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HOW TO MANAGE POST-OPERATIVE PAIN AFTER LAPAROSCOPIC CHOLECYSTECTOMY? COMPARISON OF THREE DISTINCT APPROACHES: A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Aim: Laparoscopic Cholecystectomy (LC) is one of the most performed surgeries in daily general surgery practice and inadequate pain relief following surgery is associated with prolonged hospital stay. Transverse abdominis plane block (TAPB), port site local anesthetic injection (PSLAI) and gallbladder bed local anesthetic spraying (GBLAS) account for a part of numerous pain management strategies. In this study, we aimed to compare post-operative pain after laparoscopic cholecystectomy in transverse abdominis plane block (TAPB), port site local anesthetic injection (PSLAI) and gallbladder bed local anesthetic spraying (GBLAS) approaches.
Materials and Methods: 99 patients were randomized into 3 groups. Patient-Controlled Analgesia (PCA) was utilized, and total analgesic demand and dosage were recorded along with Numerical Rating Scale (NRS) values at post-operative (p.o) 2, 6, 12 and 24 hours.
Results: At p.o 24 hours, there was no statistically significant difference between groups in terms of PCA readings. However, NRS values were significantly higher in PSLAI group compared to TAPB and GBLAS groups.
Conclusion: This study is unique as it compares the three methods in a single trial. While GBLAS gains slightly more attention as it is associated with a shorter procedure, all three methods are viable and might even be combined. We believe this study will pave way for future randomized controlled trials (RCT) in this regard.
Keywords: Laparoscopic cholecystectomy, Transverse abdominis plane block, Port site local anesthetic injection, Gallbladder bed local anesthetic spraying, Pain management

LAPAROSKOPİK KOLESİSTEKTOMİ SONRASI POSTOPERATİF AĞRI NASIL YÖNETİLİR? ÜÇ FARKLI YAKLAŞIMIN KARŞILAŞTIRILMASI: PROSPEKTİF RANDOMİZE KONTROLLÜ BİR ÇALIŞMA

ÖZET

Amaç: Laparoskopik Kolesistektomi (LC), günlük genel cerrahi pratiğinde en çok yapılan ameliyatlardan biridir ve ameliyat sonrası ağrının giderilmesinin yetersiz olması, hastanede kalış süresinin uzamasıyla ilişkilidir. Transvers abdominis düzlem bloğu (TAPB), port bölgesi lokal anestezik enjeksiyonu (PSLAI) ve safra kesesi yatağı lokal anestezik püskürtme (GBLAS), çok sayıda ağrı yönetimi stratejisinin bir parçasını oluşturur. Bu çalışmada, transvers abdominis düzlem bloğu (TAPB), port bölgesi lokal anestezik enjeksiyonu (PSLAI) ve safra kesesi yatağı lokal anestezik püskürtme (GBLAS) yaklaşımlarında laparoskopik kolesistektomi sonrası postoperatif ağrıyı karşılaştırmayı amaçladık.
Gereç ve Yöntem: 99 hasta 3 gruba randomize edildi. Hasta Kontrollü Analjezi (PCA) kullanıldı ve toplam analjezik talebi ve dozu, postoperatif (p.o) 2, 6, 12 ve 24. saatlerde Sayısal Derecelendirme Ölçeği (NRS) değerleri ile birlikte kaydedildi.
Bulgular: Postoperatif 24. saatte gruplar arasında PCA açısından istatistiksel olarak anlamlı bir fark yoktu. Bununla birlikte, NRS değerleri PSLAI grubunda TAPB ve GBLAS gruplarına kıyasla anlamlı olarak daha yüksekti.
Sonuç: Bu çalışma, tek bir denemedeki üç yöntemi karşılaştırdığı için benzersizdir. GBLAS, daha kısa bir prosedürle ilişkili olduğu için biraz daha fazla dikkat çekerken, her üç yöntem de uygulanabilir ve hatta birleştirilebilir. Bu çalışmanın, bu konuda gelecekteki randomize kontrollü çalışmaların (RCT) önünü açacağına inanıyoruz.
Anahtar kelimeler: Laparoskopik kolesistektomi, Transvers abdominis düzlem bloğu, Port bölgesi lokal anestezik enjeksiyonu, Safra kesesi yatağı lokal anestezik püskürtme, Ağrı yönetimi

