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ORIGINAL ARTICLE

Efficacy of the Game Ready® cooling device on postoperative analgesia after scoliosis surgery in children

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Abstract

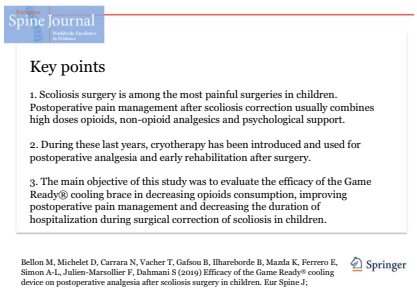
Purpose The aim of this study was to investigate the opioid-sparing effect of a cooling brace after surgical correction of idiopathic surgery in children.

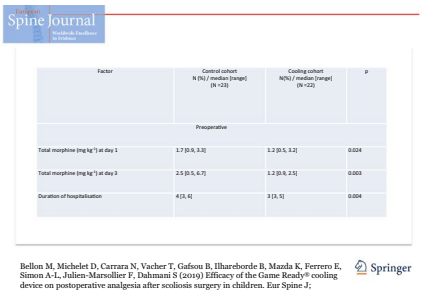
Methods We compared two consecutive cohorts of patients before and after introducing this technique in our institution. Management of patients was standardized. The primary objective of the study was to investigate the morphine consumption during the first postoperative day. Secondary outcomes were opioid consumption at day 3, pain intensity (at days 1 and 3), the mobilization in the standing position and duration of hospitalization.

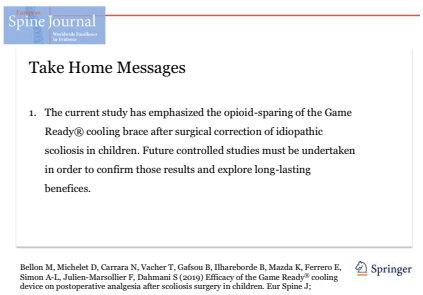
Results This study included 23 and 22 patients in the control and the cooling cohorts. Cooling brace was associated with a significant decrease in morphine consumption at day 1 (1.7 [0.9, 3.3] versus 1.2 [0.5, 3.2] mg kg^{-1}, $P=0.02$) and day 3 (2.5 [0.5, 6.7] versus 1.2 [0.9, 2.5] mg kg^{-1}, $P=0.003$), and a reduction in duration of hospitalization (4 [3, 6] versus 3 [3, 4] days, $P=0.004$). However, no difference was found on the pain intensity or the percentage of patient mobilized in the standing position. Number of level fused and intraoperative opioid consumption were also different between the two cohorts. However, multivariate analysis found only the use of the cooling brace as significantly associated with opioid consumption at day 1.

Conclusion The use of this cooling brace allows decreasing the opioid use after surgical correction of idiopathic surgery in children. The current results strongly suggest an interest of this technique in the postoperative management of patients.

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.







Keywords Cooling brace · Scoliosis · Pain · Paediatric

Introduction

Scoliosis surgery is among the most painful surgeries in children. Postoperative pain management after scoliosis correction usually combines high doses of opioids, non-opioid analgesics and psychological support [1, 2]. During

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the postoperative period, patients are largely suffering from adverse effects of opioids, such as nausea, vomiting, constipation and sedation, which impair the rehabilitation process and physiotherapy efficacy. Moreover, recent evidences suggest an association between early postoperative opioids consumption and development of persistent and chronic pain after surgery [3–5]. In the light of those evidences, decreasing morphine consumption during the postoperative period has been considered as a major objective of analgesia management after this surgery and many studies have been conducted in order to decrease the opioid consumption after surgical correction of scoliosis [2, 6–8]. Unfortunately, many of those strategies used in adults, such as anti-hyperalgesia therapy using ketamine, failed to found any opioid-sparing effect in children especially after scoliosis correction [8–11]. In addition, some opioid-sparing analgesics commonly used in adults such as nefopam are still underused in children [12–15].

