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Original article

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Abstract

Introduction: The primary aim of this study was to evaluate how the Game Ready© cryotherapy system impacts postoperative analgesia following lumbar fusion. The secondary aim was to study the effect of cryotherapy on blood loss, transfusion rate and recovery after surgery.

Materials and Methods: This was a retrospective study of 60 patients divided into two consecutive sets. The first set of 30 patients underwent the current anesthesia protocol at our facility (control group) while the second set of 30 underwent the same protocol but the patient wore the Game Ready© cryotherapy belt immediately postoperative (GR group).

Results: VAS for pain at H6 did not differ between groups (5.2 ± 1.7 vs 5.2 ± 1.8 ($p = 0.94$)); however, there was a significant decrease in pain at H24 and H48 in the GR group relative to the control group ($p = 0.04$; $p = 0.01$; $p = 0.01$). Consumption of morphine over the first 24 and 48 hours was 50% less in the GR group than in the control group ($p = 0.01$ and $p < 0.0001$). Discharge occurred significantly earlier in the GR group (3.9 ± 1.0 days) than the control group (5.1 ± 0.9 days) ($p < 0.001$). The estimated blood loss was greater in the control group than the GR group (574.7 ml ± 339.2 vs 305.9 ml ± 229.6; $p = 0.0003$).

Conclusion: Use of a cryotherapy device in the context of spine surgery is effective at controlling postoperative pain. It also decreases the consumption of analgesics, limits blood loss, reduces the need for transfusions, and contributes to enhanced recovery after surgery.

Level of evidence: IV

Keywords: enhanced recovery after surgery, spine, lumbar fusion, pain

Introduction

The enhanced recovery after surgery concept was introduced in the 1990s in Denmark by a team led by Professor H. Kehlet [1]. This concept defines the use of multidisciplinary protocols to

accelerate the postoperative recovery by targeting various factors such as pain [1–3]. Initially known as “rapid recovery” in the context of abdominal surgery [1], a working group renamed it “enhanced recovery after surgery” (ERAS) in 2016 [4]. This process uses multidisciplinary factors to optimize the pre-, intra- and postoperative management of patients. ERAS has been expanded to several surgical fields, including orthopedics in the context of total hip or knee joint replacement.

Spine surgery is not explicitly included in this document, although it falls within the scope of surgeries that may benefit from ERAS. The GRACE group [Francophone group for improved rehabilitation after surgery] provides recommendations and protocols to carry out better rehabilitation after surgery in the most optimal and safest conditions. These data were summarized in a statement by the French HAS in 2016 [4]. Lumbar fusion surgery is known as an extensive surgery with long recovery period, thus many multimodal analgesia protocols have been described [5–9].

Cryotherapy is a non-pharmacological modality that is extensively used after joint replacement surgery [10–12]. It reduces postoperative pain and analgesic intake and contributes to ERAS. The French company Game Ready© (Toulouse, France) has developed a cryotherapy system for each surgical site, including a lumbar belt that can be used in the context of lumbar spine surgery.

The primary aim of this study was to evaluate how the Game Ready© cryotherapy system impacts postoperative analgesia following lumbar fusion. The secondary aim was to study the effect of cryotherapy on blood loss, transfusion rate and recovery after surgery.

Materials and Methods

Study design

This was a retrospective study of patients managed between January 2019 and December 2019. In all 60 patients were included in this study, separated into two consecutive sets of 30 patients. The first set of 30 patients received the current anesthesia protocol at our facility (control group). The second set of 30 patients underwent the same protocol but the patients wore the Game Ready© cryotherapy belt immediately after the surgical procedure (GR group). All patients were operated by the same surgeon.

Inclusion criteria

The patients included in this study underwent primary lumbar spine surgery, with or without laminectomy; posterolateral fusion involved an anterior interbody cage at L4L5, L5S1 or L4S1. All the intervertebral cages were inserted through the transforaminal route.

Anesthesia and analgesia protocol

All patients underwent the same anesthesia protocol consisting of general anesthesia and administration of the following agents: Propofol 2-3 mg/kg; Midazolam; ketamine; Sufentanil 1µg/kg; Cisatracurium 0.1–04 mg/kg; Sevoflurane 1 MAC=2.5%; Dexamethasone 8 mg IV (single dose); Paracetamol 1 g; Nefopam 20 mg; Profenid 100 mg (if not contraindicated); tranexamic acid (if not contraindicated).

