Randomized comparison between pericapsular nerve group (PENG) block and suprainguinal fascia iliaca block for total hip arthroplasty

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ABSTRACT

Background This randomized trial compared ultrasound-guided pericapsular nerve group block and suprainguinal fascia iliaca block in patients undergoing primary total hip arthroplasty. We selected the postoperative incidence of quadriceps motor block (defined as paresis or paralysis of knee extension) at 6 hours as the primary outcome. We hypothesized that, compared with suprainguinal fascia iliaca block, pericapsular nerve group block would decrease its occurrence from 70% to 20%.

Methods Forty patients undergoing primary total hip arthroplasty under spinal anesthesia were randomly allocated to receive a pericapsular nerve group block (n=20) using 20 mL of adrenalized levobupivacaine 0.50%, or a suprainguinal fascia iliaca block (n=20) using 40 mL of adrenalized levobupivacaine 0.25%. After the performance of the block, a blinded observer recorded pain scores at 3, 6, 12, 18, 24, 36, and 48 hours; cumulative breakthrough morphine consumption at 24 and 48 hours; opioid-related side effects; ability to perform physiotherapy at 24 and 48 hours; as well as length of stay. Furthermore, the blinded observer also carried out sensory assessment (of the anterior, lateral, and medial aspects of the mid-thigh) and motor assessment (knee extension and hip adduction) at 3, 6, and 24 hours.

Results Compared with suprainguinal fascia iliaca block, pericapsular nerve group block resulted in a lower incidence of quadriceps motor block at 3 hours (45% vs 90%; p<0.001) and 6 hours (25% vs 85%; p<0.001). Furthermore, pericapsular nerve group block also provided better preservation of hip adduction at 3 hours (p=0.023) as well as decreased sensory block of the anterior, lateral, and medial thighs at all measurement intervals (all p≤0.014). No clinically significant intergroup differences were found in terms of postoperative pain scores, cumulative opioid consumption at 24 and 48 hours, ability to perform physiotherapy, opioid-related side effects, and length of hospital stay.

Conclusion For primary total hip arthroplasty, pericapsular nerve group block results in better preservation of motor function than suprainguinal fascia iliaca block. Additional investigation is required to elucidate the optimal local anesthetic volume for motor-sparing pericapsular nerve group block and to compare the latter with alternate motor-sparing strategies such as periarticular local anesthetic infiltration.

Trial registration number NCT04402450.

INTRODUCTION

In recent years, ultrasound (US)-guided suprainguinal fascia iliaca block (SIFIB) has emerged as a reliable analgesic option for total hip arthroplasty (THA)[1] that rivals lumbar plexus block in terms of pain control and breakthrough opioid consumption.[2] However, SIFIB may lead to decreased motor strength of the surgical limb[2] thereby hindering postoperative mobilization[3] and delaying discharge after outpatient THA.[4] In 2018, Girón-Arango *et al*[5] described a new block, termed pericapsular nerve group (PENG) block, which selectively targets the articular branches of the femoral and accessory obturator nerves while sparing their motor components.

In this randomized trial, we compared US-guided SIFIB and PENG block in patients undergoing primary THA. Since an important benefit associated with PENG block stems from its motor-sparing effect, we selected the incidence of quadriceps motor block (at 6 hours) as our primary outcome. We hypothesized that, compared with SIFIB, PENG block would decrease its occurrence from 70% to 20%.

MATERIAL AND METHODS

The current trial (online supplemental file 1) was registered at ClinicalTrials.gov (Study ID: NCT04402450) on 5/26/2020 prior to patient recruitment. Ethics committee approval (Hospital Clínico Universidad de Chile) was secured on 4/1/2020. All study data were collected and managed using the REDCap electronic data capture tool hosted at the University of Chile.[6] The 40 subjects were recruited over a period of 9 months (8/31/2020 to 5/25/2021) (figure 1).

After obtaining written informed consent, we enrolled 40 patients undergoing primary THA. Inclusion criteria were: age between 18 and 80 years, American Society of Anesthesiologists (ASA) physical status I to III, and body mass index between 18 and 35 kg/m^2. Exclusion criteria were: inability to consent to the study, coagulopathy, sepsis, hepatic or renal failure, allergy to local anesthetic (LA), prior surgery of the inguinal or suprainguinal area, pregnancy, and opioid intake at home

All patients received spinal anesthesia with 10 mg of isobaric bupivacaine (ie, 2 mL of bupivacaine 0.5%) and 20 µg of fentanyl. All surgical

