The Analgesic Efficacy of Ultrasound-guided Transversus Abdominis Plane (TAP) Block Combined With Oral Multimodal Analgesia In Comparison With Oral Multimodal Analgesia After Caesarean Delivery: A Randomized Controlled Trial

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Abstract

Background: The transversus abdominis plane (TAP) block is used increasing in parturients after caesarean delivery. This is a randomized controlled trial to evaluate the effectivenss of TAP in patients who received multimodal oral analgesia for postoperative pain relief.

Methods: Parturient who were scheduled for elective caesarean delivery under spinal anaesthesia were recruited and randomized to receive TAP block or placebo in addition to multimodal oral analgesia which consisted of regular tramadol, celecoxib and paracetamol, with oral oxycodone used as rescue for breakthrough pain. Only parturient in TAP group would have an injection of local anaesthesia under aseptic techniques. All the parturient were evaluated for pain or related complications in the first 24 hours after surgery.

Results: Eighty and 79 parturients were allocated to TAP and placebo group respectively. Nine out of 79 (11.4%) and 15 out of 73 (20.5%) parturients required oxycodone for breakthrough pain, P = 0.122. There was no difference in postoperative pain score and patient satisfactory score between the two groups.

Conclusions: TAP block confers little additional benefit when multi-modal oral analgesic regimen is used for postoperative pain control after caesarean section under spinal anaesthesia.

Trial registration: Clinical Trial Registry of China (http://www.chictr.org.cn, ChiCTR-INR-16010130). Retrospective registered on Dec 12, 2016

Background

With the availability of ultrasound machine, transversus abdominis plane (TAP) block may be easily performed after caesarean section for postoperative analgesia. It was shown to be effective and reduce intravenous morphine consumption in patients who used patient-controlled intravenous morphine analgesia for post-caesarean pain relief.[1] Previous systemic reviews and meta-analyses have revealed that it is only effective after caesarean delivery provides effective analgesia when spinal morphine is not used,[2,3] therefore TAP block offer little additional benefits when patients have intrathecal morphine administered. Although intrathecal morphine is the best option for post caesarean pain relief,[4] preservative free morphine is not available in our center and in most part of China. The routine post-caesarean analgesia in our center consists of multimodal oral analgesia including regular tramadol (SR 100 mg BID for 2 days), cyclooxygenase-2 inhibitor (parecoxib 200 mg BID for 3 days) and paracetamol (1000 mg QID for 4 days), with oral oxycodone (10 mg) as rescue pain relief. Our quality assurance exercise revealed satisfactory pain control with this regime, and the proportion of patients who required oxycodone rescue range from 15–20% and less than 1% of patient would need intravenous morphine as rescue analgesia. Since TAP block has been shown significantly reduce intravenous morphine consumption in the first 24 hours after caesarean section, we conducted this double-blind randomized controlled trial to test the hypothesis that TAP block would further improve post-caesarean analgesia in patients who have multi-modal oral analgesia.

Methods

The study was carried out in a tertiary care public hospital in Shenzhen, China. It was approved by the Hospital Institutional Review Board (szkcw201628) and registered with the Clinical Trial Registry of China (ChiCTR-INR-16010130). After patient informed consent was obtained, the parturients scheduled for elective caesarean delivery under spinal anaesthesia were enrolled in the study. Inclusion criteria were American Society of Anaesthesiologists physical status I or II. Exclusion criteria were inability to comprehend or use the verbal rating pain scoring system, or contraindication to the use of tramadol, cyclooxygenase-2 inhibitor or paracetamol. An independent statistician prepared a randomization list with block of group allocation was kept in a concealed opaque envelop. Attending anaesthetists would disclose group assignment at the start of surgery and prepare for the TAP block if necessary. In order to ensure the recruited parturients who had spinal anaesthesia were blind from group allocation and avoid sham block, the surgical drape which block parturients' view of her surgical site was kept after surgery. A linear 13- to 6-MHz ultrasound probe (Sonosite TM, Bothell, Washington) scan of bilateral flank was performed. Only parturients who were allocated to have TAP block would have injection of local anaesthesia under aseptic techniques. A 22-gauge, 90-mm SonoPlex Stim needle (Pajunk Medizintechnik, Geisingen, Germany), attached with flexible tubing to a syringe filled with 0.9% normal saline, was introduced through the skin anteriorly in the plane of the ultrasound beam, and advanced into the fascial plane between the internal oblique muscle and transversus abdominis muscles. Ropivacaine(Naropin, Astrazeneca AB. Sweden)15 ml (0.25%) was injected on each side for the TAP block. Since the parturients who had effective spinal block would not feel the needle injection of TAP block, it was possible to blind the participants from group allocations as ultrasound scan would be performed even if TAP block was not administered.

