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A PROSPECTIVE, RANDOMIZED STUDY OF PERIPROSTATIC LIGNOCAINE INJECTION VERSUS INTRARECTAL LIGNOCAINE OR PLACEBO GEL FOR PAIN RELIEF DURING TRANSRECTAL ULTRASOUND (TRUS) GUIDED NEEDLE BIOPSY OF THE PROSTATE

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ABSTRACT

Objective: The aim of our study was to compare the efficacy and complications of periprostatic lignocaine injection with transrectal instillation of lignocaine gel or placebo for the relief of pain associated with transrectal ultrasound (TRUS) guided needle biopsy of the prostate.

Patients and Methods: Between March 2003 and January 2004, 210 patients were prospectively randomized to recieve periprostatic injection of 10ml 2% lignocaine (Group 1, n = 83), intrarectal instllation of 15ml 2% lignocaine gel (Group 2, n = 64) or intrarectal instllation of 10ml water-souluble gel (placebo) (Group 3, n = 63). The degree of pain experienced during and 15 minutes after completion of the biopsy was recorded by the patient himself, using a visual pain score (VPS) with a scale from 0 (no pain) to 10 (the most severe pain possible). Statistical evaluation was performed using analysis of variance (ANOVA) with post-hoc analyses using the Bonferroni correction.

Results: There were no statistically significant differences between the groups with regard to the mean number of biopsy cores, serum PSA or prostate volume. The mean VPS during biopsy was 2.02, 3.05 and 5.16 in Groups 1, 2 and 3, respectively (all differences statistically significant). The mean VPS 15 minutes after biopsy was significantly lower in Group 1 (1.43) compared to Group 3 (3.28, $p<0.001$) but not Group 2 (2.17, $p = 0.086$), and it was significantly lower in Group 2 compared to Group 3 ($p=0.006$). With regard to complications, there were no statistically significant differences between the groups, except for rectal bleeding which occurred more frequently in Group 3 (23.2%) than in Groups 1 (7.9%, $p = 0.033$) and 2 (11.5%, $p=0.186$). There was no significant difference with regard to the percentage of patients who would be willing to return for a repeat biopsy (95.7%, 87% and 91.7% in Groups 1, 2 and 3 respectively).

Conclusions: For pain relief during and after TRUS guided needle biopsy of the prostate, periprostatic injection of 10 ml 2% lignocaine was significantly more effective than intrarectal instillation of 15 ml 2% lignocaine gel, which in turn was more effective than intrarectal lubricant (placebo) gel. The incidence of complications was not increased after periprostatic lignocaine injection. Although the greater pain experienced by the patient during biopsy without anesthesia did not result in a significantly greater unwillingness to return for repeat biopsy, considerations of human compassion dictate that all patients undergoing TRUS guided prostate biopsy should routinely be offered local anesthesia.

Key words: prostate, biopsy, transrectal ultrasound, local anesthesia, lignocaine

INTRODUCTION

Transrectal ultrasound (TRUS) guided prostate biopsy is a routinely performed procedure in patients with abnormally elevated serum prostate specific antigen (PSA) levels or clinical evidence of prostate cancer on digital rectal examination (DRE). Almost all

patients undergoing prostate biopsy without anesthesia experience some pain, with 20-65% reporting moderate to severe pain[1].

At present there is no universally accepted standard practice regarding the type of anesthesia administered during TRUS guided needle biopsy of the prostate. Davis et al reported that only 11% of urologists used a periprostatic nerve block and 33% used no anesthesia at all[2]. Up to 19% of patients will not return for a repeat biopsy if it is done without anesthesia[3]. Recent studies have shown that intrarectal instillation of lignocaine gel[4,5] or periprostatic injection of 1-2% lignocaine solution provides significant pain relief during TRUS guided prostate biopsy [4,6-8].

The aims of our study were to determine the most effective form of local anesthesia for TRUS guided needle biopsy of the prostate, and to summarize the published studies on methods of providing pain relief during this procedure.

PATIENTS AND METHODS

Between March 2003 and January 2004, 210 patients undergoing TRUS guided prostate biopsy were prospectively randomized to receive periprostatic lignocaine injection (Group 1, n=83), intrarectal lignocaine gel (Group 2, n=64) or intrarectal placebo gel installation (Group 3, n=63) (Table 1). The indications for biopsy were a serum PSA >4 ng/ml or an abnormal DRE. Patients with evidence of prostatitis or urinary tract infection, bleeding diathesis or anticoagulant therapy (except for low-dose aspirin) were excluded. Written informed consent was obtained from all patients. The study protocol was approved by the Committee for Human Research, Faculty of Health Sciences, University of Stellenbosch.

