# **ORIGINAL RESEARCH**



# Spinal anaesthesia with 4 mg versus 3 mg of hyperbaric bupivacaine plus 10 $\mu$ g of fentanyl for adult anorectal surgery: faster recovery with prolonged analgesia

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#### Abstract

Background: The study was designed to test the hypothesis that fentanyl added to lowdose spinal hyperbaric bupivacaine reduces the effective dose of bupivacaine with faster recovery and similar quality of anaesthesia for anorectal surgery. Methods: 132 adult consecutive American Society of Anaesthesiology (ASA) 1-3 patients were randomized to receive spinal anaesthesia (SA) in the sitting position with hyperbaric bupivacaine (Marcaine Spinal Heavy 0.5%) injected over 2 minutes: Group S4 (n = 66) 0.8 mL, Group S3F (n = 66) 0.6 mL + fentanyl 10  $\mu$ g to 0.8 mL. After sitting for 10 minutes, surgery was started. The rate of success, level and duration of sensory and motor block, time to voiding, ambulation, complications, consumption of analgesics, quality of anaesthesia according to the patient and medical staff (0-2 score) were assessed. Student's t, Mann-Whitney, Analysis of variance (ANOVA), Kruskall-Wallis and  $\chi^2$ tests were used. Characteristics of SA are presented as mean  $\pm$  standard deviation (SD), no of cases (%), median (range),  $p < 0.05^*$  regarded as statistically significant. **Results**: Maximum level of sensory block was  $7.7 \pm 1.4$  vs.  $7.0 \pm 1.8$  dermatomes, Group S3F vs. Group S4. Level of motor block was 0 Bromage score in >85% of cases in both groups. Mean duration of sensory block was  $212.7 \pm 35.1^*$  vs.  $229.5 \pm 36.5$ minutes, Group S3F vs. Group S4. Median time to urinate was 260 (120-960)\* vs. 315 (160-1140) minutes, Group S4 vs. Group S3F. Quality of anaesthesia was comparable among groups. Pruritus was recorded in 4 cases vs. 0, Group S3F vs. Group S4 (p < 0.05). Conclusions: 3 mg of spinal hyperbaric bupivacaine combined with fentanyl produce an adequate level of anaesthesia similar to 4 mg but with faster recovery and prolonged analgesia for adult anorectal surgery. Clinical Trial Registration: The trial was registered retrospectively in ISRCTN registry as ISRCTN84658134 and can be viewed at https://www.isrctn.com/ISRCTN84658134.

#### Keywords

Spinal; Bupivacaine; Fentanyl; Anorectal; Anaesthesia

# **1. Introduction**

Spinal anaesthesia offers some notable advantages over general anaesthesia, including shorter duration of anaesthesia, fewer drug requirements, relative cost-effectiveness, fewer complications [1]. However, it is known that large doses of spinal bupivacaine can lead to excessive extent and duration of sensory and motor block requiring additional efforts of medical staff and causing inconvenience to the patient [2]. Adding intrathecal opioid to spinal anaesthesia is relatively safe and can increase the effectiveness of analgesia of the neuraxial block [3, 4]. Therefore, to reduce the unwanted harmful side effects of larger doses of local anaesthetic alone, the possibility of adding intrathecal opioid should be considered [2, 5]. The goal of the double-blinded, randomised controlled study was to test the hypothesis that addition of fentanyl to low-dose spinal hyperbaric bupivacaine enables to reduce the effective dose of bupivacaine with faster recovery and similar quality of anaesthesia for anorectal surgery.

# 2. Methods

Before the study, approval by Kaunas Regional Committee of Ethics of Biomedical Research was acquired (Prot. No. 75/2003) and informed consent was obtained from 132 patients aged  $\geq$ 18 years, undergoing elective anorectal surgery (Fig. 1).

Exclusion criteria of the study comprised individuals with ASA physical scale greater than 3, a body mass index (BMI) exceeding 30 kg/m<sup>2</sup>, and patients using psychotropic or analgesic medications.



FIGURE 1. Study flow chart. Group S3F received 3 mg of spinal hyperbaric bupivacaine and 10  $\mu$ g of fentanyl. Group S4 received 4 mg of spinal hyperbaric bupivacaine only.