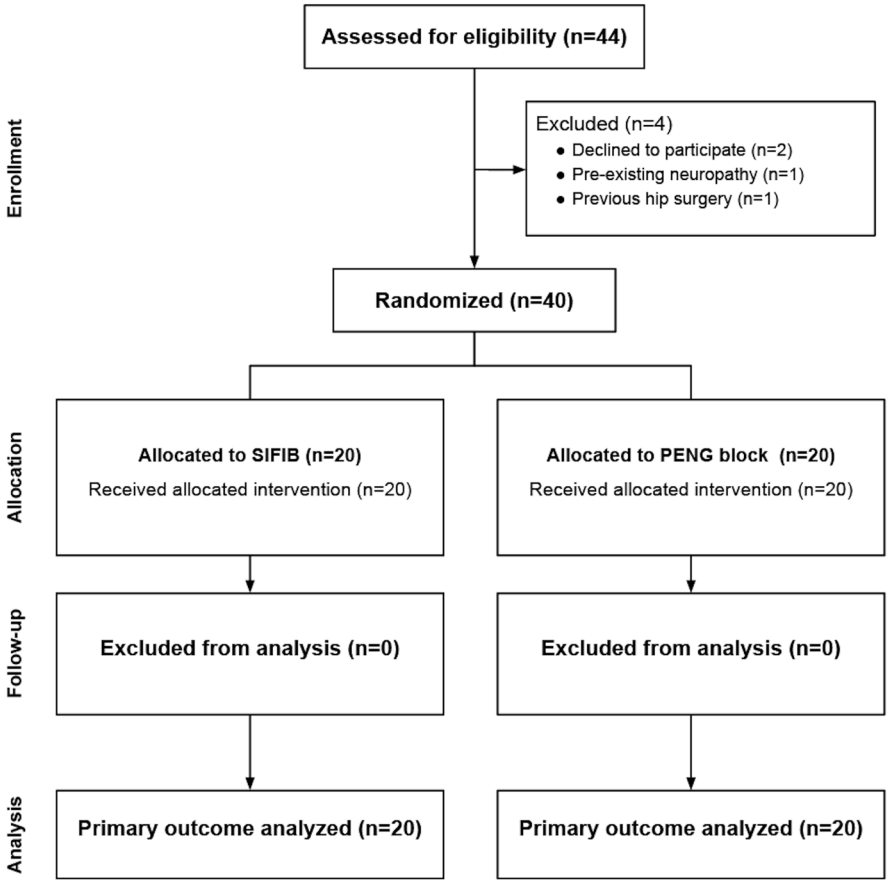

Figure 1 CONSORT diagram. PENG, pericapsular nerve group block; SIFIB, suprainguinal fascia iliaca block.

interventions were performed by the same team of surgeons (CB, RW, JB) using a posterior approach and a lateral decubitus position. During the case, propofol sedation through a target-controlled infusion (site effect concentration=0.5–1 ug/mL) was provided at the discretion of the treating anesthesiologist, provided patient response to verbal stimulus was maintained. At the end of the case, all patients received intravenous ketoprofen (100 mg) and paracetamol (1 g).

On arrival in the postanesthesia care unit (PACU), using a computer-generated sequence of random numbers and a sealed, opaque envelope technique, patients were randomly allocated to receive US-guided PENG block (n=20) or SIFIB (n=20). The randomization list and opaque envelopes were created by a research assistant who was not otherwise involved in patient care. All blocks were performed by trainees (Fellows or residents) and supervised by one of three coauthors (DB, SL, JA). The US machine (GE Logiq e, GE Healthcare, Wauwatosa, Wisconsin, USA), 4–13 MHz linear US transducer, 100 mm,

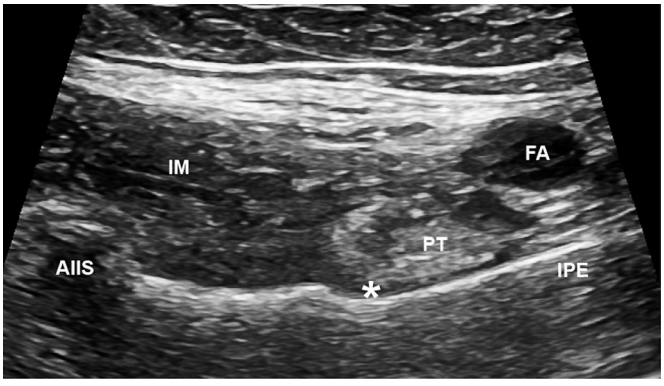

Figure 2 Sonoanatomy of PENG block. AIIS, anterior inferior iliac spine; Asterisk (white), target for local anesthetic injection; FA, femoral artery; IM, iliac muscle; IPE, iliopubic eminence; PT, psoas muscle tendon.

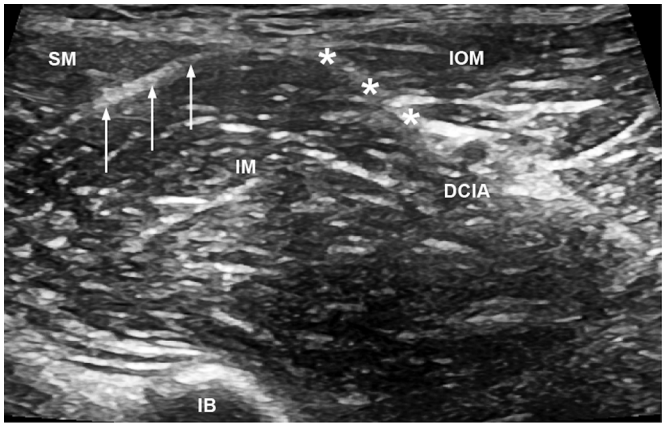

Figure 3 Sonoanatomy of suprainguinal fascia iliaca block. Asterisks (white), target for local anesthetic injection; arrows (white), fascia iliaca; DCIA, deep circumflex iliac artery; IB, iliac bone; IM, iliac muscle; IOM, internal oblique muscle; SM, sartorius muscle.