All recruited patients had intravenous cyclooxygenase-2 inhibitor before the end of operation. They were also prescribed multimodal oral analgesia postoperatively, and this included slow release tramadol 100 mg twice a day for the first two days, celecoxib 200 mg twice a day for three days, and paracetamol 1000 mg four times a day for four days. Oxycodone 10 mg was prescribed and given as rescue analgesia.

Participants were given instruction to fill in a survey for postoperative pain control. The numeric rating scale (NRS) for pain and satisfactory scale was explained. NRS consist scores of 0 to 10, with 0 equals to no pain and 10 equals to the worst pain. A scale of 5 were used as a satisfactory score, with 1 equals to "very unsatisfactory" and 5 equals to "very satisfactory" with pain relief. The participants were asked to record the NRS at rest, with movement, and with uterine massage and the satisfactory score at 2 hours, 4 hours, 6 hours and 12 hours after completion of surgery. In addition, they were asked to record if there was an episode of nausea and vomiting. The parturients would also record if oxycodone or uterotonic was used in the first 24 hours. Moreover, they would also record if there was any instant pain when NRS was greater than 6 in the first 24 hours. The survey was collected one day after surgery and the NRS at rest and with movement were also enquired by pain nurse during follow up and this pain score on day 1 after operation.

Primary outcome is the percentage of parturient who required oxycodone rescue analgesia. Secondary outcomes include the NRS at rest, with movement and during uterine massage, patient satisfactory score, the percentage of parturients who experienced pain with NRS > 6 during the first 24 hours after surgery, and the percentage of parturients who required oxycodone for breakthrough pain and the incidence of nausea and vomiting. According to our record of routine postoperative visit, approximately 20% of our patients required oxycodone rescue. If TAP block would decrease the requirement of oxycodone from 20–5%, 73 parturients per group is required for 80% power with 5% type 1 error.

Parametric primary and secondary outcomes are presented as mean (SD) or number (percentage) and were compared by t-test or Chi-square test. Non-parametric data are presented as median (IQR [range]) and compared by Mann-Whitney U test. The area under the curve (AUC) for pain scores and satisfactory scores were derived using the trapezoidal rule. The mean AUC of pain scores and satisfactory scores were presented as mean (SD) and compared using t-test. A p value < 0.05 was considered significant. Data were analysed using SPSS (version 21.0; SPSS Inc., Chicago, IL, USA).

This manuscript adheres to the applicable CONSORT guidelines.

Results

One hundred and sixty-three patients were approached, and 159 patients consented to take part in this study between April and September in 2016. Eighty parturients received TAP block and 79 were allocated to placebo group (Fig. 1). Primary outcome was available from 79 and 73 parturients in TAP and placebo group respectively. Demographic information is presented in Table 1. Nine out of 79 (11.4%) and 15 out of 73 (20.5%) parturients required oxycodone for breakthrough pain (P = 0.122,Table 3). The AUC of NRS for pain at rest (Fig. 2and during movement (Fig. 3) for the first 24 hours was not different between the two groups (P = 0.87 and P = 0.95 respectively, Table 2). The AUC of NRS for pain during uterine massage (Fig. 4) for the first 12 hours was also not different between the two groups (P = 0.66, Table 2). The AUC of patient satisfactory score for the first 12 hours was not different between the two groups (P = 0.58, Table 2). There was no difference in incidence of nausea and vomiting between the 2 groups and a similar proportion of patients required uterotonic for control of bleeding (Table 3). Similar proportion of patients experienced severe pain (with NRS > 6 at any time point) during the first 24 hours postop (Table 3).

Table 1
Subjects' characteristics.