All patients received an intrathecal injection of 100 µg morphine hydrochloride (ITM) diluted in 2 ml of injectable saline. This ITM was injected under the released level or in the L4L5 space when the canal was not released. This injection was done at the end of the surgical approach. All patients also received a subfascial injection of 20 ml Ropivacaine 7.5% (or 150 mg) before the incision was closed. The postoperative analgesia protocol was similar with step 1 analgesics (1 g paracetamol, 3–4 time per day, depending on age), step 2 (Acupan®, 20 ml, 6x per day) and step 3 (intravenous

morphine by PCA pump if pain > 4 on visual analog scale (VAS) in post-anesthesia care unit, otherwise *per os*) along with a 48-hour course of nonsteroidal anti-inflammatories (profenid 50 mg, 3x per day, if not contraindicated).

Patients in whom the preoperative hemoglobin levels were less than 12 g/L during the anesthesia consultation were given an injection of Binocrit© (INN: epoetin alfa, Sandoz GmbH).

Cryotherapy protocol

The Game Ready© belt was applied in the observation ward when the patient was moved to their bed. The continuous cryotherapy program at 4°C was maintained up to 48 hours postoperative.

Data collection

The following data were collected from medical and anesthesia records:

- ✓ Demographics: sex, height, weight, age at surgery, preoperative hematocrit
- ✓ Surgical data: operative time, levels operated and types of surgery
- ✓ Postoperative data: pain on VAS at H6, H24, H36 and H48; equivalent morphine dose consumed in mg IV equivalents at H24 and H48; date when patient first got out of bed, discharge date, postoperative hematocrit (Hct) and calculation of blood loss at a Hct of 35% using the methods validated by Mercuriali and Brecher[13,14], transfusion rate, recovery of gastrointestinal transit (1st gas), 1st solid meal, discomfort related to wearing this device (removal and re-installation each time the patient gets up), complications related to morphine use (nausea and postoperative vomiting, pruritis, respiratory depression, disorientation/confusion).

Statistical analysis

The statistical analysis was carried out using Microsoft Excel® XLSTAT. Student's *t* test was done for variables that were normally distributed and a Mann-Whitney test with non-parametric data and a Chi-square test with discrete outcome variables. Significance threshold was set at 5%. A repeated measures ANOVA was applied to the pain on VAS values and morphine consumption.

Information about Game Ready©

This cryotherapy device uses a control unit that sends cold liquid through tubes. The controller's reservoir must be filled with ice several times each day. Each control unit works with every type of Game Ready© wrap (knee, shoulder, spine). The back wraps must be disinfected between each patient. A back wrap can be reused in up to 30 patients (data from Game Ready©). The cost of a control unit is approximately €4500, and each back wrap is €550.

Results

The two groups of 30 patients had comparable demographics (Table 1).

While the VAS for pain at H6 did not differ between the groups (5.2 ± 1.7 vs 5.2 ±1.8 / $F_6(1,59) = 0.005$ ($p = 0.94$)), the VAs for pain at H24, H36 and H48 was significantly lower in the GR group than in the control group ($F_{24}(1,59)= 4.2$, $p = 0.04$; $F_{36}(1,59)=6.5$, $p = 0.01$; $F_{48}(1,59) = 6.7$, $p = 0.01$) (Table 2). Based on the repeated measures ANOVA, this inter-subject effect (effect of the GR intervention) was significant ($F_{GR}(1,59)=7.4$, $p = 0.005$). For the intra-subject effect (effect of the

GR intervention and the duration) the two effects were significant ($F_{Time}(1,59) = 35$, $p < 0.0001$; $F_{GR}(1,59) = 5.2$, $p = 0.01$).

Morphine consumption over the first 24 and 48 hours was significantly less in the GR group than in the control group (50% decrease, $p = 0.01$; $p < 0.0001$). Based on the repeated measures ANOVA, this inter-subject effect (effect of the GR intervention) was significant ($F_{GR}(1,59) = 24.9$, $p < 0.0001$). For the intra-subject effect (effect of the GR intervention and time), the two effects were significant ($F_{Time}(1,59)=152.8$, $p < 0.0001$; $F_{GR}(1,59) = 8.3$, $p = 0.005$).

The first time out of bed was similar between groups (0.9 ± 0.7 days in the GR group versus 1.1 ± 1.0 in the control group) while discharge occurred significantly earlier in the GR group patients (3.9 ± 1.0 days) than the control group patients (5.1 ± 0.9 days) ($p < 0.001$).