During these last years, cryotherapy has been introduced and used for postoperative analgesia and early rehabilitation after surgery. Many adult studies, especially in the field of prosthetic surgery, have found the efficacy of this technique in reducing postoperative analgesics consumption, improving pain management quality and allowing a more rapid postoperative rehabilitation [16–20]. A recent device consisting in a cooling brace manufactured by the Game Ready® Company (Toulouse, France) has been introduced. The device has not been associated with any complication. The main objective of this study was to evaluate the efficacy of this device in decreasing opioids consumption, improving postoperative pain management and decreasing the duration of hospitalization during surgical correction of scoliosis in children.

Materials and methods

This study is a prospective analysis of perioperative data in patients undergoing spine surgery for idiopathic scoliosis correction.

This study was approved by our institutional IRB (Comité d'Evaluation de l'Ethique des projets de Recherche Biomédicale (CEERB) Robert Debré; # 2017-021). Informed written consent was obtained for all patients.

Design of the study

The current study consisted of a before–after comparison of two cohorts (termed: the control cohort and the cooling cohorts, respectively) with the introduction of the cooling device on the 1 January 2018. All patients undergoing a surgical correction of an idiopathic scoliosis were simultaneously included in this study. Inclusion criteria were paediatric patients (aged < 18 years at time of inclusion), ASA status I to III, agreement to participate in the study, patients with an idiopathic scoliosis, surgical instrumentation using the posteromedial translation technique and the understanding of the patient-controlled analgesia device. Exclusion criteria were contraindication to one of the antalgics administered during the perioperative period (including paracetamol, opioids, non-steroidal anti-inflammatory agents: NSAIDs, dexmedetomidine, dexamethasone and gabapentin), non-idiopathic scoliosis, refusing to participate in the study and ASA status > III.

Perioperative anaesthesia

Anaesthesia was standardized, and sevoflurane and dexmedetomidine were used during the intraoperative period. Intraoperative analgesia consisted in sufentanil, dexamethasone (0.15 10 mg kg^{-1} after induction of anaesthesia), intrathecal morphine (5 µg kg^{-1} after incision), paracetamol (15 mg kg^{-1} one hour before the termination of the surgery) and ketoprofen (1 mg kg^{-1} one hour before the termination of the surgery). Core temperature was controlled during the entire procedure (maintained between 36.5° and 37°). Tracheal intubation was performed in all patients, and a non-depolarizing muscle relaxant was given. Ringer's Lactate was administered according to the Holliday and Segar formulae and haemodynamic parameters (heart rate and mean blood pressure maintained within 20% of preoperative values). Postoperative analgesia was standardized and included morphine, paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs). Morphine was administered intravenously by titration in the PACU. Patient- or nurse-controlled analgesia (PCA/NCA) was initiated before leaving PACU and continued on the ward (see protocol 1: supplemental file 1). Pain assessment employed the visual analogical scale (VAS). Pain assessments were performed every 5 min during morphine titration and every 60 min during PCA or NCA morphine administration. The pain team (a pain consultant and nurse) was responsible for painkiller treatment after discharge from PACU. All patients were assessed at least daily with respect to the continuation and/or modification of morphine therapy. Intravenous opioids were prescribed for a maximum of three days. Non-opioid analgesic therapy was also standardized and given systematically 1 h before the end of surgery or in the PACU. It consisted of intravenous or oral paracetamol (15 mg kg^{-1} 6 hourly), an NSAID where there was no contraindication (intravenous ketorolac, 1 mg kg^{-1} 8 hourly or oral ibuprofen 10 mg kg^{-1} 6 hourly). Intravenous nefopam was also administered to all patients (0.25 mg kg^{-1} 6 hourly). Postoperative fluid management consisted of intravenous crystalloids administration (Ringer's Lactate 2 ml kg^{-1} h^{-1}) where required. An enhanced recovery after surgery (ERAS) program was implemented

in each patient. Basically, it consisted in rapid oral feeding, early mobilization and rapid oral treatment (at day 1).