	TAP(n = 79)	Placebo(n = 74)
Age (year)	32.4 ± 3.5	32.5 ± 4.0
Body Weight (kg)	66.4 ± 6.9	67.0 ± 7.1
Body Height (cm)	159.5 ± 4.8	160.2 ± 5.0
BMI	26.1 ± 2.4	26.1 ± 2.6
Gestation	39 [37–39]	39 [37–39]
Gravida	2 [1–3]	2 [1–3]
Parity0:01:02	42:36:01 (53.2%: 45.6%: 1.3%)	25:46:03 (33.8%: 62.2%: 4.1%)
Blood Loss	200 [200–300]	200 [200–300]
Operation Duration (min)	58.8 ± 14.4	62.3 ± 17.4
TAP = transversus abdominis plane; BMI = body mass index		
Values in mean ± SD, median[IQR] or n(%)		

Table 2
AUC of numeric rating scale (NRS) of post-caesarean delivery pain

	TAP(n = 79)	Placebo(n = 74)	*p* value
AUC NRS(R) during 2–24 hrs	20.8 (7.1)	22.4 (7.1)	0.87
AUC NRS(M) during 2–24 hrs	37.5 (8.0)	38.2 (7.8)	0.95
AUC NRS(U) during 2–12 hrs	24.3 (5.3)	27.6 (5.3)	0.66
AUC Satisfaction Scores during 2–12 hrs	9.8 (2.1)	11.6 (2.3)	0.58
AUC of numeric rating scale (NRS) over the first 24 hours post-caesarean delivery at rest (NRS (R)), with movement (NRS (M)). The NRS over the first 12 hours with uterine massage (NRS (U)) and AUC of satisfactory score over the initial 12 hours post-caesarean delivery. NRS = numeric rating scale; AUC = area under the curve; Values are in mean (SE).			

Table 3
The incidence of nausea, vomiting, use of uterotonic, oxycodone and NRS > 6 at any instance during the first 24 hr

	TAP (n = 79)	Placebo(n = 73)	*p* value
Nausea	16 (20.30%)	8 (10.80%)	0.108
Vomit	5 (6.30%)	8 (10.80%)	0.32
Uterotonic	51 (64.60%)	46 (63.00%)	0.843
Oxycodone	9 (11.40%)	15 (20.50%)	0.122
NRS > 6 at any instance during the first 24 hr	32 (47.10%)	39(62.90%)	0.07
The incidence of nausea, vomiting, use of uterotonic, oxycodone and NRS > 6 at any instance during the first 24 hours. TAP = transversus abdominis plane; NRS = numeric rating scale			
Values are n (%)			
Additional Files			
Additional file 1- CONSORT Checklist			

Discussion

The analgesic efficacy of TAP block for caesarean delivery remains controversial. TAP block has been shown to be inferior to spinal morphine for post-caesarean delivery pain,[4,5] and it was ineffective when spinal morphine was used,[3,6,7] it is associated with effective analgesia in patients after caesarean delivery when spinal morphine is not used.[2,3] This investigation demonstrates that TAP block is not associated with reduced use of rescue oxycodone nor pain score during the first 24 hours after surgery. Moreover, it is not associated with better patient satisfaction. Although we have revealed in this study that single shot TAP block confers little additional benefit when multimodal oral analgesic regimen inclusive of tramadol, cyclooxygenase-2 inhibitor and paracetamol is used, with the advancement of ultrasound technology, TAP blocks become technically easier and safer to perform,[8] it would be up to the individual anaesthesiologist or department to decide whether this is cost effective and worthwhile additional procedure in their own setting.

If TAP block does not provide significant additional benefit to parturient who received multimodal oral analgesic after caesarean delivery, this may be indirect evidence that the current multimodal oral analgesic is as effective as intrathecal morphine for post-caesarean pain relief. The advantage of multimodal oral analgesia includes ease of administration with no device requested for drug administration. This would facilitate early mobilization after surgery. Recently the U.S. Food and Drug Administration has issued warning to mothers that breastfeeding is not recommended when taking tramadol due to the risk of serious adverse reactions in breastfed infants.[9] In a recent review on the tramadol use in breastfeeding mother and new-born, it is revealed that there have been no reported

deaths of breastfed newborns in association with maternal tramadol use.[10] Moreover, there have been no reported neonatal deaths attributed to the therapeutic use of tramadol. The authors argue that recommendation to avoid tramadol when breast feeding and the contraindication to use in children is inappropriate. Previous study has revealed the concentration of tramadol and its active metabolite was very low in breast milk.[11]In our hospital, we have used multimodal oral regimen with tramadol for all patients after caesarean section. Our delivery rate increased from 200 per year in 2014 to 1000 per year to date, with 20–30% cesarean delivery rate. We do not request mother to withhold breastfeeding during tramadol use, to date we have not encountered any adverse event in newborns related to breastfeeding since we have used this regimen in 2014. Although there are alternative to tramadol but they are either oral oxycodone or intravenous morphine with more side effects including nausea, vomiting.