Table 1 Patient characteristics

	SIFIB	PENG
Sample size, n	20	20
Mean age (SD) in years	59.6 (9.2)	56.8 (13)
Sex, n (%)		
Male	7 (35)	7 (35)
Female	13 (65)	13 (65)
Mean BMI (SD) in kg/m^2	28.4 (4.6)	27.6 (3.8)
ASA classification, n (%)		
I	6 (20)	9 (45)
II	13 (65)	11 (55)
III	1 (5)	0
Mean surgical time (SD) in minutes	73.5 (17.3)	74.9 (28)

ASA, American Society of Anesthesiologists; BMI, body mass index; PENG, pericapsular nerve group block; SIFIB, suprainguinal fascia iliaca block.

20-gauge, short-beveled block needles (Stimuplex Ultra 360, B Braun Medical, Melsungen, Germany), and block adjuvants (4 mg of intravenous dexamethasone) were identical for all subjects. Furthermore, the total dose of levobupivacaine (100 mg) was also similar for both groups; however, for PENG blocks, a concentration of 0.5% was used in order to respect the 20 mL-injectate advocated by Girón-Arango *et al*.[5] In contrast, for SIFIB, a 0.25%-concentration and a 40 mL-volume[2] were administered.

Performance of nerve blocks

For PENG blocks, patients were placed in the supine position. The US transducer was placed in a transverse orientation, medial, and caudal to the anterosuperior iliac spine in order to identify the anteroinferior iliac spine, the iliopubic eminence, and the psoas tendon.[5] Using an in-plane technique and a lateral-to-medial direction, the block needle was advanced until its tip was positioned between the periosteum and psoas tendon (figure 2). The LA (20 mL of levobupivacaine 0.5% with epinephrine 5 µg/ mL) was injected following negative aspiration.

For SIFIBs, patients were placed in the supine position. The US transducer was placed in a parasagittal orientation, medial to the anterosuperior iliac spine in order to obtain the "bow-tie" sign.[1] The sartorius, iliacus, and internal oblique muscles were identified.[2] Using an in-plane technique and a caudad-to-cephalad direction, the block needle was advanced until its tip was positioned between the internal oblique and iliacus muscles underneath the fascia iliaca (figure 3). Following negative aspiration, the LA (40 mL of levobupivacaine 0.25% with epinephrine 5 µg/ mL) was injected as the needle was slowly advanced cephalad inside the fascia iliaca compartment.

During the performance of PENG blocks and SIFIBs, the screen of the US machine was systematically turned away from the patient's field of vision.

Postoperative analgesic regimen

In the PACU, after the performance of the PENG block or SIFIB, all patients received patient-controlled analgesia (morphine bolus=1 mg; lockout interval=8 min). On the surgical ward, in addition to patient-controlled morphine analgesia, they also received regular acetaminophen (1 g *per os* every 6 hours) and ketoprofen (100 mg *per os* every 8 hours) during 48 hours.

Primary outcome

Our primary outcome was the incidence of quadriceps motor block (defined as paresis or paralysis of knee extension) at 6 hours postoperatively. Knee extension was evaluated in a supine position with the patient's hip and knee flexed at 45° and 90°, respectively. The patient was asked to extend the knee first against gravity and then against resistance. Knee extension was graded according to a 3-point scale: 0=normal strength (extension against gravity and against resistance); 1=paresis (extension against gravity but not against resistance); 2=paralysis (no extension possible).[2]

Secondary outcomes

During the performance of the blocks, recorded secondary outcomes included performance time (defined as the temporal interval between the start of skin disinfection and the end of LA injection through the block needle) as well as the incidence of block-related adverse events (ie, vascular puncture, paresthesia, LA toxicity).

Postoperatively, secondary outcomes included static (at rest) and dynamic (with hip adduction) pain scores at 3, 6, 12, 18, 24,