All patients received oral antibiotic prophylaxis with 1 gm ciprofloxacin one hour prior to biopsy followed by 3 doses of 500 mg 8-hourly.

Biopsies were performed using a Toshiba Model SSA-220A ultrasound machine with a Magnum® (Bard) biopsy gun and an 18 gauge needle. Sextant biopsy (six cores) was performed in most patients, with extended biopsy where indicated.

Group 1 patients received 10 ml 2% lignocaine injected into the periprostatic space. After insertion of the TRUS probe a 22 gauge spinal needle was guided through a working channel into the periprostatic space between Denonvillier's fascia and the prostatic capsule. Correct placement of the injection was confirmed by visualization of a hypoechoic area adjacent to the lateral border of the prostate on transverse view and superior to the base on sagittal view. After injection of 5 ml 2% lignocaine on both sides of the prostate the operator waited 2-3 minutes before performing the biopsies.

Group 2 patients received 15 ml of 2% lignocaine gel instilled into the rectum 5 minutes before biopsy.

Group 3 patients received 10 ml of watersoluble lubricant (K-Y Jelly®, Johnson and Johnson) intrarectally 5 minutes prior to biopsy.

The degree of pain experienced during and 15 minutes after completion of the biopsy was recorded by the patient himself, using a visual pain score (VPS) with a scale from 0 to 10 (0 = no pain and 10 = the most severe pain possible). The patient's tolerance of the procedure was assessed as poor, moderate or good by the doctor performing the biopsy (in total, six different operators performed the procedures).

At follow-up three weeks after the procedure a questionnaire regarding biopsy complicationswas completed by the attending physician, and the patient was asked whether he would be willing to undergo a repeat prostate biopsy if necessary.

Statistical analysis was performed using the SPSS statistical package. Analysis of

Table 1: Comparison of the study groups

	Group 1 Mean (range)	Group 2 Mean (range)	Group 3 Mean (range)	Group 1 vs 2 p-value	Group 2 vs 3 p- value	Group 1 vs 3 p-value
Patients (n)	83	64	63			
Biopsy cores (n)	6.67 (3-20)	6.37 (6-10)	6.38 (6-12)	0.732	0.767	1.00
PSA (ng/ml)	78.7 (0.59-1800)	32.8 (0.90-788)	26.1 (2.6-163)	0.603	1.00	0.449
Prostate volume (ml)	61.4 (17-294)	55.2 (18-120)	54.9 (17-101)	1.00	1.00	1.00
Prostate cancer detection rate (%)	43.4%	39.1%	31.7%			
Visual pain score (VPS)						
During biopsy (95% CI)	2.02 (1.7-2.4)	3.05 (2.5-3.6)	5.16 (4.5-5.9)	0.019	<0.001	<0.001
After biopsy (95% CI)	1.43 (1.1-1.8)	2.17 (1.6-2.7)	3.28 (2.7-3.9)	0.086	0.006	<0.001
Willing to return for repeat biopsy	95.7 %	87 %	91.7 %	0.185	1.0	1.0

Group 1: periprostatic lignocaine injection, Group 2: intrarectal lignocaine gel, Group 3: intrarectal lubricant gel

Table 2: Complications after TRUS guided prostate biopsy – number and (%)

Complications	Overall n=193	Group 1 (n=76)	Group 2 (n=61)	Group 3 (n=56)	Group 1 vs 2 p-value	Group 2 vs 3 p- value	Group 1 vs 3 p-value
Hematuria	37 (19.1)	11 (14.5)	12 (19.7)	14 (25)	1.0	1.0	0.436
Rectal bleeding	26 (13.5)	6 (7.9)	7 (11.5)	13 (23.2)	1.0	0.186	0.033
Dysuria	16 (8.3)	6 (7.9)	5 (8.3)	5 (8.9)	1.0	1.0	1.0
Hematospermia	8 (4.1)	4 (5.2)	1 (1.7)	3 (5.4)	0.881	0.951	1.0
Fever	2 (1)	0	2 (3.3)	0	0.183	0.249	1.0
Painful ejaculation	2 (1)	1 (1.3)	1 (1.6)	0	1.0	1.0	1.0
Prostatitis	2 (1)	0	1 (1.6)	1 (1.8)	1.0	1.0	0.945
Bacteremia/ Septicemia	1 (0.5)	1 (1.3)	0	0	0.869	1.0	0.904
Bacteriuria	1 (0.5)	0	0	1 (1.8)	1	0.544	0.480
Total	60 (28.7)	15 (18.3)	23 (35.9)	22 (34.9)	0.057	0.083	0.083

variance (ANOVA) was performed on all measures with post-hoc analyses using the Bonferroni correction.

