

2ª ed

MEDS

**Effect of a Single Shot Sciatic Nerve Block Combined
with a Continuous Femoral Block on Pain Scores after
Total Knee Arthroplasty.
A Randomized Controlled Trial**

Raúl Manuel da Silva Carvalho

MESTRADO EM
EVIDÊNCIA E DECISÃO EM SAÚDE
2º CICLO DE ESTUDOS

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Resumo

Efeito da associação de um bloqueio ciático simples ao bloqueio contínuo do nervo femoral na avaliação da dor em doentes submetidos a artroplastia do joelho. Um ensaio controlado e aleatorizado.

Contexto e Objectivo: A dor após artroplastia do joelho é severa em 60% dos doentes. O bloqueio contínuo do nervo femoral é uma opção nas situações de reparação major da articulação do joelho, mas permanecem controvérsias e dúvidas sobre a necessidade de suplementar com bloqueio do nervo ciático para obter melhor analgesia.

O objectivo deste estudo é avaliar o efeito da associação de um bloqueio do nervo ciático ao bloqueio contínuo do nervo femoral na redução da dor pós-operatória após artroplastia do joelho

Métodos: Estudo prospectivo, aleatorizado, controlado, com ocultação simples em 50 doentes submetidos a artroplastia total do joelho. No grupo de controle, antes da indução da anestesia geral, foi feito um bloqueio contínuo do nervo femoral; no grupo de intervenção foi realizado, depois do bloqueio femoral, um bloqueio do nervo ciático com injeção única. No recobro, todos os doentes iniciaram uma perfusão de anestésico local através do cateter femoral. Os índices de dor foram avaliados na unidade de recobro e às 12h e 24h de pós-operatório através da escala visual analógica de dor (VAS).

Resultados: Os valores (em mm) obtidos pela escala visual analógica da dor (VAS) são menores e estatisticamente significativos no grupo de intervenção até às 12h de pós-operatório: Valor médio na admissão á unidade de recobro VAS=59.4 vs. 30.2, $p=0.001$; ás 12h pós-operatório média da VAS em repouso=26.1 vs 9.2, $p=0.006$; ás 24h pós-operatório média da VAS em repouso=30.1 vs. 32.7, $p=0.723$.

Conclusão: A associação de um bloqueio do nervo ciático com injeção única a um bloqueio contínuo do nervo femoral reduz significativamente até as 12h de pós-operatório a dor após artroplastia do joelho.

Palavras Chave: Dor pós-operatória; Artroplastia do joelho; Anestesia locoregional; Bloqueio de nervos periféricos

Abstract

Effect of a Single Shot Sciatic Nerve Block Combined with a Continuous Femoral Block on Pain Scores After Knee Arthroplasty. A Randomized Controlled Trial

Background and Purpose: Postoperative pain after knee arthroplasty (TKA) is reported as severe in up to 60% of patients. Continuous femoral nerve blocks (CFNB) are a choice for major knee repair, but controversies remain about the need of supplemental sciatic nerve blocks (SNB) for better analgesia. Our aim is to assess the effect of the association of a SNB to a CFNB to reduce postoperative pain after TKA.

Methods: A prospective randomized, single blinded, controlled study, on 50 patients undergoing TKA. Control group received a CFNB before general anesthesia; in the intervention group a single shot SNB was added after the CFNB was done. After the end of surgery all patients started a continuous local anesthetic infusion through the femoral catheter in the PACU (Post-Anesthesia Care Unit). Pain scores were measured in the PACU and at 12h and 24h postoperative using a Visual Analog Scale (VAS).

Results: VAS pain scores (mm) were lower and statistically significant for the intervention group up to 12h postoperative: PACU admission mean VAS=59.4 vs. 30.2, $p=0.001$; at 12h mean VASr=26.1 vs. 9.2, $p=0.006$; at 24h mean VASr=30.1 vs. 32.7, $p=0.723$.

Conclusions: The association of a single shot SNB with a CFNB significantly reduces postoperative pain scores after TKA up to 12h. At 24 h there are no differences between groups.