Conclusions

In conclusion, this double blinded randomized controlled trial revealed that TAP block confers little additional benefit when multi-modal oral analgesic regimen is used for post caesarean section.

Abbreviations

TAP
transversus abdominis plane; NRS:numeric rating scale; AUC:area under the curve

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of University of Hong Kong - Shenzhen Hospital (szkcw201628) on April 8, 2016, and registered with the Clinical Trial Registry of China (ChiCTR-INR-16010130). We have obtained written informed consents from all of the participants in the study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available

from the corresponding author on reasonable request. The datasets used are also available from Clinical Trial Registry of China (http://www.chictr.org.cn/hvshowproject.aspx?id=11718)

Competing interests

The authors declare that they have no competing interests.

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None

Authors' contributions

VMYY, YY, XBX conceived the study.

YY, SSG, XBX performed experiments.

SW C, VMYY, YY and XBX analysed the data and prepared the manuscript.

SWC, VMYYuen, YY, SSG, XBX critically reviewed the manuscript.

All authors have read and approved the final manuscript.

Acknowledgements

Not applicable

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Figures

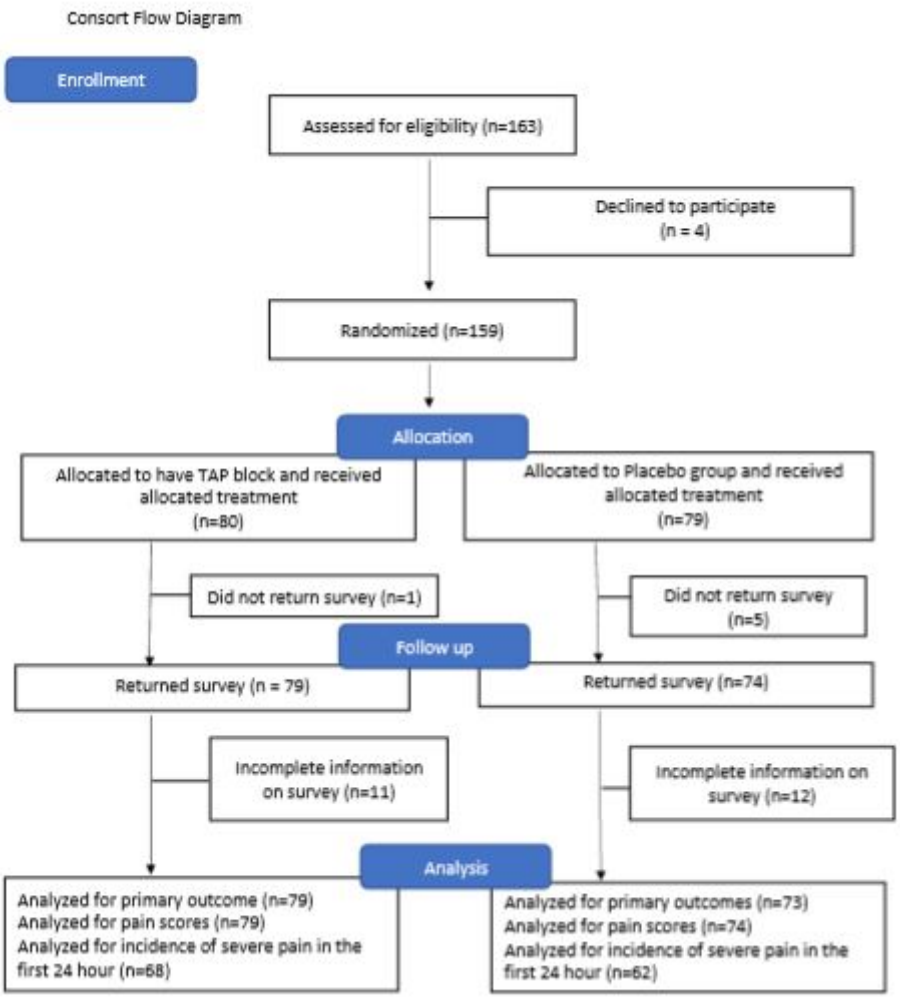

Figure 1

Consort flow diagram. Patients were excluded because of incompleting information.