RESULTS

There were no statistically significant differences between the groups with regard to the mean number of biopsy cores, serum PSA or prostate volume (Table 1).

The mean visual pain score during biopsy was significantly lower in Group 1 compared to Groups 2 and 3, and significantly lower in Group 2 compared to Group 3 (Table 1, Fig. 1). The mean visual pain score 15 minutes after biopsy was significantly lower in Group 1 compared to Group 3 but not Group 2, and it was significantly lower in Group 2 compared to Group 3. The patient's tolerance of the procedure as assessed by the doctor performing the biopsy was better in Group 1

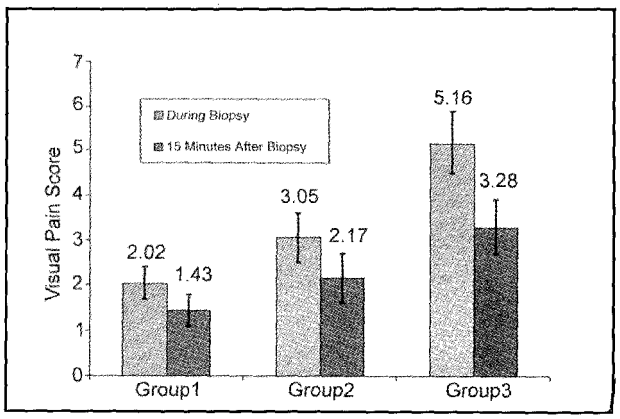

Fig. 1: Mean visual pain score during and 15 minutes after TRUS guided prostate biopsy

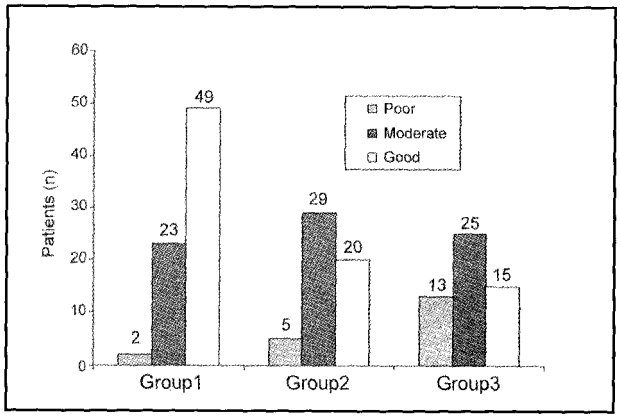

Fig. 2: Patient's tolerance of the procedure as assessed by the doctor performing the biopsy

than in Groups 2 and 3 (Fig. 2). There was no statistically significant difference between the groups with regard to the percentage of patients who were willing to return for a repeat biopsy (Table 1).

Followup was available in 193 (92%) patients, with no significant difference between the groups. The overall complication rate was 28.7% with no significant difference between the groups, except for rectal bleeding, which was significantly more common in Group 3 (Table 2).

DISCUSSION

It is generally assumed that most of the pain experienced during transrectal prostate biopsy is due to the needle piercing of the prostatic capsule and stroma, which are richly innervated by sensory nerve fibres originating from the hypogastric plexus[6]. The rectal mucosa above the level of the dentate line is not very sensitive to pain, and transrectal lignocaine gel will presumably provide anesthesia to the rectal mucosa only[4].

Periprostatic lignocaine injection has been used to provide anesthesia for a number of indications, including laser prostatectomy, brachytherapy and TRUS guided prostate biopsy[9]. All but one of the 17 prospective, randomized studies comparing lignocaine injection to placebo (either in the form of placebo gel or saline injection) for pain relief during prostate biopsy found lignocaine injection to be significantly better than placebo (Table 3)[10-24].