Patients were allocated randomly to one of two groups using sealed envelopes: Group S3F (n = 66) received 3 mg (0.6 mL) of spinal 0.5% hyperbaric bupivacaine along with 10  $\mu$ g (0.2 mL) to a total volume of 0.8 mL, while Group S4 received 4 mg (0.8 mL) of spinal 0.5% hyperbaric bupivacaine. Patients were familiarised with the visual analogue pain scale (VAS) of 0–100 mm and anaesthesia quality scale (described below). The anaesthesiologists, surgeons, and surgical nurses responsible for assessing quality of anaesthesia were blinded and unaware of the patient's group assignment.

Upon arrival at the operating room, an 18–20 G catheter was inserted, and standard monitoring, including electrocardiogram, heart rate, oxygen saturation, and non-invasive blood pressure taken every 5 minutes, was initiated.

Spinal anaesthesia was induced in the sitting position, with a 26 G spinal needle, using a median approach. The dura was punctured at L3-4 or L4-5 and hyperbaric bupivacaine (Marcaine Spinal Heavy 0.5%) injected over 2 minutes: Group S4 0.8 mL, Group S3F 0.6 mL + fentanyl 10  $\mu$ g to 0.8 mL as stated by the envelope. After sitting for 10 minutes, patients were instructed to lie down. The level of the sensory block was tested with an alcohol swab. Motor block was tested using a modified Bromage scale (0 = no motor block, 1 = able to flex ankle and bend knees, 2 = able to flex ankle, 3 = full motor block). After this, surgery was started. In case of unsuccessful block, supplementary fentanyl or sedation with thiopentone were administered.

After the surgery, the surgical ward nurse was responsible

for postoperative assessment according to postoperative protocol. Morphine was administered in increments of 2.5–5 mg if VAS pain score was >50, until VAS  $\leq$ 30.

The following variables were assessed: demographics (age, gender, type of surgery), duration of anaesthesia (from dural puncture until patient left the operating room), duration of surgery, rate of success (failed block), level and duration of sensory (dermatomes) and motor (according to Bromage scale) block 10 minutes after dural puncture, at the end of surgery, in postoperative ward every 30 minutes until full resolution of the block, time to voiding and ambulation, complications (including pruritus, urinary retention on 0–2 scale, where 0 = normal urination, 1 = difficult spontaneous urination, 2 = unable to urinate and catheterisation was required), consumption of analgesics during surgery and postoperatively, level of pain (VAS scale 0–100), quality of anaesthesia according to the patient and medical staff (0–2 scores, Table 1).

The study continued for 24 hours. Patients meeting discharge criteria were dismissed from the hospital afterwards. Patients whose stay in the hospital was prolonged for any reason received the same postoperative pain treatment but data collection was stopped.

Statistical analysis was conducted using Statistica 6.0 (Stat-Soft, Inc., Tulsa, OK, USA) and the SPSS (version 26, SPSS, Inc., Chicago, IL, USA) software package. Normal distribution was assessed using the Kolmogorov-Smirnov and Lilliefors tests. For normally distributed quantitative variables, one-way and repeated measures ANOVA tests were applied,

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Variable	Score 2	Score 1	Score 0
Anaesthesiologist OR	Excellent, no need for supplementary medication	Incomplete block, supplementation needed	Failed block, switched to general anesthesia
Anaesthesiologist day 1	Excellent	Minor complaints	Major complications
Patient	Excellent anaesthesia, would choose the same method again	Fairly good anaesthesia	Bad, would choose another method
Ward nurse	Uncomplicated care, no motor block, only analgesics needed	Additional efforts required but the patient moved into bed himself	Intensive care needed, the patient does not move himself, difficult to transfer from OR to bed
Surgeon	Excellent anaesthesia in perirectal zone	Satisfactory anaesthesia in perirectal zone	Failed block, surgery impossible
Sphincter relaxation	++ sphincter relaxation	+ sphincter relaxation	Failed block, no sphincter relaxation

TABLE 1. Quality of anesthesia according to the patient and medical staff.

Note. OR: operating room; day 1: the first postoperative day; ++: excellent sphincter relaxation; +: acceptable sphincter relaxation.

with *post hoc* Bonferroni. Homogeneity of variance was evaluated using Levene's test. Nonparametric rank values were analysed using Kruskal-Wallis and Mann-Whitney tests, while nominal values were analysed using  $\chi^2$  tests. p < 0.05 was considered significant.