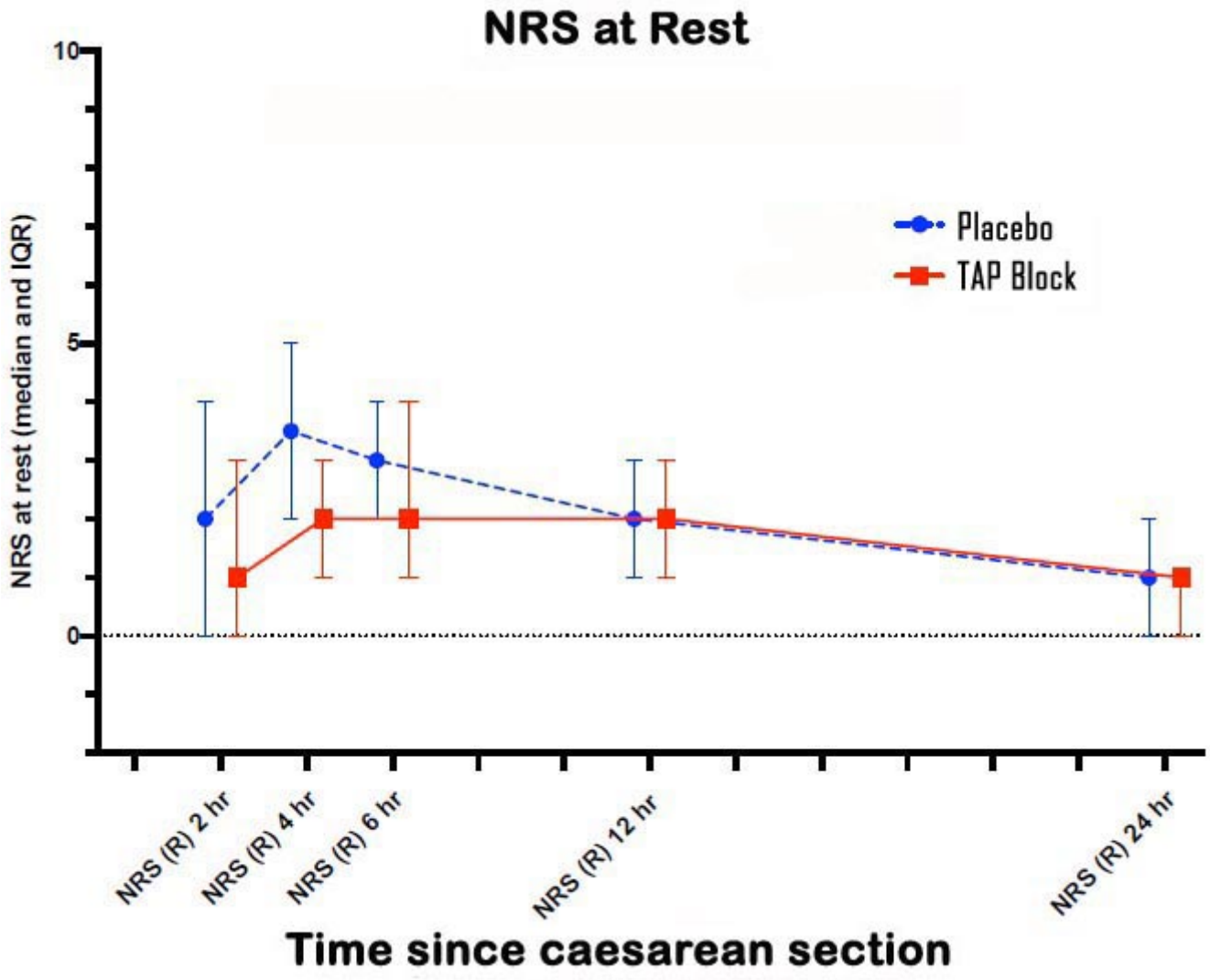

Figure 2

NRS at rest. The median (IQR) pain score in numeric rating scale (NRS) at rest in the placebo group ( ) and the TAP group ( ) over the first 24 hours after Caesarean section.

