

5 **Evaluating the pain relief effects after caesarean delivery by** 6 **ultrasound-guided transversus abdominis plane (tap) block in** 7 **Hanoi Obstetrics and Gynecology Hospital, Vietnam**

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17 **Abstract.** Evaluation of analgesic efficacy and side effects of ultrasound - guided transversus
18 abdominis plane (TAP block) in women undergoing intubation anesthesia for caesarean section in
19 Hanoi Obstetrics and Gynecology hospital, Vietnam. Comparative randomized clinical trial, 120 women
20 who underwent caesarean delivery under general anaesthesia were allocated randomly: the group
21 received a TAP block in both sides (group TAPB, n = 60) or no TAP block (group control, n = 60).
22 Both groups received analgesia with intravenous morphine controlled by the woman during 72 hours
23 after surgery. Pain scores at rest and activity, morphine consumption in 72 hours, side effects (sedation,
24 nausea and vomiting...) and satisfaction of women were recorded. The time to first analgesic request in
25 TAP block: 817 ± 311 minute ($13,6 \pm 5,2$ hours). There was reduction of VAS (visual analog scale)
26 scores after surgery in TAP block group. The total morphine consumption was reduced more than 62%
27 in Group TAPB (16,03 mg) compared with Group Control (41,65 mg). The incidence of PONV
28 (postoperative nausea and vomiting) (5%) and sedation (3,33%) was reduced in patients undergoing
29 TAP blockade. The patient satisfaction with regard to pain relief was more in Group TAPB (95% vs
30 65%). There were no complications attributable to the TAP block. Ultrasound - guided TAP block
31 provided a better analgesic effect after caesarean section, reduced the morphine consumption in 72
32 hours and reduced the side effects compared to the control group.
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34 **Key words:** TAP block, Caesarean delivery, general anaesthesia, morphine consumption, ultrasound
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37 INTRODUCTION

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39 Caesarean section is a major surgical procedure with substantial post-operative
40 pain. Good control of pain following surgery is essential to facilitate early
41 mobilization and to enable adequate care of the newborn. Achieving good pain relief is
42 challenging because of the altered physiology and of the possibility of transmission of
43 drugs through breastmilk.

44 Spinal morphine is most commonly used in postoperative analgesia because it is
45 simple and has a good analgesic effect. However, this method can not be used for
46 patients under general anesthesia for caesarean section such as: placenta previa,
47 ablatio placentae and so on.

48 Transverse Abdominis Plane Block (TAP block) is an amount of local
49 anesthetic applied to the plane between the abdominal and transverse abdominal
50 muscles, where the spinal nerve fibers pass (Charlton et al., 2010). This is a classic
51 method of regional anesthesia and since the introduction of ultrasound, it has been
52 increasingly and widely used in postoperative analgesia in general and caesarean
53 section in particular (Jankovic, 2009). Ultrasound-guided needle placement and
54 infiltration offers improved safety and reliability of anesthetic delivery. TAP block
55 reduces pain, prolongs the duration of analgesia and decreases supplemental opioid
56 consumption when used for multimodal analgesia for pain relief after caesarean
57 section (Jadon et al., 2018).

58 There are 11 published meta-analyses around the effects of TAP block. Only
59 four of them are about analgesia after caesarean section. For example, Mishriky et al.
60 (2012) published a meta-analysis, looking at analgesia after caesarean section. Nine
61 studies were included. They found that TAP block significantly reduced opioid
62 consumption (mg morphine equivalents) after caesarean section. A meta-analysis by
63 Baeriswyl et al. (2015) of 1611 patients receiving TAP block for laparoscopy,
64 laparotomy and Caesarean section showed a reduction in IV (Intravenous) morphine
65 consumption as well as reduced pain scores at rest and movement at 6 hours
66 after surgery.

67 But there is nothing about patients under general anesthesia. Therefore, we
68 conducted a study aimed at: Evaluation of analgesic efficacy and undesirable effects
69 of TAP block under the guidance of ultrasound in pregnant women who had general
70 anesthesia for caesarean section.
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72 MATERIALS AND METHODS

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74 Subject

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76 Selection criteria. Patients aged 18-50 years, ASA I, II and III. Patients after
77 caesarean section with Pfannenstiel (Horizontal incision on pubic bone) are subjected
78 to endotracheal anesthesia.

