A randomised trial of the analgesic efficacy of ultrasound-guided transversus abdominis plane block after caesarean delivery under general anaesthesia

Terry T. Tan, Wendy H.L. Teoh, David C.M. Woo, Cecilia E. Ocampo, Mukesh K. Shah and Alex T.H. Sia

Introduction
Effective pain control is an important aspect of recovery for women after caesarean delivery. Women want to be alert, mobile and pain-free to care for themselves and their newborn. Currently, the use of spinal or epidural anaesthesia, co-administered with neuraxial opioids, remains a popular and effective technique in providing anaesthesia and analgesia for women undergoing caesarean delivery. Early oral feeding in these women has also been shown to expedite other important outcomes such as reduced need for prolonged intravenous hydration, earlier removal of intravenous cannulae, earlier ambulation, earlier start of breastfeeding and shorter hospitalisation. However, there is a small proportion of patients in whom neuraxial techniques are contra-indicated or not possible. These women undergo general anaesthesia for caesarean delivery and receive morphine using an intravenous patient-controlled analgesia (PCA) system for postoperative analgesia. Apart from being less effective than neuraxial opioids, attendant opioid-related side-effects such as nausea and vomiting, sedation, pruritus and respiratory depression are common concerns. In addition, systemic morphine accumulates in breast milk and can transfer to the baby if the patient is breastfeeding.

The transversus abdominis plane (TAP) block, described by McDonnell and Laffey, is a technique whereby local anaesthetic is deposited in the TAP, blocking sensory nerves which supply the anterior abdominal wall. The TAP block has been shown to reduce morphine consumption after abdominal surgery and after caesarean delivery under spinal anaesthesia. Access to the TAP was originally described by McDonnell and Laffey, using a landmark technique through the triangle of Petit, relying on a ‘double-pop’ sensation as the needle is advanced across the neurofascial planes of the anterior abdominal wall. Increasingly, TAP blocks have been performed under ultrasound guidance which may be more precise and safer than the blind approach.

We hypothesised that the advantage of adding a TAP block could be even more obvious after caesarean section performed under general anaesthesia and that the safety of the TAP block would be enhanced by ultrasound guidance. The primary outcome of our study was 24-h consumption of morphine. The secondary outcomes were...
visual analogue scale (VAS) scores for pain at rest and on activity, the incidences of nausea and vomiting and the level of sedation and satisfaction rating.

Methods

Ethical approval for this study (Ethical Committee number 200902029) was granted by the KK Hospital Institutional Review Board (Chairperson A/Prof Chay Oh Moh) on 27 February 2009. All patients provided written informed consent. Between March and December 2009, we recruited 40 ASA (American Society of Anesthesiologists) physical status 1–2 women aged over 18 years who were scheduled to undergo elective or grade 3 emergency caesarean delivery (in which no maternal or fetal compromise exists) and who requested general anaesthesia. Informed consent was taken during pre-anaesthetic evaluation. Patients were excluded if they had chronic pain states, a history of postoperative nausea and vomiting, known allergies or contraindications to any of the medications used in the study.

Patients were allocated randomly using a computer-generated random number table to undergo TAP block (n = 20) or standard care (control) with no block (n = 20). Group allocation was concealed in sealed opaque envelopes which were not opened until consent to participate in the study had been obtained. The investigators who performed the block had no involvement in assessing outcome. The patient, primary anaesthesiologist, staff providing post-anaesthetic care and investigator assessing the patient were blinded to the group allocation.

On arrival in the operating room, physiological monitoring (pulse oximetry, continuous ECG and non-invasive blood pressure measurement) was started prior to induction of anaesthesia. An 18-gauge intravenous catheter was inserted in the left hand. Anaesthesia was induced with thiopentone 5 mg kg\(^{-1}\) with an assistant applying cricoid pressure. Tracheal intubation was facilitated by administration of suxamethonium 2 mg kg\(^{-1}\) and atracurium 0.25 mg kg\(^{-1}\) was given when the effects of suxamethonium wore off. The lungs were ventilated mechanically with a mixture of oxygen in air (FiO\(_2\) 0.5), maintaining the end-tidal carbon dioxide tension at 4.0–5.3 kPa. Anaesthesia was maintained with sevoflurane at an end-tidal concentration of 2.5%. After delivery of the baby and clamping of the umbilical cord, syntocinon 5IU was administered slowly. Analgesia was provided with intravenous morphine 0.15 mg kg\(^{-1}\). All patients received dexamethasone 4 mg and ondansetron 4 mg. At the end of surgery, neostigmine 2.5 mg and atropine 0.9 mg were administered to antagonise any residual neuromuscular blockade.

