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Adolescent Idiopathic Scoliosis: Does a Multimodal Pain Protocol Make any Difference?

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Research Article

Keywords: spine surgery, pain, pediatric and analgesia

Posted Date: June 18th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9566479/v1

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Additional Declarations: No competing interests reported.

Abstract

Purpose

We aimed to compare two groups of AIS patients undergoing PSF: the first, a control group without analgesia (MMA) protocol (G1 non-MMA), and the second, a group managed with a MMA (G2-MMA).

Methods

We assessed 203 AIS patients undergoing PSF with prospectively collected data. G1 non-MMA (151 patients), received POP analgesia based on opioids and acetaminophen and G2 MMA (52 patients), received a perioperative and post-discharge MMA protocol including opioids, acetaminophen, ibuprofen, gabapentin, ketamine, dexmedetomidine, dexamethasone, diazepam, and ondansetron. Pain was assessed using the pain Numerical Rating Scale (NRS). Statistical analysis was performed using the Chi-square test, Fisher's exact test, and the Mann–Whitney test, with $p < 0.05$ considered statistically significant.

Results

Between G1 and G2, there were no statistically significant differences in: sex, age at surgery, ASA scale, instrumented levels, duration of surgery, and pre-OP NRS score. Significant differences were found in: POP NRS score, POD1 (POP day 1) 6.1 vs. 2.1, POD2 5.4 vs. 2, POD3 5.7 vs. 1.4, POD4 4.3 vs. 1), time to first ambulation, POP nausea/vomiting, time to solid diet, drain removal, bladder catheter removal, transition from intravenous to oral analgesia, and hospital length of stay (LOS) (5.1 vs. 3.1 days).

Conclusion

A peri-operative MMA protocol in AIS patients undergoing PSF may result in significant pain relief, improve bladder catheter and drainage removal time, time to solid diet, time to ambulation, and shorten LOS without increasing complications, and potentially lower costs for the healthcare system. Implementing a simple, detailed, and reproducible peri-operative MMA protocol should be a priority in PSF in AIS.

Introduction

Adolescent idiopathic scoliosis (AIS) is a common condition in early adolescence that may require corrective surgery, such as posterior spinal fusion (PSF), one of the most invasive orthopedic procedures performed in the pediatric population. Approximately 80% of patients undergoing spinal surgery report inadequate postoperative (POP) pain management. Poor POP pain control can lead to cardiorespiratory complications, impaired wound healing, and delayed hospital discharge, among other issues. Moderate-

to-severe POP pain may also result in school absences, socioeconomic strain on families, and significant disruptions to daily life, while patients with AIS are typically previously healthy, with no comorbidities or little no pain prior to surgery.(1–6)

Pain is the most significant preoperative concern for patients and their families prior to spinal surgery for AIS, reported by 55% of the population. Fear of potential neurological deficits was cited by 18%, and fear of death by 9%. Notably, poor POP pain management is the most frequently reported memory in long-term follow-up assessments. It is important to recognize that patients with AIS generally enter surgery in good health, without comorbidities, and leave the operating room with a range of new medical needs and dependencies that were previously absent.(3–13)

The effective management of POP pain following spinal surgery remains a significant challenge within the healthcare system. Although the available medical literature is limited, it emphasizes that optimal pain control should begin prior to surgery and relies on the continuous evaluation of the patient, combined with the standardized development of a multimodal analgesic regimen tailored both to the surgical procedure and the patient's comorbidities.(3, 5, 8–15)

Multimodal analgesia (MMA) is a therapeutic strategy based on the combination of different analgesic drugs at low doses with varied administration techniques and dosing regimens that target multiple pain pathways. Its objectives are to reduce the incidence of POP pain, decrease opioid consumption, minimize drug-related adverse effects by using lower doses, shorten hospital stays, and improve functional recovery without increasing the risk of complications or the need for re-interventions. In addition, MMA contributes to the optimization of available healthcare resources.(3, 11, 13, 18, 22–25)

The hypothesis of this study was that pediatric patients undergoing spinal surgery would substantially benefit from a multimodal pharmacological protocol for perioperative pain management, applied both during hospitalization and after discharge. This protocol included detailed specifications regarding the drugs, dosing, and route of administration throughout the perioperative period. The aim of the study was to evaluate and statistically compare two groups of pediatric patients undergoing spine surgery for AIS: a control group managed without a standardized perioperative MMA protocol (G1 non-MMA), and an intervention group managed with a structured MMA pharmacological protocol implemented pre- and post-operatively, both during hospitalization and after discharge (G2-MMA), in order to assess its efficacy.

