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Original article

Dexamethasone versus Dexmedetomidine as an Adjuvant to Bupivacaine for Ilioinguinal and Iliohypogastric Nerve Block in Pediatrics, Comparative Randomized Double-Blind Study

Kerolos Sobhy Amin[a], Samaa Abou Alkassim Rashwan[a], Hazem Abd El Wahab Hussein[a]

[a] *Anesthesiology, surgical intensive care and pain management, Faculty of medicine, Beni_Suef University, Egypt.*

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Corresponding Author:

Kerolos Sobhy Amin

kerolossobhy.uk@gmail.com

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Abstract

Aim: The purpose of this research was to compare the effectiveness and safety of dexmedetomidine against dexamethasone as an adjuvant to bupivacaine in paediatric patients having elective subumbilical surgery under general anaesthesia. **Patients and methods**: This randomised controlled trial included 45 children aged 2 to 12 years who underwent subumbilical surgery. The study was done at Beni-Suef University Hospital's department of anesthesiology, surgical intensive care, and pain management following ethical approval by the faculty of medicine's research ethics committee. **Results:** The three groups (Dexamethasone with Bupivacaine versus Dexmedetomidine with Bupivacaine versus Bupivacaine only) were matched regarding their baseline characteristics. The study revealed that there was no

Block.

statistically significant difference between studied groups regarding heart rate and mean arterial blood pressure (MAP) but, there was statistically significant increase MAP 30 min in Bupivacaine only in comparison to Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine. There was no statistically significant difference between studied groups regarding fentanyl requirements, sevoflurane MAC and adverse events. There was statistically significant increase post operative heart rate (PO HR) 6 h in Bupivacaine and dexamethasone, increase PO HR 12 h and PO HR 24 h in Bupivacaine only. There was statistically significant increase post operative mean arterial blood pressure (PO MAP) in Bupivacaine only in comparison to Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine in addition to increased time of first request analgesia (hours) in Bupivacaine and dexamethasone in comparison to Bupivacaine only and Bupivacaine and dexmedetomidine.

1. Introduction:

For subumbilical surgery, ilioinguinal-iliohypogastric nerve block (IINB) is a straightforward and extensively used regional anaesthetic procedure. In order to properly manage postoperative pain, however, it is crucial to extend the length of these blocks. Clonidine (a 2-agonist) has been used with regional anaesthesia for decades, and meta-analyses based on adult studies have demonstrated that clonidine can extend the duration of peripheral nerve blocks when used as an adjuvant to local anaesthetics but, its use in children had no evidence till now (1).

Adjuvant dexmedetomidine, a modern agonist 2-agonist, looks to be an appealing new alternative for peripheral nerve blocks in adults and children. Dexmedetomidine, like clonidine, has been demonstrated to prolong analgesia duration by inhibiting hyperpolarization-activated cation current

without any symptoms of peripheral nerve damage (2).

However, there are no data on dexmedetomidine's usage in peripheral nerve blocks in children yet, despite the fact that it has been used successfully in most trials as an adjuvant to caudal blockade in children (3).

Additionally, as an adjuvant, dexamethasone reduces inflammatory mediator release, reduces ectopic neuronal discharge, and inhibits potassium channel-mediated discharge of C-fibers. Local anaesthetics can be efficiently and much extended in their analgesic effect by adding steroid to them (4).

So, this study was conducted to evaluate the efficacy and safety of dexmedetomidine versus dexamethasone when used as an adjuvant to bupivacaine in ilioinguinal and iliohypogastric nerve block for pediatric patients undergoing elective subumbilical surgery under general anesthesia.

Type of study:

Randomized double blind controlled clinical trial.

Sample Size:

Sample size calculation was done using the comparison of time to first request for analgesia (TFA) which is the primary outcome of the study. According to previous study (Sardar et al., 2017) the time to first request for analgesia (TFA) the mean ± SD of TFA in the control group (bupivacaine) is (2.83 h±2.014) and (3.98 h±2.586) bupivacaine and regional clonidine. Since dexamedetomidine is an α2-agonist similar clonidine, we assumed that it may have the same effect to clonidine. Accordingly, the calculated that the minimum proper sample size is 7 patients in each group to be able to reject the null hypothesis with 90% power at $\alpha = 0.05$ level using Student's t test for independent samples using Biostatistics, version 3.01. The number of patients were increased to 15 in each group in case of the drop in any case.