79 Exclusion criteria. Patients after caesarean section along the incision along the
80 middle white line. Contraindications to ropivacaine, coagulopathy, puncture site
81 infections, disagree with participating in the study.

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Study design

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It's prospective research, which takes a group of subjects, and monitors the group for outcomes. And it's randomized controlled study, where the subjects were randomly allocated into treatment and control groups using a computer-generated sequence of random numbers. The group sequence was concealed in opaque envelopes which were opened only after obtaining informed consent. The injectate syringes were prepared by an anaesthesiologist not involved in the study. The anaesthesiologists, the subjects and the post-operative care providers were blinded to the group assignment.

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Location, time of research: Anesthesiology Department - Hanoi Obstetrics and Gynecology Hospital. The period is from August 2018 to June 2019.

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Sample size: 120 patients divided into 2 equal groups.

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Sampling: Grouping by random drawing.

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Group 1 (Control group): The patient was not anesthetized at transverse abdominal plane (TAP block).

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Group 2 (TAPB group): The patient was relieved of postoperative pain by using a transverse abdominal muscle plane (TAP block) under the guidance of ultrasound.

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Procedure: Patients in both groups received general anesthesia for caesarean section. Immediately after the closure of the abdomen, the patient will be randomly assigned to two study groups (the group must not undergo TAP block anesthesia and the group will be under anesthetic TAP block). TAPB group was anesthetized with TAP block under ultrasound guidance with 0.3ml / kg Ropivacaine 0.25% + Dexamethasone 4mg + Adrenalin 5mcg / ml. Both groups were then fitted with intravenous morphine PCA (principal component analysis) with self-control patients.

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Evaluation criteria: Patient-related characteristics, anesthesia process and surgery. Success rate, amount and volume of anesthetic TAP block. The level of postoperative analgesia is based on a VAS scale evaluated in a state of rest (Figure 1) and when the patient is active (Figure 2). The morphine consumed in first 72 hours after surgery (Figure 3). The total morphine intake after surgery was also calculated (Figure 4). Satisfaction evaluation (Dissatisfied: Severe pain and / or undesirable effects; Satisfaction: Mild pain or unwanted but transient effects; Very satisfied: No or minor pain, comfortable and pleasant). Assessment of unwanted effects included nausea and vomiting, itching, urinary retention, sedative (Figure 5).

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Time of assessment: After extubation, after surgery 1 hour (H1), 2 hours (H2), 3 hours (H3), 6 hours (H6), 9 hours (H9), 12 hours (H12), 18 hours (H18), 24h (H24), 36h (H36), 48h (H48), 60h (H60), 72h (H72).

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Data processing

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Research data were analyzed and processed according to SPSS 20.0 software. Quantitative variables are described as mean (X) and standard deviation (SD). Qualitative variables are described as percentages (%). To compare the differences between ratios (qualitative variables), use the test when squared (χ^2). Comparing the difference between means (quantitative variables): using T - Student test when comparing 2 groups. The difference is considered to be statistically significant when p

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128 <0.05.

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130 **Research ethics**

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132 The study was in accordance with the ethical standards of the responsible
133 committee on human experimentation: the procedures were approved by the scientific
134 council of Hanoi Medical University in accordance with Decision No. 3012 / QD -
135 DHYHN on July 13, 2018 and allowed to be conducted in the Department of
136 Anesthesiology and Recovery at Hanoi Obstetrics and Gynecology Hospital.
137 Moreover, research is in accordance with the Helsinki Declaration of 1975, as revised
138 in 2000.

139 Each woman signed a voluntary informed consent to participate in the study and
140 to publish its results. Participants could refuse to take a part in the study any time.

