

1. Result

One hundred twenty patients were screened for this prospective, randomized, controlled study. Of these, One hundred and fourteen patients were recruited and randomly assigned and received interventions (Fig. 1). Among them, three patients were excluded after randomization due to refusal for participation and three not meeting inclusion criteria. After allocation four patients were changed to general anesthesia, while two cases were discharged from the hospital during follow-up. In total, One hundred and eight patients completed this study. Sociodemographic and baseline clinical variable comparison results indicated that no significant differences were detected between groups in age, body mass index, the duration of surgery, and anesthesia except height and gestational age (Table 1).

Table 1: Sociodemographic characteristics of patients who underwent elective cesarean section in HUCSH, Ethiopia July 01, 2019, to July 2020

The perioperative hemodynamics status and variables related to anesthetic and surgical interventions

There was no statistically significant difference regarding the perioperative hemodynamic status like SBP, DBP, SPO₂, RR, and level of motor and sensory block duration of surgery between the groups with a p-value of $>.05$ as shown in (table 2&3).

Table 2: perioperative variables related to anesthetic and surgical interventions who underwent elective caesarian section at Hawassa University Comprehensive Specialized Hospital, Hawassa, Ethiopia from July 01, 2019, to July 2020.

5.1 Time to first analgesic request

Time to first analgesic request was significantly shorter in TAP with a median (IQR) of 240 (180-390) minute vs 360 (270-480) minute in SM (figure 2). The cumulative proportion of patients requesting analgesia at a time of 4h after surgery in the spinal morphine group was 20% compared to 62% in TAP group. Particularly the patient in the SM Group, median time: 360min, 95% CI: [332- 387] had significantly longer time to first analgesic request compared to TAP group median time: 240min 95% CI: [217 - 262] ($p=0.004$).

Fig 2: Kaplan–Meier curve depicting of the proportion of patients in each group over time who require supplemental analgesic ($P 0.004$, log-rank test). Spinal morphine; TAP transversus abdominis plane

5.2 Postoperative pain intensity

A Mann-Whitney U test was used to determine if there were differences in postoperative pain severity scores at different points between spinal morphine and transverse abdominus plane block. Postoperative pain intensity scores at different points of time between spinal morphine and transverse abdominus plane block were significantly different, as assessed by numerical pain rating scale.

Reported median (IQR) NRS pain score postoperatively at rest 2 hours 0(0-1) in Spinal morphine group and 2(1-2) in TAP group ($p < 0.001$). Similarly, in the 6 hours, 12 hours and 24 hours postoperatively, median (IQR) NRS score was 1 (0-1) vs 3(2-4) ($p < 0.001$), 2 (1-3) vs 4(3-4) ($p < 0.001$), and 3 (3-3) vs 4(3-4) ($p < 0.001$) in the spinal morphine (SM) and TAP groups, respectively.

Fig 3: Postoperative pain scores at rest at a different time point during 24 hours assessment period. SM, spinal morphine; TAP, transversus abdominis plane block

Median postoperative NRS score during movement at 2nd hour, 6th hour, 12th hour and 24th hour were 0.5(0-1) vs 2(1-3) ($p < 0.001$), 1(0-1) vs 3(2-4) ($p < 0.001$), 2(2-3) vs 4(3-5) ($p < 0.001$) and 3(3-4) vs 4(3-5) ($p < 0.001$) in the spinal morphine (SM) and TAP groups, respectively.

Fig 4: Postoperative pain scores with movement at a different time point during 24 hours assessment period. SM, spinal morphine; TAP, transversus abdominis plane block

Group and repeated measure Interaction

After adjustment of NRS pain score at rest for repeated measurement, generalized estimating equation model show NRS score was 0.9 unit lower in spinal morphine (SM) group than TAP group during the first 24 hours postoperative period in NRS pain scores at rest ($\beta = -0.9$, 95% Confidence Interval (CI) = -1.3 - -0.5 , Wald's $\chi^2=20.8$, $p < 0.001$).

GEE indicated that there was a statistically significant group and repeated measure Interaction at 6th hours and 12th hours ($\beta = -0.827$, 95% Confidence Interval (CI) = -1.3 - -0.33 , Wald's $\chi^2=10.9$, $p=0.001$ and $\beta = -0.769$, 95% Confidence Interval (CI) = -1.2 - -0.31 , Wald's $\chi^2=11$, $p=0.001$ respectively)

Repeated measure

There were statistically significant effects of repeated measurement in the NRS score at rest 2nd hours ($\beta = -2.4$, 95% CI = -2.78 - -2.01 , Wald's $\chi^2=168$, $p < 0.001$ 6th hours postoperatively ($\beta = -1.3$, 95% CI = -1.7 , -0.9 , Wald's $\chi^2=41.7$, $p < 0.001$) in the GEE model.

