Comparing caudal block and penile block using rectal acetaminophen in postoperative analgesia of hypospadias repair: A Randomized Clinical Trial Study

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Title page

Comparing caudal block and penile block using rectal acetaminophen in postoperative analgesia of hypospadias repair: A Randomized Clinical Trial Study

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Abstract

Background and Objective: selecting the analgesia method in pediatrics is of most importance. In pediatrics required hypospadias repair, two methods of the caudal block and penile block are used increasingly. This study aimed to compare two methods of the caudal block and penile block using rectal acetaminophen in postoperative analgesia of hypospadias repair.

Methods: This clinical trial was conducted on 50 children who underwent hypospadias referred to the educational hospital of Shahid Motahari in XXXX in west-north of Iran from July 1st, 2019 to March 1st, 2020. Patients were selected using a convenient sampling method and were allocated in two groups of the caudal block and penile block using rectal acetaminophen by random allocation software. To assess analgesia, the FLACC scale was used.

Results: Mean age of participants was 27 months, the mean weight of participants was 13 kilograms, and their mean height was 82 cm. Regarding assessment changes in pain severity, the results showed in two groups that in group 1 (caudal block) in time intervals of recovery, 6 hours, 12 hours, and 24 hours after the surgery, pain severity was reached to 1.16 and in group 2 (penile block) was reached to 3.44. The results showed that in group 1 (caudal block) patients suffer significantly less pain than patients in group 2 (penile block) (P=0.001).

Conclusions: According to results obtained from this study, hypospadias repair in pediatrics using caudal block can provide longer analgesia for the patient.

Keywords: Caudal Block, Pediatric Penile Block, hypospadias; Clinical Trial; Surgery

Introduction

Hypospadias is a congenital defect in the urethra (mostly in men) and is the most common congenital malformations of the genitourinary system. According to a recent meta-analysis, the global prevalence of hypospadias is 20.9% [1]. Hypospadias is more common in men than women; in women with hypospadias, the urethra opening is located in the vagina [2]. Its prevalence in men is 1-3 cases in each 1000 living birth [3]. The probability of this status in relatives of the affected children is more than normal individuals. In children with hypospadias, recurrent urinary tract infection, urinary incontinence, and even infertility are seen, therefore, treatment with surgery is considered. Commonly, circumcision is delayed until resolving the problem due to the probability of using the skin of the foreskin to repair the urethra [4]. Most patients report unrelieved postoperative pain, it causes undesirable physiology which leads to complications in various tracts of body, it also causes mental effects, and is considered as the main leading cause of fear and anxiety, inability and hopelessness in patients [5]. Analgesia is more considered as a challenge to improve the convenience of the patient, decrease in disabilities caused by surgery, decrease in costs by shortening the time of hospitalization after surgery [6]. Post-surgery pain is one of the most important problems in surgical wards.

Accordingly, the improvement of analgesia methods after surgery becomes of most importance for anesthesiologists [7]. Various methods including using narcotic and non-narcotic analgesics are used to relieve pain. To control post-surgery pain in pediatrics, various methods, and medications such as Non- steroidal anti-inflammatory drugs and narcotics are presented [8]. Acetaminophen is widely used to control pain. Nowadays, acetaminophen is one of the common drugs used in the operating room and other hospitalizing ward to control pain in patients, since they had not the

side effects of narcotics [9]. Indications include temporary relief of mild to moderate pain, especially after surgery, rapid-acting antipyretic, and emergency relief of hyperthermia [10].