Table 2 Sensory and motor block assessment

	SIFIB (n=20)			PENG (n=20)			
Sensory block	**No block**	**Analgesia**	**Anesthesia**	**No block**	**Analgesia**	**Anesthesia**	**P value**
Lateral thigh at 3-hour postblock, n (%)	1 (5)	3 (15)	16(80)	6 (30)	12 (60)	2 (10)	<0.001
Lateral thigh at 6-hour postblock, n (%)	1 (5)	13 (65)	6 (30)	16 (80)	4 (20)	0 (0)	<0.001
Lateral thigh at 24-hour postblock, n (%)	6 (30)	12 (60)	2 (10)	18 (90)	2 (10)	0 (0)	0.001
Anterior thigh at 3-hour postblock, n (%)	0 (0)	5 (25)	15 (75)	7 (35)	11 (55)	2 (10)	<0.001
Anterior thigh at 6-hour postblock, n (%)	1 (5)	10 (50)	9 (45)	17 (85)	3 (15)	0 (0)	<0.001
Anterior thigh at 24-hour postblock, n (%)	7 (35)	12 (60)	1 (5)	20 (100)	0 (0)	0 (0)	<0.001
Medial thigh at 3-hour postblock, n (%)	3 (15)	4 (20)	13 (65)	8 (40)	11 (55)	1 (5)	0.001
Medial thigh at 6-hour postblock, n (%)	4 (20)	11 (55)	5 (25)	18 (90)	2 (10)	0 (0)	<0.001
Medial thigh at 24-hour postblock, n (%)	11 (55)	8 (40)	1 (5)	20 (100)	0 (0)	0 (0)	0.014
Motor block	**No block**	**Paresis**	**Paralysis**	**No block**	**Paresis**	**Paralysis**	
Knee extension at 3-hour postblock, n (%)	2 (10)	4 (20)	14 (70)	11 (55)	7 (35)	2 (10)	<0.001
Knee extension at 6-hour postblock, n (%)	3 (15)	6 (30)	11 (55)	15 (75)	4 (20)	1 (5)	<0.001
Knee extension at 24-hour postblock, n (%)	13 (65)	5 (25)	2 (10)	19 (95)	1 (5)	0 (0)	0.102
Hip adduction at 3-hour postblock, n (%)	2 (10)	10 (50)	8 (40)	10 (50)	6 (30)	4 (20)	0.023
Hip adduction at 6-hour postblock, n (%)	7 (35)	8 (40)	5 (25)	10 (50)	7 (35)	3 (15)	0.341
Hip adduction at 24-hour postblock, n (%)	14 (70)	5 (25)	1 (5)	15 (75)	5 (25)	0 (0)	0.738

PENG, pericapsular nerve group block; SIFIB, suprainguinal fascia iliaca block.

Table 3 Block performance data and postoperative outcomes

	SIFIB	PENG	P value
Performance time (min)	5.0 (1.6)	4.4 (1.8)	0.230
Postoperative intravenous morphine consumption at 24 hours (mg)	4.5 (4.7)	4.8 (5.3)	0.851
Postoperative intravenous morphine consumption at 48 hours (mg)	6.1 (6.8)	7.5 (8.6)	0.584
Inability to perform physiotherapy at POD1 due to motor blockade, n (%)	1 (5)	0 (0)	0.799
Inability to perform physiotherapy at POD2 due to motor blockade, n (%)	0 (0)	0 (0)	>0.999
Inability to perform physiotherapy at POD1 due to pain, n (%)	0 (0)	2 (10)	0.602
Inability to perform physiotherapy at POD2 due to pain, n (%)	0 (0)	0 (0)	>0.999
Length of stay (days)	2 (2–3)	2 (1–5)	0.664
Vascular puncture, n (%)	0 (0)	0 (0)	>0.999
Paresthesia, n (%)	0 (0)	0 (0)	>0.999
LAST, n (%)	0 (0)	0 (0)	>0.999
PONV, n (%)	0 (0)	2 (10)	0.602
Pruritus, n (%)	0 (0)	1 (5)	0.799
Respiratory depression, n (%)	0 (0)	0 (0)	>0.999

Continuous variables are presented as mean (SD); categorical variables are presented as count (percentage). Ordinal variables (length of stay) are presented as median (range).
LAST, local anesthetic systemic toxicity; PENG, pericapsular nerve group block; POD1, postoperative day 1; POD2, postoperative day 2; PONV, postoperative nausea and vomiting; SIFIB, suprainguinal fascia iliaca block.

36, and 48 hours; cumulative morphine consumption at 24 and 48 hours; opioid-related side effects (ie, postoperative nausea/vomiting, pruritus, urinary retention, respiratory depression); inability to perform physiotherapy at 24 and 48 hours due to motor block or pain; as well as length of stay.

Postoperative sensory block was assessed in the anterior, lateral and medial aspects of the mid-thigh at 3, 6, and 24 hours. For each territory, blockade was evaluated using a 3-point scale: 0=no block, 1=analgesia (patient can feel touch, not cold), 2=anesthesia (patient cannot feel touch).[2]

Postoperative motor block was assessed using knee extension and hip adduction. In addition to 6 hours, knee extension was also evaluated at 3 and 24 hours according to the same 3-point scale described for the primary outcome (*vide supra*). Since hip adduction originates from the lumbar and sacral plexi, it was evaluated by comparing postblock to baseline strength. Preoperatively, a blood pressure cuff, inflated at 40 mm Hg, was inserted between the knees of the patient: the latter was then instructed to squeeze the cuff with the operative limb as hard as possible and to sustain the effort. Postoperatively, hip adduction was assessed at 3, 6, and 24 hours. We defined hip adduction scores of 0, 1, and 2 points as decreases in strength of 0%–20%, 21%–70%, and 71%–90% compared with baseline measurement, respectively.[2 7]