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142 **RESULTS**

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144 **General characteristics of the patient**

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146 Table 1. Characteristics of studied patients

Index	Group	Control Group (n1)	TAPB group (n2)	p
Age (years)	$\bar{X} \pm SD$	30,48 ± 5,3	31,87 ± 5,9	>0.05
Height (cm)	$\bar{X} \pm SD$	156,1 ± 4,29	155,2 ± 4,57	>0.05
Weight (kg)	$\bar{X} \pm SD$	64,15 ± 4,58	63,03 ± 4,78	>0.05
BMI (kg / m2)	$\bar{X} \pm SD$	26,36 ± 2,0	26,21 ± 2,12	>0.05
Gestational age (Week)	$\bar{X} \pm SD$	38,05 ± 1,80	37,83 ± 1,66	>0.05
Surgical time (Minutes)	$\bar{X} \pm SD$	31,45 ± 7,32	30,93 ± 7,02	>0.05
Anesthesia time (minutes)	$\bar{X} \pm SD$	54,12 ± 8,2	53,70 ± 7,01	>0.05

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148 **Pain relief effect**

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TAP block anesthesia technique: 100% success rate, the average time to perform bilateral anal anesthesia technique is 8.10 ± 1.56 minutes. The average amount of ropivacaine anesthetic used was 93.8 ± 5.8 mg with 1-sided anesthetic volume of 18.7 ± 1.16 ml.

Time required for the first TAPB painkillers: 817 ± 311 minutes (13.6 ± 5.2 hours), the shortest time is 360 minutes and the longest time is 1620 minutes.