Acetaminophen is approved by the FDA for years to control mild to moderate pains alone as well as moderate to severe pains along with opioids [11]. Various studies showed the efficiency of injecting acetaminophen to control pain after surgery, but controversial results are seen in this regard [12]. Another important and common drug is lidocaine, which can be considered as the head group of local anesthetics [13]. Local anesthetics reversibly prevent impulse conduction through axons and another irritable membrane that used majorly sodium channels to produce an action potential. This effect is used in clinical practice to suppress pain feelings in specific regions of the body [14]. Caudal block is one of the most prevalent analgesics techniques in pediatrics which is simply applicable, and can be performed before initiating surgery and along with general anesthesia or immediately after surgery, or in some procedures on the lower abdomen and lower limbs as a substitute for anesthesia [15, 16]. This technique is the most popular regional anesthesia in pediatrics which is used in various surgeries such as lower abdomen surgeries, urologic, and lower limb surgeries. In most cases, 1% lidocaine or 0.25% bupivacaine are used [17]. Bupivacaine has a longer half-life comparing to lidocaine and causes longer analgesia. The major limitation of caudal anesthesia with local anesthetics is the limited effective analgesia period after surgery, mobile block, and the probability of systemic toxicity of the drug. To eliminate the above limitations, it is recommended in recent years that a combination of anesthetics with other drugs such as adrenaline, clonidine, midazolam, neostigmine, and other various types of narcotics was used in caudal anesthesia [18]. It should be considered that the caudal block method after age 6 can lose its applicability and is an appropriate option for ages of 2 months to 5 years, however, it is not indicated in case of sepsis and infection of the injection site, sacral anatomic problems,

coagulation problems and uncorrected hypovolemia [19]. One analgesia method is using penile block in which the penis dorsal nerve located in the lower section of pubis at right and left side of penis midline is blocked by anesthetics which is mostly used for circumcision and hypospadias repair [20]. Considering the importance of postsurgery analgesia in patients and controversies in this regard, this study aimed to compare post-surgery analgesia rate after hypospadias repair through two methods of the caudal block and penile block using rectal acetaminophen.

Methods and materials

Study design

The present double-blind randomized clinical trial was conducted on 50 children who underwent hypospadias referred to Shahid Motahari training hospital from 1 July 2019 to 1 March 2020 at XXXX west north of Iran. Inclusion criteria were as follow: ASA class ≤II, age between 6 months to 5 years, lack of spinal cord deformity, exclusion criteria were having coagulative problems such as hemophilia, DIC, severe infections such as septicemia, meningitis, brain tumors with the increase in intracranial pressure, real sensitivity to local anesthetics, chemotherapy with drugs such as cisplatin, uncorrected hypovolemia, and skin or subcutaneous lesions such as infection, angioma in puncture site.

Tools

To gather information, a questionnaire consisting of two sections, first section, demographic characteristics including age, gender, BMI, and second section consisting of Face, Legs, Activity, Cry, Consolability (FLACC) analgesia scale was used [21]. FLACC scale is a standard

tool to measure pain severity in which pain severity is scored from zero (analgesia) to 10 (maximum pain). This tool assesses pain in five aspects of face, legs, activity, cry, and consolability. This scoring is depended on the assessment by the researcher based on the criteria of this scale. In this project, zero is as analgesia, 1-3 is for mild pain, 4-6 is for moderate pain, and 7-10 is for severe pain. The validity and reliability of this tool are approved in the study by Williamson and Hoggart [22].

Data collection

In this study, sample size determined using a study by Khan MA et al at 2016 [23], using mean difference equation in two independent groups and by considering attrition rate of 15%, the significance level of 5%, and power of 80%, the sample size of 25 individuals were considered for each group (totally 50 patients). After coordination with the hospital and surgery ward, all eligible patients were found. Then, patients were examined based on inclusion criteria. Firstly, using a convenient sampling method, 50 individuals were selected and were allocated into two groups of group 1 (caudal block) and group 2 (the penile group with rectal acetaminophen). This was a double-blinded study, indicated that patients were not aware of allocation in the intervention group and the clinical assessor was also unaware of allocating patients in study groups, therefore the study was double-blinded. Allocation concealment was also adhered to in performing the study. In group 1 (caudal block), after general anesthesia with premedication with 0.05 mg/kg midazolam, 1 μg/kg fentanyl, 1 mg/kg lidocaine, and 3mg/kg propofol, LMA was implanted to manage airways of patients, and continuing anesthesia was preserved with inhaled anesthetics of isoflurane MAC1 and oxygen and N2O with the ratio of 50%, and then, one group of patients underwent caudal block in lateral decubitus position with guage 22 needle through hiatus sacral space with one milliliter 0.2% bupivacaine and epinephrine in 1/200000

concentration (5 μg/kg), in group 2. In group 2 (penile block using rectal acetaminophen) also after general anesthesia with the condition of caudal block group in supine position under the penile block with guage 22 needle and 0.25% bupivacaine, 0.1 ml/kg, and one acetaminophen suppository with a dose of 40 mg/kg was used before initiating of surgery. Pain severity of patients was assessed in recovery, 6, 12, ad 24 hours after surgery using the FLACC scale. Then data was gathered (Figure 1).

