experience side effects after taking analgesics [6,7]. Post-operative pain management is one of the important concerns of physicians and patients undergoing surgery [3,8] and inadequate and undesirable control of post-operative pain increases the risk of chronic pain [9,10,5,11,12]. In addition, pain can cause sleep disorders, decrees in respiratory movement, cough inhibition, and acute sputum secretion (19.2). Also, the lack of pain control causes ischemic myocardial infarction, pulmonary infection, ileus, urinary retention, thromboembolism, impaired immune function, anxiety and worry, and as a result Leads to, dissatisfaction and distrust of patients, prolonged hospitalization and increased care costs [13,5].

Control of pain in orthopedic patients is important, because undesirable pain control in these patients can be accompanied by delayed movement and limitation range of motion [14,6]. There are several studies that show that combined anesthesia, accompanied by low-invasive surgical techniques, sufficient pain treatment, and early respiratory physiotherapy in the immediate post-operative period, are essential for a significant reduction in pulmonary complications [13,12]. Currently, the most common method of pain control during and after surgery is the use of injectable opioids that can cause respiratory and cardiovascular complications which in some cases does not have the necessary efficacy [15,16,27].

Morphine is an alkaloid opioid that prevents ACTH release, which causes the release of histamine and sympatho-adrenal activity. Its side effects include itching, nausea, vomiting, headache, confusion and urinary retention [18]. It is more likely to prescribe drugs that are easier to use and less complicated. One of these kinds is buprenorphine, which is a relative agonist of opioid receptors. Buprenorphine is a semi-synthetic opioid analgesic that is derived from the brain [18,19]. The use of less complicated and easy-to-use opioids, such as buprenorphine, can be helpful in improving the quality of surgical procedures if they would be effective (18, 16, 24) Compared to morphine, it has more potency (about 33 times) and more solubility in fat (20), which, in addition to having a higher analgesic power, is an absorbable molecule for applying

thorough various pathways (intravenous, sublingual, Transdermal, etc.) [20]. The onset of the effect depends on the route of prescribing: usually 5 to 10 minutes in intravenous form, 10 to 20 minutes in intramuscular form and 15 to 45 minutes in sublingual form. The duration of the effect of buprenorphine is 6 to 8 hours and has a half-life of 4 to 5 hours [21]. On the other hand, due to the easy administration of this drug, its use for postoperative analgesia is significant [22,16,23,24,25]. Therefore, the present study was conducted to compare the effectiveness of morphine PCA pump and sublingual buprenorphine in controlling the post -operative pain in orthopedic surgeries of the lower extremities in Fatemi center.

2. MATERIALS AND METHODS

This study was a double-blind clinical trial. The statistical population of the study included all patients undergoing lower extremity orthopedic surgery of ASA I,II in Fatemi Hospital of Ardabil. pregnant women, nursing mothers with infants, those who had been taking long-lasting medications during the past six hours, those who had renal dysfunction, those with contraindication of opiate drug, and people with addiction to drug were excluded from the study. Also patients who needed more sedation or general anesthesia during the operation were excluded from the study. Prior to the operation, written informed consent was taken from all patients according to the Ethics Committee opinion. This clinical trial was proposed in the Ethics Committee of Ardabil University of Medical Sciences, and approved By the Flowing code (IR.ARUMS.REC.1395.95). It was also registered with IRCT code IRCT20160802029162N2 in clinical trial registration center of Iran. 60 patients with ASA Class I,II, in the age group of 20-60 years, who were candidates for lower extremities orthopedic surgeries under spinal anesthesia were studied: spinal procedure was done in all patients with 3ml of 0.5% bupivacaine in sitting position. The ringer serum was infused. The patient's vital signs were regularly checked. In case of hypotension, it was corrected by ephedrine and Ringer serum, 2 mg midazolam was injected to all patients for sedation, patients were divided into two groups of buprenorphine and morphine by random numbers.). Patients were not aware of the contents of the pump and the pills. (type I Blindness) Patients in the A group, received 20 mg of morphine in 100 ml saline, with a PCA (patient control analgesia) pump at 4 ml per hour speed (infusion) and a placebo tablets (similar to buprenorphine tablets both in shape and size) every 8 hours (sublingual), group B received tablets of buprenorphine 0.4 mg sublingual every 8 hours and PCA pump of normal saline as placebo at 4 ml per hour speed (infusion). Interventions were performed in recovery room and after patient's consciousness was confirmed by an intern who was not aware of the progress of the studies. The tablets were given to patients who were alert in recovery room and then every 8 hours a sublingual tablet was given (up to 24 hours and a total of 3 tablets). The PCA pump was connected to all patients in the recovery room according to the type of group. Patients' pain score at 1, 8, 16 and 24 hours, opioid drug usage (meperidine intake) and side effects including nausea, vomiting, sedation and itching at 1, 8, 16 and 24 hours were evaluated and recorded by an intern uninformed of the patient's type of medication after surgery (type II blindness). Patients' pain score was measured on the basis of Visual Analogue Scale (VAS) scores (scored from 0 to 10). This scale consists of a line of 10 cm in length, which shows the continuous spectrum of pain experience. One end is "painless" and "the worst imaginable pain" is at the other end, patients were asked to show their pain intensity along a continuous line with two distinct ends. In case of VAS equal to 4 or greater, the patient was prescribed intramuscular meperidine (0.5 mg / kg) or IV meperidine (0.4 mg/kg), nausea and vomiting was measured, evaluated and recorded according to the N & V score (1: without nausea and vomiting, 2: nausea without vomiting, 3: vomiting controlled with one drug and the number 4: vomiting required several drugs to control). The patient's sedation score was measured and recorded by the Ramsay score from 0 to 6 (zero score as alert and conscious,1: restless, 2: conscious and cooperative, 3: drowsy but cooperative, 4: deep sedation, but with rapid response to painful stimulation, 5: deep sedation and slow response to painful stimulation, 6: deep sedation without response to painful stimulation) evaluated and recorded.