Site of study:

This study was approved by the department of anesthesiology, surgical intensive care, and pain management at Beni-Suef University. The research ethics committee at Beni-Suef University's faculty of medicine granted ethical permission.

Duration of the study:

6 months (from January 2021 to July 2021)

Inclusion criteria:

The anesthetist and the surgeon were blinded to the study protocol that enrolled 45 patients with the following criteria:

- American Society of Anesthesiology physical status (ASA) I or II of both sexes.

- Age between 2 and 12 years.
- Patients slated for general anaesthesia for subumbilical surgery.

2. Exclusion criteria:

- Parents refused to give assent.
- Patient's history of allergy to bupivacaine, dexmedetomidine, or any combination of the three.
- Peripheral nerve blockade contraindications, such as (coagulopathy, infection at the injection site).

The primary outcomes:

Intraoperative sevoflurane and fentanyl requirements.

The secondary outcomes:

Post-operative pain evaluation in the form of post-operative analgesic requirement, time to first demand of analgesia in hours.

Anesthetic Technique:

Anesthesia was administered according to a specified protocol:

In children with venous access, propofol (3–5 mg/kg) and fentanyl (1 g/kg) were administered intravenously to produce general anaesthesia. Sevoflurane induction for children whose venous access could not be supplied preoperatively was increased from 1% to 5% in 100% oxygen.

The baseline noninvasive blood pressure, heart rate (HR), oxygen saturation (SpO2), continuous electrocardiography, temperature, and end-tidal carbon dioxide of all children were all monitored. Sevoflurane 1–1.5 minimum alveolar concentration and 40% air and oxygen mixture were used to maintain anaesthesia in children who were able to breathe spontaneously after the initial procedure. Aseptic peripheral nerve block employing a sterile linear high-frequency transducer with a 7–13 MHz bandwidth, Philips' ultrasonic transducer (5).

Out-of-plane approach using a 22-G needle. Under direct observation, the needle tip advances toward the nerves in the intermuscular void that separates the transversus abdominis muscle from the internal oblique muscle. In order to choose patients for one of the three therapy groups, researchers used the closed envelope method (6).

Group A (control group)

Receiving 0.125% bupivacaine 0.5ml/kg

Group B (Dexamethasone group)

Receiving 0.125% bupivacaine 0.5ml/kg + 0.1mg/kg of dexamethasone.

Group C (Dexmedetomidine group)

Receiving 0.125% bupivacaine 0.5ml/kg +1 µg/kg dexmedetomidine (Koyyalamudi et al., 2017).

Randomization:

Using sealed opaque numbered envelopes, an impartial anesthesiologist assigned each

patient to one of three groups to receive the study medication. For this trial, the anaesthesia residents who administered study medicine and collected data on patients in general were not aware of their role in a research that was being conducted.

Assessment parameters and follow up:

- Hemodynamic stability was utilised to assess the block's efficiency, with no increase in heart rate (HR) or systolic blood pressure (SBP) greater than 20% over the preoperative values of HR, oxygen saturation (SpO2) and mean arterial pressure (MAP).
- The following data were recorded by anesthesia resident unaware of the study protocol:
- Age, sex, weight, height, and physical status (ASA I/II)
- Length and type of the procedure
- HR, MAP, and Spo2 are monitored intraoperatively every 5 minutes for the first 15 minutes of operation and then every 15 minutes after that.
- Concentration requirements for fentanyl and sevoflurane during surgery.
- Postoperatively, Heart Rate and Mean Arterial blood Pressure at one, two, six, twelve, and twenty-four hours.
- The Children's and Infants' Postoperative Pain Scale (CHEOPS) was used to measure postoperative pain in children between the ages of 1 and 7 years old when they arrived in the PACU. Cry, face, vocal, torso, touch, and legs are all on the list of pain behaviours that are included on the scale, which is divided into six categories. There are three or four levels in each category. As low as 4 points (no discomfort) and as high as 13 points are conceivable for CHEOPS (the worst pain).
- The number of hours until the patient makes their initial analgesic request.
- Dosage in milligrammes of paracetamol.
- Staff nurses collected information on any possible adverse events, such as postoperative nausea and vomiting (PONV), which is defined as any nausea, retching, or vomiting, every four hours during the first 24 hours.