Keywords (MESH): Postoperative pain; Knee arthroplasty; Regional anesthesia; Nerve blocks

Preamble

For over 15 years, I have been interested in anesthesia for orthopedics and regional anesthesia.

The concern about patient safety was always accompanied by the efforts to provide the most comfortable experience to the patients and allowing for the best possible surgical conditions.

The Master Programme in Health and Evidence gave me tools and insight on how to channel my interests and try to produce work with solid evidence that could be used to answer questions, produce knowledge and help develop good working methods that could be useful to me, my colleagues and ultimately, my patients.

With this in mind, and knowing that knee arthroplasty is a common surgery, with important issues regarding pain control that are still unanswered, I used the new knowledge acquired in this programme to design a study that would be feasible, help develop skills as an evidence-based medicine researcher and provide answers to some clinical issues.

From the beginning of this master programme, we were encouraged to design a study that could be published as a scientific paper. As a result of that, this thesis is structured as a paper for publication.

I can only hope this is the beginning of a new and exciting phase.

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Abbreviations

CFNB	Continuous Femoral Nerve Block
FNB	Femoral Nerve Block
LMWH	Low Molecular Weight Heparin
MESH	Medical Subject Headings
PACU	Post-anesthesia Care Unit
SNB	Sciatic Nerve Block
TKA	Total Knee Arthroplasty
VAS	Visual Analogue Scale
VASm	Visual Analogue Scale with Movement
VASr	Visual Analogue Scale at Rest

Thesis Outline

The study “Effect of a Single Shot Sciatic Nerve Block Combined with a Continuous Femoral Block on Pain Scores after Knee Arthroplasty. A Randomized Controlled Trial” is the basis for this thesis.

Rationale and Introduction presents an extended review of available literature and establishes the need for this work. It is more comprehensive than what was submitted for publication.

The structure and contents of the paper submitted for publication is used in the main body of this thesis and is presented with the following sections:

- **Materials and Methods** section explains the approval process, type of study and the methods used for participant selection, type of interventions, data collection, variable definition and statistical analysis performed.
- **Results** show the demographic characteristics of the population and present the detailed results for primary and secondary outcomes with statistical analysis.
- A critical review of the results is presented in **Discussion**, with acknowledgement of limitations found and raising questions for further investigation.
- **Conclusions** present the answers to our main scientific questions.

Future Work elaborates on possible paths to follow the present study.

Scientific Outcomes

- Poster presentation:

1. *“Efeito do bloqueio do nervo ciático por picada única combinado com bloqueio femoral contínuo em scores de dor após artroplastia total do joelho – ensaio clínico controlado e randomizado”* – Congresso da Sociedade Portuguesa de Anestesiologia, 9-11 março 2012, Porto, Portugal.

Awarded the first prize as the best poster and selected for oral communication.

Abstract in: *Revista da Sociedade Portuguesa de Anestesiologia*, Vol 21, 2, 2012, pp 9, 49

2. *“Effect of a Single Shot Sciatic Nerve Block Combined with a Continuous Femoral Block on Pain Scores after Knee Arthroplasty. A Randomized Controlled Trial”* - 15th WFSA World Congress of Anesthesiologists, 25-30 March 2012, Buenos Aires, Argentina.

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1. Rationale and Introduction

The recently created Portuguese Registry of Arthroplasties states on its first report that from June 2009-May 2010, 6977 knee replacement surgeries were performed, with 86% under regional anesthesia ^(RPA, 2010). In 2010 there were 81979 procedures in the United Kingdom ^(Excellence, 2010) and the present number of 500 000 annual total knee arthroplasties in United States of America is expected to increase to 3.5 million annual procedures by 2030 ^(Kurtz et al., 2007).

Postoperative pain is a concern for this type of surgery and it has been reported as being severe in 60% of the patients and moderate in up to 30% in spite of several postoperative analgesia protocols used ^(Bonica, 1990).

There has been debate on which type of anesthesia is better for these patients but there is no clear evidence of any advantage of regional versus general anesthesia on long-term outcomes such as morbidity, mortality or rehabilitation ^(Macfarlane et al., 2009). Regional anesthesia provides better postoperative analgesia, and may improve early rehabilitation with fewer side effects when compared to intravenous opiates ^(Macfarlane et al., 2009, Singelyn et al., 1998), but there are no clear conclusions on what type of regional anesthesia is better.