Table 4 Postoperative pain scores

	SIFIB (n=20)	PENG (n=20)	P value
Pain 3-hour static (NRS)	0 (0–8)	1.5 (0–7)	0.209
Pain 3-hour dynamic (NRS)	1.5 (0–9)	3 (0–8)	0.021
Pain 6-hour static (NRS)	2 (0–6)	1.5 (0–7)	0.984
Pain 6-hour dynamic (NRS)	3 (0–7)	3 (0–9)	0.951
Pain 12-hour static (NRS)	1.5 (0–5)	1.5 (0–6)	0.614
Pain 12-hour dynamic (NRS)	3 (0–6)	2.5 (0–8)	0.795
Pain 18-hours static (NRS)	0 (0–4)	1 (0–5)	0.099
Pain 18-hour dynamic (NRS)	2 (0–6)	2 (0–8)	0.562
Pain 24-hour static (NRS)	0 (0–3)	0 (0–6)	0.573
Pain 24-hour dynamic (NRS)	2 (0–5)	2 (0–8)	0.675
Pain 36-hour static (NRS)	0 (0–4)	0 (0–7)	0.085
Pain 36-hour dynamic (NRS)	0 (0–5)	1.5 (0–9)	0.021
Pain 48-hour static (NRS)	0 (0–3)	0 (0–3)	0.416
Pain 48-hour dynamic (NRS)	1 (0–5)	1 (0–5)	0.332

Pain scores are presented as median (range).
NRS, numeric rating score; PENG, pericapsular nerve group block; SIFIB, suprainguinal fascia iliaca block.

Except for performance time and the incidences of vascular puncture, paresthesia and LA toxicity (which were recorded by the coauthor supervising the block), all other outcomes were evaluated by a blinded investigator. The latter also recorded demographic data (ie, sex, age, weight, height, and ASA class) and surgical duration.

Sample size calculation and statistical analysis

Our experience with SIFIB suggests that the incidence of quadriceps motor block (paralysis or paresis) at 6 hours hovers around 70%.[2] We hypothesized that PENG block would decrease its incidence to 20%. Thus, a calculated sample size of 16 patients per group was required for a statistical power of 0.80 and a two-tailed type I error of 0.05. A total of 40 subjects was recruited to account for possible dropouts.

Statistical analysis was performed using SPSS V.21 statistical software (IBM, Armonk, New York). For continuous data, normality was first assessed and then analyzed with the Student t-test. Data that did not have a normal distribution, as well as ordinal data, were analyzed with the Mann-Whitney U test. For categorical data, the χ^2 test was used. The Fisher's exact test was used when any cell for the aforementioned categorical data had an expected count of less than five. All p values presented were two-sided and values inferior to 0.05 were considered significant.

RESULTS

Demographic characteristics and surgical duration are presented in table 1.

Compared with SIFIB, PENG block resulted in a lower incidence of quadriceps motor block at 3 hours (45% vs 90%; p<0.001) and 6 hours (25% vs 85%; p<0.001) as evidenced by improved knee extension (table 2). Furthermore, PENG block also resulted in decreased paresis/paralysis of hip adduction at 3 hours (50% vs 90%; p=0.023) (table 2). Compared with SIFIB, PENG was associated with decreased sensory block of the anterior, lateral, and medial thighs at all measurement intervals (all p≤0.014) (table 2).

No intergroup differences were found in terms of block performance time, static pain scores, cumulative opioid consumption at 24 and 48 hours, time, ability to perform physiotherapy at 24 and 48 hours, block-related adverse events, opioid-related side effects, and length of hospital stay (table 3). Dynamic pain scores

were lower with SIFIB at 3 and 36 hours (both p=0.021) but no intergroup differences were observed at other time intervals (table 4).

DISCUSSION

In this randomized trial, we compared US-guided PENG block and SIFIB in patients undergoing primary THA. Our findings suggest that PENG block results in improved preservation of knee extension (at 3 and 6 hours) and hip adduction (at 3 hours) without significantly sacrificing postoperative pain control or increasing breakthrough opioid consumption. Although our findings validate the motor-sparing benefits provided by PENG blocks, we must highlight the fact that the latter do not seem to circumvent motor block altogether. For instance, at 3 hours, 45%–50% of subjects randomized to PENG blocks experienced some paresis or paralysis of knee extension or hip adduction. However, the impairment in quadriceps function appears short-lived: in our study, at 6 hours, only 25% of subjects still experienced decreased knee extension. In contrast, at 6 hours, residual impairment in hip adduction persisted in 50% of patients. We speculate that the decrease in knee extension may stem from LA spread to the femoral nerve.[8 9] In contrast, decreased hip adduction could originate from postsurgical hip pain. Alternately, some authors have reported possible obturator motor blockade in the setting of PENG block if the needle tip is positioned medially along the iliopubic eminence[10] or if large injectates are employed.[11] Consequently, future dose-finding trials are required to elucidate the *maximal* effective volume of LA in 90% of subjects (MEV90) for motor-sparing PENG block. Furthermore, future investigation is needed to compare PENG blocks with alternate motor-sparing strategies such as periarticular LA infiltration.