Ethical Considerations:

Prior to the procedure, gaining approval from the local research and ethics committee and collecting signed informed consent from each parent (assent).

Data Analysis and Statistics:

The Statistical Package for Social Science (IBM SPSS) version 20 was used to analyse the data. The data were displayed qualitatively as a collection of numbers and percentages; quantitatively, they were provided as mean values (with standard

deviations and ranges) and median values (with interquartile ranges) for non-parametric distributions.

Chi-square tests were employed to compare two groups with qualitative data, and Fisher exact tests were performed when the predicted count in any cell finding less than 5 was less than 5.

One Way Analysis of Variance (ANOVA) and Kruskall-Wallis tests were used to compare more than two groups with parametric and non-parametric distributions, respectively, in the comparison of quantitative data.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

P > 0.05: Non-significant (NS)

P ≤0.05: Significant (S).

3. Results:

Table (1): Comparison between bupivacaine only, Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine regarding baseline characteristics:

Items		**Bupivacaine only (No.=15)**		**Bupivacaine and dexamethasone (No.=15)**		**Bupivacaine and dexmedetomidine (No.=15)**		**p value**
		No	**%**	**No**	**%**	**No**	**%**	
Sex	Male	11	73.3%	10	66.7%	7	46.7%	0.293
	Female	4	26.7%	5	33.3%	8	53.3%	
Age	Mean ± SD	4.87	2.72	4.07	1.94	4.47	2.42	0.658
Weight	Mean ± SD	16.67±4.17		15.93±3.75		17.47±4.81		0.619
ASA I		15	100%	15	100%	15	100%	--
Type of Surgery	Inguinal hernia	14	93.3%	15	100.0%	13	86.7%	0.343
	Circumcision	1	6.7%	0	0.0%	2	13.3%	
Duration of Surgery	Mean ± SD	24.33±7.04		26.27±4.03		28.67±5.50		0.122

Table (1) shows that there was no statistically significant difference between studied groups regarding age, sex, ASAI, type of surgery and duration of surgery.

Table (2): Comparison between bupivacaine only, Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine regarding the heart rate and mean arterial blood pressure during the 1st 30 minutes of anesthesia:

items Mean±SD	**Bupivacaine only (No.=15)**	**Bupivacaine and dexamethasone (No.=15)**	**Bupivacaine and dexmedetomidine (No.=15)**	**p value**
HR 5 min	122.3±16.5	132.3±16.2	135.1±20.2	0.127
HR 15 min	111.1±10.9	120.8±13	120.3±15.8	0.095
HR 30 min	110.4±10.4	116.5±12.2	109.9±12.1	0.239
MAP 5 min	74.1±4.8	72.8±4.1	75.5±5.4	0.310
MAP 15 min	71.4±5.4	68.7±3.8	67±3.98	0.032
MAP 30 min	70.3±5	67.6±3.5	62.8±3.7	<0.001*

P-value is significant

This table shows that there was no statistically significant difference between studied groups regarding heart rate but, there was statistically significant increase MAP 30 min in Bupivacaine only in comparison to Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine.

Table (3): Comparison between bupivacaine only, Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine regarding fentanyl requirements and Sevoflurane minimum alveolar concentration (MAC)

	Bupivacaine only (No.=15)		**Bupivacaine and dexamethasone (No.=15)**		**Bupivacaine and dexmedetomidine (No.=15)**		**p value**
	No	**%**	**No**	**%**	**No**	**%**	

Fentanyl Requirements	Yes	1	6.7%	0	0.0%	1	6.7%	0.593
	No	14	93.3%	15	100.0%	14	93.3%	
Sevoflurane MAC		2.1±0.3		2±0		2±0		0.376

MAC: Mean alveolar concentration

This table shows that there was no statistically significant difference between studied groups regarding fentanyl requirements and sevoflurane MAC.