Fig 5: Change in postoperative numeric rating (NRS) pain score at rest during 24 hours postoperative period.

Intervention group and repeated measurement Interaction

After adjustment of NRS pain score during movement for repeated measurement, generalized estimating equation model show NRS score was 0.74 unit lower in spinal morphine (SM) group than TAP group during the first 24 hours postoperative period ($\beta = -0.74$, 95% Confidence Interval (CI) = -1.13 - -0.34 , Wald's $\chi^2=13.2$, $p<0.001$).

The GEE model indicated that there were a statistically significant intervention group and repeated measurement interaction during movement NRS pain score at 2nd hours ($\beta = -0.88$, 95% CI = -1.3 - -0.42 , Wald's $\chi^2=14.06$, $p<0.001$), 6th hours ($\beta = -1.42$, 95% CI = -1.9 - -0.9 , Wald's $\chi^2=33.00$, $p<0.001$), and 12th hours ($\beta = -1.19$, 95% CI = -1.63 - -0.75 , Wald's $\chi^2=28.08$, $p<0.001$).

Repeated measurement

There were statistically significant effects of repeated measurement on pain intensity (NRS) during movement at 2nd hours ($\beta = -1.8$, 95% CI = -2.2 - -1.4 , Wald's $\chi^2=79.10$, $p<0.001$) and 6th hours postoperatively ($\beta = -0.75$, 95% CI = -1.14 - -0.35 , Wald's $\chi^2=13.8$, $p<0.001$).

Fig 6: Change in postoperative numeric rating (NRS) pain score on movement during 24 hours postoperative period.

5.3 Postoperative analgesic consumption

In the immediate postoperative period (2 hours), median tramadol consumption was $0 \pm (0)$ mg in Spinal morphine group and $12.5 \pm (21.8)$ mg in TAP group ($p < 0.001$). Similarly, in the 6 hours, 12 hours and 24 hours postoperatively, median tramadol consumption was $8.9 \pm (23.5)$ mg vs $50.9 \pm (40.2)$ mg ($p < 0.001$), $56.2 \pm (36.2)$ mg vs $99.5 \pm (40.9)$ mg ($p < 0.001$), and $71.8 \pm (37.2)$ vs $124.5 \pm (55.8)$ mg ($p < 0.001$) in the spinal morphine (SM) and TAP groups, respectively.

Fig 7: Postoperative cumulative tramadol consumption during the first 24 hours postoperatively

Morphine equivalent consumption

Twenty four hour median morphine consumption was reduced in spinal morphine group 0 (0-4) mg compared to TAP block group 4 (0-6) mg ($p < 0.001$).

Fig 8: Total 24 hours morphine equivalent analgesic consumption

Adequacy of analgesia

At rest, 62.6% of patients in the spinal morphine group reported pain scores ≤ 3 compared with 37.4% in the TAP group. Spinal morphine group was significantly associated with adequate analgesia at rest (pain scores ≤ 3) compared to TAP group (OR: 1.96, 95% CI: 1.34-2.57, 0.001).

Fig 9: Proportion of patients achieving adequate analgesia at rest during 24 postoperative hours. SM, spinal morphine; TAP, transversus abdominis plane block

With movement, 65.8% of patients in the Spinal morphine group had pain scores ≤ 3 as opposed to 34.2% in the TAP group. Spinal morphine group was significantly associated with adequate analgesia during movement (pain scores ≤ 3) compared to TAP group (OR: 1.70, 95% CI: 1.14-2.25, $P < 0.001$).

Fig 10: Proportion of patients achieving adequate analgesia on movement during 24 postoperative hours. SM, spinal morphine; TAP, transversus abdominis plane block

5.4 Postoperative complication and patient satisfaction

Side effects are reported in table (6). None of the patients in the study develop respiratory depression. Two patients from the spinal morphine group were lightly sedated and one patient had also moderate purities but didn't require treatment. The majority of the mothers rated their satisfaction more highly satisfied in spinal morphine than the TAP group. There is a statistically

significant difference regarding their postoperative satisfaction among the two groups. There was no statically significant difference in sedation, nausea, purities scores between two groups.