There is wide variation in pain scores during biopsies done under local anesthetic injection (Table 3). The variation in pain score during injection could be due to differences in dosage and concentration of lignocaine used, site of injection and technique, number of biopsy cores obtained, operator dependent factors, and patient factors (i.e. pain tolerance). The mean pain scores in the placebo arm of these studies show a narrower range than in the lignocaine injection arms, perhaps reflecting a more consistent or predictable level of placebo response. Interestingly, our study shows a mean pain score in the placebo arm (KY jelly) of 5.16, considerably higher than that reported using saline injection as placebo in most studies (Table 3). This perhaps illustrates that saline injection has a more pronounced placebo effect than KY jelly.

There are eight prospective, randomized studies comparing periprostatic lignocaine injection to lignocaine gel installation, and all of them showed that lignocaine injection provides significantly better pain relief than lignocaine gel installation (Table 4)[1,16,17,25-28]. The results of our study support the conclusion that lignocaine injection is superior to lignocaine gel installation.

Table 3: Prospective, randomized studies comparing periprostatic lignocaine injection to placebo

Study	Patients (n)		Lignocaine injection ml (%)	Mean pain score		p-value
	Lignocaine injection	Placebo		Lignocaine injection	Placebo	
Nash et al, 1996[10]	32	32	5	1.6 ± 0.9	2.9 ± 1.2	<0.0001
Pareek et al, 2001[11]	66	66	5 ml (1%)	2.7 ± 0.21	4.7 ± 0.26	<0.0001
Seymour et al, 2001[12]	84	73	10	1.53 ± 0.7	1.95 ± 0.65	<0.001
Wu et al, 2001[13]	21	19	5 ml (1%)	2.5 ± 3	2.5 ± 2.5	=0.91
Kaver et al, 2002[14]	74	78	15	16*	50*	<0.0001
Leibovici et al, 2002[6]	45	45	5	1.51	3.98	0.0001
Schostak et al, 2002[15]	44	44	10 ml (1%)	2.33	1.68	=0.05
Stirling et al, 2002[16]	50	50	5 ml (1%)	2.6	3.8	<0.05
Von Knobloch et al, 2002[17]	68	68	10 ml (1% - articaine)	1.84	3.29	<0.0001
Walker et al, 2002[18]	48	46	x ml (1%)	2.54	4.0	<0.001
Addla et al, 2003[19]	55	43	6	3.0	4.3	<0.01
Berger et al, 2003[20]	50	50	10	0.76	3.62	<0.001
Manikandan et al, 2003[21]	75	84	10ml (1%)	1.6	2.9	<0.001
Ozden et al, 2003[8]	25	25	10 ml (1%)	1.12 ± 1.26	3.88 ± 1.94	<0.001
Inal et al, 2004[22]	25	25	6	3.16 ± 2.14	6.25 ± 2.04	<0.001
Obek et al, 2004[23]	75	75	5	2.57	4.63	<0.001
Rabets et al, 2004[24]	24	28	5 ml (0.25% bupivicaine)	2.04	4.46	<0.001

*sum of individual biopsies

Table 4: Randomized studies comparing periprostatic lignocaine injection to intrarectal lignocaine gel installation

Study	Patients (n)		Lignocaine		Mean pain score(VAS 0-10)		p- value
	Lignocaine injection	Lignocaine gel	Injection (ml, %)	Gel (ml, %)	Lignocaine Injection	Lignocaine gel	
Alavi et al., 2001[25]	75	75	10 ml (1%)	10 ml (1%)	2.4	3.7	0.0002
Lynn et al., 2002 [26]	30	27	10 ml (1%)	11 ml (2%)	0.5	2.7	<0.001
Stirling et al., 2002[16]	50	50	5 ml (1%)	10 ml (2%)	2.6	3.1	<0.05
Von Knobloch et al., 2002[17]	34	34	5-10 ml (1%)	6 ml (2%)	3.29	1.85	<0.0001
Matlaga et al., 2003[27]	25	25	22 ml (1%)	10 ml (2%)	0.5	4.2	<0.05
Rodriguez et al., 2003[28]	53	43	10 ml (1%)	10 ml (2%)	1.73	2.76	0.001
Mallick et al., 2004[29]	162	166	10 ml (1%)	15 ml (2%)	During: 2 After: 0.8	During: 2.6 After: 1.4	0.15 <0.001

Table 5: Randomized studies comparing intrarectal lignocaine gel to placebo gel installation