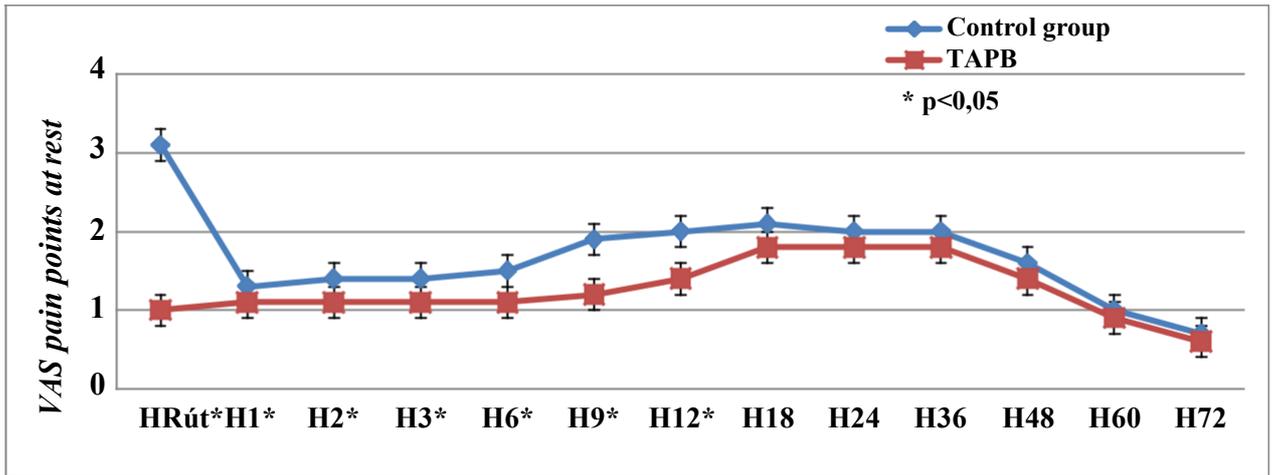


Figure 1. VAS pain points at rest

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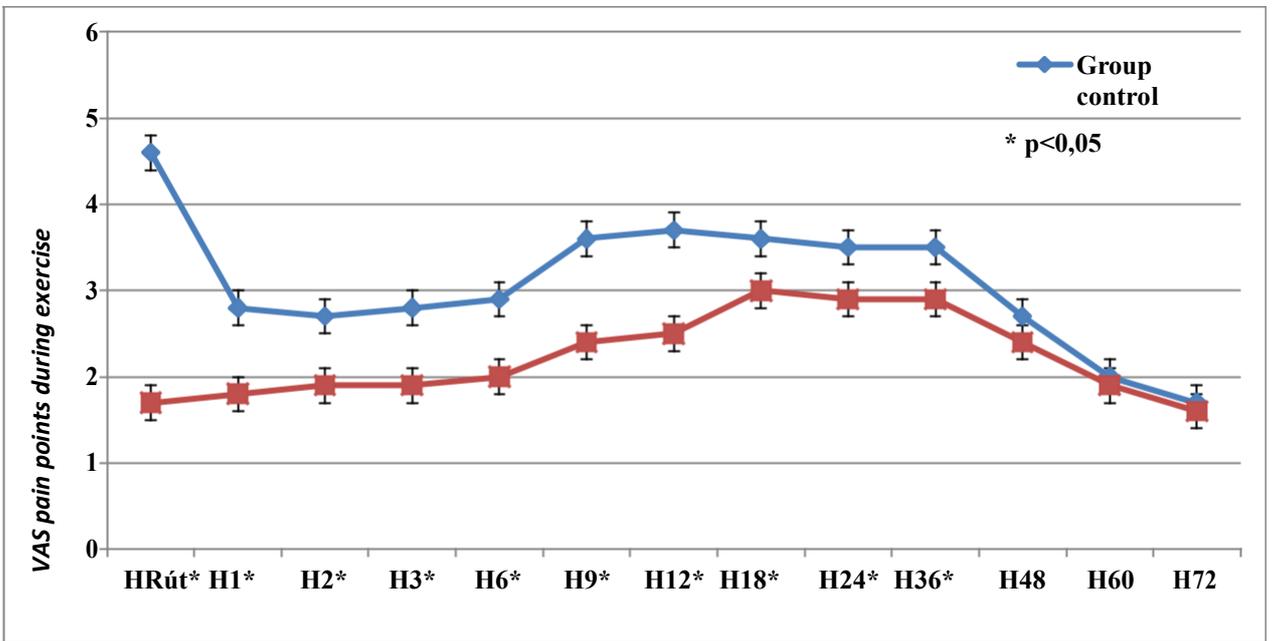