2.1 Statistical Analysis

In this study, counting the first type error of 5% and the study strength of 80% and Mean difference: 0.7. Sample size was estimated 60 patients who were candidates for lower extremity orthopedic surgeries and were randomly assigned into two groups of 30 subjects using a systematic randomized allocation method. After collecting the data from the review and arranging

the relevant tables and charts, in order to analyze descriptive information, the central indices (mean, median) and dispersion indices (standard deviation, variance, etc.) were used. All the data are presented as mean ± standard deviation (M±SD). Significance testing between groups was performed using chi-square test (Chi2-T test - repeated measure (ANOVA)) with SPSS Version 20. A Pvalue of less than 0.05 was considered statistically significant.

3. RESULTS

In this study, two groups were evaluated according to age, weight and ASA class. In the morphine group, 22patients (73.3%) were male and 8 patients (26.7%) were female and in the sublingual buprenorphine group, 23 patients (76.7%) were male and 7 patients (23.3%) were female (P = 0.766) .The mean age of patients in the morphine group was 38.97 ± 12.4 years and in the sublingual buprenorphine group was 41.90 ± 11.72 (P=0.350) The mean weight of patients in the morphine group was 76.03 ± 12.93 kg and 80.63 ± 14.24 kg in the sublingual buprenorphine group (P = 0.195) In the morphine group, 25 patients (83.3%) were ASA I and 5 patients (16.7%) were ASA II, and in the buprenorphine group, 23 patients (76.7%) were ASA I and 7 patients (23.3%) were ASA II (P0.519). Also the duration of operation was evaluated in both groups, with the mean duration of action in the morphine group 79.00 ± 35.22 minute and in the sublingual buprenorphine group 85 ± 34.86 minute (P=0.510).

In order to compare the mean pain intensity at 1, 8, 16, and 24 hours after surgery in the two groups of morphine and buprenorphine, a repeated measure ANOVA test was used which resulted as follow (Primary outcomes):