The lack of intergroup differences in terms of ability to perform physiotherapy deserves special mention. Since PENG blocks result in improved motor strength of the surgical limb, one would also expect an inherent improvement in physiotherapy performance. We attribute the lack of intergroup differences to two factors. First, the ability to perform physiotherapy constituted a secondary variable: thus, our trial may have been underpowered to detect significant differences in this outcome. More importantly, our current postoperative pathway for THA (eg, first session of physiotherapy only at 24 hours) may have been inadequate to fully reap the motor-sparing benefits of PENG blocks.

Our control group (SIFIB) requires discussion, as one could argue for the inclusion of a third (placebo) group. We elected to forego such a true control group for two reasons. First, Desmet *et al*[1] have already demonstrated that, compared with no block, SIFIB results in lower pain scores and decreased opioid consumption (at 24 and 48 hours). Second, in our center, the analgesic criterion standard for THA includes the provision of peripheral nerve blocks.[2] In hindsight, the lack of a placebo group is unlikely to hinder clinical interpretation of our results, as Pascarella *et al*[12] have recently demonstrated that, compared with no block, PENG block yields lower maximal pain scores and opioid consumption during the first 48 hours after THA. Thus, the combined findings of Desmet *et al*[1] and Pascarella *et al*[12] obviate the need for sham injections or placebo.

Our protocol contains some limitations. First, despite our best effort, our subjects may not have been blinded. Although the screen of the US machine was purposefully turned away from their field of vision during the performance of the blocks, patients could have nonetheless guessed group allocation based on more pronounced sensorimotor block (SIFIB group). Second, our results are specific to single-injection blocks. Additional studies are required to confirm our findings for continuous PENG block and SIFIB.

In conclusion, for primary THA, PENG block results in better preservation of motor function than SIFIB. Additional investigation is required to elucidate the MEV90 for motor-sparing PENG block and to compare the latter with alternate motor-sparing strategies such as periarticular LA infiltration.

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Contributors SL, JA, DB, AJ, GM, CB, RW and JB participated in the planning, conception, design, conduct, reporting, acquisition of data, data analysis, and interpretation of data. RJF and DQT participated in the planning, conception, design, data analysis, and interpretation of data.

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"Una Comparación Randomizada Entre Bloqueo de Fascia Iliaca Suprainguinal y Bloqueo de Grupo de Nervios Pericapsulares para Artroplastía Total de Cadera"

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I. INTRODUCCIÓN

En los últimos años, el bloqueo de fascia iliaca suprainguinal (BFIS) se ha convertido en una opción analgésica confiable para la artroplastia total de cadera primaria (ATC). Sin embargo, al bloquear los nervios femoral y obturador, BFIS puede provocar una disminución de la fuerza de los músculos cuádriceps y aductores, lo que dificulta el rendimiento del paciente durante la fisioterapia postoperatoria. En 2018, Giron-Arango et al describieron un nuevo bloqueo, denominado bloqueo del grupo de nervios pericapsulares o bloqueo PENG (del inglés **PE**ricapsular **N**erve **G**roup) (BPENG), que se dirige selectivamente a las ramas articulares de los nervios femoral y obturador evitando sus componentes motores (**1**). Hasta la fecha, BFIS y BPENG no se han comparado formalmente en el contexto de ATC primaria.

Por lo tanto, en este estudio randomizado, compararemos BFIS y BPENG guiados por ultrasonido (US) en pacientes sometidos a ATC primaria. Dado que el principal beneficio de BPENG deriva de su efecto preservador de la fuerza del cuádriceps, la incidencia de bloqueo motor de este músculo (a las 6 horas) se ha seleccionado como outcome principal y planteamos la hipótesis de que el BPENG producira significativamente menor incidencia de bloqueo motor en comparación con BFIS.

II. OBJETIVOS GENERALES Y ESPECÍFICOS

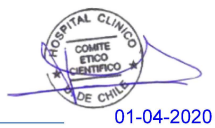
Objetivo general: comparar la incidencia de bloqueo motor postquirúrgico de los bloqueos de fascia iliaca suprainguinal y nervios pericapsulares tras la realización de una ATC para así validar el último como técnica analgésica con una potencial relación riesgo-beneficio más favorable en terminos de bloqueo motor y perfil de rehabilitación.

Objetivos específicos:

- Determinar la incidencia de bloqueo motor de cuádriceps a las 6 horas postoperatorias luego de una ATC primaria.
- Determinar el perfil analgésico de cada técnica regional por medio de la medición del consumo de analgésico (morfina), y a través del registro y comparación del dolor en reposo y dinámico en distintos intervalos temporales durante las primeras 24 horas postquirúrgicas.
- Comparar características de ambas técnicas analgésicas: tiempo de ejecución, componentes del plexo lumbar bloqueados, perfil de seguridad y efectos adversos/secundarios.
- Caracterizar demográficamente a la población estudiada.

III. HIPÓTESIS DE TRABAJO

Nuestra hipótesis es que BPENG disminuirá en un 50% (desde 70% a 20%) la incidencia absoluta de bloqueo motor de cuádriceps (parálisis total o parcial), por lo tanto, diseñamos este protocolo como un estudio de superioridad.