The lumbosacral plexus innervates the knee. The femoral nerve (L2-L4) innervates the anterior aspect of the thigh, the knee joint and synovial capsule, the obturator nerve (L2-L4) is responsible for the sensory innervation of the skin of the medial aspect of the thigh. The sciatic nerve (L4-S3) supplies nearly the whole of the skin of the leg, the muscles of the back of the thigh, and those of the leg and foot ^(John J. Callaghan, 2003).

Peripheral nerve blocks have less side effects compared to neuraxial blocks and femoral nerve blocks are well established as an option for postoperative analgesia in knee replacement surgery ^(Boezaart, 2006) and is now recommended by the Procedure Specific Postoperative Pain Management Working Group ^(PROSPECT). In spite of these recommendations, there is an ongoing debate on whether sciatic or obturator nerve blocks are needed as adjuncts to a femoral block to improve postoperative analgesia, and conflicting results have been published ^(Fowler et al., 2008, Hebl et al., 2005, Allen et al., 1998, Ben-David et al., 2004, Morin et al., 2005, Pham Dang et al., 2005). Most of these studies compare the effects of peripheral nerve blocks with neuraxial blocks and do not separate or

compare the effect of FNB versus the association of SNB to FNB. Their use of proxy measurements and some method shortcomings prevent them to give clear answers. A review by Hogan *et al.* states the benefits of peripheral nerve blocks in analgesia for hip and knee analgesia, but fails to recognize which are the most effective blocks (Hogan *et al.*, 2009). A meta-analysis published in 2010 showed no evidence for support on adding a SNB to a CFNB for postoperative analgesia in patients undergoing TKA. This statement arose from the lack of quality-randomized studies comparing both techniques (Paul *et al.*, 2010). It did not support the use of a CFNB over a single shot block either. This last conclusion raised some controversy due to some limitations on the systematic review inclusion of studies, and because the primary aim of this study was to assess the efficacy of FNB when compared to epidural analgesia after TKA. An editorial by Hadzic *et al.* challenged their conclusions and presented CFNB as the standard post-operative analgesia for knee replacement surgery in many centers (Hadzic *et al.*, 2010).

A systematic review by Abdallah & Brull compared the effect of combining SNB with FNB for postoperative analgesia after TKA. The lack of good randomized resulted in inconclusive evidence to define the effect of adding SNB to FNB on acute pain and related outcomes (Abdallah and Brull, 2011). An editorial by Ilfeld & Madison in 2011 recognized the lack of consensus and the need for additional research (Ilfeld and Madison, 2011).

The aim of this study is to determine if a combination of a single shot SNB and CFNB provide better postoperative analgesia when compared to isolated CFNB in patients undergoing TKA.

Our hypothesis is that the association of a single shot SNB to a CFNB can reduce mean pain scores at least 15% when compared to CFNB alone, as we considered this to be a clinical significant difference.

The primary outcome measure is the difference in mean VAS (Langley and Sheppard, 1985) pain scores between both groups at three postoperative moments (PACU, 12h and 24h at rest and movement).

As secondary outcomes we assessed the complications and side effects incidence as they have been reported as having significant impact (Feibel *et al.*, 2009); patient satisfaction was also monitored.

The results of this study may add useful clinical information for daily practice and give insight on further developments and studies on peripheral nerve blocks in this setting.

2. Material and Methods

The study protocol was approved by the Ethics Committee of Centro Hospitalar do Porto and received institutional approval. It was registered in Clinicaltrials.gov under the identifier NCT01337115.

Type of Study

Interventional, prospective, randomized, controlled, parallel group, single blinded, treatment efficacy study.

Selection of Participants

Eligible participants were drawn from 167 consecutive patients undergoing unilateral TKA from April 2011-February 2012, in the Orthopedic Department of Centro Hospitalar do Porto - Portugal.