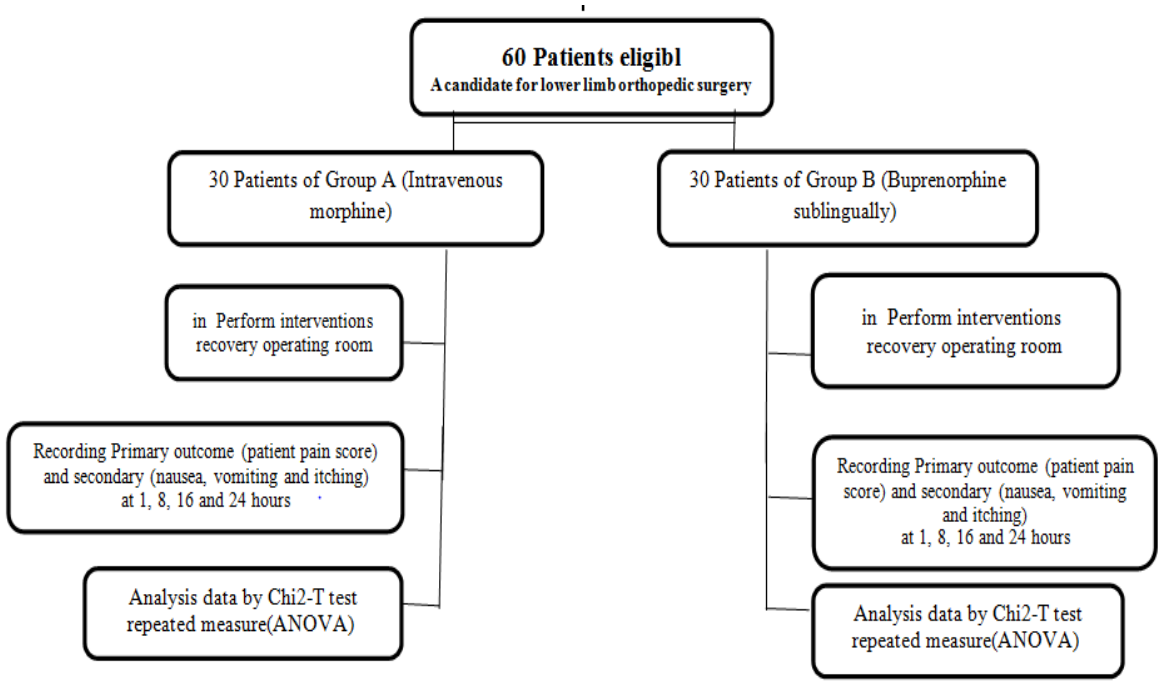

Fig. 1. Flow chart

Table 1. VAS mean pain score of patients in the two groups in different times after surgery

Time	Morphine group		Buprenorphine group		P-value**
	Pain intensity	P-value*	Pain intensity	P-value*	
First hour	6.30±1.18	Base	6.13±1.25	base	0.598
Hour 8	5.37±1.07	004/0	4.70±1.18	P<0001/0	0.025
Hour 16	4.20±1.21	P<0001/0	3.50±1.41	P<0001/0	0.044
Hour 24	2.57±1.48	P<0001/0	1.43±1.31	P<0001/0	0.003

** within groups*
*** between groups*

Table 2. The mean amount of Meperidine consumed in the two groups of morphine and sublingual buprenorphine

		Used Meperidine (mg)		P-Value
		Mean	Standard deviation	
group	Morphine	49	19	0.019
	Buprenorphine	38	16	

Table 3. Frequency of nausea and vomiting among studied patients in two groups in different times after surgery

Groupnausea and vomiting (N/V Score scale)		Morphine		Buprenorphine		P-Value
		Percent	Numbers	Percent	Numbers	
Hour 1	1	%86.7	26	%90	27	0.1
	2	%10	3	%6.7	2	
	3	%3.3	1	%3.3	1	
	4	0	0	0	0	
Hour 8	1	%83.3	25	%83.3	25	0.1
	2	%16.7	5	%13.3	4	
	3	0	0	%3.3	1	
	4	0	0	0	0	
Hour 16	1	%93.3	28	%93.3	28	0.1
	2	%3.3	1	%6.7	2	
	3	%3.3	1	0	0	
	4	0	0	0	0	
Hour 24	1	%96.7	29	%100	30	0.1
	2	%3.3	1	0	0	
	3	0	0	0	0	
	4	0	0	0	0	
Total of 24 hours	1	%83.3	25	%76.7	23	0.794
	2	%13.3	4	%16.7	5	
	3	%3.3	1	%6.7	2	
	4	0	0	0	0	

Table 4. Frequency of postoperative itching in studied patients of two groups

		Morphine		Buprenorphine		P-value
		Percent	Numbers	Percent	Numbers	
itching	have	%10	3	%3.3	1	0.612
	Do not have	%90	27	%96.7	29	

Table 5. Average score of the studied patients in the two groups in different times after surgery

		Morphine	Buprenorphine	P-value
Ramsay sedation scale	Hour 1	0.80±0.66	0.67±0.61	0.420
	Hour 8	1.23±0.86	1.47±0.73	0.261
	Hour 16	1.17±0.83	1.33±0.71	0.408
	Hour 24	1.30±0.81	1.30±0.75	0.191

It is revealed that the mean amount of Meperidine consumed in the sublingual buprenorphine group is significantly lower than that of the morphine group (38 ± 16 vs. 49± 19 and P = 0.019).