Figure 2. VAS pain points during exercise

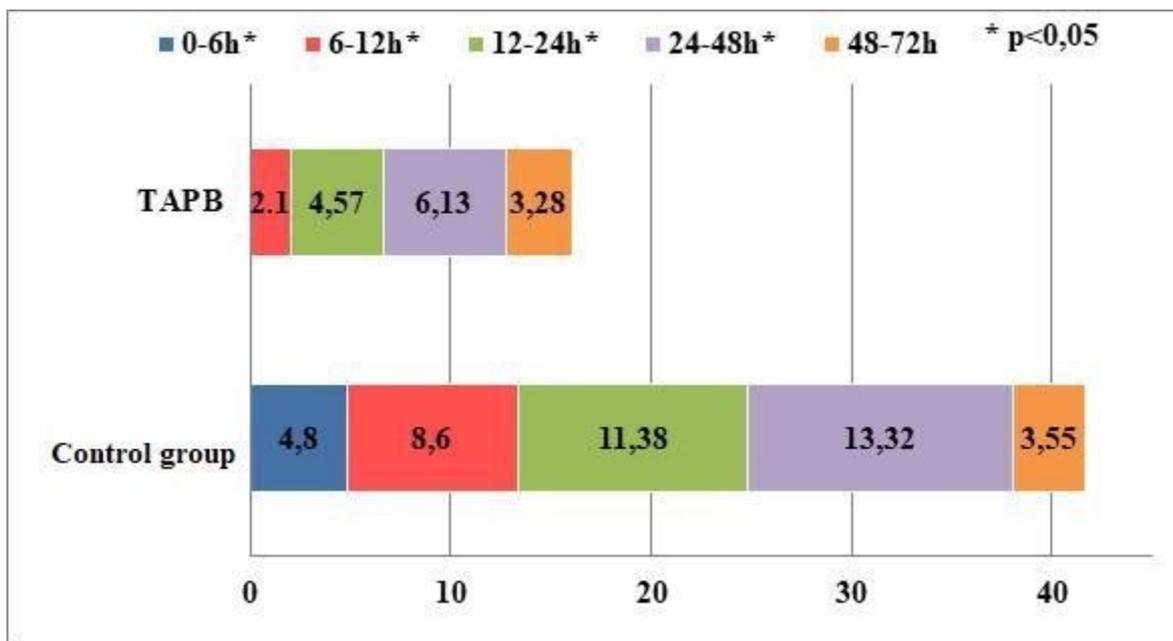


Figure 3. Morphine consumption over time

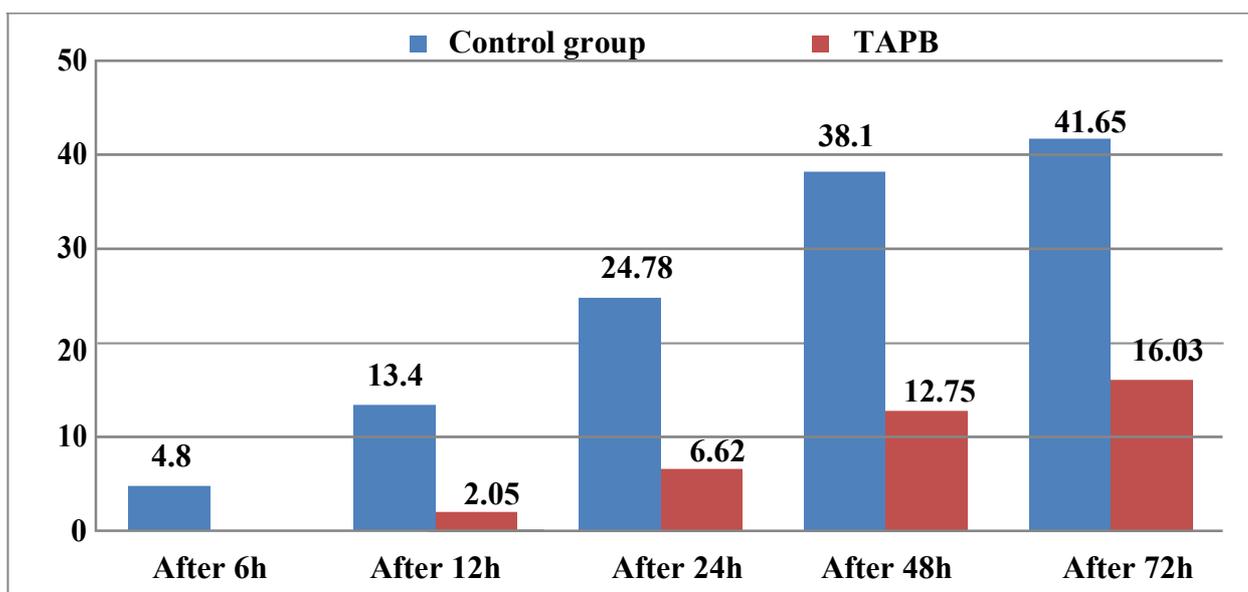


Figure 4. Cumulative morphine consumption after surgery

Satisfaction level: the percentage of Delighted and Satisfied in the TAPB group was 95% and 5%, while the control group had 35% of patients Satisfied and Delighted rate was 65%, this difference is significant. Statistical significance with $p < 0.05$.

Unwanted effects

Related complications of TAP block anesthesia. There is no case of anesthesia poisoning or damage to abdominal organs such as peritoneal injection, liver bleeding, intestinal injury or transient femoral nerve numbness.