Table (4): Comparison between bupivacaine only, Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine among postoperative heart rate: CHEOPS Score and Time of first request analgesia (hours)

postoperative (mean±SD)		**Bupivacaine only (No.=15)**	**Bupivacaine and dexamethasone (No.=15)**	**Bupivacaine and dexmedetomidine (No.=15)**	**p value**
HR	1 h	109.1±9.7	116.1±10.6	107.2±12.4	0.074
	2 h	108.4±8.7	115.1±10.2	105.8±11.9	0.051
	6 h	110.1±9.1	113.9±9.7	104.3±11.6	**0.041***
	12 h	114±7.4	112.8±9.4	104±11.1	**0.011***
	24 h	117.9±6.9	112±8.5	104.9±10.1	**0.001***
APM	1 h	69.3±4.5	66.6±3.4	61.1±3.2	**<0.001***
	2 h	68.9±4.15	65±3.1	59.9±3.3	**<0.001***
	6 h	71.2±3.9	64±2.9	59.2±2.5	**<0.001***
	12 h	72.9±4.2	63.1±3.3	58.5±2.2	**<0.001***
	24 h	75.5±4.2	64.2±3.5	59.1±1.7	**<0.001**
CHEOPS Score		5.9±0.9	5.5±0.7	5.5±1.3	0.332
Time of first request analgesia (hours)		3.6±0.8	9±2.9	7.7±0.9	**<0.001***

P-value is significant HR: Hear rate MAP: Mean arterial blood pressure

Table (4) shows that there was statistically significant increase PO HR 6 h in Bupivacaine and dexamethasone, increase post operative (PO) HR 12 h and PO HR 24 h in Bupivacaine only. There was statistically significant increase PO MAP in Bupivacaine only in comparison to Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine. There was statistically significant increase time of first request analgesia (hours) in Bupivacaine and dexamethasone in comparison to Bupivacaine only and Bupivacaine and dexmedetomidine. There was no statistically significant difference between studied groups regarding Adverse Events.

4. Discussion:

In paediatric patients, peripheral nerve blocks are essential for postoperative analgesia. Surgical operations in the inguinal region, such as inguinal hernia repair, paediatric orchiopexy, and emergency procedures such as an obstructed hernia need the most frequent abdominal wall block: the ilioinguinal and iliohypogastric nerve block (7,8).

As a result of their lower tolerance level and a number of medicines being contraindicated in youth, children are more vulnerable to postoperative pain. A lack of pain management following surgery can lead to complications such as respiratory distress, extended hospital stays, and an increased risk of persistent pain (9).

The duration of action and dose-dependent side effects on the heart and neurological system restrict the use of local anaesthetics. Since they increase the duration of sensory-motor block and decrease the cumulative dosage required of local anaesthetics, adjuvants are frequently used in conjunction with them (10).

Extending the analgesic effect of anaesthetics like bupivacaine or rupivacaine by adding adjuvants like epinephrine, clonidine, or dexmedetomidine is common in the clinical setting. However, none of these adjuvants has been approved by the FDA and must be used as an off-label drug, so the risk to benefit ratio must be carefully weighed before using them (12).

Dexmedetomidine is eight times more powerful than clonidine at stimulating the 2-adrenoceptors. It's also useful in peripheral nerve blocks, when it's used with long-acting local anaesthetics for greater safety and less haemodynamic swings (13).

The contribution of steroid to local anaesthetics efficiently and considerably extends the duration of analgesia and produces an earlier start of action. Adjuvant

Dexamethasone reduces the release of mediators of inflammation, reduces ectopic discharge from neurons, and inhibits the discharge from potassium channel-mediated of nociceptive C-fibers (4,14).

Although adjuvants to anaesthetics have been demonstrated to improve peripheral nerve block in adults, more randomised controlled studies are required to establish regional anaesthesia as a necessary component of postoperative analgesia in children (15).

Thus, the purpose of this study was to compare the effectiveness and safety of dexmedetomidine and dexamethasone when administered as an adjuvant to bupivacaine in paediatric patients having elective subumbilical surgery under general anaesthesia.