Table 4: postoperative complication and satisfaction of parturients underwent elective caesarian section at Hawassa University Comprehensive Specialized Hospital, Hawassa, Ethiopia from July 01, 2019, to July 2020

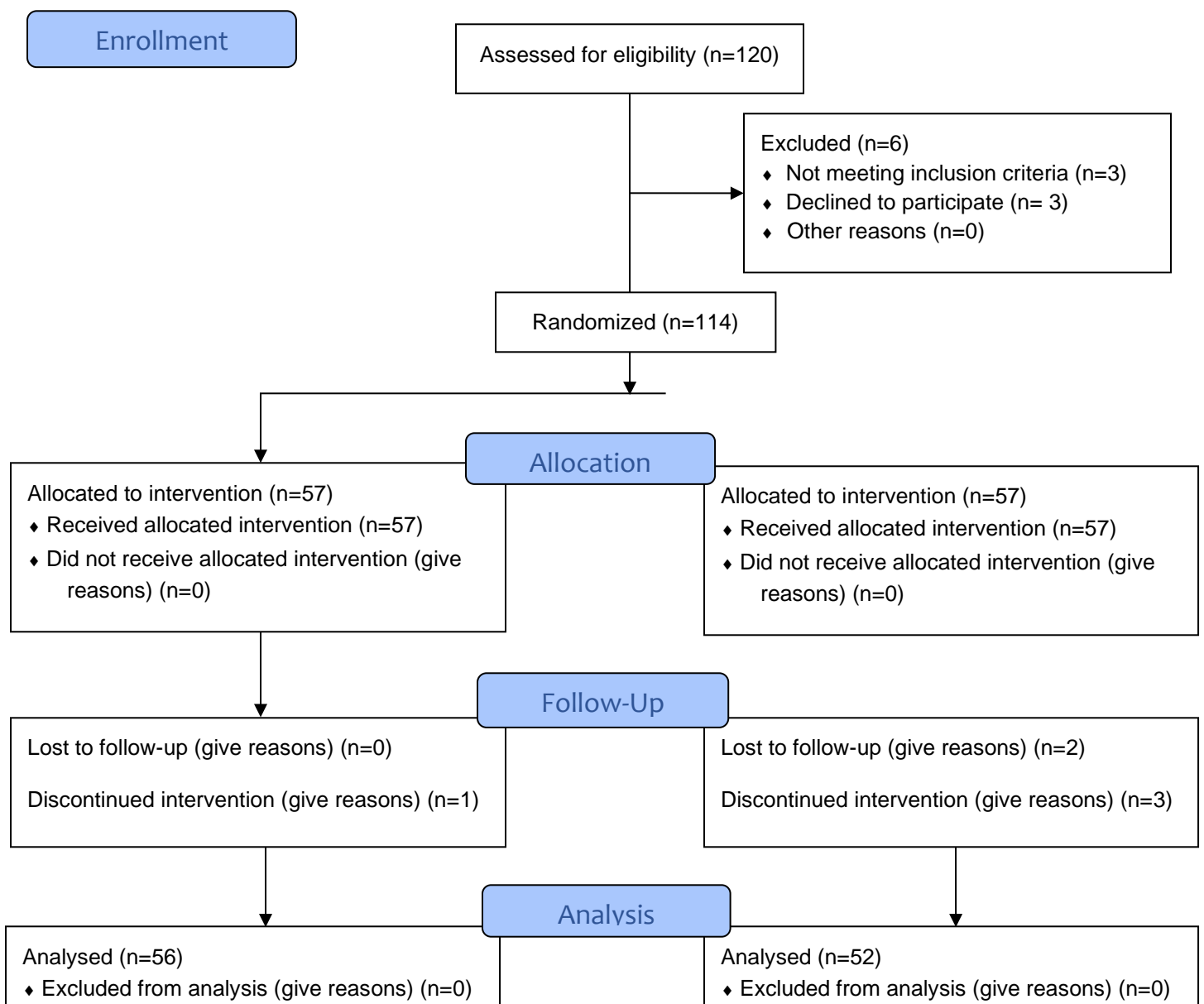


Figure 1: Consort flow diagram of patient enrolment

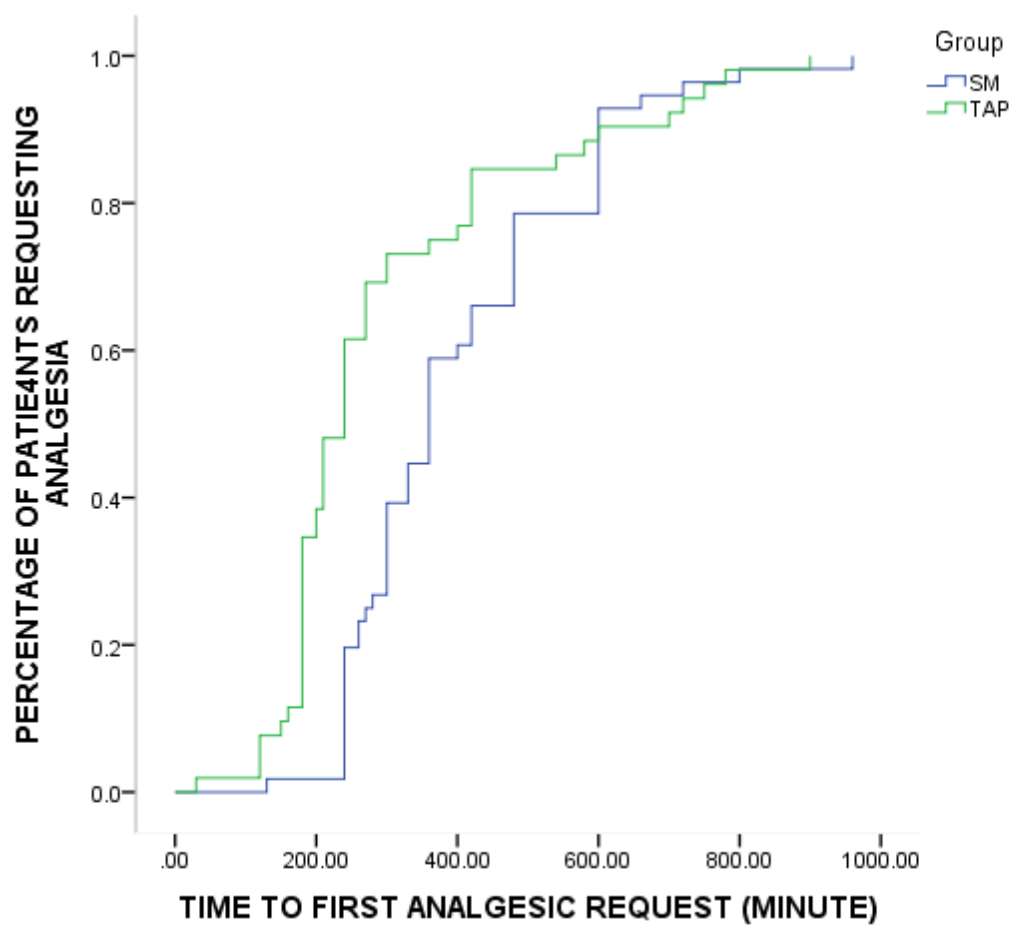
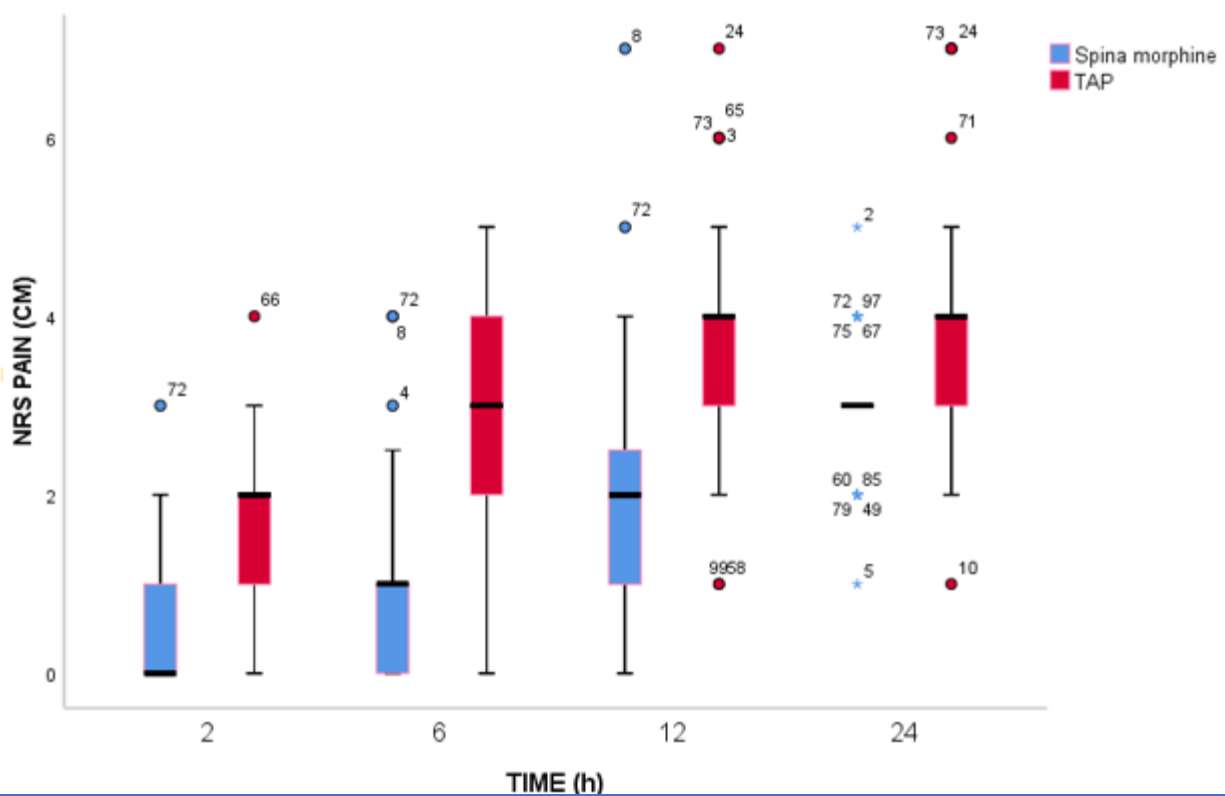