There was no significant difference in the preoperative Hct level between groups (43.9% ± 4.3 in the control group versus 42.9% ± 4.4 in the GR group; $p = 0.17$). The share of patients who received preoperative Binocrit© was similar between groups (13% in the control group (n = 4) versus 23% in the GR group (n = 7); $p = 0.16$). The postoperative Hct (D3) and the blood loss calculated at 35% Hct was statistically significant. In fact, the mean Hct in the control group was lower than in the GR group (33.1% ± 5.9% vs 36.8% ± 4.4%; $p = 0.003$) and the CBL35 was higher in the control group than in the GR group (574.7 ml ± 339.2 vs 305.9 ml ± 229.6; $p = 0.0003$) (Table 3). The transfusion rate in the GR group was significantly lower than in the control group (6.7% vs 26.7%; $p = 0.01$).

Resumption of GI transit occurred significantly earlier in the GR group than in the control group, although the time to first meal was similar (0.8 ± 0.7 days versus 1.4 ± 1 days, $p = 0.02$; 1.2 ± 0.4 days versus 1.3 ± 1 days, $p = 0.41$). Complications related to morphine consumption are reported in Table 4.

The need to remove and replace the Game Ready© belt hindered 17% of patients, while 90% were satisfied with this device.

Discussion

Our study's main finding is the reduction in pain and morphine consumption after lumbar fusion surgery in patients using the Game Ready© cryotherapy system. The second finding was that ERAS is reliable in the context of lumbar fusion, meeting the secondary aim of this study. Lastly, the cryotherapy system greatly reduces the blood loss in lumbar fusion surgery along with a significant reduction in complications generally attributed to morphine consumption. The transfusion rate and mean length of hospital stay were also reduced.

Cryotherapy has widely been used and described in the context of arthroplasty. It is known to be effective at reducing postoperative pain and limiting the consumption of analgesics, especially morphine [10–12,15]. There are only a few published studies on the benefits of cryotherapy after lumbar fusion surgery. Murata et al [16] reported less postoperative pain and shorter hospital stays because of the use of a cryotherapy system. Fountas et al [17] found lower pain levels and morphine consumption in the subset of patients who followed a cryotherapy protocol. Nabiyev et al [18] also reported reduction in pain and analgesic intake in their study with the Game Ready© system. Bellon et al [19] reported similar results with lower VAS for pain, and cumulative morphine doses and length of hospital stay in the patients who used a Game Ready© wrap.

The ERAS in spine surgery is one of the strong points of our study. The HAS set out certain criteria to "allow" a patient to be discharged from an ERAS protocol [4]: no intravenous infusion, pain

under control, able to eat solid food, able to walk independently, GI transit re-established, no signs of infection, patient agrees to discharge.

Given the results of our study, these criteria were met to implement the ERAS protocol under optimal efficacy and safety conditions. Beyond the cost of the cryotherapy wrap, the various procedures implemented are neither difficult nor restrictive for surgeons and other members of the medical team. The multimodal analgesia procedures are crucial to carrying out the ERAS [8,9,20–22].

Some studies have focused on the feasibility of ERAS in the context of major spine surgery. Wainwright et *al* [23] highlighted the improved postoperative recovery when a well-defined ERAS protocol is implemented. Smith et *al* [24] concluded that implementing an ERAS protocol is directly related to a reduction in postoperative nausea, shorter duration of opioid treatment and reduction in use of extended-release opioids. However, these authors did not find a link between the ERAS protocol and shorter hospital stays or lower pain scores.

Procedures have been developed by certain working groups to simplify ERAS in the context of spine surgery. Thus Chang et *al* in 2020 and Soffin et *al* in 2019 described minimally invasive surgery to make ERAS easier [25,26]. Soffin et *al* also proposed using an anesthesia protocol without opioids. Thanks to their protocols, these two studies found reduction in morphine consumption postoperatively. Soffin et *al* also reported a reduction in the mean length of hospital stay, which is consistent with our study.

The meta-analysis of 19 studies by Dietz et *al* concluded that ERAS protocols were effective at reducing complications, re-hospitalization, mean length of stay and opioid consumption. They also noted improved outcomes reported by patients and functional recovery [27].

Given these results, it appears that ERAS is feasible for spine surgery. Conversely, one can question the reliability of the elements proposed for implementing ERAS protocols. In fact, as noted by Dietz et al [27], there are multiple protocols and disparate patient cohorts. This makes it difficult to establish standardized protocols. Some avenues have been suggested such as minimally invasive surgery [25,26], no opioids given during anesthesia [26] or like in this study, a combination of subfascial injection of local anesthetics, ITM and use of a cryotherapy back wrap.