Operative procedure

All surgeries were performed by one of the two senior spine surgeons of the department. Posteromedial translation was the main technique used for correction, under spinal cord monitoring. All patients were instrumented with 5.5-mm CoCr rods and hybrid constructs, combining lumbar pedicle screws (up to T11) and thoracic sublaminar bands (Jazz, IMPLANET, Bordeaux France). Fusion levels were selected according to the same criteria during the entire study period [21].

The cooling brace

The cooling brace consisted of a brace connected to a freezing circuit system generated by ice (Fig. 1). The temperature of the brace was set at 4° Celsius. The brace was placed on patient at the end of the surgery and then connected to the cooling system soon after arriving to the PACU and maintained for 24 h after the admission to the PACU.

Data collected

The primary objective of the study was to investigate the morphine consumption during the first postoperative day. Secondary outcomes were opioid consumption at day 3, pain intensity (at rest and movement at days 1 and 3), the mobilization in the standing position at days 1 and 3 and duration of hospitalization. In addition, unusual events in relation (or suspected as so) to the studied device such as cutaneous lesion and postoperative infection (wound infection) were also recorded. Reason for limiting the study to the 3 first postoperative days was the frequent discharge of patients from the hospital at day 4. Data collected included age, weight, type of surgery, Cobb angle, ASA status, preoperative analgesics administration, premedication with gabapentin, intraoperative sufentanil administration, anaesthesia and surgery duration, tolerance of the brace postoperative paracetamol, nefopam and NSAIDs administration at days 1 and 3, pain intensity (at rest and movement at days 1 and 3), the physiotherapy in the standing position at days 1 and 3, morphine titrated in the PACU (mg kg^{-1}), morphine administered in the first and third postoperative days (mg kg^{-1}) and duration of hospitalization.

Fig. 1 Full image of the cooling device

Statistical analysis

Sample size calculation was based on previous studies using the same device. Based on a previous survey on postoperative consumption at day 1 after idiopathic scoliosis surgery, morphine consumption was found to be 1.6 ± 0.45 mg kg^{-1}. Expecting a decrease of 25% of the opioid consumption at day 1 [16] with an alpha risk of 5% and a power of 80% found 20 patients to be included in this study. Given the number of performed surgeries for idiopathic scoliosis per year (140) and an estimated recruitment of 60% of patients, we planned to recruit the adequate sample size in two periods of 3 months. We planned to introduce the device on the 1 January 2018, and consequently, the control cohort included patients operated the last trimester of 2017 and the cooling one during the first trimester of 2018.

Description statistics used median [range] for continuous variables and *N* (%) for discrete ones. Statistical comparisons between the two cohorts used the Mann–Whitney nonparametric test for continuous variables and the χ^2 (or exact test of Fisher) for discrete variables. Finally, in order to account for differences between the two cohorts, a multivariate analysis including all significant different factors was performed (including the use or not of the cooling device) with main outcome consisting in the morphine consumption at day 1. Tolerance of each factor was computed, and those with a value < 0.2 (with a high risk of collinearity) were not allowed to enter the model.

Results

Overall, 41 and 47 patients underwent scoliosis surgery during the 6-month period of the study. Importantly, no scheduled patient was postponed during the study period, and all patients have tolerated the brace during the entire treatment period. Figure 2 displays the flow chart of patients and the final number of patients included (23 and 22 in the control and cooling cohorts, respectively).