Ethical considerations and Registration

This study was approved in the ethics committee of xxxxx University of Medical Sciences with ethical code: IR.UMSU.REC.1398.508. The study protocol was registered in the Iranian Clinical Trial Center with registry number of IRCT20170516033992N2. Written and oral informed consent was obtained from all participants. The participants were assured about the confidentiality of their information. CONSORT checklist was used to report the study [24].

Data analysis

Data were analyzed in SPSS software version 18. To describe the demographic characteristics of participants, descriptive statistical tests (mean, standard deviation, frequency, and percentage), and inferential tests (Chi-squared test) were used. Also, to use pain severity at various times, repeated measure ANOVA was used. The significance level of the P-value was considered less than 0.05.

Results

Out of 62 patients entered in the first stages of the study, seven individuals were excluded due to not meeting the inclusion criteria, and five individuals did not agree to participate in the study, therefore, 50 individuals entered the final stage and were located in two groups. In this study, 50

patients underwent hypospadias repair were assessed with two methods of group 1 (caudal block) and group 2 (penile block) which their mean age was 27.04 ± 17.58 months.

Regarding height and weight, the mean values obtained were 82.40 ± 12.39 cm and 13.02±3.94 kg. Body mass index was achieved as the mean value of 15.51±2.66 kg/m^2. In the assessment of difference among two study groups regarding age, height, weight, and BMI, the results showed no significant difference among the two groups (P>0.05) (Table 1).

Assessment of changes of pain severity in two groups, results showed that pain in group 1 (caudal block) was reached to 1.16 in time intervals of recovery, 6 hours, 12 hours, and 24 hours after surgery, and group 2 (penile block) was reached to 3.44. So that patients in group 2 (penile block) suffer more pain. In recovery and 6 hours after surgery, the pain was almost zero, indicating both methods showed identical efficiency up to that time, but at 12 hours after surgery, the penile block had weak efficiency in applying analgesia, and the pain score was reached to 3.44, while it reaches to 1.16 in the caudal group. Results showed that patients in group 1 (caudal block) suffer lesser pain comparing to patients in group 2 (penile block) (p=0.001) (Table 2). Additionally, the results showed no significant association among the type of analgesia method and demographic characteristics of age and gender (p=0.219).

Discussion

For surgeries on the lower abdomen or lower organs, the caudal block is one of the analgesia techniques used in pediatrics, which can be performed before surgery and with general anesthesia or immediately after ending of the surgery [25]. Caudal block loses its practicability after 6 years and would be an appropriate option for ages of 2 months to 5 years, however, in the case of sepsis and infection of the injection site, sacral anatomical problems, coagulative problems, and uncorrected hypovolemia is not applicable [26]. The penile block is mostly used for circumcision and hypospadias repair which the penis dorsal nerve located in the lower part of the pubis at the right and left side of the penis midline would be blocked and used (29).

In this study, we performed a comparative assessment on analgesia after hypospadias repair through two methods of the caudal block and penile block using rectal acetaminophen. The results of the current study showed in the assessment of changes of pain severity in two groups of the penile block and caudal block, the changes were significant over time. So that pain severity in the penile group was allocated a higher number. In general, it can be stated that at the first hour of recovery, six hours after surgery and 24 hours after surgery, no difference was observed among the two groups. The results of the present study consistent with studies conducted by M Al-Metwally and HG Salama in Egypt [27, 28]. Despite the present study were inconsistent with the results of the study by Khan MA et al as a clinical trial in surgical