TAP block was performed bilaterally at the end of the operation, when the patient was still under general anaesthesia, by one of the investigators, who had each performed at least 10 ultrasound-guided TAP blocks prior to the start of the study. The investigator who performed the block was a different anaesthesiologist from the primary one managing the patient (who left the room when the block was performed and returned after the wound was covered with a dressing) to maintain blinding. An anaesthesia resident not involved in the study monitored the patient. A Sonosite Titan ultrasound machine (SonoSite, Bothell, Washington, USA) with an L38 linear broadband transducer (7–13 MHz) was used for the procedure. The blocks were performed using a sterile technique, with the operator wearing sterile gloves, the transducer covered with a sterile plastic sheath and the skin prepared with 0.5% chlorhexidine solution. The transducer was placed in the mid-axillary line, between the iliac crest and costal margin in the axial plane, approximately at the level of the T10 dermatome. When the external oblique muscle (EOM), internal oblique muscle (IOM), transversus abdominis muscle (TAM) and peritoneum were visualised best, a 22-gauge 70-mm nerve block needle (Pajunk GmBH, Geisingen, Germany) was introduced in-plane to the transducer. A loss of resistance or ‘pop’ was felt as the needle was seen to enter the plane between the EOM and IOM. A second loss of resistance or ‘pop’ was felt as the needle entered the plane between the IOM and TAM. Once the tip of the needle was in the TAP, a 1-ml test dose of solution was injected to confirm the location of the needle, seen as the formation of a hypo-echoic lens-shaped image. After confirmation of the position of the needle, and negative aspiration, 20 ml of levobupivacaine 2.5 mg ml\(^{-1}\) (Abbott Laboratories, Hycomed Pharma AS, Elverum, Norway) was injected, with aspiration after every 5 ml. This was repeated on the opposite side of the abdomen. Patients in the control group did not receive the TAP block or have their skin punctured. It was not necessary to cover the TAP block puncture sites with a plaster to aid blinding because the abdominal wound was covered with a pressure dressing (as per surgical routine). The width and lateral extent of this surgical bandage covered the TAP block puncture sites, thus maintaining blinding of the patient and primary anaesthesiologist.

After the surgical procedure, postoperative analgesia was provided with a PCA system using intravenous morphine (bolus dose 1 mg, lockout interval 5 min, maximum dose 40 mg in 4 h). Postoperative nausea and vomiting was treated with intramuscular metoclopramide 10 mg as needed. A dedicated investigator blinded to the group assignment collected the following data at 0, 1, 2, 3, 4, 5, 6, 8, 12, 16 and 24 h after the TAP block: pain severity at rest and on activity (knee and hip flexion, akin to a modified Bromage test) measured on a VAS pain score (0 = none, 1 = mild, 2 = moderate, 3 = severe); and level of sedation (1 = wide awake, 2 = minimally sedated,
appropriate response to conversation, 3 = asleep, rousable by tactile stimulation, 4 = deeply asleep, rousable only with significant physical stimulation, 5 = unrousable). Patients were asked to assess their satisfaction with their pain relief on a four-point categorical scale: very dissatisfied, dissatisfied, satisfied or very satisfied after 24 h. The primary outcome of the study was 24-h consumption of morphine.

**Statistical analysis**
The sample size was computed to detect a 25% difference in 24-h PCA morphine consumption as a clinically significant endpoint. On the basis of previous institutional data, it was calculated that 15 patients per group (total 30 patients) would be required to detect a 25% decrease in the mean 24-h morphine consumption at a significance level of 0.05 (α = 0.05, β = 0.2). Using these calculations, we randomised 20 patients into each group (total 40) to account for protocol breaches and dropouts.