Patients had to be anesthetized by one of 5 senior anesthesiologists of the orthopedic anesthesia group of the department. Exclusion criteria were refusal to give informed consent, contraindication to general anesthesia, infection at needle insertion site, coagulation disorders, preexisting neurologic disorders, known allergies to local anesthetics, diclofenac or tramadol, severe dyspepsia, ASA status 4 or 5, weigh less than 50kg, body mass index>40, inability to understand and use the VAS pain score.

Group allocation was made by a computer generated random number list (Office Excel 2011[®] - Microsoft Corporation, Redmond, WA, USA) and codes stored in opaque sealed envelopes.

Written consent was obtained immediately prior to envelope opening and group allocation.

Intervention

Blocks were performed using Stimuplex[®] HNS12 nerve stimulator (B. Braun Melsungen AG, Germany). For CFNB, the paravascular approach (*Winnie et al., 1973*) was

used to identify the femoral nerve. A positive location was considered when quadriceps contraction (patellar elevation) was elicited with a current of 0.46 mA or less (*Tsui, 2007*). Ten milliliters of ropivacaine 0.375% were injected through the needle (Contiplex[®] Tuohy 18G 50 mm length needle, with 20G, 100mm catheter – B. Braun Melsungen AG, Germany), a catheter was then inserted and 20ml of ropivacaine 0.375% were administered through the catheter.

For the single shot sciatic block, the anterior approach (*Beck, 1963*) was chosen. A Stimuplex[®] insulated needle 21G x 100mm or 20G x 150mm was used (B. Braun Melsungen, Germany) and 25 ml of ropivacaine 0.375% were administered when either the common peroneal or tibial nerve (dorsiflexion or plantar flexion of the foot) were identified with a stimulation of 0.46 mA or less (*Tsui, 2007*). Blocks success was assessed by absence of thermal sensitivity with an alcohol swab on the anterior region of the thigh and dorsum of the foot.

All patients were then induced to general anesthesia with propofol (1.2-2mg/kg) and fentanyl (0.15-0.2µg/kg) and maintained with short action halogenated anesthetics (Desflurane or Sevoflurane). Airway was maintained with laryngeal mask airway and pressure support ventilation. Additional fentanyl was given during the procedure if attending anesthesiologist considered necessary. Total intraoperative fentanyl dose was registered.

Thirty minutes before the end of the procedure, IV ketorolac 30mg and paracetamol 1000mg was administered.

On arrival to the post-anesthesia unit (PACU), neurologic function was assessed by an independent observer and an infusion of ropivacaine 0.2% was started on the femoral catheter at a rate of 8ml/h using an Easypump[®] C-bloc RA 400-8 (B. Braun Melsungen AG, Germany).

Both groups got diclofenac 50mg q12h PO and paracetamol 1000mg q6h PO and as rescue analgesia, tramadol 100mg q6h prn IV. Thromboprophylaxis with LMWH was started in the first 24h and maintained for 5 weeks.

Data collection

We assessed pain using a standard 100mm VAS (VAS=0 no pain; VAS=100 worst pain).

At 15-30 minutes after arrival to PACU, with the patient awake and fully collaborating, there was a first pain evaluation. If VAS > 30, and the patient asked for treatment, morphine 2mg IV was given every 15 minutes until VAS 30 or less and patient was comfortable.

VAS pain scores, morphine consumption, and time of discharge from PACU were recorded. Presence of toe movements was confirmed before PACU discharge.

Additional measurements of VAS pain scores (VASr – at rest; VASm – with movement) at 12h and 24h (+/- 2h) after surgery were made.

Rescue tramadol usage and complications (falls, foot paralysis, paresthesias, nausea and vomiting) were registered up to 24h.

One month after surgery, subjects were contacted by telephone and asked to rate their satisfaction with postoperative analgesia in a categorical scale of 4 groups (bad; average; good; excellent).

Investigators blinded for the allocation group of the subjects made all assessments.

Variables

Pain scores on VAS is a continuous variable with a range of 0-100.

The primary outcome of the trial is the difference in mean scores from VAS pain assessment in both groups (0=no pain; 100mm=worst pain) at three predefined moments on the first 24h after surgery: 15-30min (in PACU); 12h and 24h (+/- 2h).

Tramadol consumption and patient satisfaction are ordinal variables.

Side effects and complications (as previously defined) are reported and incidence calculated.