The sample size was calculated considering duration of sensory block as the primary variable [6]. Regarding duration of sensory block, 62 patients in Groups S3F and S4 were needed to obtain a significant difference with  $\alpha = 0.05$  and  $\beta = 0.2$ . To compensate for possible losses, 66 patients were included in Groups S3F and S4.

# 3. Results

The study was completed after evaluating 132 patients. Patient characteristics, including demographics, type and duration of surgery were comparable between groups. Duration of anaesthesia was 10 minutes shorter in Group S3F (Table 2).

## 3.1 Characteristics of the block

In Group S3F, one case of a failed block was observed (Fig. 1). Groups were comparable in terms of supplementary intravenous (IV) medication. The maximum level of sensory block was significantly higher in Group S3F. More than 85% of patients in both groups were able to position themselves on the operating table with Bromage scores of 0 (Table 3).

Mean duration of sensory block was statistically significantly shorter in Group S3F compared to Group S4. Moreover, Group S3F demonstrated a longer duration of analgesia, compared to 217.8  $\pm$  48.5 minutes in Group S4. Motor block in Group S3F had the same low level of motor block as in Group S4 but was of significantly shorter duration. Median time required to urinate following block regression was statistically significantly shorter in Group S4 than in Group S3F (Table 4).

Statistically significant differences were observed in the highest level of sensory block among the groups. These differences were evident at 10 minutes after dural puncture, at the end of the operation, and 150 minutes postoperatively. Group S3F exhibited the highest values at 10 minutes after dural puncture and at the end of the operation, while Group S4 demonstrated the highest values at 150 minutes postoperatively (Fig. 2).

Variable	Group S4 $(n = 66)$	Group S3F $(n = 65)$	<i>p</i> value
$Age^a$	$49.1 \pm 14.6$	$47.9 \pm 12.9$	ns
Male/female	32/34	33/32	ns
Haemorrhoids <sup>b</sup>	33 (50.0)	30 (46.1)	
Anorectal fistula	19 (28.7)	14 (21.5)	ns
Other surgery	14 (21.3)	21 (32.4)	
Duration of surgery <sup>a</sup>	$20.5\pm10.5$	$17.7\pm11.8$	ns
Duration of anaesthesia $^a$	$48.3\pm13.8$	$38.1 \pm 13.8 *$	*p < 0.0001

TABLE 2. Patient demographics, duration of anaesthesia, duration and type of surgery.

<sup>*a*</sup>values are mean  $\pm$  SD. <sup>*b*</sup>values are cases (%). ns: non-significant, p > 0.05. \*p < 0.05.

TABLE 3. Characteristics of the block.			
Variable	Group S4	Group S3F	<i>p</i> value
Max level of sensory block, dermatomes $a$	$\textbf{7.0} \pm \textbf{1.8}$	$\textbf{7.7} \pm \textbf{1.4}$	p = 0.009 $1 - \beta = 0.75$
Max level of motor block, Bromage scale <sup>b</sup>			
0	58 (87.8)	63 (96.9)	
1	5 (7.6)	1 (1.5)	ns, by exact $\chi^2$
2	3 (4.5)	1 (1.5)	
Supplementary fentanyl <sup>b</sup>	4 (3.0)	1 (1.5)	ns, by exact $\chi^2$
Sedation with thiopentone <sup>b</sup>	4 (6.0)	3 (4.6)	ns, by exact $\chi^2$

<sup>*a*</sup>values are mean  $\pm$  SD. <sup>*b*</sup>values are cases (%). ns: non-significant, p > 0.05.

Results in bold numbers are most important.

TABLE 4.	Characteristics	of block	regression.
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Variable	Group S4	Group S3F	<i>p</i> value
Duration of sensory block, $\min^a$	$229.5\pm36.5$	$212.7\pm35.1*$	* $p = 0.008$ , by Student's $t$
Duration of motor block, $\min^b$	0 (0–90)	0 (0–30)*	* <i>p</i> = 0.015, by M-W
Duration of analgesia, min <sup>b</sup>	$217.8\pm48.5$	$242.2\pm67.6*$	* $p = 0.019$ , by Student's $t$
Time to urinate, min <sup>b</sup>	260 (120–960)*	315 (160–1140)	* $p = 0.023$ , by M-W

<sup>*a*</sup>values are mean  $\pm$  SD. <sup>*b*</sup>values are median (range). \*p < 0.05. M-W: Mann-Whitney.