There was no statistically significant difference in demographic data, ASA physical status, kind of surgery, or duration of operation between the study groups (P value>0.05). These findings demonstrated that proper randomization occurred between the present research groups. Additionally, this eliminated any prejudice that would have biased the results in favour of one group over another.

Regarding the changes in heart rate (HR) after 5, 15 and 30 minutes intraoperatively, the current study results indicated no statistically significant difference between studied groups (P value>0.05).

Such findings were in agreement with Oriba et al. (2021) that indicated no significant difference between the three groups regarding the intraoperative heart rate, therefore, indicating equal effective analgesia with block in the three groups (P value>0.05) (16).

The current results also were in agreement with El-Feky and Abd El Aziz, (2015) When it came to intra-operative heart rate, there were no significant differences between dexmedetomidine, dexamethasone and fentanyl as adjuvant to local anaesthesia for children's caudal analgesia until 3 hours after surgery commenced (17).

Contrarily, such findings were in disagreement with Azemati et al. (2020) study that indicated significant decreased in HR in the bupivacaine-dexmedetomidine group at 10 and 20 min after injection in comparison with the bupivacaine only group (P < 0.05) (15).

Karan et al. (2018) found that when dexmedetomidine was added to ropivacaine for ilioinguinal-iliohypogastric nerve block in children undergoing inguinal hernia repair, the HR was significantly reduced 5-min intraoperatively in the ropivacaine-

dexmedetomidine group compared to the ropivacaine-only group (18).

Regarding the changes in mean arterial pressure (MAP) after 5, 15 and 30 minutes, the current study results indicated a statistically significant increase in MAP 30 min in group A (Bupivacaine only) in comparison to group B (Bupivacaine and dexamethasone) and group C (Bupivacaine and dexmedetomidine) (P value<0.001).

Such findings were in disagreement with Oriba et al. (2021) that indicated no significant difference detected between patients administered Bupivacaine only, Bupivacaine and dexamethasone, and Bupivacaine and dexmedetomidine groups regarding MAP measurements either intraoperatively or postoperatively (16).

El-Feky and Abd El Aziz (2015) found no significant differences in the means of mean arterial blood pressure (MAP) variations until 3 hours after the commencement of surgery between fentanyl, dexmedetomidine, or dexamethasone used as adjuvants to local anaesthetics in caudal analgesia in children (17).

Regarding the changes in spO2 after 5, 15 and 30 minutes, the current study results indicated no statistically significant difference between studied groups (P value>0.05).

Azemati et al. (2020) study indicated that systolic blood pressure (SBP) was not different between bupivacaine-dexmedetomidine and bupivacaine only groups (15).

Regarding the changes in post-operative heart rate (poHR) at 1, 2, 6, 12, and 24 h, the current study results indicated a statistically significant increase at poHR 12 h and poHR 24 h in Bupivacaine only in comparison with other groups (p value<0.05). The present study results indicated a statistically significant increase poMAP in Bupivacaine only in comparison to Bupivacaine and dexamethasone and Bupivacaine and dexmedetomidine (p value <0.001).

A study by Oriba et al. (2021) indicated that 8 hours after operation, the Bupivacaine only patients showed increase in heart rate followed by Bupivacaine dexmedetomidine group that expressed elevated heart rates at 12 hours and that Bupivacaine dexamethasone group was the last one to develop elevated heart rate after 16 hours (16).

However, a study by Ravichandra and Sumalatha, (2020) indicated that the intraoperative and postoperative hemodynamic HR was not significantly different in both bupivacaine only and bupivacaine dexmedetomidine groups (19).

On the other hand, a previous study by Almarakbi and Kaki, (2014) indicated significant fall in the heart rate 60 minutes following administration of (1µg/kg) dexmedetomidine in TAP block in comparison with bupivacaine alone group and this effect persisted 4 hours without any hemodynamic instability (20). Moreover, Abdallah and Brull, (2013) indicated that the incidence of bradycardia was higher in patients receiving dexmedetomidine (2).