One of the novel points of our study is the analysis of blood loss in the context of extensive spine surgery and the use of a cryotherapy system. Our study reveals significantly less blood loss in patients who used the cryotherapy system (574.7 ± 339.2 ml vs 305.9 ± 229.6 ml; $p = 0.0003$) and a lower blood transfusion rate (6.7% vs 26.7%; $p = 0.01$). Blood-saving procedures may also be relevant for implementing ERAS in spine surgery.

Rapid resumption of GI transit and solid food intake are also important points for implementing ERAS. Also, limiting the side effects of morphine by reducing its intake (50% reduction) contributes to rapid recovery. The first time out of bed is earlier and the hospital stay is shorter because these postoperative multimodal analgesia procedures were implemented.

Financially, the initial investment is certainly sizeable, but the investment had a relatively quick return given the average length of stay data in our study (about 1 day less of hospitalization).

Limitations

Our study has limitations related to its retrospective nature and limited sample size. Also, we only included procedures with short fusion constructs. These constructs are associated with less blood loss [28,29]. The study was not randomized, nor prospective and the sample size was not

estimated before the study. Use of this device yields relevant results, opening avenues for a prospective randomized study in the future, since this study for the first step in this research.

Conclusion

Use of a cryotherapy device in the context of spine surgery is effective for controlling postoperative pain. It also decreases the consumption of analgesics, limits blood loss and transfusions, reduces morphine-related complications and contributes to enhanced recovery after surgery. This device also helps to decrease the average length of stay following lumbar fusion surgery.

Conflict of interest: None

Funding: None

Author contributions:

- A. De Bie: Data collection, writing of article
- R. Siboni: Critical review of article
- MF. Smati: Creation of anesthesia protocol, anesthesia of patients in the study
- X. Ohl: Study sponsor, review and correction of final version of article
- S. Bredin: Primary investigator, surgery on all patients, correction of article

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Table 1: Demographic data

	GR group	Control group	*p* value
Age (years)	59.7 ± 15.1 (26; 76)	63 ± 9.5 (45; 81)	0.16
Sex ratio (M/F)	11/19	2/3	0.39
BMI (kg/m²)	25 ± 4.75 (17.6; 32.7)	26.9 ± 6.7 (16.7; 38.5)	0.11
Operative time (min)	125.6 ± 29.4 (75; 176)	129.6 ± 29.2 (75; 184)	0.29
Laminectomy (%)	47%	53%	0.40

Values are mean ± standard deviation (min; max). BMI: Body mass index

Table 2: Pain on VAS and morphine consumption in the first 48 hours after lumbar fusion surgery

	GR group	**Control group**	***p* value**
Pain H6 (cm)	5.2 ± 1.7 (3; 8)	5.2 ± 1.8 (3; 8)	0.94
Pain H24 (cm)	3.5 ± 1.4 (1; 6)	4.2 ± 1.7 (1; 6)	0.04
Pain H36 (cm)	2.7 ± 1.4 (1; 5)	3.8 ± 1.9 (1; 5)	0.01
Pain H48 (cm)	2.3 ± 1.3 (1; 6)	3.4 ± 1.9 (1; 6)	0.01
Morphine consumption H24 (mg)	10.9 ± 3.3 (5; 31)	20.4 ± 5.3 (12; 32)	<0.0001
Morphine consumption H48 (mg)	16.3 ± 4 (10; 37)	30.8 ± 3.9 (21; 39)	<0.0001

Values are mean ± standard deviation (min; max).

Table 3: Calculated blood loss

	GR group	Control group	*p* value
Preop Hematocrit (D–1) (%)	42.9 ± 4.4 (39; 50)	43.9 ± 4.3 (37; 52)	0.17
Postop Hematocrit (D3) (%)	36.8 ± 4.4 (31; 44)	33.1 ± 5.9 (23; 46)	0.003
CBL35% (ml)	305.9 ± 229.6 (0; 673.4)	574.7 ± 339.2 (37.1; 1715)	0.0003

Values are mean ± standard deviation (min; max), CBL35%: Estimated blood loss at 35% hematocrit using the methods described by Mercuriali and Brecher

Table 4: Complications related to morphine consumption

	GR group	Control group	*p* value
Postop nausea or vomiting (n)	**5**	**12**	**0.01**
Respiratory depression (n)	**0**	**0**	**ns**
Urinary retention (n)	**2**	**5**	**0.05**
Pruritis (n)	**5**	**9**	**0.02**
Confusion/disorientation	**1**	**4**	**0.02**

Values given are the number of patients (30 patients per group)