Statistical analysis

Fifty subjects were randomized into Control (CFNB; n=25) and Intervention (CFNB+SNB; n=25) groups.

Power analysis for sample size was calculated using a web free application (*Lentil*) and was designed to detect minimum differences of 15%, with type I error 0.05 and 80% power.

A two-tailed t-test for independent variables was used to analyze differences in mean VAS scores in intention-to-treat manner.

The normal distribution of the continuous variables was assessed by the Kolmogorov-Smirnov test.

Our null hypothesis states that there is no difference between the mean pain scores of control and intervention groups. Statistical significance is assumed if $p < 0.05$.

Ordinal variables were analyzed with Fisher's exact test (*Fosse*).

Continuous variables analysis was done with IBM® PASWStatistics 18.0.3 for MAC (IBM Corporation, Somers, NY, USA).

3. Results

A total of 167 subjects were assessed for eligibility from April 2011 until February 2012.

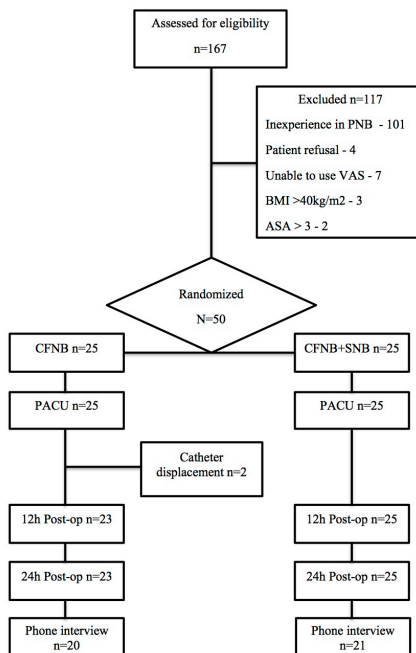


Figure 1 - Participants Flowchart

A high number of excluded patients were due to the fact that only 5 senior anesthesiologists were involved in the study.

Figure1 shows a flowchart of patient selection and participation in the study.

Table 1 - Participants Demographics

	CFNB	CFNB+SNB
	(n=25)	(n=25)
Sex (female, male)	20, 5	16, 9
Age, mean (SD), y	68 (10)	65 (9)
ASA physical status I, II, III	0, 22, 3	3, 21, 1
Body mass index (SD), kg/m²	28.1 (4.6)	29.9 (3.7)

Continuous variables are reported as mean (SD); Categorical variables are reported as absolute numbers

Two patients were excluded before the 12h assessment because of femoral catheter displacement. The drop out of 2 patients in the control group (CFNB) did not affect the statistical power because the sample needed only 23 patients in each group.

Table 1 shows the patient demographic data. There were no differences between groups.

Table 2 shows the overall results. Pain scores are significantly reduced at PACU admission ($P=0.001$) and at 12 hours post-operative ($P=0.006$) on the intervention group (CFNB+SNB). These differences remained if pain was assessed for movement.

Morphine consumption ($P<0.001$) and time spent in PACU ($P=0.045$) are also reduced in the intervention group. PACU time is influenced by several organizational factors that were not controlled and should be valued with care.

Only 19 patients used tramadol as rescue analgesia (CFNB $n=9$; CFNB+SNB $n=10$) and there are no differences between groups (Fisher's exact test $P=0.459$).

No serious complications were found in either group. Two patients had mild nausea after tramadol administration.

At 24h none of the subjects of either group had motor block or paresthesias in the sciatic territory. Weakness of quadriceps femoral muscle was present. Femoral catheter stayed in place up to 48h and was managed by the Acute Pain Unit as normally with controlled ambulation starting at 48h postoperative.