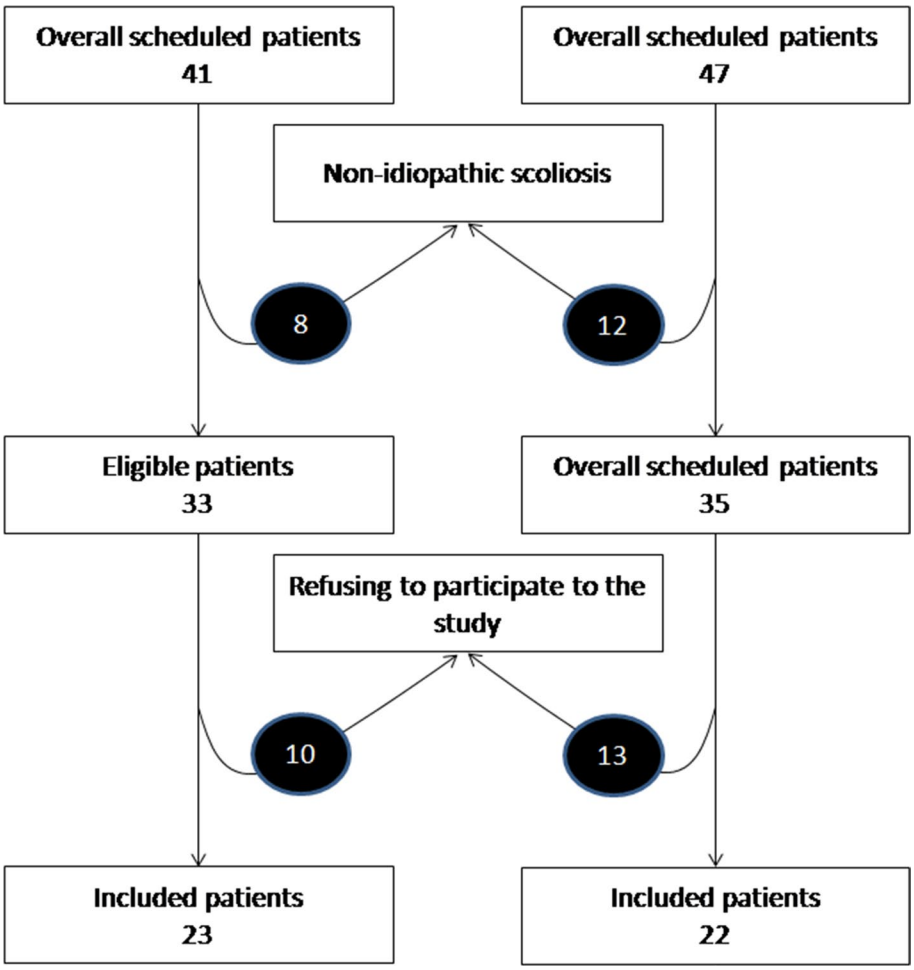

Fig. 2 Flow chart of included patients

Comparison between the two cohorts found no differences in the demographic or perioperative factors except for the number of fusion levels that was more important in the cooling cohort and the doses of intraoperative sufentanil that were less important in the cooling cohorts. Concerning the primary outcome of the study, the morphine consumption was significantly decreased in the cooling cohort (Table 1). Similar results were found concerning the postoperative morphine consumption at day 3 and the duration of hospitalization. Moreover, the cumulative days of hospitalization were 101 days in the control group and 76 days in the treatment one (difference = 25 days). According to our results and assuming the cost of a day of hospitalization to be 2000 euros, the use of this cooling device is associated with 2000 euros per patient (1 day difference between the two cohorts). Extending these forecasts to the year activity in our centre (150 patients) would result in saving 300.000 euros. Conversely, no difference was exhibited between the two cohorts on the pain intensity (either at rest or at movement) at days 1 or 3.

The multivariate analysis (Table 2) with the morphine consumption as the main outcome found the use of the cooling device as an independent significant factor, while both the number of level fused and the doses of intraoperative sufentanil were not associated with the difference in the main outcome. All three factors exhibited a tolerance > 0.2 and were not excluded from the analysis.

Finally, no adverse effects were associated with the brace (no cutaneous lesion, no postoperative infection up to 30 days after the surgery).

Discussion

The main finding of the current study is that the cryotherapy using the Game Ready® cooling brace administered during the first 24 postoperative hours after idiopathic scoliosis surgery was associated with a decrease in the amount of opioid consumption at days 1 and 3 without impacting the quality of analgesia and a decrease in duration of hospitalization.