Materials and methods

We evaluated 203 pediatric patients with AIS who underwent primary PSF involving more than 10 vertebral levels, between the ages of 10 and 18 years, from January 2021 to December 2023. Patients were excluded if they had a history of thoracic or abdominal surgery, medication intolerance or substance abuse lasting more than 3 months, a history of adverse drug reactions, or hepatic or renal insufficiency.

Two patient populations were compared: one group that did not receive a standardized pharmacological protocol during the pre-OP and POP periods (G1 non-MMA), and was managed with an analgesic regimen based on opioids and nonsteroidal anti-inflammatory drugs (NSAIDs) (opioids and acetaminophen), including morphine 0.1 mg/kg/day IV, and morphine 0.04 mg/kg/dose IV (maximum every 4 hours if needed) and acetaminophen 15 mg/kg/dose IV every 6 hours (CI) till discharge; and a second group (G2-MMA) that received a structured MMA protocol covering the perioperative period of spinal surgery. Both groups were treated and evaluated by the same surgical team, using the same preoperative and postoperative procedures. The G2-MMA perioperative pain management protocol, developed through a review of the literature, includes a detailed treatment scheme specifying drug, dose, route of administration, and timing, covering the days prior to hospitalization, the in-hospital period, and the post-discharge phase. Table 1.

The prospectively recorded and retrospectively evaluated variables covered the following aspects for both groups: age and sex, baseline disease, pre-OP and POP scoliosis and kyphosis angular values, number of instrumented levels, American Society of Anesthesiologists (ASA) scale, duration of surgery (hours), preoperative and daily POP pain NRS scores until hospital discharge, incidence of POP nausea and vomiting, time to transition to oral food intake (recorded as hours postoperatively – h/POP), time to removal of surgical site drainage (h/POP), time to active mobilization out of bed with physical therapy (h/POP), time to removal of the bladder catheter (h/POP), time to transition from intravenous (IV) to oral (PO) analgesia (h/POP), and length of hospital stay (days). Postoperative hours were defined as beginning at the exact time the patient left the operating room and entered the POP recovery unit ("time zero").

The pain Numerical Rating Scale (NRS) (where 0 indicates no pain and 10 indicates the worst pain ever experienced) was assessed once daily during the first hour of the morning (60 minutes after analgesia administration) until hospital discharge. POP evaluation in both groups consisted of daily clinical and imaging assessments performed by the Departments of Spine Surgery and Internal Medicine during hospitalization, followed by periodic remote evaluations after discharge conducted by the surgical team.

The Ethics Committee approved this prospective cohort study and granted the requirement for informed consent under the IRB# 267/24.

Statistical analysis

Results are presented as mean and range for numerical variables and as percentages for categorical variables. To explore differences associated with the use of a pain management protocol, data from G1 non-MMA were compared with those from G2-MMA. To explore differences associated with the use of a pain management protocol, data from the G1 non-MMA group were compared with those from the G2-MMA group. The chi-square test or Fisher’s exact test was used to compare proportions, and the Mann-Whitney test was used to compare numerical variables. In all analyses, a p-value of less than 0.05 was

considered statistically significant. Statistical analysis was performed using Stata version 16.1 (StataCorp, Texas, USA).

Results

In the G1-non-MMA group, which included 152 patients, pharmacological treatment was primarily based on opioids and NSAIDs, without preoperative analgesic intervention and without a regulated analgesic plan at the time of hospital discharge, relying instead on the eventual use of NSAIDs as needed.