Table 2 - Global Results: Pain Scores, PACU time and Morphine consumption

	CFNB (n=25)	CFNB+SNB (n=25)	95% CI	P
Intraoperative fentanyl (μg)*	208.0 (64.0)	172.0 (66.3)	[(-1.06)-73.06]	0.057
Pain PACU admission VAS*	59.4 (27.2)	30.2 (30.5)	[12.83-45.65]	0.001
Max PACU Pain VAS*	69.8 (24.0)	36.7 (31.4)	[17.23-49.01]	<0.001
Morphine PACU (mg)*	6.2 (3.5)	2.2 (2.7)	[0.89-2.18]	<0.001
PACU time (min)*	126.5 (47.3)	97.2 (53.2)	[0.65-57.91]	0.045
Pain 12h VASr**,**	26.1 (23.8)	9.2 (14.8)	[5.52-28.33]	0.006
Pain 12h VAS m**,**	36.2 (26.6)	18.6 (22.9)	[3.23-32.00]	0.018
Pain 24h VASr**,**	30.1 (25.0)	32.7 (24.5)	[(-16.93)-11.83]	0.723
Pain 24h VASm**,**	49.8 (29.7)	46.9 (29.0)	[(-14.12)-20.00]	0.730

CFNB – Continuous femoral nerve block; SNB – Sciatic nerve block; VASr – VAS at rest; VASm – VAS with movement; * - mean (SD); ** -

CFNB n= 23

In spite of three attempts, 9 patients could not be contacted for the final satisfaction assessment. Fisher's exact test showed no difference in overall satisfaction with analgesia (P=0.537).

4. Discussion

A SNB reduced postoperative pain for up to 12 hours after TKA. This reduction is seen at rest and with movement and is from intense to moderate pain. At 24 hours postoperative no effect can be seen.

Morphine consumption is also reduced in the intervention group in PACU. Using analgesic consumption for measuring pain has limitations (*Moore et al., 2011*), however these results are in accordance with the measurements from VAS and support the benefits of associating sciatic and femoral blocks for TKA. Intraoperative analgesic techniques may influence early postoperative pain scores. Using a general anesthesia with short acting inhalational agents (sevoflurane or desflurane) minimized the possibility of this bias. The intraoperative fentanyl used by both groups was not statistically different so its influence in early postoperative pain scores would be minimal.

The resolution of the SNB may explain the absence of differences in pain scores at 24h, but to confirm this would need a different study design as the use of a single shot SNB limits our capability to detect effects only on the early postoperative period.

Contradicting results from several studies (*Allen et al., 1998*) and studies comparing the efficacy of different techniques (*Davies et al., 2004*) led to the absence of strong evidence to recommend or not the SNB for analgesia after TKA (*Paul et al., 2010, Abdallah and Brill, 2011*).

We directly compare the two techniques (CFNB vs. CFNB+SNB) and show an effect of the SNB. Limiting our study to the first 24h postoperative and directly measuring pain scores as a primary outcome instead of proxy measurements allowed for less confounding results.

Nineteen patients (CFNB=9; CFNB+SNB=10) used rescue analgesia (tramadol 100mg 6/6h prn IV) with no difference between groups (Fisher's exact test $P=0.459$). Patients in the intervention group needed analgesia only after 12h postoperative and the control group used it from the immediate post-operative period. The onset of new pain from the resolution of the SNB in patients of the CFNB+SNB group may be an explanation for this difference. The control group also had a wider range of the tramadol dose (0-300mg) vs. the intervention group (0-200mg). Due to the small number we cannot give statistical significance to these

findings and this is a limitation of our study that was not powered to evaluate these findings.

The overall patient satisfaction with analgesia was very high in both groups (Good/Very Good – Control 85%; Intervention 86% of the valid subjects; Fisher's exact test $P=0.537$), but there were 18% of patients that did not answer our phone interview (5 in the CFNB vs. 4 in the CFNB+SNB group) and the study is underpowered for this variable.

Patients had difficulties in distinguishing between anesthesia/analgesia experience from the overall hospital experience and this may be an important bias in this parameter. Satisfaction assessment probably should have been done earlier to be more objective. A study about patient experiences regarding the use of regional anesthesia for hip and knee arthroplasty shows the difficulties and complexity in assessing patient preferences and establishes the surgeons and anesthesiologists preferences as the most influential parameter on patient preferences (*Webster et al., 2011*).

An important limitation of our study is that it is single blinded, and the patient is aware if a SNB was performed or not and could influence patients complaints, but due to the risk of complications we chose not to perform sham SNBs.