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INTRODUCTION

Laparoscopic Cholecystectomy (LC) is one of the most common surgical operations and frequently performed globally in general surgery practices (1,2). Generally, a short hospital stay is expected in the post-operative (p.o) period. Despite being a minimally invasive procedure, post-operative pain is not rare and inadequate pain management might complicate this process (3). Although there is less postoperative pain in LC surgeries than in open cholecystectomy, severe pain, especially in the first 24 hours, is a common complaint (4). Pain after LC consists of somatic and visceral components, and various modalities have been tried to reduce post-operative pain (5). Transverse abdominis plane block (TAPB), port site local anesthetic injection (PSLAI) and gallbladder bed local anesthetic spraying (GBLAS) are among the preferred pain relief options and various studies revealed their significance compared to placebo, in this regard (6-11).

The existing studies in the literature demonstrate that findings of pain management approaches are controversial. Naturally, pain is a subjective perception and thus findings can be controversial. However, this fact alone emphasizes that standardized prospective studies are still invaluable to determine the true efficacy of these individual applications and their superiority, if there is any indeed. In this study, we aimed to compare these three methods in p.o. pain management in patients who underwent elective LC at General Surgery Department of University of Health Sciences Sultan 2. Abdulhamid Han Training and Research Hospital, Istanbul.

MATERIALS AND METHODS

The study was designed as an open label randomized controlled trial. To determine the necessary number of patients with a α=0.05 (error rate) and power=0.90 (1-β), G-power programme (Version 3.1) was utilized. To homogenize and randomize the groups, functions, which are present at "https://www.random.org/integer-sets" were utilized and 99 sets were created. With "RANDBETWEEN" command in Excel, 11 blocks were created and thus patients were randomized accordingly (Table 1). The study included a time range of November 1, 2021, to March 1, 2022. The age of the patients included in the study are 21-83 (avg. 50.3).

Table 1. Randomization Sets

Set No	No.	Set
10	1	D3, D1, D3, D1, D3, D1, D2, D2, D2
71	2	D3, D3, D2, D3, D1, D1, D2, D1, D2
49	3	D3, D3, D1, D2, D2, D3, D1, D1, D2
89	4	D2, D3, D1, D1, D3, D3, D2, D2, D1
90	5	D3, D1, D2, D2, D2, D3, D3, D1, D1
22	6	D3, D2, D2, D1, D2, D3, D3, D1, D1
66	7	D2, D1, D3, D3, D1, D2, D1, D2, D3
55	8	D1, D3, D3, D2, D3, D1, D1, D2, D2
96	9	D2, D2, D1, D2, D1, D1, D3, D3, D3
38	10	D2, D1, D3, D3, D1, D1, D2, D3, D2
78	11	D2, D3, D1, D2, D2, D3, D3, D1, D1
Group Encodings		D1=Local anesthesia group D2= Subcostal TAP group D3=Port entry site analgesia group

Following a brief study introduction and obtaining informed consent, a total of 99 patients were randomized into three groups. All patients were operated on under general anesthesia. A standard LC was performed by utilizing two 10-mm and two 5-mm trocars. In Group 1,5 mm bupivacain was injected at each trocar sites at the end of the procedure. In Group 2, the plane between external oblique and transverse abdominis muscles in right lumbar triangle of Petit's was reached with a 21GX100mm needle (StimuplexR A, Braun, Insulated Needle, USA) under real time visualization with a high frequency ultrasound probe (SonoSite MTurbo HFL50x/15-6 MHz Lineer Transducer SonoSite, Inc. Bothell, WA 98021 USA). 20 ml 0.5% concentrated bupivacaine (Bustesin® 0,5%, Vem, Türkiye) was injected into this plane at the end of the procedure. In group 3, 20 ml 0.5% concentrated bupivacaine was sprayed onto the gallbladder bed before trocar removal. PCA administration was ensured for all patients (5mg/ml Tramadol with 20 mg initial dose). Patients' analgesic demands, administrations, total analgesic dosage, nausea-vomitting, and if applicated, extra analgesics and their dosages were recorded at p.o 2, 6, 12 and 24 hours. Also, the first-time frame, in which NRS exceeded 3 points were recorded and these patients were given IV paracetamol 1 gr 3*1 and if necessary IV dexketoprofen 50 mg. For the patients, whose NRS scores never exceeded 3, the latter mentioned analgesic treatment was omitted.