In this group we evaluated 128 females (84%) and 24 males (16%) were assessed. The mean age at the time of surgery was 13 years and 8 month (10 years to 16 years and 9 months). The mean angular values (AV) were: pre-OP scoliosis, 72° (3°–103°) and POP scoliosis, 24.3° (1°–48°); pre-OP kyphosis, 41° (3°–60°) and POP kyphosis, 34° (4°–45°). The mean ASA scale was ASA I in 75% of patients and ASA II in 25%. A mean of 10 levels were instrumented per patient (6–14). Pain onset was recorded at a mean of 3.6 hours after surgery (1–12 hours). The mean pain score on the NRS was 2 (3–9) during the preoperative period; 6 (2–9) on postoperative day 1 (POD1); 6 (2–10) on POD2; 5 (1–9) on POD3; 4 (2–6) on POD4; 4 (2–7) on POD5; and 3 (1–6) on POD6. The mean duration of surgery was 4 hours and 5 minutes (2 hours 30 minutes to 4 hours 30 minutes). Overall, 53% of the patients reported nausea and vomiting on POD1. The mean time to transition to a solid diet was 22 hours (10–30 hours). The mean time to removal of the surgical site drainage was 57 hours (18–72 hours). The mean time to first ambulation was 34 hours (12–48 hours), and the mean time to removal of the bladder catheter was 60 hours (12–72 hours). The mean time to transition from IV to oral analgesia was 55 hours (10–96 hours). The mean length of hospital stay was 5.1 days (3–6 days). Complications recorded among G1 non-MMA patients included two cases of superficial wound infection, treated with surgical debridement and local antibiotics, and one case of deep surgical site infection (SSI), managed with irrigation, debridement, and intravenous antibiotics, with a satisfactory response to treatment.

In the G2-MMA group, which included 51 patients, a pre-OP and POP MMA protocol was implemented, with regular analgesic medication prescribed at hospital discharge and periodic remote monitoring. Among the G2-MMA patients, 39 were female (81%) and nine were male (19%). The mean age at the time of surgery was 13 years and 7 month (10 years 2 months to 17 years). The mean pre-OP scoliosis AV was 61.5° (3°–77°), with a mean POP AV of 20.5° (1°–35°). The mean pre-OP kyphosis AV was 41.5° (21°–70°), and the mean POP kyphosis AV was 27.5° (14°–57°). These patients had a mean ASA scale of 1.4 (1–3), with 79% classified as ASA I and 21% as ASA II. An mean of 10.5 levels were instrumented per patient (6–13), and the mean operative time was 3 hours 45 minutes (2 hours 45 minutes to 4 hours 45 minutes). The mean preoperative NRS score was 1.8 (0–6); 2.1 (1–3) on postoperative day 1 (POD1); 2 (1–3) on POD2; 1.3 (0–2) on POD3; and, if still hospitalized for reasons unrelated to pain (in one patient), 1 (1–2) on POD4. The onset of pain was recorded at a mean of 18.5 hours after surgery (6–36 hours), and six patients (13%) reported nausea and vomiting on POD1. The mean time to transition to solid food was 5.3 hours (4–10 hours). Overall, the mean time to ambulation was 20 hours (8–24 hours), the mean time to surgical drainage removal was 32.5 hours (2–48 hours), the mean time to bladder

catheter removal was 22.2 hours (12–48 hours), and the mean time to transition from IV to oral analgesia was 23.5 hours (24–30 hours). The mean length of hospital stay was 3.1 days (2–4 days). One complication was recorded, consisting of a superficial wound infection treated with surgical debridement and local antibiotic therapy. Table 2. Figures 1 and 2.