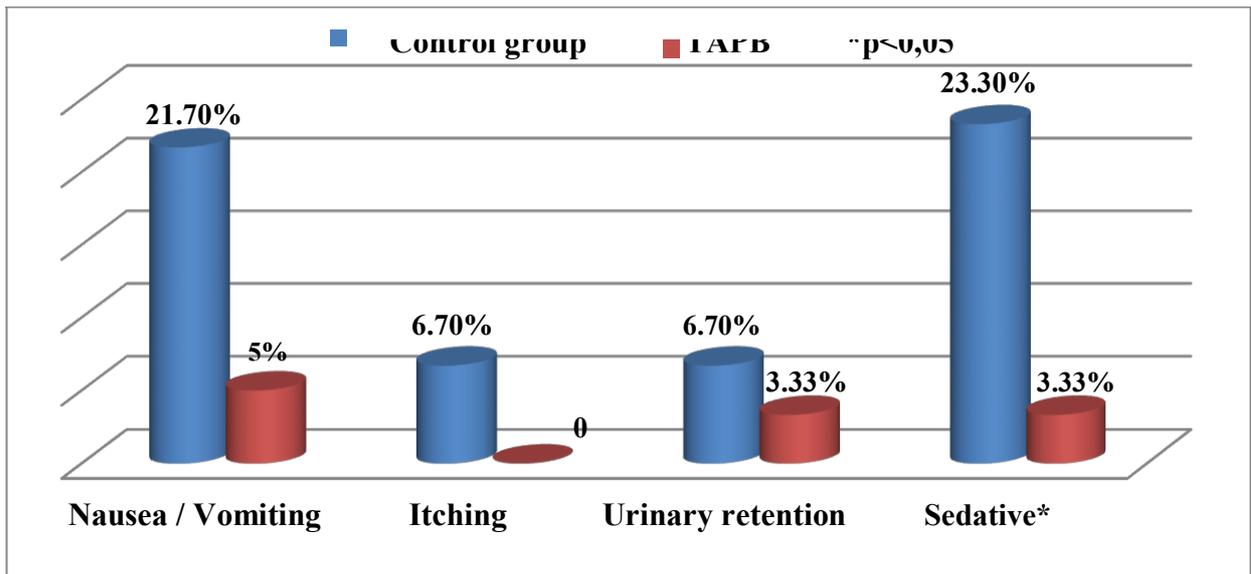


Figure 5. The rate of unwanted effects

DISCUSSION

Patient characteristics

The patients in our study are of reproductive age from 22 to 45 years old, the solid and obstetric indicators are similar. The factors related to anesthesia and surgery are similar, $p > 0.05$.

Analgesic effect

TAP block anesthesia technique. 100% success rate, the average time to perform bilateral anal anesthesia technique is 8.10 ± 1.56 minutes. This result is similar to the research results of Kiran (8.67 minutes) (Kiran et al., 2017). The average amount of ropivacaine anesthetic used was 93.8 ± 5.8 mg with 1-sided anesthetic volume of 18.7

± 1.16 ml. The dose of anesthetic we used was 1.5 mg / kg in accordance with the condition of the pregnant woman, not exceeding the toxic threshold of the recommended ropivacaine anesthetic 100mg (Ng et al., 2018).

Time required for the first TAPB painkillers: 817 ± 311 minutes (13.6 ± 5.2 hours), the shortest time is 360 minutes and the longest time is 1620 minutes. This result is similar to Deshpande (13.2 ± 7.6 hours) (Deshpande et al., 2017). The addition of anesthetics Dexamethasone and adrenalin increased analgesic effect, lasting over 2.98 hours to 3.08 hours (Zhang et al., 2019; Chen et al., 2018). The analgesic effect of dexamethasone is due to many mechanisms: possibly due to its anti-inflammatory and immunosuppressive effects, the direct mechanism of neurotransmitters that induces pain sensation and prolongs the depolarization phase of nerve cells, Local vasoconstriction reduces the rate of absorption of anesthetic agents, increases the inhibitory activity of potassium channels on C fibers.

Pain points of VAS. VAS at both groups were < 4 at times, VAS at TAPB was

252 always smaller than the control group at the same time in 12 hours after surgery, this
253 difference was statistically significant with $p < 0,05$. This proves that anesthesia in the
254 abdominal plane under the guidance of ultrasound has good postoperative analgesia
255 effect. In 36 hours after surgery, we found that the VAS score in TAPB group was
256 significantly smaller than the control group at the same time, $p < 0.05$. This result is
257 also consistent with Abdallah et al. (2012), showing that the effect of TAP block was
258 effective up to 36 hours after surgery with the VAS score in the TAP block was 1.29
259 points lower than the control group (95% CI - 3.74 to - 1.16, $p = 0.01$).