In this study, itching was evaluated. The results are as follow: in the morphine group, there are 3 patients (10% suffering from itching) and in the buprenorphine group 1 patient (3.3%).

4. DISCUSSION

Patients in the two groups receiving morphine and buprenorphine did not have a significant difference in terms of basal variables including

sex distribution, mean age, mean weight, ASA class, and mean duration of surgery. In order to compare the mean pain intensity at 1, 8, 16, and 24 hours after surgery in two groups of morphine and buprenorphine, using repeated measured of variance analysis showed that the mean pain intensity at different times (regardless of the morphine group or buprenorphine), was significantly different (P< 0.0001, F(3,174) = 117.68). Paired comparison of the mean pain intensity between different times for the effect of time indicated that there was a significant difference in the mean pain intensity between all studied hours, that is, between hours 1 and 8 (P< 0.0001) 1 and 16 (P <0.0001), 1 and 24 (P <0.0001), 8 and 16 (P <0.0001), 8 and 24 (P <0.0001), and 16 and 24 (P< 0.0001).

The measurement of pain intensity during the first 24 hours after surgery in the two groups of morphine and buprenorphine showed that pain intensity in both groups of morphine and buprenorphine decreased significantly with time so that the mean postoperative pain severity decreased in the morphine group from 6.30 ± 1.18 in hour 1 to 2. 57 ± 1.48 in hour24 (P <0.0001) and in the buprenorphine group from 6.13 ± 1.25 in hour1 to 1.43 ± 1.31 at hour 24 (P <0.0001); in other words, both morphine and buprenorphine had a significant effect on postoperative pain relief. However, the comparison of the severity of pain in these two groups showed that the mean postoperative pain intensity in the buprenorphine group was significantly lower than that of the morphine group (P = 0.001), indicating that the effect of buprenorphine is significantly higher than morphine.

So far, several studies have compared the efficacy of buprenorphine (by intramuscular injection or sublingual administration) and morphine (intravenous) in relieving pain after various surgeries [26,27]. In a study by Alizadeh et al. [28] with the aim of comparing morphine and sublingual buprenorphine in pain relief after laparotomy in drug dependent patients, the results were similar to those of our study so that the severity of pain was significantly lower in the sublingual buprenorphine group within 24 hours after surgery (2.67 ± 0.53 versus 4.59 ± 0.74 and P <0.001). The study conducted by Soltani et al. [29] which compared the effectiveness of sublingual buprenorphine and intravenous morphine in postoperative pain management in patients undergoing Closed Reduction Orthopedic Surgery showed similar findings to our study so that the severity of pain in 12 hours after operation in patients receiving sublingual buprenorphine was significantly lower than that of the intravenous morphine group (1.5 ± 1.3 vs. 5.6 ± 2.1 and P <0.001). The study by Alijanpour et al. [25] that compared the effectiveness of sublingual buprenorphine and intravenous morphine in controlling the pain of patients undergoing elective inguinal herniorrhaphy, showed that the severity of pain during the 24 hours postoperative period in the buprenorphine sublingual group was significantly less than that of the morphine group (1.83 ± 0.62 versus 3.83 ± 1.17 and P = 0.0001). In this regard, in a study by Sogandarajapa et al. [30] aimed at comparing the effectiveness of intra-articular buprenorphine with intra-articular morphine in relieving pain after knee arthroscopy, the results showed that within 8 hours after surgery, compared with morphine, buprenorphine results in significantly better postoperative pain control.

However, Unlike our findings and studies above, a number of studies did not report the difference between the analgesic effect of buprenorphine and morphine, including a study by Chang et al. [31] that compared the effect of buprenorphine PCA and PCA morphine used to reduce pain after lumbar spine fusion surgery. There was no significant difference between the effect of buprenorphine and morphine during the 48 hours after surgery. In addition to the differences in the type of surgery, in their study, buprenorphine was used as PCA, while in our study it was sublingually prescribed, as this study was only available in abstract form, it is not possible to check the exact differences with the current study. In the study by Payandeh Mehr et al. [32] who compared the effect of sublingual buprenorphine and intravenous morphine on managing acute renal colic pain, no significant difference was indicated between the two drugs in reducing the pain of patients with acute renal colic.