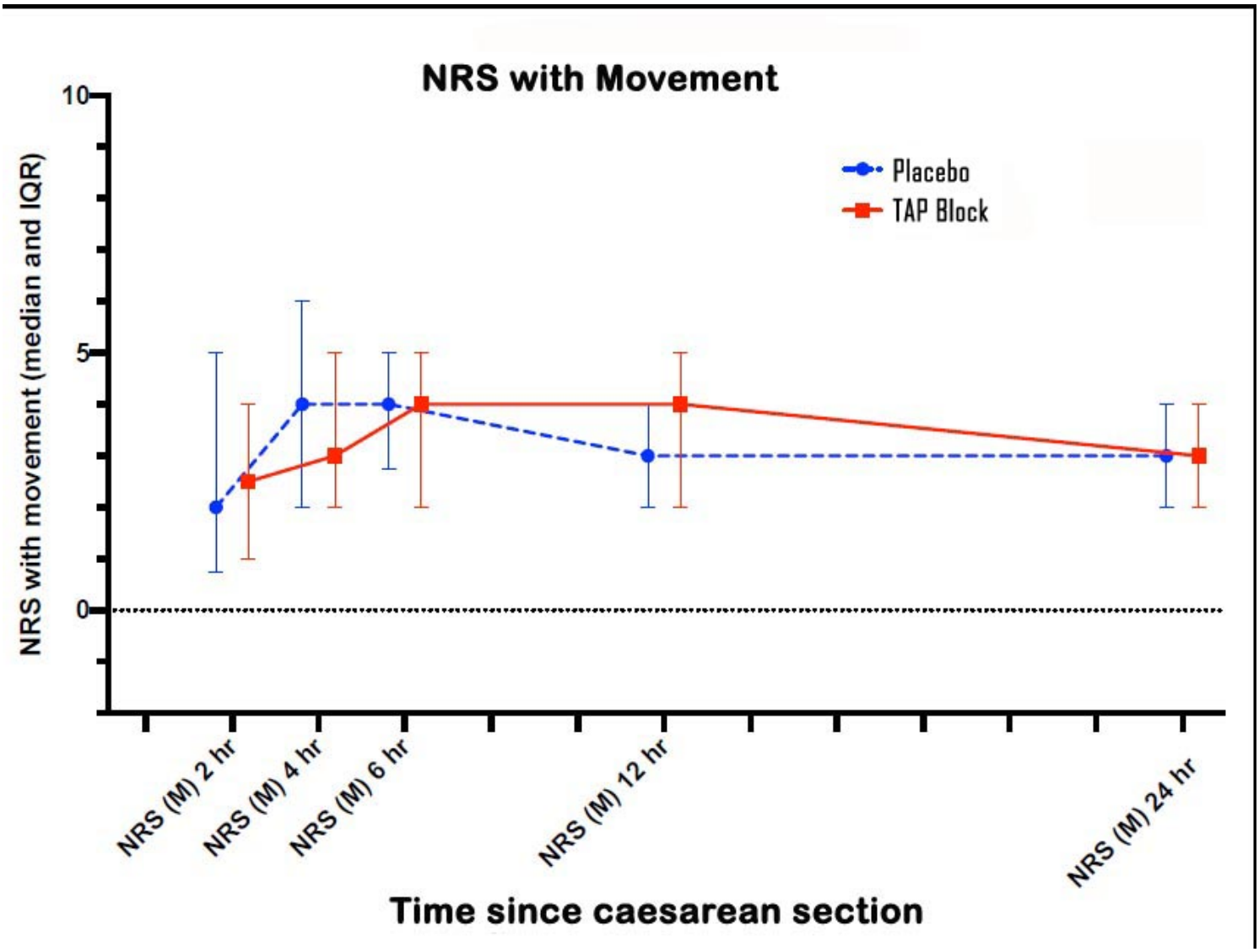

Figure 3

NRS with movement. The median (IQR) pain score in numeric rating scale (NRS) with movement in the placebo group ( ) and the TAP group ( ) over the first 24 hours after Caesarean section.