procedures of hypospadias repair, since their results were in line with the priority of penile block comparing to caudal block group [23]. The mean score in the penile and caudal group was 3.6 and 5.5, respectively, while in our study, pain in two groups was the lowest, and both methods showed their analgesic effects properly. In the study by Kundra et al, post-surgery mean pain score was assessed at times of 0, 0.5, 3, 6, 12, and 24 hours and once on the fourth day after surgery. The penile block group had lower scores of analgesia compared to the caudal block group, which is considered a better status for pediatrics, and showed lesser significant scores at times of 0.5 to three days after surgery of the penile block group [29]. These results were in line with the study by Khan MA et al, but no preferability was observed similar to our results and the caudal group was almost better than the penile group [23]. In one study by Seyedhejazi Hejazi et al in Iran, which compared effects of the caudal block using bupivacaine with the penile block in hypospadias repair, the mean score in both groups was compared after surgery. The acceptable rate of analgesia in the caudal block group was achieved at 97.7% and in the penile block group was achieved at 92.6%. In the penile block group, 29 individuals out of 41 individuals needed post-surgery prescription of analgesic, while in the caudal group, 19 individuals out of 43 individuals required prescribing analgesic which was statistically significant. The authors recommended that in pediatrics aged less than 6 years or with weight lesser than 25 kg, the caudal block method was more considered [30]. These results were in line with ours since it states the tendency to preferability of caudal. It should be noted that since these procedures require clinical skills, therefore, the skill of the anesthesiologist which performs this procedure is not ineffective, and a history of performing such procedures can double efficiency. In the study by Dareshiri et al, post-surgery pain in the caudal block group was significantly lesser than the acetaminophen group, and the need for narcotics in acetaminophen was considerably higher.

Therefore, they showed that caudal block comparing to venous acetaminophen is more effective in decreasing post-surgery pain and the rate of need for narcotics will be decreased (33). In another study similar to the stud by Darrehshiri et al, post-surgery pain in the caudal block group was significantly lesser than the acetaminophen group, and the need for narcotics was considerably higher in the acetaminophen group [31]. In the study in Turkey, in the assessment of effects of analgesia of caudal block method, penile block and intravenous prescription of acetaminophen were performed in circumcision, at time points of 30, 60, 120, and 180 minutes after surgery, which intravenous prescription of acetaminophen did not provide proper efficiency while two methods of the penile block and caudal block induced similarly acceptable analgesia for patients and all three groups was appropriate regarding safety for pediatrics [32]. This study result was also consistent with the present study and its results were in line with ours no considerable difference was seen among two methods of caudal and penile, and the caudal block is prioritized, and almost produces longer anesthesia, since in the penile method, due to terminality of the organ, anesthesia medications with longer effects can not be used, but this limitation is not seen in the caudal block.

Limitations

The most important limitation was the small sample size which the results can not be generalized.

Conclusions

According to results obtained in this study, hypospadias repair in pediatrics using caudal block can provide almost longer analgesia for the patient. Due to the small sample size, further studies with larger sample sizes are recommended.

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Tables

Table 1: Demographic characteristics of participants

Variables	Groups	Mean	SD	P-value
Age	Group 2 (penile block)	24.44	18.12	0.812
	Group 1 (caudal block)	27.64	17.38	
Height	Group 2 (penile block)	81.92	12.99	0.770
	Group 1 (caudal block)	82.40	11.99	
Weight	Group 2 (penile block)	12.76	4.20	0.663
	Group 1 (caudal block)	13.28	3.73	