FIGURE 2. Mean level of sensory block at times after start of anaesthesia with spinal hyperbaric bupivacaine 4 mg (Group S4), 3 mg + fentanyl (Group S3F). Values on the Y axis are: 0-no block, 2-S4, 4-S2, 6-L5, 8-L3 and 10-L1 level. Values on X axis are: 0-level at 10 min after dural puncture, op-at the end of operation, 30 and others-minutes after the operation. \*p < 0.05 and  $\beta \leq 0.2$ , by ANOVA and *post hoc* Bonferroni.

## 3.2 Postoperative pain intensity

Following the surgical procedure, pain intensity was assessed using the 0–100 VAS scale in both groups at rest and movement. The findings indicated that pain intensity was significantly lower in Group S3F group at 2, 2.5, 3 and 6 hours both at rest and during movement. Notably, pain peaked at 6 hours both during rest and movement (VAS scores 15.6 and 20.6, respectively) in Group S4, while the peak occurred at 12 hours (VAS scores 10 and 15.9, respectively) in Group S3F. However, starting from 9 hours onward, no statistically significant difference between groups was observed in the measured mean pain intensity (Figs. 3,4).

The necessity for postoperative opioids, specifically morphine, was also assessed. Most of the patients, 72.7% in Group S4 and 84.6% in Group S3F did not require morphine for postoperative analgesia, and no statistically significant difference was observed (p = 0.1). The range of morphine doses was measured, reaching up to 10 mg in both groups (Table 5).

## 3.3 Postoperative characteristics

After the surgical intervention, an evaluation was conducted to assess postoperative pruritus and urinary retention. Pruritus was identified in 4 cases of Group S3F, the result being statistically significantly different from Group S4, where no cases of pruritus were observed (Table 5). No statistically significant difference was observed concerning urinary retention between the two groups. However, difficulties in spontaneous urination were noted by patients in both groups from 10.8 to 12.1% of cases, and 2 patients in Group S3F even experienced complete urinary retention necessitating bladder catheterization (Table 5).

## 3.4 Quality of anaesthesia

The assessment of anaesthesia quality involved evaluations by the anaesthesiologist in the operating room (Anaesthesiologist OR), the anaesthesiologist on the postoperative care ward (Anaesthesiologist day 1), the patient post-surgery, the ward nurse and the surgeon. Sphincter relaxation was also considered as one of the indicators of anaesthesia quality. In the majority of cases assessed (greater than 90% in each group), both groups received feedback indicating excellent anaesthesia quality. No significant differences were observed when comparing S3F and S4 groups (Table 6).

# 4. Discussion

The main finding of our study was that the addition of lowdose fentanyl to spinal hyperbaric bupivacaine compared to anaesthesia with bupivacaine alone improves the quality of analgesia and reduces the dose of local anaesthetic required for minor anorectal surgery. This leads to a comparable level of anaesthesia with shorter duration of sensory and motor block.

A significantly higher sensory block was observed in Group S3F (3 mg bupivacaine + fentanyl) compared to Group S4 (4 mg bupivacaine), indicating a more rapid intrathecal spread of the solution associated with the adjunctive use of fentanyl.

However, the difference in one dermatome is not clinically relevant and the level fixed either at L3 in Group S3F or at L4 in Group S4, respectively. Shim et al. [7] reported a uniform level of sensory blockade at S1 in both experimental cohorts-Group B (bupivacaine alone) and Group BF (bupivacaine with fentanyl). The difference from our study can be explained by methodological variations: patient positioning after dural puncture and higher doses of medications they used (5 mg of bupivacaine + saline or 15  $\mu$ g of fentanyl to total volume of 1.3 mL) [7]. Gurbet et al. [8] demonstrated significantly higher level of sensory block, T9 in bupivacaine 2.5 mg + fentanyl  $25 \ \mu g$  group versus T8 bupivacaine 5 mg group. An important methodological difference from our study was immediate repositioning of patients into the prone position after subarachnoid injection, a factor that might have influenced the spread of local anaesthetic solution [8].