Statistical analyses were performed with Prism 5 for Mac OS, version 5.0a (GraphPad Software, San Diego California USA). Parametric data were analysed using Student’s t-test and are presented as mean (SD). Between-group comparisons for nonparametric data were analysed using Wilcoxon’s ranked-sum test and categorical data were analysed using Fisher’s exact test. Nonparametric data are presented as median and interquartile range and categorical data as raw data and incidence. A P value of less than 0.05 was considered statistically significant.

**Results**
All patients who were recruited completed the study. Their baseline characteristics are shown in Table 1. The abdominal wall muscle layers were well visualised, and injection of local anaesthetic produced a distinct lens-shaped hypo-echoic image between the IOM and TAM planes in all the patients in the study group. None of the patients experienced any complications or adverse effects.

Patients in the TAP block group consumed significantly less morphine in 24 h than those in the control group [mean (SD) 12.3 (2.6) vs. 31.4 mg (3.1), P < 0.001 (Fig. 1)]. The median VAS pain scores at rest and on activity are shown in Figs 2 and 3. There were no differences between groups in the mean area under the curve of VAS pain scores at rest [20.4 (4.4) vs. 22.8 cm h⁻¹ (4.0), P = 0.69] or on activity [59.6 (8.3) vs. 73.6 cm h⁻¹ (8.3), P = 0.24].

There were no significant differences in nausea and vomiting. Eighteen patients in the TAP group (90%) and 16 in the control group (80%) experienced no nausea. Mild nausea was reported in two patients in the TAP group (10%) and four patients in the control group (20%). None of the patients in the TAP group vomited. One patient in the control group vomited at 6 h. None of the patients complained of itching. There was no difference in use of rescue antiemetics [two patients in the TAP group (10%) and four patients in the control group (20%)]. There was no significant difference between groups in the level of sedation (Table 2). None of the patients was very dissatisfied or dissatisfied with their pain relief. Significantly more patients in the TAP group were very satisfied [16 in the TAP group (80%) compared with five patients in the control group (25%), P = 0.012].

**Discussion**
The vast majority of caesarean deliveries are conducted under neuraxial anaesthesia with either intrathecal or epidural opioids to provide effective postoperative analgesia. However, there are still circumstances in which women either request general anaesthesia, require rapid-onset anaesthesia for emergency caesarean delivery or have absolute or relative contraindications to neuraxial anaesthesia (e.g. coagulopathy, existing neuropathy, prior spinal surgery or instrumentation) and undergo caesarean delivery under general anaesthesia, relying predominantly on intravenous opioids for postoperative pain relief.

The opioid-sparing effects of the TAP block have been demonstrated by McDonnell et al.⁹ after caesarean section conducted with intrathecal bupivacaine and fentanyl, but these findings were contradicted by those of Costello et al.,⁹ who found no improvement in postoperative analgesia after spinal morphine. We found that the use of TAP blocks resulted in a substantial reduction in morphine consumption of 19.1 mg in the first 24 h in parturient patients who had received no spinal morphine. To our knowledge, this is the first study of patients undergoing caesarean section under general anaesthesia which has described the postoperative analgesic efficacy of TAP blocks, without intrathecal morphine.¹⁰

We demonstrated that ultrasound-guided TAP block reduces morphine consumption and improves satisfaction in women undergoing caesarean delivery under general anaesthesia. However, there were no reductions in the incidences of opioid-related side-effects of nausea and vomiting, or the need for rescue antiemetics. First, our study was not powered to detect a difference in these outcomes. Second, these findings may be related to our study protocol and institutional practice of administering