We do not assess the importance of peripheral nerve blocks in rehabilitation (*Macfarlane et al., 2009*), nor the effect of the femoral continuous block beyond the first 24h, but the short term efficacy and safety can be seen from the low pain scores and absence of complications. A recent study showed no differences in time-to-discharge readiness or flexion rate at time of discharge irrespective of the use of a single injection or continuous SNB (*Wegener et al., 2011*).

5. Conclusions

The association of a single shot sciatic nerve block to a continuous femoral nerve block significantly reduces pain scores after knee arthroplasty up to 12h postoperative.

This association also reduces PACU time stay and morphine consumption.

6. Future Work

Once the usefulness of the association of SNB and CFNB is established, other questions arise. The role of peripheral nerve blocks in early mobilization and rehabilitation is a key issue for TKA patients.

There is some concern on the safety of peripheral nerve blocks on early ambulation and there are reports on increased incidence in post-operative falls with these techniques (*Hjfeld et al., 2010*). The role of selective branch blocks is reported as having good analgesic results (*Sinha et al., 2012*) and may have a better safety profile.

Finding better anesthetic concentrations, blocks duration and establishing safety rules for ambulation is the basis for future investigation. Another area of interest is the role of peripheral nerve blocks on preventing chronic pain after TKA, still reported as high as 20% (*Hofmann et al., 2011*).

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Appendix

A – Ethical Approval

centro hospitalar
do Porto

Hospital de Santo António Maternidade João Dânis Hospital Maria Pia

Lúcio Proença Abel Salazar
4700-041 ESTRELA
www.chsp.pt

COMISSÃO DE ÉTICA PARA A SAÚDE

APRECIÇÃO E VOTAÇÃO DO PARECER

Deliberação	Data: 16/3/2011	Órgão: Reunião Plenária
Título: "Efeito da associação de um bloqueio ciático simples ao bloqueio contínuo do nervo femoral na avaliação da dor em doentes submetidos a artroplastia do joelho. Um ensaio controlado e aleatorizado"		Ref.º: 007/11(004-DEFI/007-CES)
Protocolo/Versão:		Investigador: Dr. Raul Carvalho Serviço de Anestesiologia

A Comissão de Ética para a Saúde – CES do CHP, ao abrigo do disposto no Decreto-Lei n.º 97/95, de 10 de Maio, em reunião realizada nesta data, apreciou a fundamentação do relator sobre o pedido de parecer para a realização de **Trabalho Académico – Mestrado** acima referenciado:

Ouvido o Relator, o processo foi votado pelos Membros da CES presentes:

Presidente: Dr.ª Luisa Bernardo
Vice-Presidente: Dr. Paulo Maia

Dr.ª Paulina Aguiar, Enf.ª Paula Duarte, Dr.ª Fernanda Manuela, Prof.ª Doutora Maria Manuel Araújo Jorge

Resultado da votação:

PARECER FAVORÁVEL


A deliberação foi aprovada por unanimidade.

Pelo que se submete à consideração superior.

Data 16/3/2011

23/3/11
DR. SILVERO TORRES
Adjunto do Director Clínico

A Presidente da CES


 Dr.ª Luisa Bernardo

B – Institutional Approval

centro hospitalar
do Porto

Hospital de Santo António Maternidade Júlio Dinis Hospital Maria Pia

União Professora Abel Salazar
4050-301 PORTO
www.hosp.pt

Para: DR. RAUL CARVALHO
SERVIÇO DE ANESTESIOLOGIA

De: PEDRO ESTEVES
PRESIDENTE DO CONSELHO DE
ADMINISTRAÇÃO

Fax: _____ Data: 25 DE MARÇO DE 2011

Tel.: _____ Págs.: _____

Ref.: **N/ REF.º 007/11(004-DEFI/007-CES)** CC: _____

Urgente Apreciar p.f. Comentar p.f. Responder p.f. Fazer circular p.f.