In addition, the findings of this study showed that the mean amount of Meperidine consumed during the 24 hours after surgery in the sublingual buprenorphine group was significantly lower than that in the morphine group (38± 16 mg vs. 49 ± 19 and P = 0.019). Together with this finding, in the study by Sogandarajapa et al. [30], the overall dose of tramadol received by patients in the morphine group was significantly higher than that of the buprenorphine group (1000 mg versus zero and P <0.0001). Regarding the fact that buprenorphine is 33 times stronger than morphine and is more

effective than morphine, due to the high binding power of buprenorphine to nociceptive receptors (about 100 to 75 times that of morphine), it can have a long period of analgesia, suggesting a slower separation of receptors than morphine, therefore, leading to a reduction in the amount of pain and a decrease in the need for another analgesic compared to morphine [25].

The findings of this study showed that there are no differences between the two groups of sublingual buprenorphine and PCA morphine in terms of sedation during the 24 hours after surgery. Along with this finding, a study by Soltani et al. [33,29] also showed that there were no differences between the two groups of intravenous morphine and sublingual buprenorphine in terms of the level of sedation during the 12 hours after orthopedic surgery. Also, the study of Oifa et al. [34] in favor our finding showed that the two groups receiving buprenorphine and morphine PCA do not differ in the level of sedation after abdominal surgery. The study by Hosseini Nejad et al. [35] also showed that receiving sublingual buprenorphine or intravenous morphine in patients with acute renal colic did not differ significantly in terms of sedation, which was favorable to our findings.

One of the most important aspects for choosing a drug is its side effects [36]. Therefore, in the present study, two groups receiving sublingual buprenorphine and morphine PCA were studied in terms of side effects including nausea, vomiting, and itching during 24 hours after the operation. Our findings showed that the frequency of nausea and vomiting in the buprenorphine group was slightly higher in the buprenorphine group than that of the morphine group during the 24-hour period, so that the frequency of nausea without vomiting and vomiting control with a drug in the buprenorphine group were 4 patients (13.3%) and 1 patient (3/3) respectively, while their frequency in the buprenorphine group were 5 patients (16.7%) and 2 patients (6.7%) respectively, but the two groups had no significant difference (P = 0.794). Our findings on the incidence of itching also showed that itching was more frequent in the morphine group than in the buprenorphine group (10% vs. 3. 3%), however the difference between the two groups was not significant here as well (P=0.612). Along approving this finding, in the study by Sogandarajapa et al. [30], there were no differences between the two groups receiving buprenorphine and intra-articular morphine in terms of side effects including nausea, vomiting, and itching. In the study by Soltani et al. [29], along favorable to our study, the two groups of recipients of intravenous morphine and sublingual buprenorphine did not differ regarding the frequency of nausea and vomiting, but in their study, unlike our findings, the frequency of itching in the morphine group was significantly more than that in the sublingual buprenorphine group. The findings of the study by Payandeh mehr et al. [32] showed that patients receiving sublingual buprenorphine and intravenous morphine did not have a significant difference in nausea, vomiting, or itching, which was favor of our findings. Other studies, favorable to our findings, have shown no difference in the frequency of postoperative nausea and vomiting in adults [37]. This study, like most studies, has limitations, including, The threshold for pain varies in each patient and can interfere with the final interpretation. On the other hand, this study was performed only in orthopedic surgery patients and the results can not be expanded to other patients.

5. CONCLUSION

The findings of this study showed that, firstly, sublingual buprenorphine compared with Intravenous morphine, is more effective in relieving pain after lower extremity (below the knee) orthopedic surgeries and, secondly, in terms of side effects, it has less Side Effect and its safety profile is comparable to morphine. According to that the present study was conducted only on patients undergoing lower extremity limb (below the knee) orthopedic surgeries, in order to confirm the results and generalizations of findings, clinical trials for candidates for other surgical procedures are also recommended. It is also recommended that similar studies showed be Dane, regarding precautionary conditions, below in patients at higher risk.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the author(s).

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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