BMI	Group 2 (penile block)	15.25	2.84	0.5
	Group 1 (caudal block)	15.77	2.50	

Table 2: comparing pain severity in four-time points measured in two groups

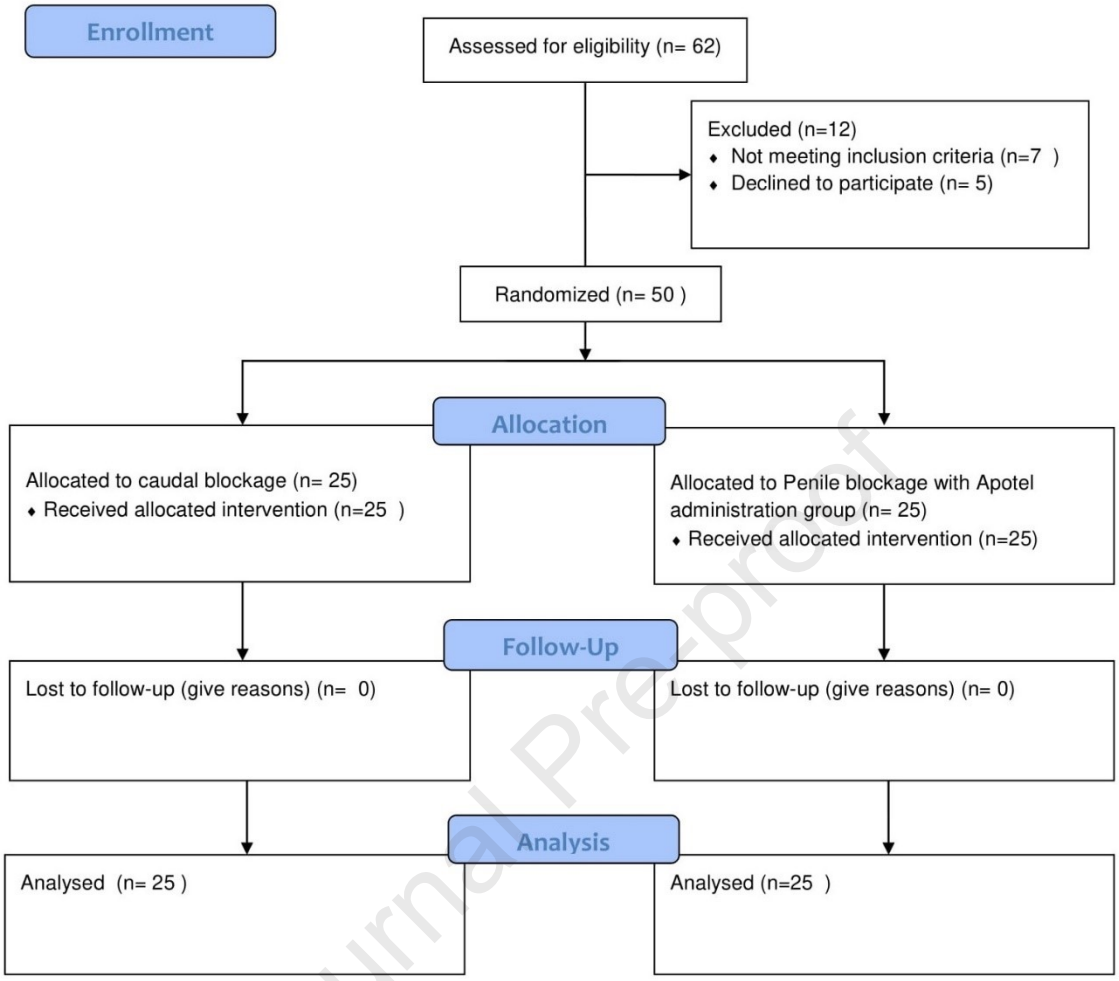
Time	Pain	Mean	SD	P-value
Recovery	Group 2 (penile block)	0	0	0.001
	Group 1 (caudal block)	0	0	
After 6 h	Group 2 (penile block)	0	0	
	Group 1 (caudal block)	0.08	0.26	
After 12 h	Group 2 (penile block)	3.44	1.26	
	Group 1 (caudal block)	1.16	0.94	
After 24 h	Group 2 (penile block)	1.12	0.72	