Our research demonstrates that lower dose of local anaesthetic used, 3 mg, leads to almost no motor block in the legs (only 3% of cases developed score 1 or 2 motor block) compared to 12% of cases when 4 mg of bupivacaine was used, and this provides unlimited patient mobility maintaining acceptable conditions for surgery although the difference is not statistically significant. This outcome is consistent with the findings from Shim et al. [7], where the level of motor blockade was rated as 0 on the Bromage scale in both groups. In contrast, the study by Gurbet et al. [8] reported a maximal motor blockade of score 2 (range 1-3) on the Bromage scale, in both groups of the study [7]. Al-Bahar et al. [9] demonstrated a completely different profile of the spread of intrathecal solutions: 77% of patients developed Bromage score 3 motor block 5 minutes after dural puncture in the group where 25  $\mu$ g of fentanyl was added to 2.5 mg of bupivacaine compared to 20% cases of Bromage score 3 block in the group of 5 mg of bupivacaine. The authors did not report the levels of sensory block [9].

Median (range) duration of motor block was statistically significantly lower in Group S3F versus Group S4: 0 (0–30 minutes) versus 0 (0–90 minutes), respectively. The study by Wang *et al.* [10] demonstrated that mean duration of Bromage score 1 block was comparable between groups: 183 minutes in Group B (bupivacaine) versus 193 minutes in Group F (bupivacaine + fentanyl).

Regarding the supplementary need of i/v fentanyl or sedation with thiopental during surgery, our research indicates that a subset of patients requires supplementary analgesia; however, statistical analysis revealed no significant difference between the two groups. This observation goes in line with the outcomes reported by Gurbet *et al.* [8], where groups required comparable rate of analgesic supplementation. Shim *et al.* [7] reported no pain during surgery and no cases of conversion into general anaesthesia.

In our study, mean duration of sensory block was 212.7  $\pm$  35.1 minutes in Group S3F, which was statistically significantly shorter compared to Group S4, where mean duration was 229.5  $\pm$  36.5 minutes. Duration of analgesia is prolonged by addition of fentanyl and it is almost 30 minutes longer than duration of sensory block inside the group as well as compared to duration of analgesia in Group S4. Honca *et al.* [11] studied the effectiveness of combining low-dose



**FIGURE 3.** Pain intensity at rest in groups according to time. \*p < 0.05, by ANOVA and *post hoc* Bonferroni. VAS: visual analogue pain scale.



**FIGURE 4.** Pain intensity at movement in groups according to time. \*p < 0.05, by ANOVA and *post hoc* Bonferroni. VAS: visual analogue pain scale.

TABLE 5. Fostoperative Characteristics.					
Group S4	Group S3F	<i>p</i> value			
Morphine, mg					
48 (72.7)	55 (84.6)				
5 (7.6)	3 (4.6)				
11 (16.7)	3 (4.6)	p = 0.1			
0	2 (3.1)				
2 (3.0)	2 (3.1)				
0	4 (6.2)*	* $p$ = 0.04, by exact $\chi^2$			
Urinary retention, scores					
58 (87.9)	56 (86.1)				
8 (12.1)	7 (10.8)	ns			
0 (0.0)	2 (3.1)				
	Group S4 48 (72.7) 5 (7.6) 11 (16.7) 0 2 (3.0) 0 on, scores 58 (87.9) 8 (12.1) 0 (0.0)	Group S4Group S3F48 (72.7)55 (84.6) $5$ (7.6)3 (4.6)11 (16.7)3 (4.6)02 (3.1)2 (3.0)2 (3.1)04 (6.2)*on, scores56 (86.1)8 (12.1)7 (10.8)0 (0.0)2 (3.1)			

TABLE 5. Postoperative Characteristics

Values are cases (%). p < 0.05. ns: non-significant, p > 0.05. Bold numbers highlight most important results.