Study	Patients (n)		Lignocaine gel		Mean pain score		p-value
	Lignocaine gel	Placebo gel	Volume (ml)	%	Lignocaine	Placebo	
Desgrandchamps et al, 1999[29]	56	53	15	2%	(VRS) 12.5%	(VRS) 11%	0.39
Issa et al, 2000[4]	25	25	10	2%	2.5	5	0.0001
Chang et al, 2001[30]	56	52	10	2%	2.89	2.83	0.88
Cevik et al, 2002[31]	50	50	20	2%	4.8 ± 2.2	4.4 ± 2.1	0.643
Lynn et al, 2002[25]	27	14	11	2%	2.7	4.8	0.186
Saad et al, 2002[32]	180	180	10	2%	2	3	0.0001
Antunes et al, 2004[33]	34	38	20	2%			0.29

VRS - verbal rating scale - percentage of patients who experienced moderate to severe pain.

Five of the seven randomized studies comparing intrarectal installation of 10-15 ml 2% lignocaine gel versus placebo gel showed no significant benefit (Table 5)[4,26,30-34]. In our study intrarectal instillation of lignocaine gel provided significantly better pain control than placebo gel. There has been one study suggesting that a combination of intrarectal lignocaine gel plus injection may be more effective than if either is used alone[5].

Operator assessment of how well or poorly patients tolerated the procedure is, of course, a subjective estimate, and most studies did not consider this an important endpoint. Nevertheless, our data using six different operators show that patient tolerance (as assessed by the operator) was best in Group1 and worst in Group 3, supporting the patient reported pain assessment. This is similar to the findings reported by Leibovici and colleagues[6].

Periprostatic nerve block has also been compared to intraprostatic lignocaine injection with a significant difference in pain score favoring the latter[34]. Although there was no significant difference in complications between the two groups in this study, the question of whether injection of large volumes of lignocaine into prostatic tissue alters the histological analysis of the biopsy remains unanswered.

With regard to pain experienced after biopsy, some studies showed no difference between the techniques used, as well a similar requirement for post-biopsy analgesia. Our study showed no statistically significant difference in pain between the lignocaine injection and lignocaine gel instillation groups 15 minutes after the biopsy. This may be due to slow diffusion of the lignocaine gel across the rectal mucosa, making it more effective after 15 minutes.

Stirling and colleagues compared injection of 5 ml 1% lignocaine with instillation of 10 ml 2% lignocaine gel, and found that postprocedural pain was significantly less in the injection than in the gel group[16]. The fact that we assessed postprocedural pain 15 minutes after the biopsy may explain the difference between our findings and those of Stirling and associates.

In our study there was no significant difference between the groups with regard to the number of patients who would return for a repeat biopsy, a finding which is consistent with other studies[12,16]. This is contrary to the expectation that patients who experienced less pain during or after biopsy would be more readily willing to undergo a repeat biopsy.

We found no significant difference in complications between our study groups, except for rectal bleeding, which was significantly less common in the injection group. This is similar to the findings of Obek and colleagues[35], who reported a significantly lower incidence of rectal bleeding in patients

after periprostatic nerve block, and postulated that this was due to greater patient comfort[35]. Most other studies indicated no greater risk of rectal or urethral bleeding after periprostatic lignocaine injection.

The incidence of rectal bleeding and hematuria in our study was 13.5% and 19.1%, respectively, which is comparable to that reported in the literature. Ghani and colleagues found the incidence of rectal bleeding to be directly related to the number of biopsy cores taken and not to the performance of periprostatic lignocaine injection[36].

In a randomized study comparing periprostatic lignocaine injection with analgesia using Entonox inhalation (50% oxygen and 50% nitrous oxide) 2 minutes before biopsy, the mean pain scores were lower (1.6) in the lignocaine injection than in the Entonox group (2.2), but this difference was not statistically significant[21]. Entonox was significantly better than no anesthesia. However, contraindications to the use of Entonox (congestive cardiac failure, chronic obstructive airways disease, previous ear surgery and anemia) may limit its use. Minor side effects (lightheadedness, dry mouth, nausea and tingling in the fingers) may occur.

Insertion of the rectal probe through the external anal sphincter is believed to cause mild to moderate discomfort, with more severe pain experienced during the biopsy itself. Kravchick and colleagues recently demonstrated that using a combination of 40% dimethylsulfoxide (DMSO) and lignocaine gel rectally, compared to injection of 10 ml 1% lignocaine around the anal sphincter, significantly reduced pain associated with probe insertion[5]. However, with regard to pain experienced during biopsy, there was no statistically significant difference between intrarectal DMSO plus lignocaine gel compared to perianal lignocaine injection, whereas periprostatic lignocaine nerve block provided significantly better pain relief [5].