Discussion

Spine surgery is among the procedures with the highest rates of morbidity and mortality within the pediatric surgical population. These procedures often involve the placement of implants and vertebral osteotomies, decompression, as well as subsequent distraction and derotation of bone, tendons, nerves, muscles, and vascular structures. POP pain is usually severe and requires advanced pharmacological management during the perioperative period. The use of systemic opioids, either as a primary analgesic, is associated with numerous adverse effects. The other group of drugs commonly used in the management of perioperative pain are NSAIDs, for which gastrointestinal, hepatic, neurological, and cardiovascular toxicities, anaphylaxis, and inhibition of platelet aggregation must be considered. The prevention and effective multimodal management of acute pain can improve clinical outcomes and quality of life of both patients and families, while also reducing the risk of complications and lowering costs for families and the healthcare system.(19–25) In our study, the G1 non-MMA group received an analgesia scheme plan based on opioids and NSAIDs, while the G2-MMA group received a perioperative protocol including opioids, NSAIDs, acetaminophen, muscle relaxants, gabapentinoids, glucocorticoids, and adjuvants such as dexmedetomidine (DEX), ketamine, and prokinetics such as ondansetron. The comparison of adverse effects, functional recovery times, pain intensity (measured using the NRS), time to solid food intake, surgical drainage removal, ambulation, bladder catheter removal, and transition to oral medication appeared encouraging in the G2-MMA group compared to the group without a structured plan.

Lee et al., Fletcher et al., and other authors have described the importance of multimodal POP pain management in the pediatric population following PSF for AIS, which is the most common surgical indication. Yoo et al. reported on the use of protocolled MMA for POP pain management in spine surgery, a concept first described by Kehlet and Dahl in 1993. This approach involves the use of multiple drugs acting synergistically in order to achieve better pain control, minimizing the adverse effects associated with each drug, and allowing the use of lower doses. The aim of MMA is to reduce opioid requirements and their associated adverse effects, while promoting early mobilization, early transition to oral medication, and early removal of catheters, drains, and IV lines, thereby facilitating earlier functional recovery and hospital discharge.(20, 23–25) In our study, we shared the objectives of these authors in reinforcing the value of MMA in G2-MMA, both pre- and postoperatively, as described in several other studies. The regimen was based on opioids, NSAIDs, acetaminophen, muscle relaxants, corticosteroids, and adjuvants such as gabapentinoids, ketamine, dexmedetomidine, antiemetic, and gastric protectors, with truly satisfactory results.

On the other hand, Rawal et al. evaluated 746 hospitals and identified a lack of pain assessment in 34% of institutions, absence of documentation in 54%, and no written pain protocols in 75%. The most commonly used method for pain management was IV morphine administered via a patient-controlled analgesia (PCA) device; notably, these protocols were managed by surgeons in 75% of the hospitals.(16) This observation, together with the absence of a pain management protocol in the G1 non-MMA, motivated us to develop an original protocol and implement it in G2-MMA, where it was managed by orthopedic surgeons.

Shah et al., among other authors, concluded that pain relief following spine surgery in the pediatric population can be achieved using various methods and tools. Commonly employed strategies include an IV morphine or PCA. To date, PCA and oral opioids remain the standard of care for POP pain management in spine surgery. An alternative approach to provide neuroaxial analgesia is the intrathecal (IT) administration of morphine, which has been found to offer safe and effective analgesia during the early postoperative period (12–24 hours).(5, 10, 13–19, 21–23) In our setting, a PCA device is not currently available for all patients; therefore, it was not included as a method within the MMA pharmacological protocol used in either the G1 non-MMA or G2-MMA. IT morphine was excluded from the methods in both groups, as all patients were hospitalized in medium- to low-complexity POP Care Units without strict cardiorespiratory monitoring.

Rao et al, Fletcher et al, among others, reported in several studies the use of IV opioids, fentanyl, PCA, IT opioids, acetaminophen, NSAIDs, ketamine, DEX, and local anesthetic infiltration.(9, 24, 25) Chan et al, describes the use of multimodal regimens involving several drugs administered according to a schedule, but without specifying the doses, the number of POP days, or discharge instructions.(18) In our study, we specifically addressed this topic, detailing the use of these drugs in the G2-MMA group according to dose, duration (POP days), and routes of administration.