ASSUNTO: Trabalho Académico de Mestrado - "Efeito da associação de um bloquete cático simples ao bloquete contínuo do nervo femoral na avaliação da dor em doentes submetidos a artroplastia do joelho. Um ensaio controlado e aleatorizado"

Em resposta ao solicitado por V.º Ex.º, informo que, após apreciação por parte do Gabinete Coordenador de Investigação/DEFI e da CES, foi emitido **parecer favorável** sobre o assunto em epígrafe pelo que nada há a opor à realização do mesmo nesta Instituição, no Serviço de Anestesiologia, sendo Investigador Principal o Dr. Raul Manuel da Silva Carvalho.

Cumprimentos,



Pedro Esteves
Presidente do Conselho de Administração

* Em todas as eventuais comunicações posteriores sobre este estudo é indispensável indicar a nossa ref.º.

C – Participant Information Form



Folheto Informativo para todos os participantes no estudo:

“Efeito da associação de um bloqueio ciático simples ao bloqueio contínuo do nervo femoral na avaliação da dor em doentes submetidos a artroplastia do joelho. Um ensaio controlado e aleatorizado”

Este folheto destina-se a dar uma explicação simples e com linguagem fácil de entender sobre as técnicas a utilizar no estudo que lhe é proposto. Qualquer dúvida ou questão será prontamente respondida pelo anestesista responsável.

Um bloqueio de um nervo periférico é uma técnica que consiste na colocação de anestésico local junto a um nervo através de uma agulha ou de um pequeno tubo chamado cateter. Nos bloqueios propostos (femoral e/ou ciático), esta técnica faz-se junto á raiz da coxa da perna a operar.

Espera-se que durante algum tempo a sensibilidade na perna esteja diminuída e exista um período depois da cirurgia em que a dor esteja aliviada.

Os riscos são muito raros mas pode acontecer dor no local da picada, pisadura devido a ruptura de um vaso sanguíneo ou adormecimento da perna. Ainda mais raramente pode acontecer convulsão ou dor por lesão do nervo.

Esta técnica é habitualmente utilizada para anestesia para prótese do joelho neste hospital.

Associado ao(s) bloqueio(s) será realizada uma anestesia geral.

O responsável pelo Estudo

Raúl Carvalho
Médico Anestesiologista
Assistente Graduado Hospitalar
Serviço de Anestesia
Centro Hospitalar do Porto

Nota: Informação incluída de acordo com o recomendado na ASRA 35th Annual Spring Meeting 2010 (PBLD19 Parallel Session 4) para bloqueios de nervos periféricos.

D – Informed Consent Form



TERMO DE CONSENTIMENTO INFORMADO

TÍTULO DO ESTUDO DE INVESTIGAÇÃO

Efeito da associação de um bloqueio ciático simples ao bloqueio contínuo do nervo femoral na avaliação da dor em doentes submetidos a artroplastia do joelho. Um ensaio controlado e aleatorizado

Eu, abaixo-assinado (NOME COMPLETO DO INDIVÍDUO PARTICIPANTE DO ESTUDO):

Fui informado de que o Estudo de Investigação acima mencionado se destina a avaliar a eficácia do controlo da dor pós-operatória com a utilização de anestesia loco-regional, nomeadamente bloqueios periféricos.

Sei que neste estudo está prevista a realização de bloqueios dos nervos femoral e/ou ciático e a avaliação pós-operatória da qualidade do controlo da dor através de uma escala simples, tendo-me sido explicado em que consistem e quais os seus possíveis efeitos.

Foi-me garantido que todos os dados relativos à identificação dos Participantes neste estudo são confidenciais e que será mantido o anonimato para qualquer elemento que não faça parte da equipa de investigação.

Sei que posso recusar-me a participar ou interromper a qualquer momento a participação no estudo, sem nenhum tipo de penalização por este facto

Compreendi a informação que me foi dada, tive oportunidade de fazer perguntas e as minhas dúvidas foram esclarecidas.

Aceito participar de livre vontade no estudo acima mencionado

Também autorizo a divulgação dos resultados obtidos no meio científico, garantindo o anonimato.

Nome do Participante no estudo.

Data
//___

Assinatura

Nome do Médico Responsável ou Nome do Investigador Responsável [assinalar conforme o caso]

Data
//___

Assinatura

E – ClinicalTrials.gov

Available at

<http://dl.dropbox.com/u/1513036/Clinicaltrialsreceipt.pdf>