Variable, scores	Group S4	Group S3F	<i>p</i> value		
Anaesthesiologist OR	Anaesthesiologist OR				
1	4 (6.0)	2 (3.0)	ne		
2	62 (93.9)	63 (96.9)	ns		
Anaesthesiologist day	1				
1	0	1 (1.5)	ns		
2	66 (100.0)	64 (98.4)	115		
Patient					
1	6 (9.1)	6 (9.2)	ns		
2	60 (90.9)	59 (90.7)	115		
Ward nurse					
1	1 (1.5)	0	ns		
2	65 (98.4)	65 (100.0)			
Surgeon					
1	1 (1.5)	3 (4.6)	ns		
2	65 (98.4)	62 (95.3)	115		
Sphincter relaxation					
1	1 (1.5)	3 (4.6)	ns		
2	65 (98.4)	62 (95.3)	115		

TABLE 6. Quality of anaesthesia.

levobupivacaine and fentanyl for spinal anesthesia in anorectal surgeries. Group I, receiving 2.5 mg levobupivacaine and 12.5  $\mu$ g fentanyl, experienced a significantly shorter time to the first request of analgesics (180 minutes) compared to Group II, which received 2.5 mg levobupivacaine and 25  $\mu$ g fentanyl (250 minutes). It is worth stating, that patients were kept in the sitting position for five minutes after dural puncture before being positioned prone, after the spinal block, patients were seated for 5 minutes before being positioned prone [11]. In Wang et al.'s [10] study on elderly patients undergoing total hip arthroplasty, additive analgesic effect of spinal fentanyl similar to our results was observed between Group B (10 mg bupivacaine) and Group F (7.5 mg bupivacaine + 20  $\mu$ g fentanyl). The time to first analgesic requirement was significantly shorter in Group B (6.3 hours) compared to Group F (7.8 hours). Both groups received higher doses of local anaesthetic compared to our study [10].

Our study indicates that the addition of 10  $\mu$ g of intrathecal fentanyl alongside hyperbaric bupivacaine reduces pain intensity for up to 6 hours postoperatively. This goes on line with findings of other authors who observed significantly decreased pain levels during the first 6 hours after surgery [7, 12]. Moreover, intrathecal fentanyl is associated with reduced consumption of post-operative opioids [7, 12]. However, we were unable to replicate this finding: no significant difference was found in terms of postoperative morphine consumption between groups (p = 0.1). Median time to the first postoperative urination exceeded 4 hours in Group S4 and it was significantly shorter than in Group S3F, >5 hours. The effect of prolonged recovery to normal urination can be attributed to intrathecal opioid. In contrast, A Gurbet *et al.* [8] revealed that the time to urinate (126 minutes) was considerably shorter for Group BF (bupivacaine + fentanyl), compared to the time of urination of Group B (bupivacaine, 154 minutes).

Urinary retention is one of the possible side effects of anorectal surgery as well as spinal anaesthesia. Our findings indicate that groups were comparable with respect to urinary retention, although two patients in Group S3F required catheterization and difficulty in voiding was noted in >12% of cases in both groups. Shim et al. [7] also found no difference in the rate of urinary retention between the studied groups; however, the incidence was notably higher, 47.5% in the bupivacaine group and 42.5% in the bupivacaine and fentanyl group. The difference from our findings could be attributed to the higher doses of administered medications. Other factors contributing to postoperative urinary retention may include a history of prior retention or extensive intraoperative fluid administration [13]. Nevertheless, most studies report the rate of urinary retention closely resembling ours either minimal or absent, irrespective of the type of surgery or the dose of medication [11, 12, 14]. A meta-analysis by Fonseca et al. [15], including 10 studies and 689 patients, also revealed no significant variance in urinary retention associated with the

*Values are cases (%). OR: operating room; day 1: the first postoperative day; ns: non-significant, p* > 0.05.

use of intrathecal opioid.