IV. METODOLOGÍA

Llevaremos a cabo un estudio prospectivo, randomizado y doble ciego. Con la aprobación del Comité de Ética del Hospital Clínico de la Universidad de Chile, serán reclutados 40 sujetos de un universo de pacientes programados para cirugía de artroplastía total primaria de cadera que den su consentimiento a participar en el estudio y que cumplan con criterios de inclusión y de exclusión. El enrolamiento se llevará a cabo durante la evaluación preanestésica por un investigador no involucrado en los cuidados del paciente.

Reclutamiento de pacientes

Los criterios de inclusión incluirán:

- Edad entre 18 y 80 años
- Clasificación de la American Society of Anesthesiologists 1-3
- Índice de masa corporal entre 20 y 35 (kg/m^2)
- Artroplastía total primaria de cadera

Los criterios de exclusión incluirán:

- Adultos que no pueden dar su propio consentimiento
- Neuropatía preexistente (evaluada por la historia y el examen físico)
- Coagulopatía (evaluada por la historia y el examen físico y, si se considera clínicamente necesario, por análisis de sangre, es decir, plaquetas ≤ 100, índice internacional normalizado ≥ 1,4 o tiempo de protrombina ≥ 50s)
- Insuficiencia renal (evaluada por la historia y el examen físico y, si se considera clínicamente necesario, mediante análisis de sangre, es decir, creatinina ≥ 1,5)
- Insuficiencia hepática (evaluada según los antecedentes y el examen físico y, si se considera clínicamente necesario, mediante análisis de sangre, es decir, transaminasas ≥ 100)
- Alergia a los anestésicos locales o morfina
- Embarazo
- Cirugía previa en la zona inguinal correspondiente
- Artroplastía por fractura de cadera
- Síndromes de dolor crónico que requieren del uso de opioides domiciliarios

La confidencialidad de los pacientes se protegerá a través de dos mecanismos:

- Los sujetos de investigación se identifican por números de serie
- El acceso a los datos de investigación del paciente se limitará a los investigadores

V. PROTOCOLO DE ESTUDIO

General

Los pacientes que acepten participar en el protocolo serán asignados a un grupo u otro (BFIS y BPENG) mediante aleatorización en bloque generada computacionalmente. Se empleará un sistema de sobre sellado opaco para que quien lleve a cabo el procedimiento sea informado del bloqueo a realizar sólo en el momento de ejecución. Evaluadores ciegos a la aleatorización realizarán todas las mediciones involucradas en los resultados.

Todos los bloqueos serán realizados o supervisados por uno de los coautores y conducidos en la sala de recuperación una vez que se complete la cirugía. Esta área tiene acceso

completo a equipos de reanimación y todos los pacientes serán monitoreados de acuerdo a los estándares vigentes.

Anestesia Espinal

Todos los pacientes se someterán a anestesia espinal utilizando bupivacaína (10mg) más 20µg de fentanilo. Ambos grupos también recibirán ácido tranexámico 1 gr EV, ketoprofeno 100mg EV y paracetamol 1gr EV. Dependiendo del deseo del paciente, se administrará sedación con propofol guiada con un modelo de infusión controlada (TCI) para obtener un nivel adecuado de sedación.

Técnica Quirúrgica

Todas las cirugías serán conducidas por el mismo equipo de cirujanos que operan con una técnica de abordaje posterior en posición de decúbito lateral.

Desempeño del Bloqueo

La dosis de anestésico local (AL) será idéntica en ambos grupos, levobupivacaina 100 mg y epinefrina 5ug/ml. Además en paralelo en ambos grupos junto al bloqueo se administrará 4 mg de dexametasona por vía intravenosa lento.

En el grupo BFIS, el bloqueo se llevará a cabo utilizando una técnica descrita anteriormente (**2**). Utilizando US, cuarenta ml de levobupivacaina 0.25% con epinefrina 5ug/ml se depositarán en la cara anterior del músculo ileopsoas debajo de la fascia iliaca a nivel suprainguinal.

En el grupo BPENG, el bloqueo se llevará a cabo utilizando una técnica descrita anteriormente (**1**). Utilizando US, veinte mL de levobupivacaina 0.5% con epinefrina 5ug/ml se inyectará entre el periosteo del hueso iliaco y el tendón del músculo ileopsoas.

Analgesia Postoperatoria

En la unidad de recuperación postanestésica (URPA) y luego en su servicio de hospitalización, todos los pacientes recibirán analgesia endovenosa controlada por el paciente (bolo de morfina = 1 mg, intervalo de bloqueo = 8 minutos), paracetamol (1 g por vía oral cada 6 horas), ketoprofeno (100 mg por vía oral cada 8 horas).

VI. PROTOCOLO DE ESTUDIO: MEDICIONES DE RESULTADO

Outcome primario

La incidencia de bloqueo motor de cuádriceps (definida como parálisis total o parcial) a las 6 horas después del bloqueo constituirá el outcome primario.