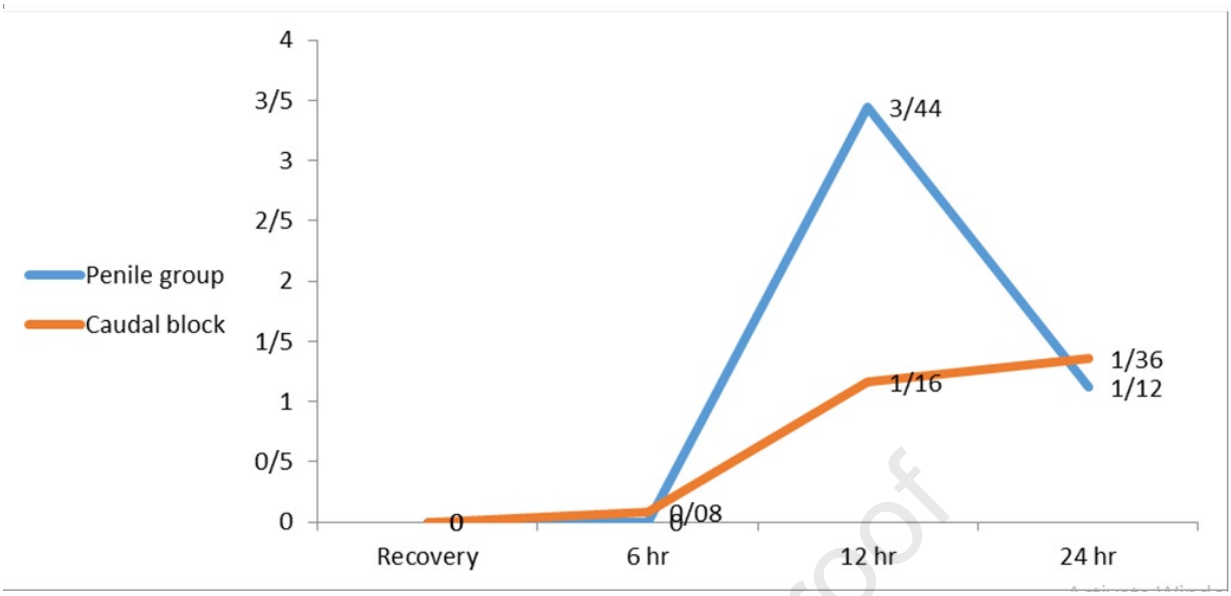
	Group 1 (caudal block)	1.36	0.81	

Figures legends

Figure 1. CONSORT study flow diagram

Figure 2: mean pain of four-time pints measured based on study groups





Highlights

- ✓ Select the best analgesia method in pediatrics is so important.
- ✓ This is a RSCT which conducted on 50 children who underwent hypospadias referred.
- ✓ The results showed hypospadias repair in pediatrics using caudal block can provide longer analgesia for the patient.

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All authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

None declared.

Please state any sources of funding for your research
All sources of funding should be declared as an acknowledgement at the end of the text. Authors should declare the role of study sponsors, if any, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should so state.

None declared.

Ethical Approval

Research studies involving patients require ethical approval. Please state whether approval has been given, name the relevant ethics committee and the state the reference number for their judgement.

This study was approved in the ethics committee of Urmia University of Medical Sciences with ethical code: IR.UMSU.REC.1398.508. The study protocol was registered in the Iranian Clinical Trial Center with registry number of IRCT20170516033992N2. Written and oral informed consent was obtained from all participants. The participants were assured about the confidentiality of their information. CONSORT checklist was used to report the study

Consent

Studies on patients or volunteers require ethics committee approval and fully informed written consent which should be documented in the paper.

Authors must obtain written and signed consent to publish a case report from the patient (or, where applicable, the patient's guardian or next of kin) prior to submission. We ask Authors to confirm as part of the submission process that such consent has been obtained, and the manuscript must include a statement to this effect in a consent section at the end of the manuscript, as follows: "Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request".

Patients have a right to privacy. Patients' and volunteers' names, initials, or hospital numbers should not be used. Images of patients or volunteers should not be used unless the information is essential for scientific purposes and explicit permission has been given as part of the consent. If such consent is made subject to any conditions, the Editor in Chief must be made aware of all such conditions.

Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

Approved

Author contribution

Please specify the contribution of each author to the paper, e.g. study concept or design, data collection, data analysis or interpretation, writing the paper, others, who have contributed in other ways, should be listed as contributors.

Dr. Tohid Karami, and Hadi Hoshyar: concept, design , drafted the initial manuscript, and reviewed and revised the manuscript. Dr Hadi Hoshyar , Afshin Mokhtari Tavana : Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Registration of Research Studies

The World Medical Association's Declaration of Helsinki 2013 states in article 35: *'Every research study involving human subjects must be registered in a publicly accessible database*

before recruitment of the first subject'. Editors of IJSO require that all types of research studies involving human participants should be registered prospectively but failing that retrospectively. There are many places to register your research, and you can choose which is the most suitable for your needs:

•https://www.clinicaltrials.gov/ - for all human studies - free
•http://www.chictr.org.cn/index.aspx - for all human studies - free
•https://www.researchregistry.com/ - for all human studies - charge
•https://www.isrctn.com/ - for all human studies - charge
•Prospero - for systematic reviews - free
•There are many national registries approved by the UN that can be found here

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Once registered, you will need to submit your assigned Unique Identifying Number (UIN) from your registration body as a mandatory part of your submission.

Name of the registry: Iranian Registry of Clinical Trials (IRCT)
Unique Identifying number or registration ID: IRCT20170516033992N2.

Hyperlink to the registration (must be publicly accessible): https://www.irct.ir/trial/50862

Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish

Hadi Hoshyar