Fig 2: Kaplan–Meier curve depicting of the proportion of patients in each group over time who require supplemental analgesic (P 0.004, log-rank test). Spinal morphine; TAP transversus abdominis plane

A



B

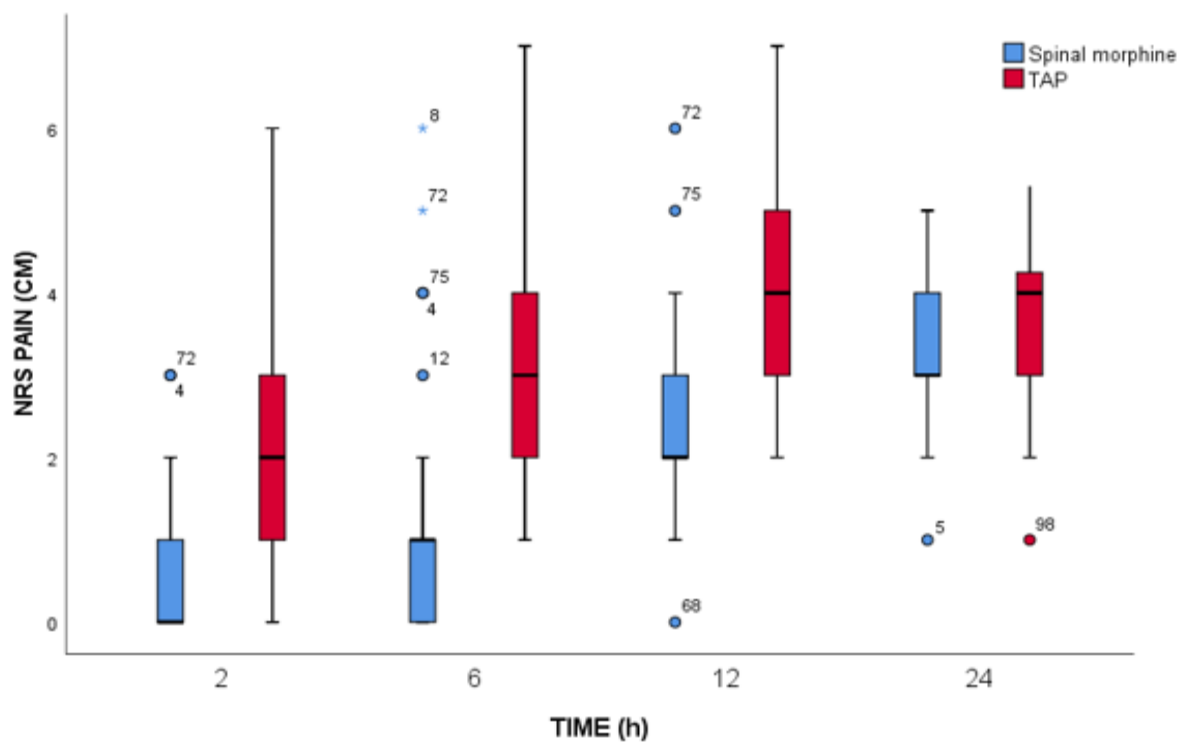


Fig 3: Postoperative pain scores at rest at a different time point during 24 hours