<table>
<thead>
<tr>
<th>Table 1 Baseline data of patients recruited</th>
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<tr>
<td>Group</td>
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<tr>
<td>-------</td>
</tr>
<tr>
<td>Age, years</td>
</tr>
<tr>
<td>BMI, kg m⁻²</td>
</tr>
<tr>
<td>Duration of surgery, min</td>
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<tr>
<td>Intraoperative morphine, mg</td>
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¹Values are mean (SD).
prophylactic intravenous ondansetron and dexamethasone. Third, our findings echo those of a recent Cochrane review on perioperative TAP blocks after abdominal surgery which included eight studies (358 participants) up to June 2010 with a background of general anaesthesia in both arms in most cases. Compared with no TAP block or placebo, TAP block resulted in significantly less postoperative requirement for morphine at 24 h [mean difference −21.95 mg, 95% confidence interval (CI) −37.91 to 5.96; five studies, 236 participants] and at 48 h (mean difference −28.50, 95% CI −38.92 to −18.08; one study of 50 participants), but not at 2 h. This Cochrane review also found that TAP blocks made no apparent impact on nausea, vomiting or sedation scores. However, none of the studies involved parturient patients undergoing caesarean section. It would have been interesting to measure respiratory rate during sleep as a measure of morphine side-effects. This was not performed because respiratory depression with PCA morphine is not a problem which we have encountered in our obstetric practice, probably due to the increased metabolic rate and increased respiratory rate bestowed by the physiological changes of pregnancy. We chose to monitor the level of sedation as a more clinically relevant and appropriate measure of the side-effects of morphine in this setting, as it may potentially interfere with attempts to bond and breastfeed a newborn baby.

We found no differences in pain VAS scores between groups. We postulate that this was because both groups received PCA morphine and would have self-administered
when experiencing pain. Moreover, our study was not powered to detect a difference in VAS pain scores. Interestingly, despite the lack of statistical difference in pain scores, patients in the TAP group had a higher rating of maternal satisfaction.

McDonnell et al. found that TAP blocks resulted in an impressive 80% reduction in postoperative morphine consumption. Their study differed from ours in that they did not use ultrasound guidance, their patients received a spinal anaesthetic with bupivacaine 12 mg and fentanyl 25 μg, bilateral TAP blocks were performed using ropivacaine 3 mg kg\(^{-1}\) (to a maximum dose of 150 mg) or a saline placebo and their patients received patient-controlled intravenous morphine analgesia and regular rectal diclofenac and paracetamol. They reported a significant reduction in VAS pain scores, sedation and 48-h total morphine requirements.

Another recent study by Belavy et al., published after completion of our trial, confirmed the efficacy of TAP blocks in the absence of long-acting intrathecal opioid. They showed that ultrasound-guided TAP block with ropivacaine 0.5% in women undergoing caesarean delivery with spinal anaesthesia (bupivacaine 11 mg and fentanyl 15 μg) reduced 24-h morphine consumption by 43% compared with saline placebo, as part of a multimodal analgesic regimen which included postoperative paracetamol and NSAIDs. As in our study, they found higher patient satisfaction with pain relief, but no difference in VAS pain scores. They were also able to demonstrate significantly less antiemetic use in the TAP block group because their study protocol omitted prophylactic antiemetics.

In contrast to these two trials, Costello et al. performed a typical obstetric spinal anaesthetic with long-acting neuraxial opioids (bupivacaine 12 mg, fentanyl 10 μg and morphine 100 μg) and found that TAP blocks (20 ml of ropivacaine 0.375% on each side) did not improve postoperative analgesia despite being part of a multimodal analgesic regimen. Far from disproving efficacy, their findings lend weight to the fact that intrathecal morphine is very efficacious at decreasing pain after caesarean section, lasting longer than the local anaesthetic of the TAP block. As the TAP block provides analgesia only for somatic pain from the incision site on the anterior abdominal wall, visceral pain from the uterus can be addressed by other modalities.