Considering the internal validation of the current study, morphine consumption was similar to previous studies focusing on the same topic (~ 1–1.5 mg kg^{-1}) [11, 22–24]. In addition, as expected by previous studies using

Table 1 Descriptive statistics and comparison between the control group and the cooling group

Factor	Control cohort *N* (%)/ median [range] (*N* = 23)	Cooling cohort *N* (%)/ median [range] (*N* = 22)	*P*
Preoperative			
Gender (female)	18 (78.3%)	18 (81.8%)	1
Age (months)	15 [11, 17]	15 [12, 17]	0.56
Weight (kg)	55 [43, 70]	54 [43, 80]	0.48
ASA status I and II	23 (100%)	22 (100%)	1
Preoperative pain (VAS score > 3)	1 (4.3%)	3 (13.6%)	0.5
Preoperative non-opioid therapy	0 (0%)	1 (4.5%)	0.5
Preoperative opioid therapy	0 (0%)	0 (0%)	1
Gabapentin premedication	23 (100%)	21 (95.5%)	0.5
Surgery characteristics			
Cobb angle	59 [42, 80]	56 [39, 80]	0.84
Level fused	10 [9, 12]	12 [7, 14]	< 0.0001
Sacral fusion	0 (0%)	0 (0%)	1
Kephotomy	9 (39.1%)	5 (22.7%)	0.2
Intraoperative			
Duration of surgery (min)	240 [145, 300]	200 [150, 300]	0.11
Duration of anaesthesia (min)	317 [230, 390]	270 [195, 390]	0.4
Intraoperative sufentanil doses (μg kg^{-1})	0.4 [0.2, 2]	0.3 [0.2, 0.6]	0.03
Intrathecal morphine	23 (100%)	22 (100%)	1
Dexmedetomidine	23 (100%)	22 (100%)	1
Dexamethasone	23 (100%)	22 (100%)	1
Paracetamol	22 (95.7%)	22 (100%)	0.5
Ketoprofene	15 (65.2%)	18 (81.8%)	0.23
Nefopam	18 (78.3%)	21 (95.5%)	0.2
Postoperative day 1			
Paracetamol	23 (100%)	22 (100%)	1
Ketoprofene	22 (95.7%)	22 (100%)	0.5
Nefopam	22 (95.7%)	22 (100%)	0.5
Active physiotherapy	21 (91.3%)	22 (100%)	0.3
Total morphine (mg kg^{-1})	1.7 [0.9, 3.3]	1.2 [0.5, 3.2]	0.024
VAS rest	0 [0, 2]	0 [0, 1]	0.4
VAS Movement	4 [0, 9]	4 [0, 10]	0.7
Postoperative day 3			
Paracetamol	23 (100%)	22 (100%)	1
Ketoprofene	23 (100%)	22 (100%)	1
Active physiotherapy	23 (100%)	22 (100%)	1
Total morphine (mg kg^{-1})	2.5 [0.5, 6.7]	1.2 [0.9, 2.5]	0.003
VAS rest	0 [0, 2]	0 [0, 1]	0.3
VAS Movement	6 [2, 8]	6 [2, 8]	0.8
Postoperative day 1 to discharge from hospital			
Gabapentin	23 (100%)	22 (100%)	1
Duration of hospitalization	4 [3, 6]	3 [3, 5]	0.004

VAS visual analogical scale

cryotherapy, the percentage decrease in opioid consumption was 29% in the current study (while sample size calculation based on previous studies estimated this decrease to 25%). Consequently, data concerning the current study seem corresponding to current practices and expectation from the studied device. The quality of analgesia was not improved by the use of the cooling device. This might be explained by the lack of pain at rest in all patients (including the control cohort) and the absence of any anticipated analgesia before mobilization with the cooling device.