A significantly higher incidence of postoperative pruritus compared to the control group was found in Group S3F: 6.2% vs. 0%. The result is in line with previous investigations on the use of intrathecal fentanyl during peri-anal and other surgeries but the incidence in our study is considerably lower, and we presume this is due to a lower dose of intrathecal fentanyl compared to other authors [8, 9, 14]. Gurbet et al. [8] administered 25  $\mu$ g of intrathecal fentanyl, reporting the incidence of pruritus in 44.4% of cases compared to 5.9% in the control group; pruritus was mild and requiring no further treatment. Al-Bahar et al. [9] reported the incidence of pruritus was 27% in the group of fentanyl compared to 8% in the control group. Kairaluoma et al. [14] used articaine and an identical fentanyl dose to ours (10  $\mu$ g), with similar findings - the rate of pruritus was 16% with intrathecal fentanyl use compared to 2% without fentanyl; pruritus was mild and no additional treatment was required. However, Wang et al. [10] found no significant difference in the incidence of pruritus (3.3% vs. 0%) between groups with supplementary fentanyl versus control. The authors concluded that it is a potentially lesser concern for elderly patients. Nonetheless, larger-scale studies are needed to validate this observation. A recent metaanalysis revealed that pruritus can be regarded as a consistent complication of intrathecal opioid use across different surgical procedures and various opioid/local anaesthetic doses [15].

Regarding the quality of anaesthesia, neither medical staff nor patients reported any considerable difference between groups. The quality of anaesthesia was regarded as excellent (score 2 in our study) by the patient in 91% of cases in both groups. This implies that, subjectively, the efficacy of fentanyl in spinal anaesthesia is comparable to using only a local anaesthetic. Quality of anaesthesia and sphincter relaxation assessed by the surgeon was excellent (score 2) in >98% of cases in Group S4 compared to 95% of cases in Group S3F, both regarded as of very high quality. Quality of anaesthesia assessed by the anaesthesiologist and surgical ward nurse was comparable between groups and almost reaching 100% of cases. Honca et al. [11] examined the effect of different doses of fentanyl (12.5 and 25  $\mu$ g) on the quality of anaesthesia: no statistically significant difference was found. According to the patient feedback, anaesthesia was regarded as perfect in 76.9% and satisfactory in 23.1% of cases in Group I (levobupivacaine + 12.5  $\mu$ g of fentanyl) compared to 84.6% and 15.4% of cases in Group II (levobupivacaine + 25  $\mu$ g of fentanyl). Rhee et al. [16] identified the following factors contributing to patient dissatisfaction with spinal anaesthesia: multiple puncture attempts during the procedure, paraesthesia at the puncture site, postoperative nausea and vomiting, and postoperative backache. A recent study by Botea et al. [17] found that intrathecal fentanyl is associated with significantly fewer cases of high-intensity pruritus, nausea, vomiting and dizziness when compared to intrathecal morphine. However, the latter provides better management post-operative pain and a more satisfactory experience for the patient [17].

Our study was limited to the investigation of favourable and adverse effects of a low-dose spinal anaesthesia made with a single local anaesthetic, hyperbaric bupivacaine and a single opioid, fentanyl. It would be interesting to compare clinical effects of low-dose spinal anaesthesia with different, shorter-acting local anaesthetics, e.g. hyperbaric prilocaine or ropivacaine. However, they are not available in our country under ordinary basis. Another limitation of our study is that it was performed in a single center.

# 5. Conclusions

In conclusion, our research has demonstrated that a combination of 3 mg of spinal hyperbaric bupivacaine with fentanyl produces an adequate level of anaesthesia similar to a dose of 4 mg but with faster recovery and prolonged analgesia for adult anorectal surgery. Nevertheless, potential side effects such as delayed urination or pruritus must be considered when administering intrathecal fentanyl. Ultimately, from a subjective standpoint, the efficacy of bupivacaine alone is comparable to that of the bupivacaine-fentanyl combination. To gain a thorough understanding of the benefits and potential drawbacks of using intrathecal fentanyl in anorectal surgeries, conducting further large-scale randomised clinical trials is essential.

## AVAILABILITY OF DATA AND MATERIALS

All data used to support the findings of this research are included in this article.

#### AUTHOR CONTRIBUTIONS

JG—developed the methodology, carried out the research, collected data from patients; reviewed and edited the paper. EBJ and TŠ—contributed to the initial drafting of the manuscript. All authors read and approved the final manuscript.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Approval by Kaunas Regional Committee of Ethics of Biomedical Research was acquired (Prot. No. 75/2003) and informed consent was obtained from 132 patients aged >18 years, undergoing elective anorectal surgery. The trial was registered retrospectively in ISRCTN registry as ISRCTN84658134 and can be viewed at https://www.isrctn.com/ISRCTN84658134.

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#### **CONFLICT OF INTEREST**

The authors declare that there is no conflict of interest regarding the publication of this article.

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