assessment period. SM, spinal morphine; TAP, transversus abdominis plane block

Fig 4: Postoperative pain scores with movement at a different time point during 24 hours assessment period. SM, spinal morphine; TAP, transversus abdominis plane block

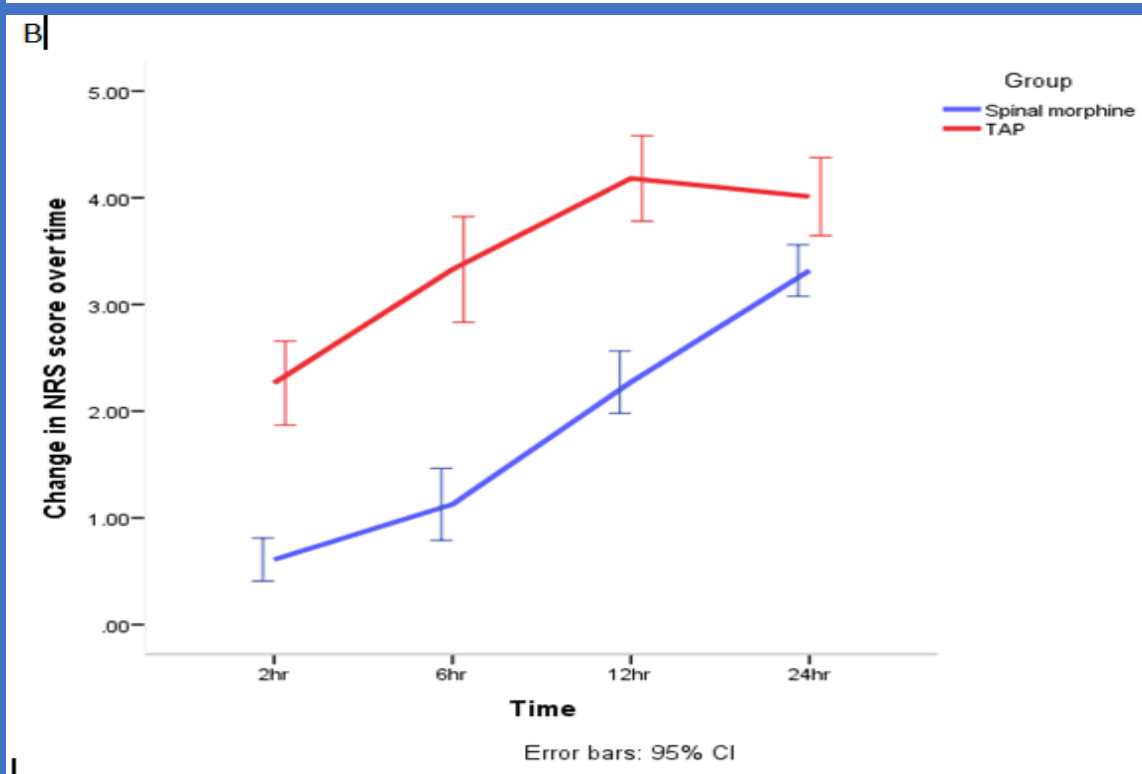
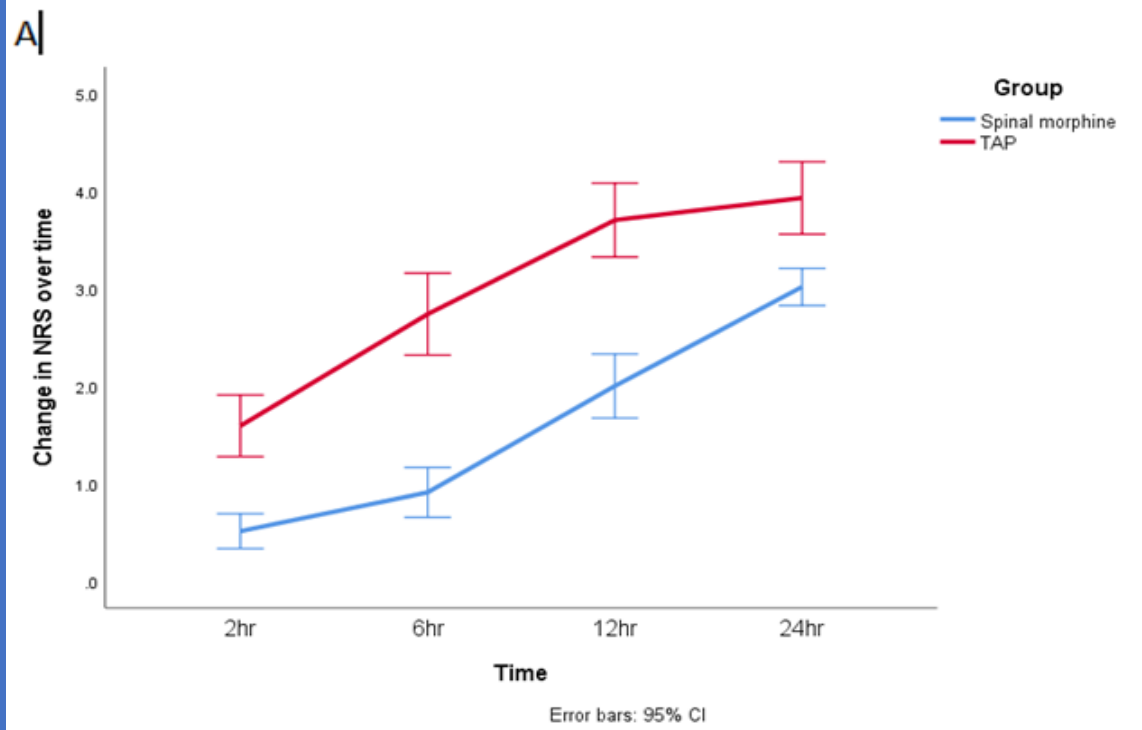