Table 2 Multivariate analysis of factors associated with the postoperative morphine consumption at day 1

	B	Standard deviation of B	*P*	Tolerence
Level fused	0.08	0.05	0.12	0.89
Intraoperative sufentanil (μg kg^{-1})	0.01	0.3	1	0.89
Cooling device	−0.46	0.2	0.04	0.80

B: partial regression coefficient

Alternatively, a lack of power of this study for exploring this outcome might also be involved. However, this is unlikely to be the case given the absence of any tendency towards a decrease in pain intensity (either at rest or movement) in the cooling cohort. Finally, the duration of hospitalization decreased in the cooling cohort. Although we did not explore reasons of this result, one can hypothesize that the decrease in amount of postoperative morphine might favour a more rapid postoperative rehabilitation and speed the discharge from hospital as previously found in other studies [25]. Conclusively, one can expect a decrease in the expenditure in relation to the treatment of idiopathic scoliosis without impacting the quality of care.

Concerning potential mechanisms of the observed effect, many hypotheses have been suggested. The decrease in local inflammation has been among the most classical reason given the strong relation between tissue aggression, inflammation and pain during the early postoperative pain [26]. However, more recently, activation of pain receptors such as the TRPM8 receptors has been found as a potential mechanism for the analgesic effect of cold [27, 28]. Finally, another complementary explanation might be considered to account for the efficacy of cryotherapy observed in the current trail. One can hypothesize that the special care delivered to patients might improve their psychological well-being and quality of analgesia. This is supported by the level of psychological distress exhibited by paediatric patients [29, 30] especially before major surgery [1, 31].

Results of the current study indicate that the use of cooling brace might be of interest in decreasing postoperative opioid consumption which might help the postoperative rehabilitation, as suggested by our result concerning the duration of hospitalization. This is supported by the external validation of the current study given the surgical technique widely used and the anaesthesia and analgesia techniques that are shared by many teams caring for the studied population [2, 10, 22, 24]. Moreover, the current results are also in agreement with previous ones performed in adult surgeries, especially after orthopaedic prosthetic surgeries such as knee or hip arthroplasty [16, 17, 20]. Finally, one must keep in mind that the use of this device is not associated with adverse effects observed with pharmacological interventions [20].

Limitations

The present study has some limitations. First, the study is not randomized, and bias related to unblinding might occur. Second, the cooling brace was kept in place for 24 h; although its efficacy was effective and lasted during the hospitalization time, one can hypothesize a more important effect with the increasing time of cooling. Nonetheless, previous reports about adult knee surgery found that the effectiveness of the device is more related to the early set-up of the device more than the duration over time [16, 17, 20]. Finally, long-lasting effect of this technique on rehabilitation and outcomes, such as mobilization and chronic pain, still needs to be investigated [5].

Conclusion

The current study has emphasized the opioid-sparing effect and the decrease in duration of hospital stay associated with the use of the Game Ready® cooling brace after surgical correction of idiopathic scoliosis in children, and the future controlled studies must be undertaken in order to confirm those results and explore long-lasting benefits.

Author's contribution MB: conceptualized and designed the study, included patients, collected data, corrected the manuscript and approved the final manuscript as submitted. DM: conceptualized and designed the study, included patients, verified statistics, corrected the manuscript and approved the final manuscript as submitted. NC: conceptualized and designed the study, included patients, collected data, corrected the manuscript and approved the final manuscript as submitted. TV: included patients, collected data, corrected the manuscript and approved the final manuscript as submitted. BG: included patients, collected data, corrected the manuscript and approved the final manuscript as submitted. BI: conceptualized and designed the study, corrected the manuscript and approved the final manuscript as submitted. KM: included patients, collected data, corrected the manuscript and approved the final manuscript as submitted. ALS: included patients, conceptualized and designed the study, collected data, verified statistics, corrected the manuscript and approved the final manuscript as submitted. EF: included patients, conceptualized and designed the study, collected data, verified statistics, corrected the manuscript and approved the final manuscript as submitted. FJM: conceptualized and designed the study, collected data, corrected the manuscript. SD: conceptualized and designed the study, designed the data collection instruments, included patients, carried out the initial analyses and verified statistics, drafted the initial manuscript, corrected the manuscript and approved the final manuscript as submitted.

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Compliance with ethical standards

Conflict of interest Pr Keyvan Mazda is a consultant for Zymmer®.

Financial Disclosure Statement Pr Keyvan Mazda is a consultant for Zymmer®.

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