Statistical Analysis

Statistical analysis was performed with SPSS 28.0. Distribution of variables was assessed with Kolmogorov Simirnov test. Independent quantitative data were analyzed with ANOVA, unpaired t-test, KNSRkal-Wallis and Mann-Whitney U tests. Dependent qualitative data were analyzed with MC Nemar test. Independent qualitative data were analyzed with Chi-square and Fischer tests.

RESULTS

Table 2 demonstrates the demographic findings along with ASA scores, additional analgesic treatment, procedures and their respective durations. There was no statistically significant difference between groups in terms of age, BMI, ASA scores and additional analgesic treatment ($p>0.05$) (Table 3). However, male population percentage was significantly higher in Group 1 compared to others ($p<0.05$). Procedure duration was significantly longer in Group 2 ($p<0.05$). However, total operative time comparison between groups was insignificant ($p>0.05$). No statistically significant difference was found between groups in terms of PCA demands ($p>0.05$) (Table 4). NRS scores were indifferent between groups at p.o 2, 6, and 12 hours. However, p.o 24-hours evaluation revealed significantly higher NRS scores in Group 1 compared to others ($p<0.05$).

DISCUSSION

P.o pain management is critical in all surgical procedures. Considering the LC frequency, even a slight increase in patients' comfort may have tremendous effects on health care systems and providers. Despite being a routine procedure, this aspect remains controversial. Therefore, we evaluated three different approaches in a single clinical trial.

Patients were homogenously distributed between groups, despite a male predominance coincidence in Group 1. Along with proper randomization, especially selection bias was avoided in this study and the above-mentioned differences and/or indifferences can be attributed to the procedures alone. TAPB duration was significantly longer than others. However, this prolongation did not affect the total operative time significantly. And considering the complexity of the procedure, a longer time requirement is only natural. PSLAI Group's NRS scores at 24 hours were found to be significantly higher in Group 1 compared to others. While it might be considered as a disadvantage, any pain which does not necessitate PCA usage, can be considered as tolerable and therefore the significance of this finding is open to debate.

Table 2. Demographic Data

		Min - Max			Median	Avg.±SD/n-%		
Age		21.0	-	83.0	51.0	50.3	±	14.5
Sex	**Female**					64		65.3%
	Male					34		34.7%
Height		150.0	-	190.0	165.0	165.3	±	8.3
Weight		59.0	-	105.0	77.0	77.5	±	11.0
BMI		19.5	-	38.3	27.5	28.4	±	3.9
ASA Score	**I**					34		34.7%
	II					60		60.2%
	III					4		4.1%
Additional Analgesic	**(-)**					91		92.9%
	(+)					7		7.1%
Procedure Duration (Sn)		2.0	-	900.0	20.0	127.3	±	197.4
Operation Duration (min)		15.0	-	150.0	50.0	54.8	±	21.8

Table 3. Demographic Data and Results of TAPB, PSLAI and GBLAS Approaches

			TAPB			PSLAI			GBLAS			p	
Age		Avg.±SD	48.9	±	11.8	54.9	±	13.7	47.1	±	16.7	0.072	A
		Median	49.0			56.0			50.0				
Sex	**Female**	n-%	22		68.8%	16		48.5%	26		78.8%	***0.031***	X^2
	Male	n-%	10		31.3%	17		51.5%	7		21.2%		
Height		Avg.±SD	165.0	±	7.0	167.8	±	9.8	163.0	±	7.2	0.141	K
		Median	165.0			168.0			162.0				
Weight		Avg.±SD	80.0	±	9.8	77.7	±	12.1	74.9	±	10.6	0.173	A
		Median	79.0			78.0			75.0				
BMI		Avg.±SD	29.5	±	3.9	27.7	±	4.1	28.2	±	3.7	0.093	K
		Median	29.4			27.5			27.2				
ASA Score	**I**	n-%	12		37.5%	7		21.9%	15		45.5%	0.129	x^2
	II	n-%	19		59.4%	24		71.9%	17		51.5%		
	III	n-%	1		3.1%	2		6.3%	1		3.0%		
Additional Analgesic	**(-)**	n-%	30		93.8%	31		93.9%	30		90.9%	0.867	x^2
	(+)	n-%	2		6.3%	2		6.1%	3		9.1%		
Procedure Duration (Sn)		Avg.±SD	363.8	±	189.7	18.6	±	12.1	6.8	±	5.1	***0.000***	K
		Median	300.0			15.0			5.0				
Operation Duration (min)		Avg.±SD	54.4	±	21.2	60.8	±	24.5	49.4	±	18.5	0.141	K
		Median	50.0			55.0			45.0				