260 Morphine consumption after surgery. In the first 48 hours after surgery, the
261 amount of morphine consumed at the time of the study in the TAPB group was
262 significantly less than the control group, this difference was statistically significant
263 with $p < 0.05$. Especially at the first 6 hours after surgery in the TAPB group, no case
264 had to use morphine. However, at the time of 48 - 72 hours after surgery, the
265 morphine consumption of the two groups is similar. The total amount of morphine
266 consumed 72 hours after surgery of the TAPB group was 16.03 mg, a decrease of 62%
267 compared to the control group (41.65 mg). This result is similar to that of Baajet al.
268 (2010) (down 60%), Jankovic (2009) (down 70%), McDonnell et al. (2007)
269 (down 72%).

270 Satisfaction level. The level of satisfaction depends on the pain relief effect as
271 well as the unwanted effects. TAP block anesthesia with the rate of patients with
272 satisfaction level of satisfaction is 100% (delighted 95% and satisfied 65%). No
273 patient requested to stop analgesia after surgery. Meanwhile, the control group had
274 35% of patients Satisfied and Delighted rate was 65%, and the difference between the
275 two groups was statistically significant with $p < 0.05$. This result is similar to Fusco et
276 al. (2016). In the TAP block group, the rate of patients was delighted 95.8% and
277 satisfied was 4.2%, while the control group had the delighted rate of 62.5% and
278 satisfaction was 37.5%.

280 **Undesirable effects**

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282 Our research results showed that the rate of nausea and vomiting in 72 hours of
283 PCA morphine after surgery in the control group was 21.7%, much higher than the
284 TAPB group of 5%. This difference is significant with $p < 0.05$. This result is similar
285 to the study of Belavy et al. (2009) with the rate of nausea and vomiting in the control
286 group was 20.8% and the group anesthetized TAP block was 4.3%. Sivapurapuet al.
287 (2013) with a proportion of PONV of TAP block accounted for 4% significantly lower
288 than that of control group 23%. In our study, there were 2 sedation cases in the TAPB
289 group (3.33%), while in the control group we had 14 cases (23.3%) of the sedative
290 patients. Thus, the TAPB group reduced 20% of patients with sedation compared to
291 the control group, this difference was significant with $p < 0.05$. All patients with
292 sedation in 2 groups are at level 1, sometimes drowsiness and easy to wake up
293 verbally. We did not encounter any case of deep sedative patients difficult to awaken,
294 to support breathing or to handle naloxon. Our results are similar to those of Khasayet
295 al. (2017). TAP block group reduced 23% of patients with sedation. The rate of
296 pruritus and urinary retention of 2 groups did not differ. Anesthesia under the
297 guidance of ultrasound ensures the accuracy and safety, in our study there were no

298 complications related to TAP block anesthesia.

299 **CONCLUSION**

301
302 TAP block under the guidance of ultrasound has a better analgesic effect after
303 caesarean section, reducing total morphine consumption in 72 hours and reducing
304 unwanted effects compared to the non-group be anesthetized. TAP block is a
305 comfortable and feasible method which reduces post-operative analgesia need and
306 does not lead any serious complications.

307 There are many options for developing this topic. For example, researchers have
308 studied the effect of the TAP block in healthy volunteers, but there are prospects for
309 using this method in obstetric or gynecological pathology (Jakobsson et al., 2015).

310 However, the risk of local anaesthetic systemic toxicity remains unknown with
311 this block. There is a need to develop new and well-designed randomized clinical
312 trials, with enough statistical power to compare different approaches, drugs, doses, and
313 volumes for the same intervention, aiming to answer the current questions and assess
314 the effect of TAP-block effects in routine clinicalpractice.

315 In the near future, we hope to see studies that better define the clinical
316 characteristics of blocks and studies that compare the TAP block to local anesthetic
317 infiltration and epidural technique for postoperative pain management (Ortiz and
318 Wofford, 2016).

319 Role of ultrasound guided transversus abdominis plane block as a component
320 of multimodal analgesic regimen for lower segment caesarean section: arandomized
321 double blind clinicalstudy.

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323 of multimodal analgesic regimen for lower segment caesarean section: arandomized
324 double blind clinicalstudy.

325 **ACKNOWLEDGEMENT**

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329 financial support.

330 **CONFLICTS OF INTEREST**

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332
333 The authors declare no conflict of interest.

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