Other studies have reported the use of benzodiazepines and gabapentinoids, which are now considered important adjuvant agents in MMA protocols, as shown in the studies by Walker et al., Lee et al., and some others.(14, 20, 21, 23) Borgeat et al., Man et al., among others, have extensively described the incorporation of glucocorticoids into MMA protocols, demystifying concerns about immunosuppression raised in the literature.(15, 22–25) In our study, we incorporated the use of glucocorticoids into the G2-MMA group as part of the perioperative protocol.

Man et al., among others, have described very interesting pre-OP and/or POP MMA protocols, as detailed in a systematic review by Piantoni et al.(10, 22) Some studies provided detailed pre-OP pharmacological regimens, including specific drugs, doses, and frequencies, while others focused on POP protocols or perioperative treatments, also specifying the drugs, doses, and frequencies, based on PCA and opioid use. Several of these protocols appeared incomplete at hospital discharge, a pattern observed across several studies. Some studies lacked of clarification regarding the drugs used, their dosages, and the number of POP days; others did not adequately describe the in-hospital treatment or the complete protocolled regimen at discharge.(2, 3, 5, 10, 19–25) We believe that the G2-MMA protocol addresses all

of these information gaps, providing details on the drugs, dosages, routes of administration, and timing (pre-OP and POP days), both during hospitalization and after discharge, up to the first 30 days after surgery.

It should be noted that in the present study, the G1 non-MMA population and G2 MMA population might reefer a cultural, educational, and socioeconomic different perspective, these variables are not supported in the literature as predisposing factors for increased perioperative pain and/or higher morbidity and mortality, either pre-OP or POP. On the other hand, questionnaires such as the SRS-22, SF-36, and others were not considered, as we believe that the categories assessed could not be easily correlated with a numerical scale. Moreover, many of these categories could be influenced by behavioral, psychological, demographic, cultural, and educational factors, rather than by the intensity of pain itself. (22–24)

Among the limitations of the study, the pharmacological plan used in G1 non-MMA was not recognized as a formal scheme or protocol; however, we clarified that it was based on morphine and NSAIDs, without preoperative treatment and without a standardized POP analgesic plan at hospital discharge. Another limitation was that the NRS was recorded only once a day, which may not accurately reflect the patient's pain experience over a 24-hour period. A financial analysis was not performed; however, a potential reduction of two days in hospital length of stay would represent a substantial economic benefit to the healthcare system.

One of the strengths of this study is the large number of patients evaluated and the prospective nature of data collection, together with the extensive search and review of the literature to support the rationale for the proposed protocol. Additionally, the study presents a novel, comprehensive, simple, and reproducible as well as the first protocol for pain management in patients undergoing pediatric spine surgery, covering the pre-OP, intraoperative, and POP periods, both during hospitalization and throughout the first 30 days after surgery.

A protocol should establishes a sequence over time for its implementation, systematically detailing the steps and actions to be followed, and be regarded as a supportive guide that provides clear direction, rather than as an absolute, unquestionable, or unalterable set of rules.

Conclusion

MMA protocol in perioperative pediatric spine surgery for AIS and PSF > 10 levels, provides significant pain relief with fewer adverse effects, compared to single-drug regimens. The MMA protocol reduces the intensity of POP pain, improves the timing of bladder catheter and wound drainage removal, accelerates the resumption of oral intake, shorten time to ambulation, and reduces hospital stay without increasing complications, thereby potentially lowering associated costs for the healthcare system.

The use of a detailed, simple, and easily reproducible perioperative MMA protocol for pain management should be a priority in pediatric spine surgery, both pre- and postoperatively, during hospitalization, and

after discharge.

Declarations

Statements, declaration of interest and funding

Authors have nothing to declare.

No funding was received during the conduct of this study.