It is arguable that the concomitant administration of adjuvant analgesics would not have confounded evaluation of the true analgesic efficacy of the TAP blocks, which we had sought to elucidate, as both groups would have benefited from adjuvants, particularly NSAIDs which are effective in relieving visceral pain not

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**Table 2**  Level of sedation in both groups of patients

<table>
<thead>
<tr>
<th>Group</th>
<th>Control (n = 20)</th>
<th>TAP (n = 20)</th>
<th>P value</th>
</tr>
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<tbody>
<tr>
<td>Alert</td>
<td>9 (45%)</td>
<td>5 (25%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Minimally sedated</td>
<td>6 (30%)</td>
<td>9 (45%)</td>
<td>0.51</td>
</tr>
<tr>
<td>Asleep, awakened by tactile stimulation</td>
<td>5 (25%)</td>
<td>6 (30%)</td>
<td>1</td>
</tr>
<tr>
<td>Deeply asleep, awakened by significant stimulation</td>
<td>0</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Unrousable</td>
<td>0</td>
<td>0</td>
<td>–</td>
</tr>
</tbody>
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Values are number (proportion). No significant difference between groups.

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reduced by the TAP block. However, our hospital ethics committee did not feel that our patients would be disadvantaged by the omission of rectal NSAIDs or paracetamol for 24 h because all the patients had PCA morphine at their disposal. Hence, true cumulative morphine consumption could be recorded. We also limited our study assessment to only 24 h postoperatively because, based on historical data, the requirement for systemic opioids beyond that time is significantly diminished in the majority of our patients.

Different concentrations and volumes of local anaesthetic have been used by other investigators in performing the TAP block. Kato et al. examined plasma lidocaine concentrations after TAP block with 40 ml of lidocaine 1% and showed potentially toxic plasma concentrations peaking at 15 min. They suggested that local anaesthetic absorption after TAP block may, in part, result from leakage of injectate from the TAP out into the surrounding abdominal musculature. It was postulated that ultrasound guidance may increase the accuracy of injection and decrease plasma concentrations compared with the blind technique.

As the TAP block is a plane block, and sufficient volume is required to fill the plane, all of the studies used a minimum volume of 20 ml on each side of the abdomen. Our patients had a mean body weight of 70 kg. We chose levobupivacaine 0.25%, as this concentration would allow us to administer a volume of 20 ml of local anaesthetic bilaterally (a total of 40 ml) without exceeding the recommended maximum dose of 2 mg kg⁻¹ for bupivacaine and, in so doing, aimed to reduce any concerns about toxicity.

The ethical legitimacy of using interventional placebo controls in regional anaesthesia has been questioned. McGuirk et al. graded the risks of placebo interventions used in 59 randomised trials of local anaesthetic blocks using their novel ‘SHAM’ (Serious Harm and Morbidity) scale in which grade 0 = no risk (no intervention); grade 1 = minimal risk (skin allergy to dressing); grade 2 = minor risk (subcutaneous haematoma, infection); grade 3 = moderate risk (nerve injury); and grade 4 = major risk (blindness, pneumothorax, liver laceration). They found that more than half of the randomised study designs subjected patients in control groups to serious risks or irreversible harm. This prompted an accompanying recent editorial which echoes our sentiments. We did not incorporate an invasive placebo arm into our trial methodology because injecting saline through a needle may cause harm simply by the mechanics of the injection itself, such as pressurisation within a nerve fascicle, with potential for axonal ischaemia and nerve injury.

We acknowledge some limitations of our study. True blinding may not be possible in these type of studies, as the TAP block renders the abdominal wall insensitive. However, the patient undergoing TAP block at the end of surgery was still under general anaesthesia and the investigator conducting the postoperative assessments were technically blinded to group allocation. We also attempted to map out the extent of the dermatomal blockade postoperatively, but this was abandoned as we found this virtually impossible because many of our patients had pressure bandages covering the abdominal wound. Removal of bandages would have compromised the sterility of the wound. Furthermore, the patients and investigators may be inadvertently unblinded when performing sensory tests on the abdomen. Studying the incidence of chronic pain in both groups would also be an interesting topic for future work.

In conclusion, our study showed that ultrasound-guided TAP blocks in the manner we have described resulted in reduced systemic morphine consumption and a positive impact on maternal satisfaction in women undergoing caesarean section under general anaesthesia. We propose that the TAP block is another arsenal in the obstetric anaesthesiologist’s armamentarium in managing pain after caesarean section and is a valuable resource in patients undergoing general anaesthesia, or in those with contraindications to long-acting neuraxial opioids.

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