[A] ANOVA / [K] Kruskal-wallis (Mann-whitney u test) / [X^2] Chi-Square test (Fischer test)

Table 4. Results of TAPB, PSLAI and GBLAS Approaches

			TAPB			PSLAI			GBLAS			p	
PCA													
2. hour		Avg.±SD	3.0	±	3.9	10.3	±	26.0	4.7	±	9.7	0.798	K
		Median	1.5			2.0			2.0				
6. hour		Avg.±SD	3.3	±	6.7	5.2	±	18.7	3.8	±	8.8	0.852	K
		Median	1.0			1.0			1.0				
12. hour		Avg.±SD	2.8	±	4.8	4.9	±	19.4	2.2	±	4.2	0.749	K
		Median	1.0			0.0			1.0				
24. hour		Avg.±SD	1.7	±	3.6	4.1	±	20.9	0.7	±	1.4	0.217	K
		Median	0.0			0.0			0.0				
NSR													
2. hour		Avg.±SD	2.4	±	1.7	1.9	±	1.2	2.0	±	1.2	0.482	K
		Median	2.0			2.0			2.0				
6. hour		Avg.±SD	1.8	±	1.1	1.9	±	1.0	1.5	±	1.0	0.378	K
		Median	2.0			2.0			1.0				
12. hour		Avg.±SD	1.5	±	1.1	1.7	±	1.2	1.3	±	1.1	0.349	K
		Median	1.5			1.0			1.0				
24. hour		Avg.±SD	1.0	±	1.0	1.2	±	0.7	0.8	±	0.9	0.105	K
		Median	1.0			1.0			1.0				
NSR													
2. hour	**(-)**	n-%	5		15.6%	3		9.1%	5		15.2%	0.685	X^2
	(+)	n-%	27		84.4%	30		90.9%	28		84.8%		
6. hour	**(-)**	n-%	5		15.6%	1		3.0%	5		15.2%	0.187	X^2
	(+)	n-%	27		84.4%	32		97.0%	28		84.8%		
12. hour	**(-)**	n-%	7		21.9%	2		6.1%	5		15.2%	0.187	X^2
	(+)	n-%	25		78.1%	31		93.9%	28		84.8%		
24. hour	**(-)**	n-%	12		37.5%	3		9.1%	15		45.5%	***0.003***	X^2
	(+)	n-%	20		62.5%	30		90.9%	18		54.5%		

^{K} Kruskal-wallis (Mann-whitney u test) / $^{X^2}$ Chi-Square test (Fischer test)

A RCT revealed that subcostal TAPB relieves pain significantly in both resting and coughing following LC (12). Another study demonstrated significant pain relief (including shoulder pain) and nausea-vomitting reduction with GBLAS (13). Other studies evaluated PSLAI and found it to be beneficial (14,15). A meta-analysis including 10 trials and 668 patients demonstrated the superiority of TAPB to PSLAI, in terms of resting pain at p.o 2, 12 and 24 hours and pain associated with movement at p.o 24 hours following LC (16). Another study evaluated 60 patients and found that PSLAI was associated with better pain management throughout p.o 24 hours compared to GBLAS (17). A different RCT included 294 patients and found intraperitoneal anesthesia to be superior to PSLAI in this regard (18).

Limitations of the study

The lack of different pain types of comparison (at rest, with cough and ambulation) and conduction in a single center constitute its main disadvantages of the study.

CONCLUSION

The advantages of our study are its prospective randomized design with a proper number of patients, its unique structure as it evaluates all three methods in a single trial, standard and professional surgical practice and being the first study to compare TAPB and GBLAS to our knowledge.

Consequently, considering the higher NRS scores at 24 hours in PSLAI Group and more time consumption in TABP Group, GBLAS gains slightly more attention, although there was no difference in PCA demands. Keeping this in mind, physicians and scholars should not limit themselves to a single approach. We believe that further prospective randomized multi-center studies are necessary, and these studies should also include combined approaches.

Declarations

Ethical Approval

The Ethics Committee approval no. 21/98 was obtained from University of Health Sciences Hamidiye Clinical Research Ethics Committee with the decision dated 03/02/2022 for the presented study.

Conflicts of Interest

The authors disclosed no conflict of interest during the preparation or publication of this study.

Financial Disclosure

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