La función motora del cuádriceps se evaluará con el paciente en decúbito supino y con la cadera y la rodilla flexionadas a 45º y 90º, respectivamente. Se le pedirá al sujeto que extienda la rodilla primero contra gravedad y luego contra resistencia. La fuerza del

cuádriceps se calificará de acuerdo con una escala de 3 puntos: fuerza normal = 0 puntos (extensión contra resistencia); paresia = 1 punto (extensión contra gravedad, pero no contra resistencia); y parálisis = 2 puntos (sin extensión).

Resultados secundarios

El coautor que supervisa el bloqueo registrará el tiempo de ejecución de este (definido como el intervalo temporal entre el inicio de la desinfección de la piel y el final de la inyección de AL a través de la aguja del bloqueo).

Un observador ciego al grupo de tratamiento evaluará el dolor estático y dinámico utilizando una escala numérica (EN) con un rango de 0 a 10 (0 = sin dolor y 10 = peor dolor imaginable) a las 3, 6, 12, 18, 24, 48 horas, así como el tiempo hasta el primer consumo de morfina y el consumo total de morfina a las 24 y 48 horas.

Tres horas después del bloqueo, un investigador ciego al grupo de tratamiento evaluará el bloqueo sensorial al frio en las caras anterior, lateral y medial de la mitad del muslo. Para cada territorio, el bloqueo se evaluará utilizando una escala de 3 puntos: 0 = sin bloqueo, 1 = analgesia (el paciente puede sentir el tacto, no frío), 2 = anestesia (el paciente no puede sentir el tacto). Esta evaluación se repetirá a las 6 y 24 horas.

Usando la misma metodología que para el resultado principal, el evaluador ciego también evaluará la función del cuádriceps (extensión de la rodilla) a las 3 y 24 horas.

Finalmente, la aducción de cadera se evaluará a las 3, 6 y 24 horas después del bloqueo. La aducción de cadera se evaluará comparándola con la fuerza basal (es decir, antes de la anestesia espinal). Se insertará un manguito de presión arterial, inflado a 40 mmHg, entre las rodillas del paciente: a este último se le indicará que apriete el manguito lo más fuerte posible y que mantenga el esfuerzo. Definiremos puntajes de aducción de cadera de 0, 1 y 2 puntos como disminuciones en la fuerza de 0-20%, 21-70% y 71-90% respectivamente, en comparación con la medición basal.

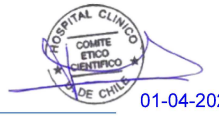
Otros datos medidos

El coautor que supervisa el bloqueo registrará las complicaciones relacionadas con el bloqueo (p. Ej., Punción vascular, toxicidad LA).

Datos demográficos (sexo, edad, peso, altura), duración quirúrgica, efectos secundarios relacionados con los opioides (es decir, náuseas postoperatorias, vómitos, prurito, retención urinaria, depresión respiratoria), incapacidad para realizar fisioterapia debido al bloqueo motor, incapacidad para realizar fisioterapia debido al dolor será registrado por el evaluador ciego.

VII. CÁLCULO DEL TAMAÑO DE LA MUESTRA

Nuestra experiencia en un ensayo en curso revela que la incidencia de bloqueo motor (parálisis o paresia) 6 horas después de BFIS es del 70%. Presumimos que el bloqueo PENG disminuirá su incidencia al 20%. Por lo tanto, se requerirá un tamaño de muestra calculado de 16 pacientes por grupo para una potencia estadística de 0,80 y un error tipo I de 0,05 a



dos colas. Un total de 40 pacientes serán reclutados para dar cuenta de posibles pérdidas de seguimiento.

VIII. BENEFICIOS POTENCIALES DEL ESTUDIO

Este estudio nos permitirá determinar si BPENG guiado por US representa una alternativa analgésica preservante de fuerza de cuádriceps en comparación a BFIS. Esto puede representar una ventaja en términos de rehabilitación después de ATC.

IX. EFECTOS SECUNDARIOS POTENCIALES DEL ESTUDIO

La participación en este protocolo no pondrá a los pacientes en mayor riesgo de complicaciones ya que BFIS y BPENG se usan comúnmente para proporcionar analgesia para ATC primaria en nuestro hospital.

El protocolo propuesto no tendrá un impacto negativo en el funcionamiento de la sala de operaciones o la URPA en términos de personal médico y de enfermería, ya que todos los bloqueos (es decir, bloqueo espinal, BFIS o BPENG) que se llevarán a cabo se ejecutan independientemente de si los pacientes están inscritos en un estudio o no.

No habrá riesgos laborales para los investigadores o asistentes.

X. CALENDARIO PROPUESTO

Realizamos un promedio semanal de 5 THA. Después de recibir la aprobación del Comité de Ética y de asumir una tasa de reclutamiento del 50%, deberíamos demorar aproximadamente 4 meses en reclutar 40 pacientes.

XI. REFERENCIAS

1. Girón-Arango L, Peng P, Chin KJ, et al. Pericapsular Nerve Group (PENG) Block for Hip Fracture. Reg Anesth Pain Med 2018;43: 00–00.
2. Hebbard P, Ivanusic J, sha S. Ultrasound–guided suprainguinal fascia iliaca block: a cadaveric evaluation of a novel approach. Anaesthesia 2011; 66(4): 300-05.