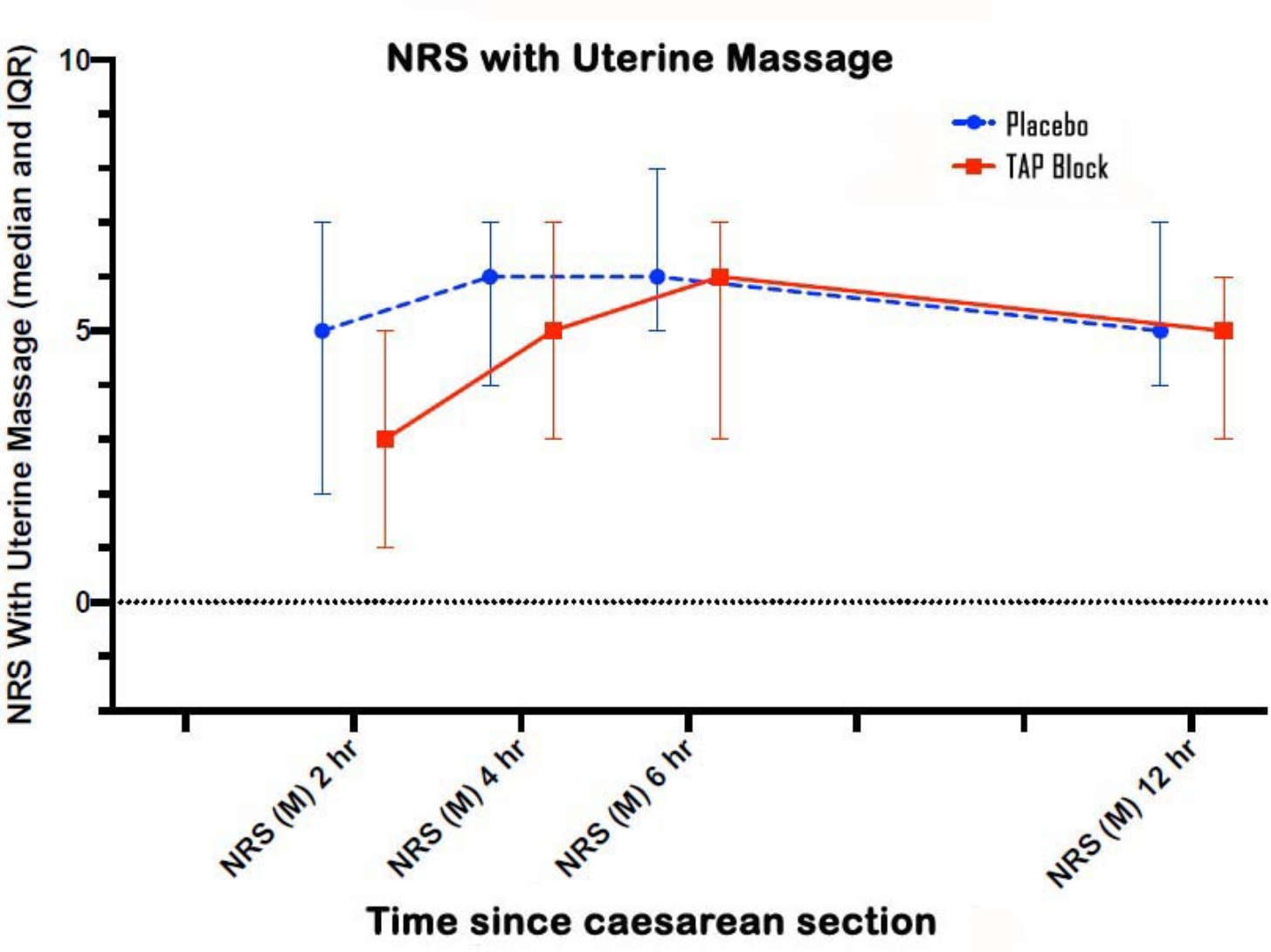

Figure 4

NRS Uterine massage. The median (IQR) pain score in numeric rating scale (NRS) with uterine massage in the placebo group ( ) and the TAP group ( ) over the first 12 hours after Caesarean section.

Supplementary Files

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- CONSORTChecklistR1.doc