Fig 5: Change in postoperative numeric rating (NRS) pain score at rest during 24 hours postoperative period.

Fig 6: Change in postoperative numeric rating (NRS) pain score on movement during 24 hours postoperative period.

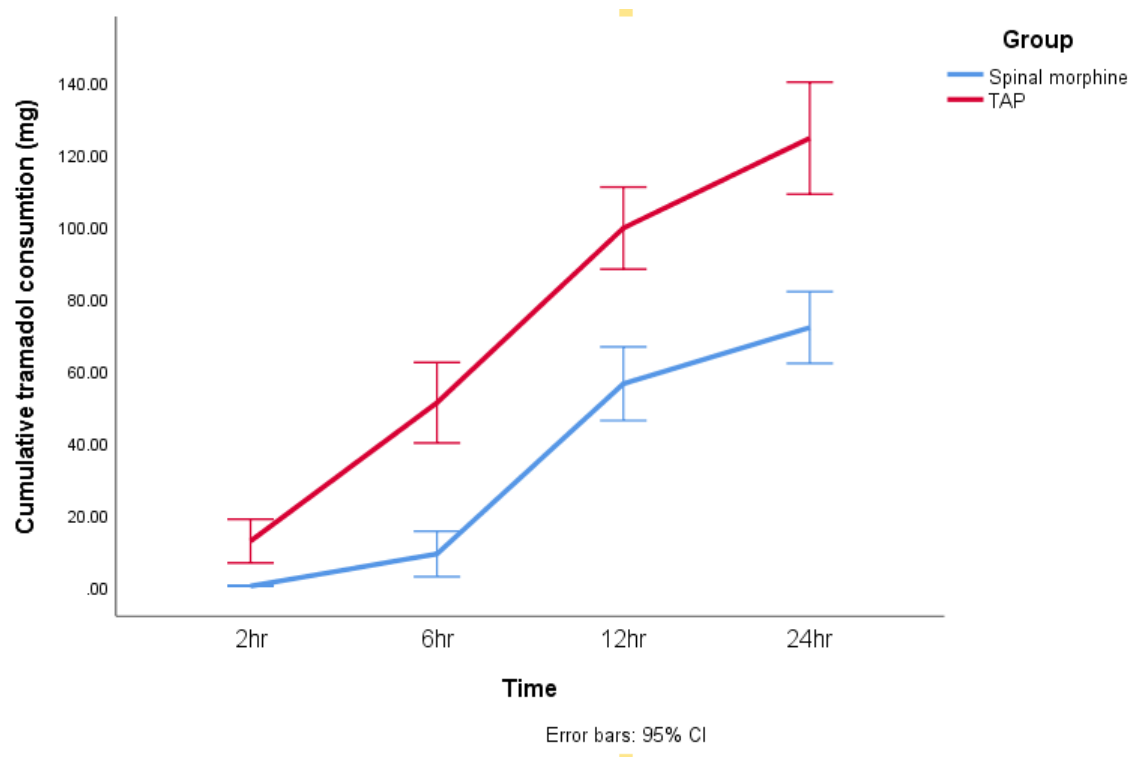


Fig 7: Postoperative cumulative tramadol consumption during the first 24 hours postoperatively

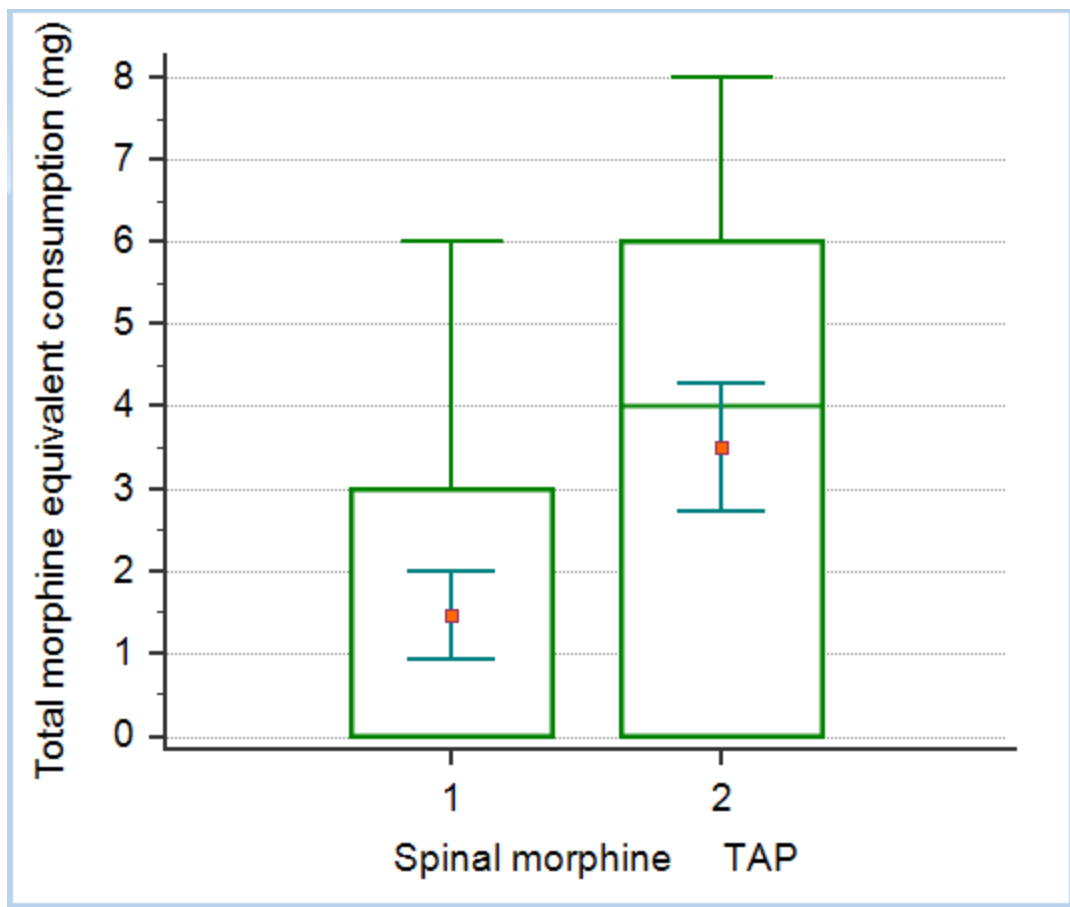


Fig 8: Total 24 hours morphine equivalent analgesic consumption