Author Contribution

Design of study: A,B,DConsulting references: A, B,CParticipation in draft manuscript: B,A,C,DRevise manuscript: B,D,CApproved the final version of the paper: B, A,D,CLucas Piantoni ACarlos A Tello BEduardo Galaretto CRodrigo Remondino D

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Tables

Tables 1 and 2 are available in the supplementary files section

Figures

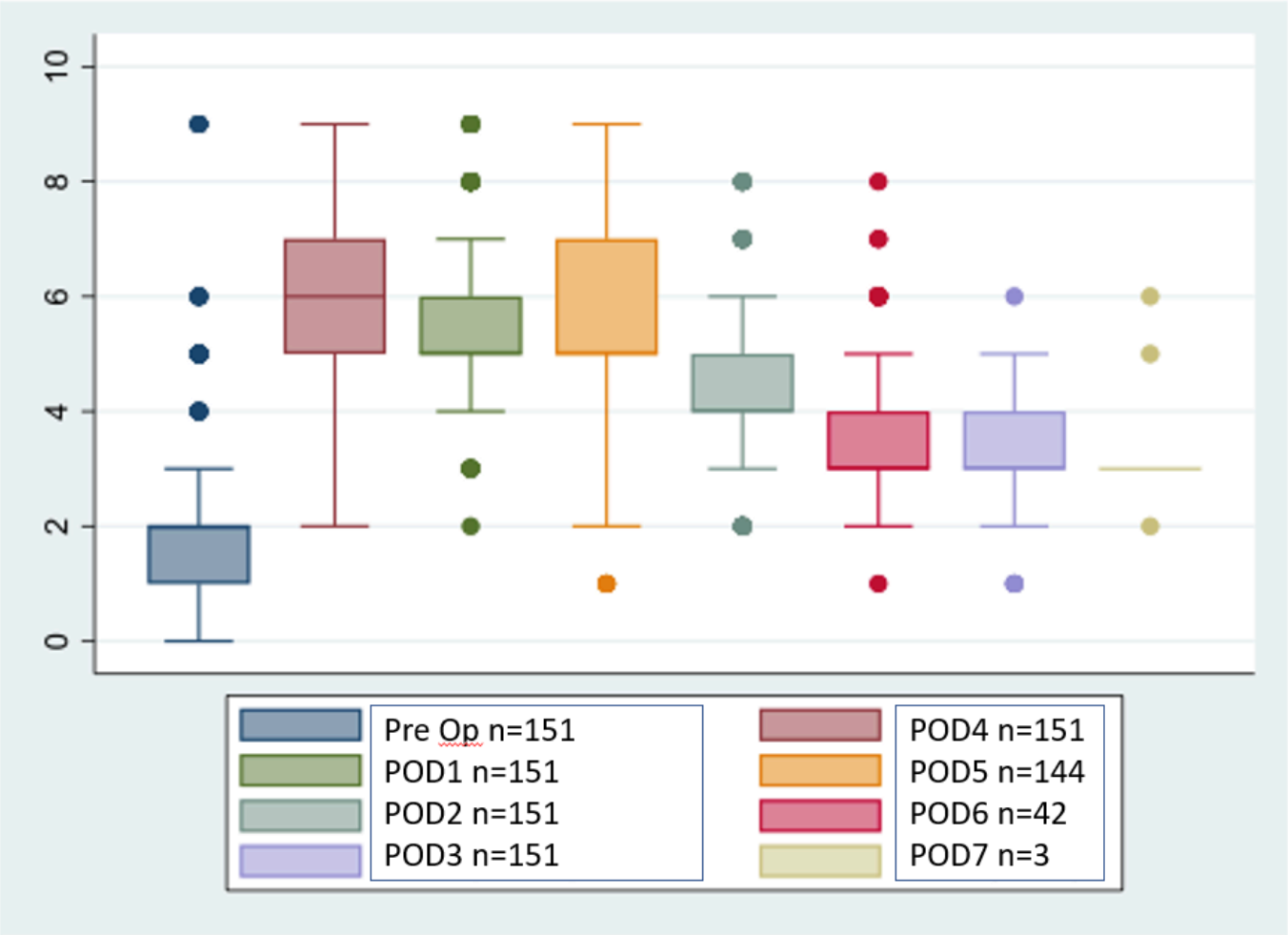


Figure 1

Figure 1 and 2. Numerical Rating Scale score in G1 non-MMA, and G2-MMA according to postoperative days.