Regarding the Children's and Infants' Postoperative Pain Scale (CHEOPS) Score and Time of first request analgesia, the current study results indicated a statistically significant increase in time of first request analgesia in group B (Bupivacaine and dexamethasone) (9.00 ± 2.90 hrs) in comparison to group A (Bupivacaine only) (3.60 ± 0.83 hrs) and group C (Bupivacaine and dexmedetomidine) (7.73 ± 0.96 hrs).

Such findings were in agreement with studies by Oriba et al. (2021) that indicated that the mean duration of analgesia (hours) in pediatric patients received bupivacaine and dexamethasone was the highest followed by Bupivacaine and dexmedetomidine and that the Bupivacaine only group showed the lowest duration of analgesia (P value >0.05) (16).

According to Lundblad et al. (2015), using dexmedetomidine as an adjuvant to an ilioinguinal/iliohypogastric nerve block resulted in a substantial reduction in the number of patients having CHIPPS pain ratings of 4 or more during early recovery following inguinal hernia surgery in children (21).

In addition, Abdelwahab et al. (2020) shown that when dexamethasone was combined with local anaesthesia in an ultrasound-guided transversus abdominis plane (TAP) block, it substantially lowered the FLACC pain score at 8, 10, and 12 hours postoperatively. The time required to obtain analgesia was delayed in the dexamethasone group, and the total dosage of acetaminophen consumed during the 36-hour period following surgery was similarly decreased (22).

Contrarily, a prospective, randomized, double-blind study by El-Emam, (2019) indicated that the use of dexmedetomidine as an adjuvant to bupivacaine in infraorbital nerve block (IONB) for cleft lip repair resulted in lower pain score and more prolonged duration of analgesia compared to dexamethasone in pediatric patients and the time of first request of analgesic was 20% longer in dexmedetomidine compared to dexamethasone group (P=0.0001) (23).

Another randomised, double-blind, control

experiment conducted by Karan et al. (2018) shown that combining ropivacaine and dexmedetomidine in ilioinguinal-iliohypogastric nerve blocks (IINB) significantly prolonged postoperative analgesia in paediatric patients undergoing inguinal hernia repair (16).

Additionally, a double-blind, randomised clinical experiment conducted by Azemati et al. (2020) shown that the addition of dexmedetomidine to local infiltration of bupivacaine dramatically decreased postoperative pain and boosted sedation in children undergoing herniorrhaphy (15).

On the other hand, a comparative study by El-Feky and Abd El Aziz, (2015) indicated the non-significant difference regarding the prolonged duration of analgesia in both dexmedetomidine group and the dexamethasone group (17).

Regarding the adverse events, the present study results indicated no statistically significant differences between the studied groups.

Such findings were in agreement with studies by El-Feky and Abd El Aziz, (2015) that indicated no significant increase in postoperative adverse effects (respiratory depression, vomiting and itching) among both dexamethasone and dexmedetomidine groups, while they were increased significantly in the fentanyl group (17).

Hamada et al. (2019) study comparing dexmedetomidine and dexamethasone as adjuvants to bupivacaine in ultrasound-guided supraclavicular brachial plexus block in upper limb surgeries found no complications associated with the block techniques in the form of nausea and vomiting, hemodynamic instability, injury to underlying structures, hematoma formation, infection, or local anaesthetic toxicity (24).

Oriba et al. (2021) indicated that both dexamethasone and dexmedetomidine were efficient adjuvants to local anesthetics as they were associated with significant prolongation of the duration of analgesia, decrease in postoperative analgesia, and better patient satisfaction compared to bupivacaine alone in in pediatric abdominal surgery (16).

Additionally, Ravichandra and Sumalatha's (2020) clinical comparative research shown that adding 0.5g/kg dexmedetomidine to bupivacaine for infra-orbital nerve block substantially prolonged the duration of analgesia without causing any intraoperative or postoperative side effects (17).

5. Conclusion:

In paediatric patients, adjuvant dexamethasone or dexmedetomidine to bupivacaine for ilioinguinal and iliohypogastric nerve block significantly lowers postoperative pain and analgesic needs compared to bupivacaine nerve block alone.

Recommendations:

Further research with lengthier follow-up periods and bigger sample sizes may identify the optimal anaesthetic for children undergoing abdominal surgery.

Additional research is necessary to identify the dosage–response relationship and the optimal adjuvant dose.

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