In conclusion, our data show that, for pain relief during and after TRUS guided needle biopsy of the prostate, transrectal periprostatic injection of 10 ml 2% lignocaine was significantly more effective than intrarectal instillation of 15 ml 2% lignocaine gel, which in turn was significantly more effective than intrarectal lubricant (placebo) gel. Although the greater pain experienced by the patient during biopsy without anesthesia did not result in a significantly greater unwillingness to return for repeat biopsy, considerations of human compassion dictate that all patients undergoing TRUS guided prostate biopsy should routinely be offered the option of receiving local anesthesia.

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RESUME

L'INJECTION DE LA LIDOCAÏNE EN PERI PROSTATIQUE VERSUS GEL DE LIDOCAÏNE EN INTRA RECTAL OU PLACEBO POUR LE SOULAGEMENT DE LA DOULEUR PENDANT L'ECHOGRAPHIE TRANSRECTALE (TRUS) ET LA PONCTION-BIOPSIE GUIDEE DE LA PROSTATE. UNE ETUDE PROSPECTIVE, RANDOMISEE.

Objectif: Le but de notre étude était de comparer l'efficacité et les complications de l'injection de lidocaïne en périprostatique avec l'instillation transrectale de gel de lidocaïne ou placebo pour le soulagement de douleurs associées à l'échographie transrectale (TRUS) et la ponction-biopsie guidée de la prostate.

Matériel et Méthodes: Entre mars 2003 et janvier 2004, 210 malades ont été randomisés éventuellement pour recevoir injection periprostatique de 10 ml de lidocaïne à 2% (Groupe 1, n=83), instillation intra rectale de 15 ml de gel de lidocaïne à 2% (Groupe 2, n=64) ou instillation de l'intra rectale de 10 ml de gel soluble dans l'eau (placebo) (Groupe 3, n=63). Le degré de douleur éprouvée pendant et 15 minutes après achèvement de la biopsie ait été enregistré par le malade lui-même, en utilisant un score de la douleur visuel (VPS) avec une échelle de 0 (aucune douleur) à 10 (la douleur la plus sévère possible). L'évaluation statistique a été exécutée utilisant l'analyse de la variance (ANOVA) avec post hoc analyses qui utilisent la correction Bonferroni.

Résultats: Il n'y avait pas de différences

statistiquement significatives entre les groupes quant au nombre moyen de carottes biopsiques, taux sériques de PSA ou le volume de la prostate. Le VPS moyen pendant la biopsie était 2.02, 3.05 et 5.16 respectivement dans les Groupes 1, 2 et 3 (toutes les différences sont statistiquement significatives). Le VPS moyen 15 minutes après la biopsie fût considérablement inférieur dans le Groupe 1 (1.43) comparé au Groupe 3 (3.28, p <0.001) mais pas pour le Groupe 2 (2.17, p=0.086), et c'était considérablement inférieur dans le Groupe 2 à comparer au Groupe 3 (p=0.006). Quant aux complications, il n'y avait pas de différences statistiquement significatives entre les groupes, à l'exception de saignement rectal qui a plus fréquemment eu lieu dans le Groupe 3 (23.2%) que dans le Groupes 1 (7.9%, p=0.033) et 2 (11.5%, p=0.186). Il n'y avait aucune différence significative quant au pourcentage de malades qui seraient disposés à retourner pour une 2ème série de biopsies (95.7%, 87% et 91.7% dans les Groupes 1, 2 et 3 respectivement).

Conclusions: Pour soulagement de la douleur pendant et après que TRUS ait guidé la ponction-biopsie de la prostate, l'injection en péri prostatique de 10 ml de lidocaïne à 2% était considérablement plus efficace que l'instillation intrarectale de 15 ml de gel de lidocaïne à 2% , qui à son tour était plus efficace que le lubrifiant intrarectal (placebo) gel. La fréquence de complications n'a pas été augmentée après injection de la lidocaïne en péri prostatique. Bien que la plus grande douleur ait été éprouvée par le malade pendant la biopsie sans anesthésie, cela n'a pas empêché les patients d'être favorables à une 2ème série de biopsies. Pour des considérations humaines tous les patients qui subissent des biopsies écho-guidées de la prostate devraient bénéficier d'anesthésie locale.

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