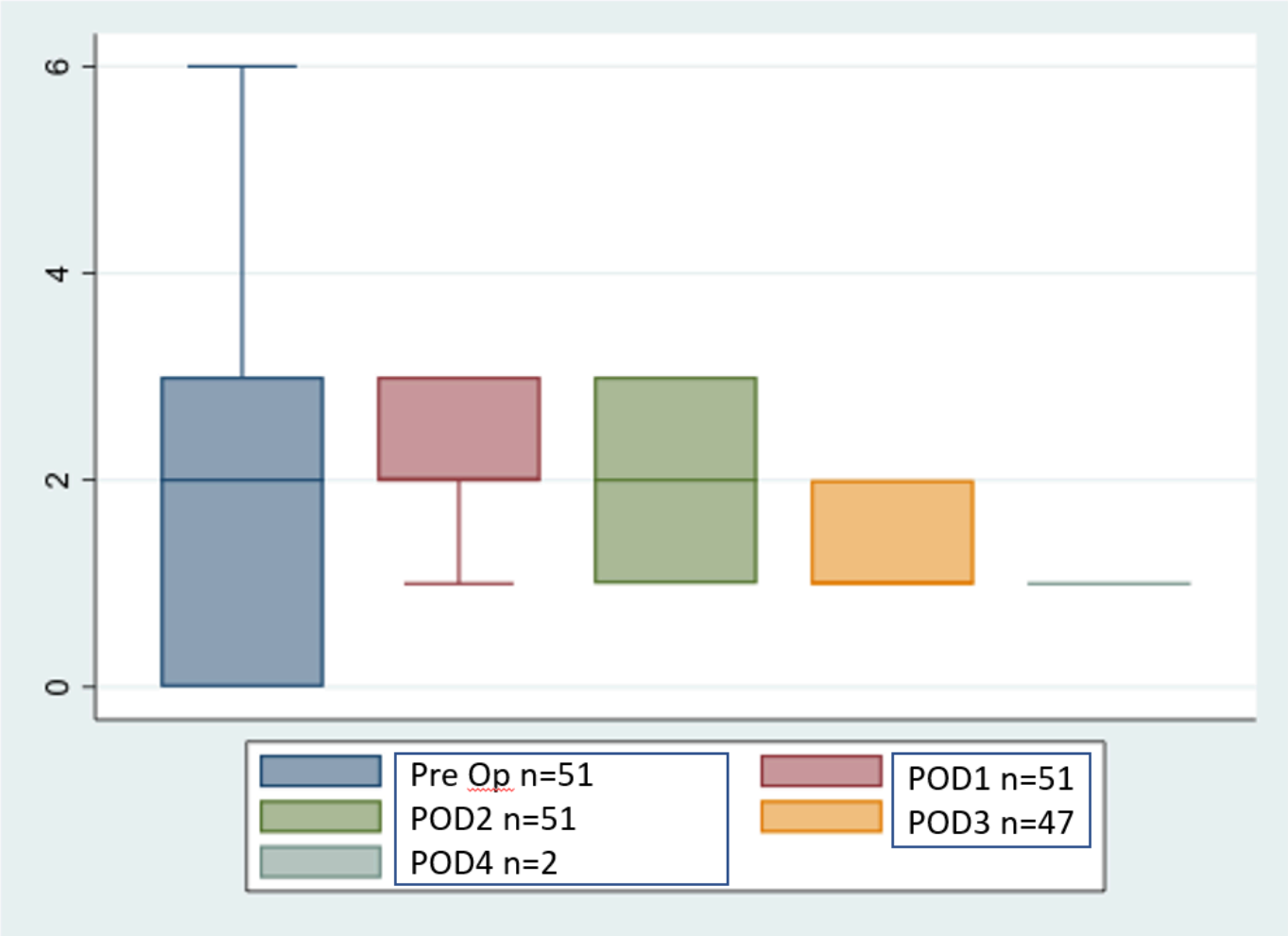


Figure 2

Figure 1 and 2. Numerical Rating Scale score in G1 non-MMA, and G2-MMA according to postoperative days.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- ESJTable1G2MMA.docx
- ESJTable2MMAG1G2.xlsx